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From the Editor's Desk

Jennifer E. Taylor

Tennesee Tech University

The Journal of Research Administration (JRA) is the premier scholarly publication for the field of research administration and management. We publish timely work that covers all facets of our discipline. The journal is an important education and career development platform. Our authors share best practices and innovative means of performing research administration and management work in our fast-paced, ever-changing environments while also enhancing their own careers through the process of publishing peer-reviewed scholarly journal articles.

As we have moved toward the holiday season of 2021 and continued to deal with the challenges brought on by COVID-19 we were fortunate to continue to receive high quality, important manuscripts that address a range of key issues in Research Administration. I want to thank our authors and editorial board members for their hard work and commitment during this challenging period.

I am pleased to share with you the important and wide-ranging manuscripts that are in our current issue and that reflect those efforts. We have a "voice of experience" essay from someone who has been a university leader across four decades. This essay is followed by seven original articles that reflect the journal's ongoing growth in its international reach and impact. In addition to two original articles from the United States, the other five manuscripts come from Europe, Asia, Australia, and Africa. We hope that researchers from across the globe will continue to view JRA as a preferred outlet for their work as well as a source of important conceptual and practical scholarship to guide their work.

Our voice of experience essay is entitled "Overview of University Finances: Accounting and Budgeting Principles for Higher Education." In this essay, Dean Smith provides us with a discussion of the genesis and goals of his insightful and highly informative books regarding university administration and what they offer to our readers. Collectively, the four volumes that are considered provide deep dives into critical aspects of university finances and share broader lessons regarding the intricacies of how universities function.

Laura Pastor-Sanz and her colleagues from across Europe and Australia provide a case study in their article, "A Managerial Framework for a Large, Multi-centre Clinical Trial within an EU-funded Collaborative Project." In this article they discuss the advantages and complexities of research and clinical trials that involve centres that span multiple cities and countries. In the article "Strategies to Obtain Research Funding for Rural Medical Colleges in Japan", Yuko Amano-Ito offers us a detailed examination of the challenges, and potential solutions, that researchers in Japan's rural medical colleges are grappling with as they deal with a national context in which the operating budget has been reduced year-by-year since 2004. Loralin Welch and Noorie K. Brantmeier in "Examining Employee Retention and Motivation Trends in Research Administration" provide us with a timely examination of motivational factors contributing to retention and voluntary turn-

over they found to be most important through their mixed-methods national survey of research administrators in the United States Professor Mackworth-Young in his article entitled, "A Proportionate Peer Review Service," examined the use, efficacy, and functioning of the peer review service as it has operated over more than a decade at Imperial College in London. Charmaine Williamson and Christina Shuttleworth discuss the genesis and implementation of a program based on, "A Social Innovation Model as a Bridge-Builder Between Academia and Research Management" in which staff involved in institutional research management may be collaborative and strategic partners in research development among faculty and students. Lisa Boyce from the University of Surrey offers us a four-year study of the relationship of overhead rates, including waiver of overhead, to the number of awards and their overall value/amounts across seven UK universities. In her article "Overhead Rates: Impact on Research Application Success", she offers some lessons the results may hold for considerations of adjusting or waiving overhead as well as possible extensions of the work internationally. Finally, in the article "Development and Implementation of Work Engagement Strategies in a Clinical Research Consortium During the Coronavirus Disease 2019 (COVID-19) Pandemic", Marcus Johnson – along with colleagues in Veterans Affairs (VA) settings across the United States – describes the development and implementation of strategies to maintain work engagement during the COVID-19 pandemic among clinical research staff involved in a consortium of ten VA medical centers involved in collaborative clinical trials.

In 2022, we will begin the process of pre-publishing articles online soon after they have been formally accepted. These articles, once copyedited and proofed by the authors will be both posted on the JRA's webpage and then as part of the framework of the full Fall or Spring JRA issue in which it will be published. We hope that this will get the important lessons that our articles may offer readers to them to draw on much sooner. We also hope that it will encourage potential authors to consider JRA as an outlet for their work as will allow their work to be available in discoverable and citable form much sooner than if it was held until the formal issues were released.

This is my first issue as Editor-in-Chief of JRA. I am humbled and excited about being given the charge to continue to help move our field forward. There are many people that I would like to thank for their help and support as I transition into this role and for their ongoing critical contributions to the success of the journal. First, the communications committee of JRA provides important guidance and input on all phases of the journal. Nathan Vanderford, my predecessor as Editor-in-Chief, provided six years of leadership to the journal as deputy editor and editor-in-chief. He left it much stronger and vital than when he began his service. He provided me with both the opportunity to serve as Deputy Editor and invaluable mentorship during that time as well as throughout this transition. Holly Zink, who has served as Associate Editor over the past three years has continued her important contributions to JRA, now as Deputy Editor. I thank her for her ongoing support and partnership in this work. The members of the editorial board are essential partners in ensuring that the manuscripts that appear in the journal are exceptional and that they make important contributions to the work of our readers and the field of research administration more broadly. Without the countless hours they contribute to the review process, the journal and its continued growth would not be possible. The Author Fellowship Committee

and the Author Fellow Advisors provide essential guidance to the Author Fellows as they develop and publish their first scholarly articles and I am grateful that they will continue to provide this unique and important work for JRA. There are also many behind the scenes SRAI staff who have shared their knowledge, guidance, and expertise during my time as Deputy Editor and through my transition to the Editor-in-Chief role. Gina Cuevas and Jim Mitchell have my gratitude and appreciation. They are truly the glue that holds the production of the journal together and are critical to ensuring that it meets the highest professional standards.

Lastly, and as always, if you are a non-SRAI member and wish to have the journal delivered to you via email, please sign up through the online system at http://www.journalra.org.
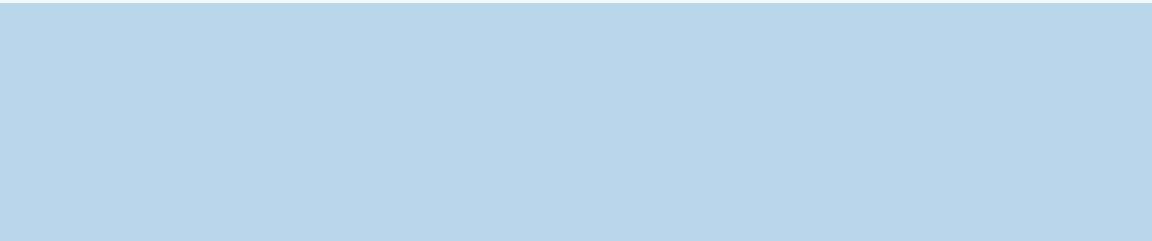
Overview of University Finances: Accounting and Budgeting Principles for Higher Education

Dean O. Smith
Professor Emeritus
University of Hawaii

During the past ten years, I have attempted to retire three times and written four books on university administration. Right after my first attempt at retirement, I wrote the first book, *Managing the Research University* (Oxford, 2011). I had served in research administration in one capacity or another for more than half of my academic career. Surely, I thought, I learned something during all of those years, something that might benefit younger colleagues in the field. So, I wrote the book, which became "research administration 101."

Shortly after my second attempt at retirement, I got the writing "bug" again. This time, I wanted to expand on a topic mentioned only briefly in the first book: the limits of authority. Who's in charge of what, and who can and can't do what in the university? After spending many long hours of research in the law library, the result was *Understanding Authority in Higher Education* (Rowman and Littlefield, 2015). I learned more about universities while writing this book than I did in 37 years as a professor and administrator.

Then, on my third attempt at retirement, I decided to write about the topic that caused me as an administrator the most consternation, the greatest frustration, the worst headaches: university finances. The result was *University Finances: Accounting and Budgeting Principles for Higher Education* (Johns Hopkins, 2019). As I wrote in the book's preface, when I was a university executive officer responsible for generating sufficient revenue and managing expenditures to support the university's mission, I wrestled with finances on a daily basis. This entailed regular conversations with university fiscal officers, governing board members, state legislators, auditors, and accountants. Through this on-the-job experience, I developed a profound interest in university finances.

In my administrative role, I was usually the one who had to explain the university's financial condition to faculty members, deans, and various other campus constituencies. These explanations were not always easy, especially during times of budgetary stress. Occasionally, I encountered rumors about troves of money hoarded by the administration. The rumors were partly true; the university did have sizable restricted fund balances. Understandably, frustrated colleagues questioned why these funds could not be used to alleviate financial hardship in the operating budget. As former Stanford University president Donald Kennedy noted, "If we're so rich, why do we feel so poor?" The explanations sometimes involved financial reporting methods that were familiar to professional accountants but were unfamiliar to most college and university

faculty and staff members. Or to many others who worked directly or indirectly with colleges and universities. This unfamiliarity was unfortunate because it bred confusion and misunderstanding about the university's financial condition. And that weakened university governance.

To ease this confusion, I decided to write *University Finances*, explaining basic accounting procedures, budgets, and financial statements for the extended academic community. My goal was to clarify topics that I encountered routinely and that often bewildered my colleagues. In addition, I sought to clarify less ordinary (but certainly important) financial topics, such as methods for computing fringe benefit rates, refunding bonds, allocating Federal formula funds, and calculating institutional indirect (F&A) cost rates. As it turned out, this book became "research administration 201," for it covered financial aspects of research administration in considerable detail.

As I was finishing work on *University Finances*, my editor asked me to prepare a shorter companion book focused on budgets: *How University Budgets Work* (Johns Hopkins University Press, 2019). I took this opportunity to expand on the one-chapter introduction to budgets in *University Finances*. The two books complement each other, with minimal overlap. Thus, for research administrators, this companion book constitutes "research administration 202," because of its explanations about budget construction and management, alignment with the strategic plan, year-end closeouts, and so forth.

While preparing to write *University Finances* I discovered the theoretical rigor of the accounting profession. As a medical school professor and university administrator, my work had entailed extensive analysis of data, so I was comfortable working with numbers. But, I had no formal training in accounting. So, doing my homework, so to speak, at the outset I studied accounting assiduously: read textbooks, consulted experts, took courses, studied financial reports, and so forth. Ultimately, I developed an appreciation of the underlying principles, the theoretical underpinnings, of accounting and budgeting; they made sense.

Pedagogically, the hallmark feature of *University Finances* is its rigor. It brings together theoretical and practical approaches to nearly all of the major issues confronting administrators in higher education. Notably, it provides useful examples of calculations that sometimes can be quite daunting. In fact, to enable readers to "follow the numbers," all numerical examples throughout the book derive from two sets of core expenditure data, one set for a private university and one set for a public university. In that way, the respective examples are linked together; every number can be traced back to these core expenditure data. This linkage proved to be a daunting task (that is, a real headache), because a change in one number in one calculation rippled through the entire set of calculations related to that number, extending into numerous examples in different chapters. Consequently, after changing a number for one reason or another, I had to spend many hours poring over text and tables, looking for inaccuracies or inconsistencies resulting from the change. In that way, the book's examples demonstrate the interdependence of data in the real world of university finances.

Most sample calculations involved straightforward arithmetic. Plug in numbers, calculate percentages, et cetera, and come up with answers. However, sample calculations of Federal

formula funding allocations, such as Hatch or Smith-Lever Act funds, proved ironically to be particularly challenging. By statute, the allocations to various universities were based on exact financial data and formulas. The raw data, formulas, and Federal allocations were easy to find on the internet. But, using the same raw data and formulas, I often had difficulty coming up with the same allocations. The Federal agencies used algorithms that I found counter-intuitive. Ultimately, an agency director provided me copies of their Excel spreadsheets, which enabled me to decipher their algorithm and reproduce their calculations. Looking back, I learned (and wrote about) valuable lessons in Federal accounting procedures from these calculations.

While analyzing university finances, I encountered a familiar "eye-opener": universities lose money on every research grant due to under-recovery of indirect costs. As a seasoned chief research officer, I knew that universities did not always recover their full indirect-cost reimbursement for one reason or another: the administrative cap (26 percent), institutional waivers, agency limitations, and so forth. Nonetheless, I adhered axiomatically to the quest for more and more grant funding. Naively, I seldom pondered the true financial implications of this under-recovery. Just bring in more money, increase research expenditures. But now, in retrospect, a question arose: why do universities strive so ardently to increase the number of grant awards if it just costs them money? After analyzing numerous potential benefits of increased research expenditures, I discovered that there were few significant advantages—financial or otherwise. The only significant financial reward is increased annual donations to the university, but the increased giving isn't enough to offset the under-recovery of indirect costs. Not by a long way. Otherwise, the major advantage to increased research expenditures is simply institutional prestige, a costly but highly prized commodity.

University Finances debunks the widely-held suspicion that universities have large stashes of money available for general use. This suspicion becomes particularly prevalent during periods of budgetary stress. True, universities have sizable reserves of money. But, as this book points out, nearly all of that money is restricted legally for specific uses, which may include select faculty members' salaries and student financial aid but not discretionary general-fund expenses. Thus, universities may appear wealthy on their balance sheets, but the use of this wealth is highly restricted. That is, use of the money must adhere to guidelines imposed by donors, bondholders, government regulators, and others. These restrictions are not always recognized or understood by many observers, including faculty members and legislators.

From its inception, I have hoped that *University Finances* will become a trusted resource for members of the extended university community. It may sit on the shelf for a while, but when readers seek answers to specific financial questions, they can reach for this book, confident that it will provide the answers.

Managerial Framework for a large Multi-centre Clinical Trial within an EU-funded Collaborative Project – the "PREVIEW" Case Study

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Abstract: *A multi-centre clinical trial involves the implementation of the same clinical protocol at several independent investigational centres. Multi-centre clinical trials may be preferable to single-centre trials, but their implementation and management is more complex. EU-funded collaborative projects involve several participating organizations and countries and their consortia are typically multidisciplinary. Their coordination requires a joint effort from several actors, and an appropriate managerial structure and procedures need to be defined and established. The management of the Framework Programme 7 (FP7) PREVIEW project, whose core consisted of a clinical trial with 8 intervention centres/sites is presented as case study. PREVIEW was coordinated by the University of Copenhagen. The project management was implemented by a combination of decentralised project management, at the department level, jointly by the Project Coordinator (PC) and Project Manager (PM), and centralised, by a dedicated EU Liaison Officer from the Project Management Office (PMO). The Quality Manager role was undertaken by the PC, with support from selected consortium members. The Exploitation Manager role was assumed by*

the leader of the dissemination and exploitation work package. The Data Manager (DM) at the University of Copenhagen established and maintained a datahub for all data from the clinical trial. The General Assembly and Steering Committee were key decision bodies with regard to taking and implementing decisions. The Scientific Advisory Board (SAB) was formed by reputed external experts providing guidance and advice. The project website was the main channel to reach the general public. A password protected private section was used as internal repository for the project. Regular meetings at all levels were key to ensure good communication and collaboration among the project team. Appropriate attention to data management was given from the start. The privacy of personal data was ensured in accordance with national and EU regulations. The PC was also the Sponsor of the multi-centre clinical trial, and the PM served as the overall Clinical Trial Administrator. Each centre was led by a Principal Investigator (PI), running the trial together with the local daily responsible. The tasks and responsibilities for the clinical trial of the Coordinating Centre were shared between Copenhagen and Helsinki centres. The trial was overall led by the Clinical Trial Manager (CTM), who was the PI at the Helsinki centre. The local Independent Ethical Committees approved the protocol prior to the start of the intervention. One member of the SAB acted as Ethical Officer. The trial/study had an overall statistician. The Analyst role was shared among different people from the Copenhagen and Helsinki centres. The DM created and maintained database for the intervention and the Clinical Report Forms by using OpenClinica open source software. The staff in the intervention received training in Good Clinical Practices, the protocol and its procedures. The monitoring tasks were jointly undertaken by the Sponsor and the CTM. The documents from the Trial Master File were saved in the Internal Repository. A set of Standard Operation Procedures was defined. Meetings among all PIs, and within the Instructors' Network were key in the success of the intervention. This case study aims at serving as guidance to coordinating researchers, both during the proposal preparation and project implementation phases, as well as to provide visibility and insight into the multi-faceted role of the project managers and administrators of such projects.

Introduction

The aim of this paper is to propose a governance structure and a set of managerial procedures and tools to be used as guidance, in order to effectively manage EU-funded collaborative projects running a multi-centre clinical trial.

Clinical trials are a key research tool in the development of new interventions to improve patient care and quality of life. Most recent interventions are a direct result of clinical research. Even

though computer simulation and animal testing can provide valuable information, they present limitations with respect to determining how a new intervention will work in the human body. Therefore, clinical trials are in most cases unavoidable and still needed.

A multi-centre clinical trial involves two or more independent investigational centres, where participants are engaged for an intervention, following the same clinical protocol (National Institutes of Health, National Heart, Lung and Blood Institute, n.d.). One centre is in charge of processing and analysing the data from all centres (Kraemer, 2000).

Multi-centre clinical trials have several advantages compared to single-centre trials. Firstly, multi-centre clinical trials generate larger sample sizes and therefore have more power to test hypotheses and estimate population parameters. This is crucial when the number of potential participants is low, if one centre alone cannot generate a large enough sample, or participants' retention is challenging (CareSearch, 2018). Secondly, the findings from multi-centre clinical trials are more generalizable than the ones obtained from single-centre trials. Participants involved in multi-centre clinical trials usually present greater variations in sociodemographic and clinical characteristics. The intervention may bring different results from one centre to another, even if it is uniformly delivered and evaluated. Thus, multi-centre studies prevent over-generalization of conclusions, since they minimize risks of idiosyncratic research findings. Thirdly, and crucially, multi-centre clinical trials can resolve belligerent conflicts in a field (Kraemer, 2000). They will often be better designed and implemented, and their results better reported than in single-centre studies (Friese et al., 2017).

The management of multi-centre clinical trials is more complicated than in the case of single-centre clinical trials (Friese, 2017). Obtaining and retaining an adequate sample while maintaining data integrity can be challenging (Forjuoh et al., 2015). Furthermore, the communication between researchers from different locations and time zones usually requires additional considerations and pre-planning. Effective communication involves adaption to various leadership styles and organizational commitment (Forjuoh et al., 2015). It is crucial to define managerial strategies, both within each clinical centre and through all centres (Kraemer, 2000).

Since 1984, the research and development activities from the European Union (EU) (European Community until 1993) have been defined and implemented by a series of multi-annual Framework Programmes (FPs): The 1st FP (1984-1987), the 2nd FP (1987-1991), the 3rd FP (1990-1994), the 4th FP (1994-1998), the 5th FP (1998-2002), the 6th FP (2002-2006), the 7th FP (2007-2013), Horizon 2020 (2014-2020) and currently Horizon Europe (2021-2027) The EU financially supports activities covering most scientific disciplines through the FPs, which are proposed by the European Commission (EC) and adopted by the European Council and the European Parliament (Eurostat, n.d.).

The EU awards grants in many different fields to organisations and, occasionally, individuals, to help them carry out projects in line with its policies (European Commission, n.d.-c). Collaborative EU-funded projects are focused research projects that are carried out by multidisciplinary consortia consisting of several participants from different countries, coming from both academia

and industry (European Commission, 2007). Support for Collaborative Projects is provided within predefined themes (topics) that are published by the EU Commission on a running basis. An exact match with a topic is needed in order to be considered for obtaining funding (top-down approach). The funding amount varies and it is specified in the topic description. The coordination of EU-funded collaborative projects is challenging, and requires a joint effort from several actors.
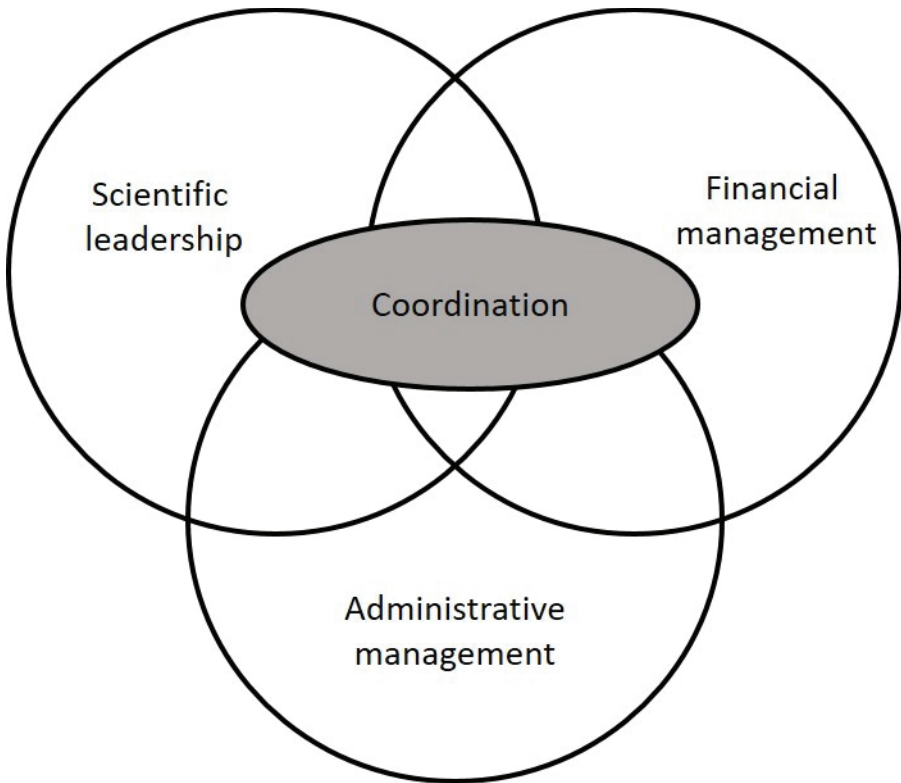
Figure 1. The three dimensions of the project coordination.

As illustrated in Figure 1, the project coordination involves three different dimensions: scientific leadership, administrative management, and financial management.

The coordinator is often the individual that has the project idea, gathers the consortium, leads the writing process, including the division of work and allocation of tasks and resources to each partner, represents the consortium towards the EC and submits the proposal. The budget of the coordinating organisation, where the coordinator belongs, includes a designated share for project management activities (Enspire.Science, n.d.-a). Once the project is running, the coordinator has many roles. He/she will be often regarded as the financial and administrative manager, as well as scientific leader, even though the last is not a contractual requirement for the coordinator.

The coordinator should monitor the project and ensure that it is implemented on time and with the expected quality. The coordinator should facilitate the communication among the consortium partners, in order to produce fruitful collaborative work. This can be challenging, given the heterogeneity of partners: by type of organization (academic vs. industrial partners), size (big vs. small organisations), previous participation in collaborative EU-funded projects (very experienced vs. new) and country of origin (with the associated cultural differences). In addition, the coordinator should be mediator between the project consortium and the EC.

The coordination role is often considered prestigious and is associated with decision power and visibility for both the individual and his/her organisation. Despite these advantages, potential coordinators are often reluctant to assume this role, because the non-scientific and administrative activities may be perceived as tedious, too time-consuming and little rewarding (Enspire.Science, n.d.-a).

The benefits of applying project management to research, for funders, researchers and research managers have been previously described (Gist & Langley, 2007). In the case of coordinators coming from academia, it is especially important to have a managerial structure in place that allows coordinators to focus on their scientific tasks and scientific leadership, which are appealing to most of them, while guaranteeing that the administrative and financial management of the project is given appropriate attention.

A search in CORDIS, the Community Research and Development Information Service, for projects funded by the Framework Programmes, from FP1 up to H2020 with the search words "clinical trials" provides more than 2000 results (European Commission, n.d.-b), and many of these projects involve multi-centre clinical trials. As example, in January 2020, the EC launched an emergency call, with a budget of 48.5 M€, looking for research projects that will advance the knowledge about the novel coronavirus epidemic, contribute to more efficient clinical management of patients infected with the virus, as well as public health preparedness and response. The EC has already provided funding to 18 projects, involving 151 research teams from across the EU and beyond (European Commission, 2020d), and several will involve clinical trials. Therefore, it is expected that in the future, and during the current FP Horizon Europe (HORIZON), that will run from 2021 to 2027 (European Commission, n.d.-a) and has the largest budget so far, the EC is launching more calls for proposals on topics involving multi-centre clinical trials.

Materials and Methods

Multi-centre Clinical Trials: Managerial Roles and Structure

This section describes some of the key roles in the management of a multi-centre clinical trial. They are represented in Figure 2.
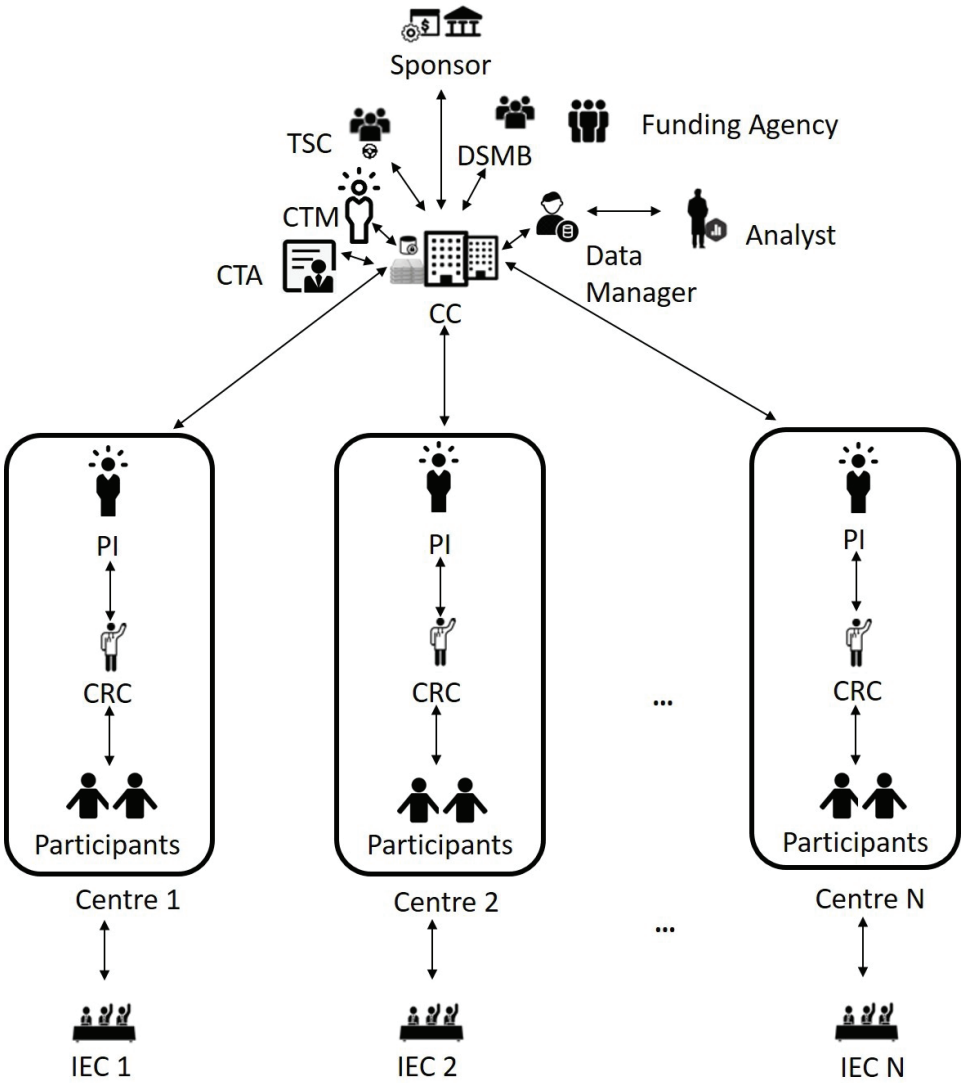
Figure 2. Managerial Framework for a Multi-centre Clinical Trial
(adapted from Choudhury et al., 2019a).

Sponsor means an individual, institution, or organization that initiates and manages a clinical trial, but does not actually conduct it (U.S. Food & Drug Administration [FDA], 2020). Sponsor-investigator means an individual who both initiates and actually conducts a clinical investigation, alone or with others. The obligations of a sponsor-investigator include both the ones of an investigator and those of a sponsor (FDA, 2020).

Contract Research Organisation (CRO) is a person or an organization contracted by the sponsor to assume some of the sponsor's trial-related tasks and duties. However, the sponsor has the ultimate responsibility for the quality and integrity of the trial data (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH], 1996). A CRO helps the sponsor to write the protocol and submit the data to the regulatory agencies. The CROs also hire their own CRAs (Clinical Research Associates), who visit and monitor the centres throughout the trial, in order to make sure that it is carried out in agreement with the protocol and good clinical practice (GCP) standards (Medium, 2015). The structure depicted in Figure 2 does not contemplate this role, but a structure with a coordinating centre instead.

Coordinating Centre (CC) is a centre that is responsible for overseeing and monitoring a clinical trial and facilitating the communication among all centres (Johns Hopkins Medicine, 2016). They are in charge of the overall data management, and maintain a central database with all data from the trial (Choudhury et al., 2019b). They generate reports based on the data collected, schedule activities for participants, and communicate them to appropriate stakeholders (JHM, 2016). This structure is key in facilitating Coordinated Collaborative Science (Rolland et al., 2017).

Clinical Research Associate (CRA) can also be known as Clinical Research Coordinator (CRC) and Clinical Trial Manager (CTM). They are responsible for the planning and coordination of medical research projects and clinical trials. In this text, we will use the term Clinical Trial Manager (CTM) to refer to the CRA working at the Coordinating Centre, and the term Clinical Research Coordinator (CRC) to refer to the person coordinating the trial on a daily basis in each one of the centres.

Clinical Trial Manager (CTM) is the chief investigator working at the Coordinating Centre, responsible for coordinating the trial among the different trial centres and monitoring the trial, on behalf of the sponsor. The CTM has in most cases a very significant contribution to the design of the trial, and the definition of the clinical trial protocol and the Standard Operating Procedures (SOPs).

Principal Investigator (PI) is the main person responsible for preparing, implementing and administering the study at each centre of a multi-centre clinical trial (Choudhury et al., 2019a). The PI takes large responsibility for the ongoing conduct of the trial and may review some or all data from a clinical point of view (McFadden, 2007).

Clinical Research Coordinator (CRC) responsibilities include preparing the Institutional Review Board submission, writing the informed consent document and developing a detailed cost analysis for their centres. The CRCs should be involved to some extent in the design and pilot testing of the Case Report Forms (CRF), as well as in the evaluation of proposed systems, software and procedures. The CRC is usually also responsible for recruiting and registering/randomising participants, scheduling visits and tests, completing the CRFs and submitting those and other data to the CC, adverse event reporting and study close-out (McFadden, 2007).

Clinical Trial Administrator (CTA) primarily manages the administrative aspects of a clinical trial, at every stage of the process. The CTA works with study protocols, prepares, distributes, tracks and files the clinical trial documents (such as the Trial Master File [TMF]). He/she may also deal with Serious Adverse Events (SAE) notifications.

Trial Steering Committee (TSC) is generally comprised of an independent chair, a minimum of two additional independent members, up to two PIs and a CTM or statistician, as appropriate. The TSC is responsible for providing overall supervision and advice and has the ultimate decision for the continuation of the trial (Molloy & Henley, 2016).

Data Safety and Monitoring Board (DSMB) is also called Data Monitoring Committee (DMC). The DSMB is an independent group of experts that periodically review and evaluate the accumulated study data concerning the study progress and participant safety and make recommendations concerning the continuation, modification, or termination of the trial. Its main duty is to monitor safety of the trial, in particular to review SAEs, especially the Suspected Unexpected Serious Adverse Reactions (SUSAR) and mortality, per arm of the trial and overall. The DSMB provides recommendations to the TSC, the CTM and the sponsor regarding the continuation or early stopping of the trial based on safety or ethical issues (Molloy & Henley, 2016).

Institutional Review Boards (IRBs)/Independent Ethical Committees (IECs) have the aim to protect the rights, safety, and wellbeing of human participants participating in a clinical trial. This board reviews all aspects of a trial, before and during the study. They should approve/provide favourable option to the protocol, as well as other study material such as the informed consent documents and investigator brochures, before the trial can start (FDA, 1998; ICH, 2016).

Participant is an individual that takes part in a research study and from whom data are collected through intervention or interaction with the individual (Choudhury et al., 2019a).

Funding agencies provide financial resources for carrying out a research study. The term often connotes funding obtained through a competitive process, in which potential research projects are evaluated and only the most promising receive funding.

Analyst is a researcher or statistician who gathers and analyses trial data throughout the study and organizes trial results. He/she participates in the study design, calculates the sample size and defines the statistical methodology to be used in the analyses, which is described in the Statistical Analysis Plan for the trial (Choudhury et al., 2019a; McFadden, 2007).

Data Manager (DM) (also called Data Coordinator and Data Specialist) is in charge of quality control of data in the Coordinating Centre. He/she should be involved in the design of Case Report Forms (CRFs), review of the protocol document and development and testing of some of the trial SOPs. The DM randomises participants, maintains all study CRFs and generates queries upon data requests. The DM assists the Analyst in preparing data sets for analysis and he/she is the main contact with the trials personnel at the participating centres. The DM usually also performs a Database Administrator (DBA) role, being responsible for designing, and setting up the trial database, ensuring its security and integrity and maintaining a backup of all the electronic

files and database(s). Additionally, he/she is often also performing tasks corresponding to a System Analyst, such as the design, development, testing, documenting and validation of the trials software (McFadden, 2007).

Multi-centre Clinical Trials: Managerial Procedures and Tools

This section describes the main managerial procedures that need to be taken into consideration and applied in a multi-centre clinical trial.

Good Clinical Research Practice (GCP) is a process that applies established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical trials involving the participation of human participants. Compliance with GCP ensures that the rights, safety and well-being of research participants are protected and respected, in agreement with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines, and ensures the integrity of clinical research data (World Health Organization [WHO], 2005). Some renowned institutions from the USA also provide resources and advice on how to design, plan and implement clinical trials according to GCP principles (Multiregional Clinical Trials Center [MRCT] of Brigham and Women´s Hospital and Harvard 2021; Clinical Trials Transformation Initiative, 2021).

Monitoring is a process that is an integral part of GCP and ensures that a trial is conducted in compliance with international regulations, standards and guidelines. The sponsor is responsible for ensuring that the trial is adequately monitored, even though the task can be delegated (Molloy & Henley, 2016).

Protocol is a document that describes how a clinical trial will be conducted (the objectives, design, methodology, organization and statistical considerations of a clinical trial) and ensures the safety of the trial participants and integrity of the data collected (Clinical Research Resource Hub [HUB], University of California San Francisco, 2017). In the case of a multi-centre clinical trial, it is crucial that the protocol is common and shared among all the clinical centres.

Trial Master File (TMF) refers to the collection of essential documents from the clinical trial that facilitate evaluation of the trial's implementation and the quality of data, and therefore compliance with GCP guidelines and applicable law (GCP-Enhederne, 2021).

Case Report Form (CRF) "is a printed, optical or electronic document designed to collect the data that is described in the protocol for each trial participant". Before designing the CRF, it is advisable to consider how the data will be handled and stored in the database, as these decisions may impact the data collection process (GCP-Enhederne, 2021).

Standard Operating Procedures (SOPs) are detailed, written instructions aimed at ensuring that a procedure is conducted in a uniform manner and according to plans. Furthermore, SOPs are useful tools when training new trial staff (GCP-Enhederne, 2021). Ensuring uniformity in the procedures is even more crucial in multi-centre clinical trials.

Meetings: Regular internal meetings within the staff involved in a clinical trial are crucial for the good planning and implementation of the trial. In the case of a multi-centre clinical trial, regular meetings among the centres are as well needed for alignment, discussion of clinical practices, etc.

Collaborative EU-funded projects: Managerial Roles and Structure

The next paragraphs will describe some of the key roles in the management of an EU-funded project.

Project Coordinator (PC): During the project's life time, and in addition to the scientific tasks that the coordinator may have as a consortium partner, there is a line of mandatory responsibilities that the coordinator is obligated to perform, such as: "1) monitor that the action is implemented properly; 2) act as the intermediary for all communications between the beneficiaries and the EC; 3) request and review any documents or information required by the EC and verify their completeness and correctness before passing them on to the EC; 4) submit the deliverables and reports to the EC; 5) ensure that all payments are made to the other beneficiaries without unjustified delay and 6) inform the EC of the amounts paid to each beneficiary, when required under the Agreement" (European Commission, 2019).

Project Manager (PM) oversees the project on a daily basis, in collaboration with the PC, in order to ensure timely and high-quality results within the budgeted resources. Other responsibilities include project communication, stakeholder management as well as risk management (PM² Alliance, 2018). The PM needs to have excellent administrative and financial management skills, but also a certain degree of understanding of the science behind the project in order to efficiently collaborate and provide support to the scientific coordinator (Enspire.Science, n.d.-b). Therefore, the scientific-leadership and the administrative and financial management roles in the project are not completely independent of each other. Some of the administrative tasks of the PM are as follows: 1) provide administrative support to the project; 2) define requirements for reporting and communication; 3) administer project meetings and draft related minutes; 4) support the PC in planning, monitoring and controlling the project; 5) advise on project management tools and administrative services; and 6) manage the project documentation (versioning, archiving, etc.) (PM2 Alliance, 2018).

Project Management Office (PMO) is a management structure that standardises the project-related governance processes and facilitates the sharing of resources, methodologies, tools and techniques. It provides support to one or more projects, and may be established as a separate entity within the organization. A primary function of a PMO is to support the PC and the PM by: 1) managing shared resources across all projects administered by the PMO; 2) identifying and developing project management methodologies, best practices and standards; 3) coaching, mentoring and training; 4) monitoring compliance with project management standards, policies, procedures, and templates; 5) developing and managing project policies, procedures, templates, and other shared documentation; and 6) coordinating communication across projects (Project Management Institute [PMI], 2017). The PMO is well suited to the academic world and research projects where knowledge generation and dissemination is of paramount importance (Wedekind & Philbin, 2018).

Quality Manager (QM): This role is responsible for monitoring and ensuring the quality of processes and outcomes of the project. In some cases, the PC undertakes also the QM role. In some other cases, it is undertaken by another project partner(s) or representatives. In the case of projects implementing an explicit peer-review process of the main project deliverables, the QM is in charge of collecting the reviewers' comments, distributing them to the responsible deliverable authors and deciding on the final deliverable status (Nathanail et al., 2015).

Exploitation and/or Innovation Manager: This role, when it exists, focuses on identifying opportunities for exploitation of the project's research and development results in compliance with the terms and conditions of both the Grant Agreement and the Consortium Agreement. This person facilitates the process of bringing the project's innovations to the market and is responsible for defining the business model and exploitation plan and strategies. He/she also is in charge of monitoring the needs of end-user groups in order to align the products/services emerging from the project to the real needs of the market. The Exploitation and Innovation Manager monitors the potential intellectual property rights (IPR) resulting from the project, including any possible patents and facilitating the process of patent application to the parties. He/she reports to the PC in order to keep the project's innovation capacity under constant surveillance, and participates in the SC meetings, without voting rights.

Data Manager focuses on ensuring the efficient and effective treatment and use of data. In some occasions, the PC or someone in the coordinating organization will undertake this role. In other cases, a partner/person with specific IT skills will assume it. This role has acquired an increased relevance since 2017, when the EC started running the Open Research Data Pilot, aiming at improving and maximizing access to and re-use of research data generated by Horizon 2020 (European Commission, 2021a).

Project Management Team (PMT) is typically composed by the PC, the PM and the PMO representatives. In addition, it sometimes also includes the exploitation and/or innovation manager, for those projects that have such a role.

Steering Committee (SC) is chaired by the PC and is the key-decision making and issue-resolution body for the project. Any significant decisions that may affect the project or the teams' ability to deliver on the objectives will be escalated to the SC. Approval of key documents and deliverables, resolution of important project issues or significant amendment requests will be discussed and decided upon here (PM2 Alliance, 2018; Andersen et al., 2018). In other contexts it is also referred as to Executive Board (ttopstart, n.d.).

General Assembly (GA) is usually formed by one representative of each project partner and is led by the PC. The GA typically meets several times during the course of the project, where it provides information about the progress of activities and helps resolving issues (PM² Alliance, 2018).

Advisory Board(s) (ABs) are valued groups of external experts who regularly meet with the Consortium through the project (Tsioutsia et al., 2016). They typically provide guidance on scientific, technical, ethical and legal matters. They often encourage the interactions of the project with other projects, initiatives and activities.

Collaborative EU-funded projects: Managerial Procedures and Tools

This section describes the managerial procedures and tools required for a successful implementation of a collaborative EU-funded project.

Website: In an EU-funded project, the project website is one of the main dissemination and communication channels. It ideally should present the project hypothesis and main goal, the administrative data of the project, describe the Consortium and provide access to the public deliverables of the project.

Internal Repository: In order to share internal documents among the Consortium members, it is very useful to set a file repository. There a several solutions and file hosting services, but it is important that access is protected and restricted to the Consortium.

Meetings: In order to ensure appropriate communication within the project, it is imperative that the different managerial boards meet regularly. These meetings can be either in person or remotely by use of teleconference media.

Data Management: Good research data management allows data and knowledge integration and reuse, and therefore plays a key role in knowledge discovery and innovation. The objective is to make project research data Findable, Accessible, Interoperable and Reusable (FAIR). Data Management Plans (DMPs) are a key element of good data management. A DMP describes the data management life cycle for the data to be collected, processed and/or generated by an EU-funded project (European Commission, 2021a). The General Data Protection Regulation (GDPR) is applicable since 5 May 2018. Since that date, all entities concerned must comply with the new rules when processing personal data (European Union, 2016).

Results

After presenting the managerial structure and tools for both multi-centre clinical trials and EU-funded collaborative projects, the next sections aim at describing the PREVIEW project (Raben et al., 2013), as a case study illustrating and merging both features.

Case Study, the PREVIEW project

Diabetes is a costly disease and according to WHO, the direct health care costs of diabetes range from 2.5% to 15% of annual national health care budgets. Type-2 diabetes (T2D) represents about 90% of all cases of diabetes and is mainly caused by the worldwide obesity epidemic (WHO, 2003).

PREVIEW "PREVention of diabetes through lifestyle Intervention and population studies in Europe and around the World" project (Grant Agreement no. 312057, 2017) addressed potential solutions to the massive problems associated with the global diabesity epidemic (obesity and T2D). PREVIEW aimed at increasing the knowledge on how specific lifestyle factors can help preventing type-2 diabetes (PREVIEW, n.d.).

PREVIEW started on 01-January 2013 and finished on 31-December 2018. It had a budget of 14 M€ corresponding to a maximum funding from the European Commission of 9 M€ plus national funds from the Australia, New Zealand and Canada (European Commission, n.d.-b).

The project was coordinated by Prof. Anne Raben from the University of Copenhagen (UCPH), Denmark (PREVIEW, n.d.).

PREVIEW included 15 beneficiaries, 12 of them from Europe (East, West, North and South) and 3 overseas (Australia, New Zealand, and Canada). Among them are 12 Universities, 1 research centre, 1 SME and 1 industrial partner (PREVIEW, n.d.). The project was multidisciplinary, involving experts in fields such as human nutrition and dietetics, paediatric nutrition, medicine, sport science, psychology, cooking, laboratory analyses and information and communication technologies.

The project consisted of 6 work packages (WPs): WP1: Multicentre intervention: Randomized, controlled, multicentre trial (RCT); WP2: Population studies; WP3: The role of sleep and stress in interaction with the role of diet and physical activity; WP4: Other lifestyle variables: Behavioural, sociological, environmental, cultural, socio-ecological, and socioeconomic components; WP5: Dissemination and exploitation; and WP6: Management (PREVIEW, n.d.).

Figure 3 illustrates the interrelation between the different work-packages. WP1: The clinical intervention RCT was the core element of the project.
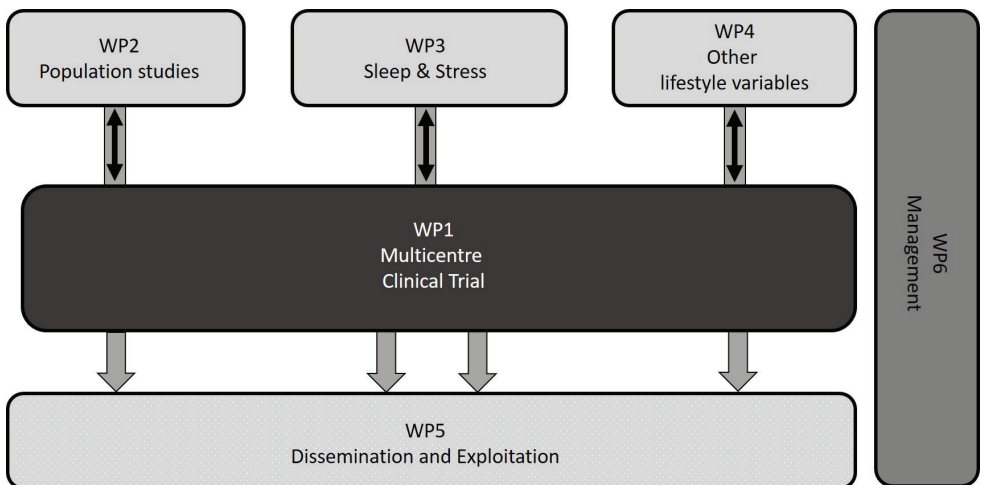
Figure 3. PREVIEW EU Project Pert Diagram (adapted from PREVIEW, 2017).

The primary goal was to identify the most efficient lifestyle pattern for the prevention of T2D in a population of pre-diabetic overweight or obese individuals (European Commission, n.d.-b).

The project comprised two distinct lines of evidence:

1) A multi-centre, randomized, controlled intervention trial (RCT) (WP1) with participants in all ages, with overweight or obesity and pre-diabetes.
2) Large population studies (WP2) using multinational data sets from all age groups (European Commission, n.d.-b).

Focus in both lines of evidence was on diet (specifically protein and glycaemic index) and intensity of physical activity, as well as their interaction with the lifestyle factors, habitual stress, and sleeping patterns, as well as behavioural, environmental, cultural and socioeconomic variables (European Commission, n.d.-b).

PREVIEW Multi-centre Clinical Trial: Managerial Roles and Structure

PREVIEW WP1 comprised a randomised, controlled, multi-centre (multi-site) and multinational trial comparing the effect of two diets as well as two intensities of physical activity on T2D incidence and weight control in overweight pre-diabetic participants (Fogelholm et al., 2017).

A large number of participants was needed in order to aim at sufficient study power. Since different ethnic and socioeconomic groups should be represented, a collaborative international approach (in and beyond Europe) rather than a national one was needed (PREVIEW, 2017).

The intervention part of PREVIEW ran over 3 years (2 years for children and adolescents) in 6 EU countries, New Zealand and Australia, and 2,326 adults and 126 children and adolescents were enrolled (Fogelholm et al., 2017; Dorenbos et al., 2018).
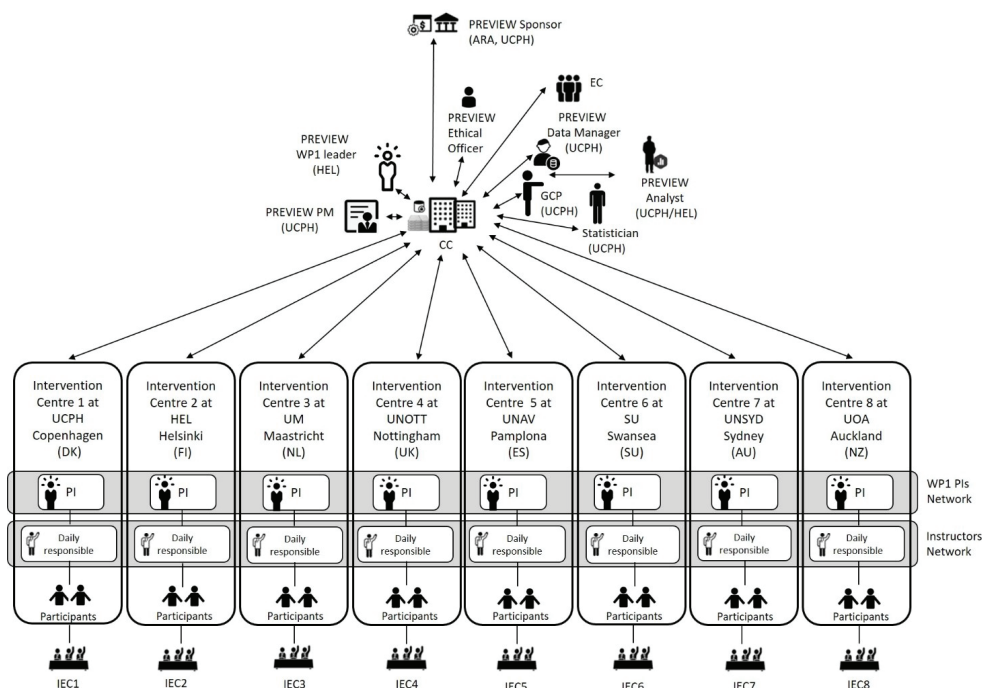
Figure 4. Managerial Structure in PREVIEW Multi-centre Clinical Trial.

PREVIEW Sponsor and Clinical Trial Manager (CTM): PREVIEW Sponsor was Prof. Anne Raben from the University of Copenhagen. She was furthermore the overall coordinator of PREVIEW project (PREVIEW, n.d.; Raben et al., 2013). In this case, she was a sponsor-investigator, who had the responsibility for the clinical study, but did not finance it, since the funding agency was the European Commission (National Institutes of Health [NIH] U.S. National Library of Medicine, n.d.).

In PREVIEW, both the Sponsor (in this case the same person as the PC) and the CTM (in this case the same person as the WP1 leader, Prof. Mikael Fogelholm) developed the project protocol jointly and performed monitoring tasks in the different intervention centres (Fogelholm et al., 2017).

PREVIEW Intervention Centres/Sites: The Clinical Trial Centres (CTCs) in PREVIEW received the name of Intervention Centres or Intervention Sites. There were 8 centres located in 6 European cities (Copenhagen, Helsinki, Maastricht, Nottingham, Pamplona and Swansea) and 2 overseas cities (Sydney and Auckland) (Fogelholm et al., 2017).

PREVIEW Coordinating Centre: The tasks allocated to the CC in PREVIEW intervention were shared between Copenhagen centre, run by The University of Copenhagen (UCPH) (organization of the Sponsor and overall PC) and Helsinki centre, run by The University of

Helsinki (HEL) (organization of the CTM/WP1 leader). Both the clinical protocol and the CRFs were developed together by Copenhagen and Helsinki centres.

The Data Manager at Copenhagen centre established and maintained the central database for the clinical study (WP1) in PREVIEW. The DM was also in charge of retrieving data upon demand from the intervention centres.

The Copenhagen centre was in charge of collating and analysing overall data for the study. This centre also provided the study with a statistician, who was consulted for doing the statistical calculations and statistical analysis plan.

Both the sponsor at Copenhagen centre and the CTM at Helsinki centre were performing several monitoring visits to the intervention centres and ensuring high quality and consistency of the intervention across all centres.

PREVIEW Principal Investigators (PIs): Each one of the eight intervention centres in PREVIEW had one Study Principal Investigator (often referred to simply as Principal Investigator, PI) as overall responsible for the trial and activities in their centres, reporting to the CTM.

Their names were as follows: Assoc. Prof. Thomas Meinert Larsen (Copenhagen, DK), Prof. Mikael Fogelholm (Helskinki, FI), Prof. Margriet Westerterp-Plantenga (Maastricht, NL), Prof. Ian Macdonald (Nottinhgam, UK), Prof. Alfredo Martinez (Navarra, ES), Prof. Svetoslav Handjiev (Sofia, BG), Prof. Jennie Brand-Miller (Sydney, AUS) and Prof. Sally Poppitt (Auckland, NZ).

PREVIEW Clinical Research Coordinators (CRCs): Each of the intervention centres in PREVIEW was coordinated on a daily basis by a CRC, usually with specific background in nutrition and/or medicine, on behalf of their respective PIs.

PREVIEW Clinical Trial Administrator (CTA): The role of the CTA was undertaken by the PREVIEW PM at the University of Copenhagen (UCPH), which was the organisation where the sponsor/PC belonged.

The CTA was in charge of the administrative aspects of the intervention when dealing with the protocol and its amendments, SOPs and instructions to participants. The CTA in PREVIEW maintained the overall TMF, both electronically and in paper, and was filing SAEs.

In addition, the CTA performed the data cleaning of data from all centres, in order to ensure their consistence and quality, in collaboration with PREVIEW DM.

PREVIEW Trial Steering Committee (TSC), Data Safety and Monitoring Board (DSMB) and Institutional Review Boards (IRBs)/IECs (Independent Ethics Committees): There was no TSC appointed in PREVIEW project. Instead, similar tasks were performed by the group of the eight PIs from the intervention centres, who met monthly during the recruitment period and bi-monthly afterwards, and consulted the project statistician when needed.

Any adverse events during the trial were notified to the local PI, the sponsor, the CTM and the PM. There was no DSMB in PREVIEW, but a similar role was performed by one of the members

of the SAB, appointed as Ethical Officer, who was in charge of reporting about SAEs and their occurrence.

The intervention centres in PREVIEW fully conformed to national legislation and applicable codes of conduct. Each centre obtained the ethical approval by their corresponding local IEC/IRB, prior to the trial start, namely:

1) Copenhagen centre: The Research Ethics Committee A of the Capital Region, DK;

2) Helsinki centre: Coordinating Ethics Committee Helsinki and Uusimaa Hospital District, FI;

3) Maastricht centre: Medical Ethical Committee (METC), Academic Hospital Maastricht, Maastricht, NL;

4) Nottingham centre: NHS Health Research Authority, NRES Committee East Midlands – Leicester, UK;

5) Navarra centre: Research Ethics Committee of the University of Navarra, ES;

6) Sofia centre: Ethics Committee for Scientific Research at the Medical University Sofia (KENIMUS), Sofia, BG;

7) Sydney centre: The University of Sydney Human Research Ethics Committee (HREC), AU;

8) Auckland centre: Northern B Health and Disability Ethics Committee (HDEC), Ministry of Health, NZ.

Furthermore, these IRBs/IECs approved the subsequent amendments to the protocol.

PREVIEW study participants were people with overweight or obesity (defined as Body Mass Index equal or over 25) with diabetes, belonging to the age ranges 10-18 years and 25-70 years. More detailed inclusion and exclusion criteria were defined in the clinical protocol (NIH, n.d.).

PREVIEW funding agencies: PREVIEW project (including WP1, the multi-centre clinical intervention) was funded by the 7th Framework Programme of the European Commission, under Grant Agreement no. (312057). The total funding provided by the EC was 9 M€.

In addition, funding was provided the New Zealand Health Research Council, Grant No. 14/191; and the NHMRC-EU Collaborative Grant, Australia. All Low Calorie Diet (LCD) products consumed by all participants from all centres during 8 weeks were provided by Cambridge Weight Plan®, UK.

PREVIEW Analyst and Data Manager (DM): The role and tasks of the Analyst in PREVIEW were shared among different people. The analyses of the trial data through the study and organisation of the trial results were done by both the Sponsor and the CRC at Copenhagen centre and the CTM at the CC in Helsinki. The project statistician from the University of Copenhagen participated in the study design, calculated the sample size and defined the Statistical Analysis Plan for the trial.

The PREVIEW DM was a person working at the Copenhagen centre, acting as overall data manager for the clinical intervention. The DM was involved in the design CRFs, review of the protocol document and development of the trial SOPs related to data management.

The PREVIEW DM randomized the participants and created and maintained the CRFs, which were populated by staff in each intervention centre. The DM was responsible for designing, and setting up and maintaining the trial databases. The DM also generated queries and prepared datasets upon request from personnel in the intervention centres.

PREVIEW Multi-centre Clinical Trial: Managerial Procedures and Tools

PREVIEW GCP: The work of PREVIEW was carried out in compliance with the relevant requirements of the latest version of the Declaration of Helsinki (59th WMA General Assembly, Seoul, Korea, October 2008), and the ICH-GCP, The International Conference on Harmonisation (ICH) for Good Clinical Practice to the extent that was possible and relevant considering financial and time-constraints (ICH, 1997, 2016). All participants provided written informed consent prior to commencing screening procedures in clinic. All information obtained during the trial was handled according to local regulations and the European Directive 95/46/CE (directive on protection of individuals with regard to the processing of personal data and on the free movement of such data) (Fogelholm et al., 2017). The trial is registered with ClinicalTrials. gov, NCT01777893.

All staff involved in the PREVIEW study followed specific training in Good Clinical Practices. For example, personnel in Copenhagen who had not received training previously, followed 1-h GCP training in http://www.gcp-enhed.dk/elaering/. In addition, key personnel received the GCP training offered as a PhD course at the University of Copenhagen (duration of 3 days).

UCPH had a general GCP advisor for the project, who trained the project manager (PM) in how to build and keep the Trial Master File.

Monitoring in PREVIEW: The intervention centres received monitoring visits either from the Sponsor or from the PREVIEW WP1 Leader (as CTM), to check whether the protocol and procedures were followed, and ensured that corrective actions were taken, as appropriate.

PREVIEW study protocol was prepared before the start of the intervention, and approved by the local Human Ethics Committees (IECs) at each study centre. Amendments were issued when relevant, and a new approval obtained, when the local laws required so.

PREVIEW Trial Master File (TMF) and the Internal Repository: An electronic TMF with relevant documents was designed and maintained by the University of Copenhagen, both in paper and electronically. All written study material was uploaded and made available at a private section of the PREVIEW website, including the protocol and its amendments, SOPs, and instruction materials for the intervention participants, in order ensure that comparable methods were followed across the eight centres (Fogelholm et al., 2017).

PREVIEW Case Report Forms (CRFs): The PREVIEW CRFs were designed before the trial started. They were initially developed in paper, mainly by the Sponsor, the Copenhagen PI and the CTM/Helsinki PI, but with contribution and reviews from the PIs in all centres and involvement of the DM. The CRFs were afterwards implemented electronically by using OpenClinica (n.d.) open source software.

Some centres decided to drop the paper CRFs and directly type the data into the OpenClinica CRFs. Other centres initially gathered the data from the participants in paper, and subsequently included it in OpenClinica. Only selected people in each centre had permission and credentials to access OpenClinica.

PREVIEW Standard Operating Procedures (SOPs): Twenty-four SOPs were developed for PREVIEW project, in order to ensure homogeneity of procedures in the intervention among the centres. They covered aspects such: the Low Calorie Diet (Christensen et al., 2018), diet and physical activity, group supervision, pre-screening, screening and randomisation of participants, measurements from the participants, samples collection, data quality, CRFs and questionnaires.

PREVIEW Meetings: Specific working groups with relevant centre representatives were established. Their aim was to discuss and agree on questions related to dietary topics, physical activity, data management and other methodological and medical issues (Fogelholm et al., 2017).

During the recruitment phase, PIs from each centre, together with the PC and PM participated in a monthly teleconference, which continued at regular intervals throughout the intervention (Fogelholm et al., 2017).

In addition to regular internal meetings at each intervention centre (more frequent at the beginning of the study, i.e. once a week, and less as the intervention was progressing), representatives from all centres were meeting in person at least once a year at a three-day meeting, and in connection with the PREVIEW project GA meetings (Fogelholm et al., 2017).

An Instructors' network formed by the CRCs, together with key hands-on staff from each centre, was meeting regularly by teleconference, in order to discuss problems and challenges and share best practices.

Training in PREVIEW: Before the start of the trial, representatives from each centre participated in two training sessions, each of 2-3 days duration. One session at the University of Copenhagen focused on the study protocol, GCP, instructions for study participants, and all outcome measurements (Fogelholm et al., 2017). The other session, arranged by the University of Stuttgart, dealt with the behaviour change methods for group counselling. Attendees then trained their local staff (Kahlert et al., 2016).

PREVIEW Collaborative EU-funded Project: Managerial Roles and Structure

The project management structure of the PREVIEW project consisted of the following 7 bodies: 1) Project Coordinator (PC); 2) Project Manager (PM); 3) EU Liaison Office; 4) General Assembly (GA); 5) Scientific Advisory Board (SAB); 6) Steering Committee (SC); and 7) Work Package Leaders (WPL) (PREVIEW, 2017).

The Coordinator and the leading organisations of the respective work packages (WPs) of PREVIEW are indicated in parenthesis: Project Coordinator, University of Copenhagen (UCPH): Prof. A. Raben, WP1: University of Helsinki (HEL), leader: Prof. M. Fogelholm; WP2: Wageningen University (WU), leader: Prof. E. Feskens; WP3: Maastricht University (UM), leader: Prof. M. Westerterp-Plantenga; WP4: University of Stuttgart (USTUTT), leader: Prof. W. Schlicht; WP5: University of Sydney (UNSYD), leader: Prof. J. Brand-Miller; WP6: University of Copenhagen (UCPH), leader: Prof. A. Raben, EU Liaison Office at University of Copenhagen (UCPH): Senior Executive Consultant P. Petersen (PREVIEW, 2017).
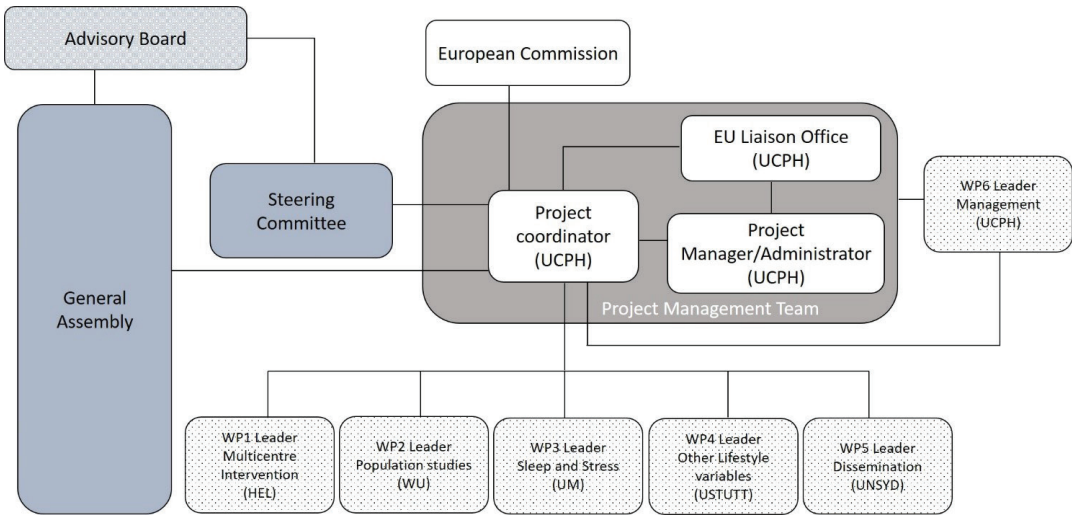
Figure 5. PREVIEW EU Project Management Structure.
UCPH: University of Copenhagen; HEL: University of Helsinki; WU: University of Wageningen; UM: University of Maastricht; USTUTT: University of Stuttgart and UNSYD: University of Sydney (adapted from PREVIEW, 2017).

PREVIEW Project Management Team (PMT): The PREVIEW PMT was formed by the Project Coordinator (PC), the Project Manager (PM) and the PMO. The managerial responsibilities with regards to the project were shared among them, as described below:

PREVIEW Project Coordinator (PC): In addition to the overall scientific coordination of the project, the responsibilities of the PC in PREVIEW were: 1) to act as the intermediary between the Consortium and the EC; 2) to ensure that the other partners duly signed the contract with the Commission in good time; 3) to distribute the funds among the partners, keep accounts and inform the EC accordingly; 4) to collect all deliverables, from the responsible partners, do a quality review of them and forward them to the Commission; and 5) to prepare periodic reports to the Commission (PREVIEW, 2017).

Even if all these responsibilities stayed with the PC, some of the related tasks were delegated to the PM or the PMO.

PREVIEW Project Manager/Administrator (PM): The daily management was carried out by the PM, under responsibility of the PC and in close collaboration with the EU-Liaison Office at the University of Copenhagen (former EU Office, currently Office of Research Services, Department of Research and Innovation), functioning as a PMO (PREVIEW, 2017).

The PM belonged to the same department as the PC (Department of Nutrition, Exercise and Sports –NEXS, Faculty of SCIENCE, University of Copenhagen), and was hired on demand and for the specific purpose of the PREVIEW project. The tasks of the PM were: 1) to manage the project on a daily basis, in agreement with the PC; 2) to arrange and prepare meeting agendas (kick-off, SC and GA meetings) and communicate decisions/prepare minutes; 3) to ensure and facilitate communication within the project partners; 4) to communicate with the EC, on behalf of the PC; 5) to collate, revise, format and submit deliverables to the EC; 6) to prepare Periodic and Final Reports, together with the PC, and with contribution from the SC members (and eventually from other partners); 7) to design and maintain the internal repository with all the project-related documents; 8) to prepare dissemination material; 9) to participate in Technical Reviews with the European Commission; and 10) to track and keep an updated list of synopses for publication.

PREVIEW Project Management Office (PMO): The PC and the PM in PREVIEW were in close contact with the central EU-Liaison Office at the University of Copenhagen. The University of Copenhagen has extensive experience in managing EU Projects. In FP7, the University of Copenhagen coordinated 21 collaborative projects and participated in total in 410 projects. In H2020 it participates in total in more than 689 projects, coordinating so far 14 collaborative projects (European Commission, 2021b).

The post-award team at the EU-Liaison Office was in charge of the following tasks: 1) support to the PC with regard to contractual matters between the Coordinator and the European Commission); 2) receipt of pre-financing and payments from the EC; 3) distribution of pre-financing and payments to the partners according to procedures agreed upon; 4) communication with the EC regarding administrative matters (such as eventual amendments) and financial reporting; 5) collation of financial reports (Form Cs and Certificates of Financial Statement; 6) provision of legal and financial advice to project partners; 7) participation in GA meetings and specific SC meetings upon request; and 8) participation in Technical Reviews in front of the EC, when deemed needed.

In addition, the EU-Liaison Office at the University of Copenhagen was involved in the preparation of the proposal (pre-award team), and during negotiation by reviewing the Grant Agreement (GA) and Consortium Agreement (CA) (legal team).

PREVIEW Quality Manager (QM) and Exploitation/Innovation Manager: PREVIEW did not have a QM appointed. This role was undertaken jointly by the PC and the PM, with involvement from selected internal Consortium members, when needed.

PREVIEW also did not have an Exploitation/Innovation Manager. However, the leader of WP5: Exploitation and Dissemination, Prof. Jennie Brand-Miller (USTUTT) undertook this role and developed together with Prof. Wolfgang Schlicht (USTUTT) an IPR Policy document,

promoting exploitation of project results, awareness of IPR and knowledge transfer.

PREVIEW Data Manager (DM): The PREVIEW multicentre clinical intervention (WP1) appointed an overall DM working at the University of Copenhagen. In addition to the previously described Data Management tasks related to the clinical trial, the DM was in charge of the following: 1) setting up and maintaining the PREVIEW datahub, a central structure collecting all study data and 2) providing data sets to researchers, after approval from the SC of the relevant synopsis for publication.

PREVIEW WP Leaders (WPLs): Every WP (1-6) was led by a WP Leader (WPL). The WPLs were responsible for the scientific coordination of their WP and tasks, including also the coordination of the workflow between their WP and others. The WPLs provided written input to all reports on activities when requested (e.g. Periodic Reports and Final Report) and collated deliverables and other information (PREVIEW, 2017). The specific allocation of responsibilities within WP1, PREVIEW Intervention/Multi-centre clinical trial, is illustrated in Figure 4.

PREVIEW Steering Committee (SC): The SC in PREVIEW was the decision-implementing body of the project. It was formed by the work package leaders (WPLs) and chaired by the PC. The PC in cooperation with the SC was in charge of the operational management of all the activities of the PREVIEW project. The SC facilitated exchange of information, enabling the PMT to make important decisions regarding the direction of a given WP. The SC was meeting four times a year. The SC consisted of: Prof. Anne Raben (UCPH), Project Coordinator, WP6 leader; Prof. Mikael Fogelholm (HEL), WP1 leader; Prof. Edith Feskens (WU), WP2 leader; Prof. Margriet Westerterp-Plantenga (UM), WP3 leader; Prof. Wolfgang Schlicht (USTUTT), WP4 leader and Prof. Jennie Brand-Miller (UNSYD), WP5 leader (PREVIEW, 2017).

PREVIEW General Assembly (GA): The GA in PREVIEW consisted of the partners' representatives, chaired by the PC. The GA was the final decision-making authority within the project. The GA was able to make overall decisions concerning the PREVIEW project.

Formal exchange of information largely took place as part of the GA annual meeting. The PC was ultimately responsible for the content of these meetings and was largely assisted by the members of the SC regarding both scientific content, as well as practical details (PREVIEW, 2017).

PREVIEW Scientific Advisory Board (SAB): The GA and the SC in PREVIEW were assisted by a Scientific Advisory Board (SAB) consisting of independent renowned experts in the fields of obesity and diabetes (PREVIEW, 2017).

The SAB was consulted on specific strategic matters regarding the scope of the project activities and to ensure that the direction of the PREVIEW project kept in touch with ongoing international diabetes research (PREVIEW, 2017).

Exchange of information between PREVIEW and SAB largely took place as part of the GA annual meetings, and in some occasions via mail communication. Travelling and living expenses for this Board were covered by the project management budget. The SAB in PREVIEW consisted of the following members: Prof. Louise Dye, Prof. Richard L. Atkinson, Prof. Lauren Lissner, Prof Boyd Swinburn, and Grethe Andersen (Fogelholm et al., 2017).

PREVIEW EU-funded Collaborative Project: Managerial Procedures and Tools

PREVIEW Website: A project website was established at the start of the project. It was developed by the University of Sydney, by using the ning.com platform (http://preview.ning.com/) (Fogelholm et al., 2017).

The project website was the main means to reach the general public and currently is still active. It contains information about the project objectives, WPs structure and Consortium. It includes project-specific dissemination material, such as the project flyer and the 6-monthly newsletters and a list of dissemination activities and publications derived from the project. It also gives access to the project e-learning material and some multimedia material, such as project-related videos.

PREVIEW Internal Repository: A password-protected repository of documents was established early in the project, as an internal part of PREVIEW website for only Consortium members (Fogelholm et al., 2017).

It contained project related documents, such as the Grant Agreement, Consortium Agreement, deliverables, reports, meeting agendas and minutes, approved synopses for publications and project publications. As previously described, it also gave access to documents related to the multi-centre clinical trial/intervention, such as the TMF, including the protocol and its amendments, ethical approvals from the IRBs/IECs, SOPs and instructions to participants. The PM was in charge of granting access to only Consortium members and maintaining contents up to date.

Project Meetings in PREVIEW: The partners in the PREVIEW communicated and shared information by email and conference calls, in order to reduce travel cost and improve use of executive time. When possible, the annual GA meetings or SC 3-monthly meetings were held in connection with relevant international scientific conferences.

The kick-off meeting was of special relevance. It was held during M2 of the project, at the coordinator premises at the University of Copenhagen, Copenhagen, Denmark. This meeting was the first occasion where all project partners met in person. The project coordinator chaired the meeting, and the project manager was introduced. The project scene was settled, and the managerial structure and procedures were explained to all participants. Subsequent GA meetings were hosted each time by one Consortium partner.

Table 1 provides an overview of the general management procedures, including the frequency of meetings (PREVIEW, 2017).

Table 1. PREVIEW EU project Management procedures (PREVIEW, 2017).

WHO	WHEN	WHAT
The Project Coordinator/ Project Manager	Daily	Performing the day-to-day management of the project
Partners	Monthly	Reporting to WPLs, through progress report and meetings
WP leaders	Every three months	Reporting to PC, in connection to the SC meetings
Project Coordinator	At the end of each reporting period (M12, M30, M48, M72)	Reporting to the EC, through the periodic activity report and final report
Project Coordinator	At project start, and after approval of periodic reports	Distribution of pre-financing and project payments to the Consortium
Project Coordinator / Steering Committee	Annual	Reporting to the GA Minutes of meeting circulated to all partners
Project Coordinator/ General Assembly	Annual	Presenting for the SAB
Scientific Advisory Board	Annual	Reporting to the GA Providing feedback about the project
All partners	Annual	Participating in the annual GA meeting Kick-off meeting hosted by the coordinator Rest of meetings hosted by turns by different project partners
All partners	Annual	Researcher's forum: arranged in connection with the GA meeting

During the project, in addition to regular meetings among the Consortium partners, the project went through 3 technical reviews upon request from the EC. During these, independent experts analysed the status and challenges of the project, and provided a set of recommendations and action points to which the Consortium should provide a response, and eventually react and adjust the project accordingly.

Data Management in PREVIEW: Appropriate attention to Data Management in PREVIEW was ensured from the start. However, a formal Data Management Plan was not officially issued, since it was not a requirement under FP7 (vs. H2020 projects participating in the Open Research Data Pilot).

Personal data included aspects of health, ethnicity and information related to lifestyle variables such as dietary preferences and habits and physical activity habits as well as sleep, stress, habitual behaviour, social environmental influences, cultural habits, as well as socio-ecologic and socioeconomic information. The project did not collect data on political opinions, religious or philosophical convictions. None of the data collected were disclosed to third parties and the information collected was only used within the project (PREVIEW, 2017).

Each partner in PREVIEW should ensure the confidentiality of any personal data held or transmitted on paper, files, manual or electronic systems or any other manner, for example by protecting access to databases and buildings (PREVIEW, 2017).

The clinical samples obtained were treated as confidential and labelled with a trial code number. For additional privacy protection, the trial code number was replaced by a unique new identifier, which was used in all subsequent work. The key linking both identifiers was kept safely locked at each intervention centre (PREVIEW, 2017).

The privacy of personal data was ensured during handling, storage and transfer of data, in accordance with national regulations and EU regulations such as the Data Protection Directive 95/46/EC, which was superseded by the GDPR from 2016.

PREVIEW EU-funded Collaborative project including a large Multi-centre Clinical Trial

The second and third sub-sections focused on PREVIEW multi-centre clinical trial, while the fourth and fifth sub-sections presented PREVIEW seen from the perspective of an EU-funded collaborative project.

It can be challenging to understand the interrelation between both scenarios, as well as to comply with the rules and requirements of both as the same time.

Table 2 aims at establishing, when applicable, a parallelism between the managerial roles of both scenarios in PREVIEW.

Table 2. Summary of Managerial Roles, Structure, Procedures and Tools in Multi-centre Clinical Trials (Left) and in Collaborative EU-funded Projects (Right).

Managerial roles and structure	
Multi-centre Clinical Trials	**Collaborative EU-funded projects**
Sponsor	Project coordinator (PC)
	Exploitation and/or Innovation Manager
-	General Assembly (GA)
Contract Research Organisation (CRO)	Quality Manager (QM)
Coordinating Centre (CC)	Coordinating organisation
Clinical Research Associate (CRA)	-
-	Project Management Team (PMT)
Clinical Trial Manager (CTM)	Project Manager (PM)
Principal Investigator (PI)	Principal Investigator (PI)
Clinical Research Coordinator (CRC)	Daily responsible from each beneficiary
Clinical Trial Administrator (CTA)	Project Management Office (PMO)/ Project Administrator
Trial Steering Committee (TSC)	Steering Committee (SC)
Data Safety and Monitoring Board (DSMB)/ Data Monitoring Committee (DMC)	Advisory Boards (ABs)
Institutional Review Boards (IRBs)/ Independent Ethical Committees (IECs)	Ethics Manager
Working Group Leader	Work package leader (WPL)
Participants	Users, stakeholders
Funding Agencies	European Commission (EC)
Analyst Data Manager (DM)	Data Manager (DM)

Managerial Procedures and Tools	
Multi-centre Clinical Trials	**Collaborative EU-funded projects**
Good Clinical Research Practice (GCP)	Quality Management
Register in Clinicaltrials.gov	Project website
Monitoring	Periodic Reporting and Project Reviews
Data Management	Data Management
Protocol	Description of Work (DoW)
Standard Operating Procedures (SOPs)	
Case Report Form (CRF)	-
Trial Master File (TMF)	Internal repository
Principal Investigator (PI)	Principal Investigator (PI)
Data hub	Data hub, central database
Meetings	Meetings
Training	Training

Figure 6 is a timeline aiming at providing an integrated overview of the procedures and time events for both scenarios in PREVIEW.
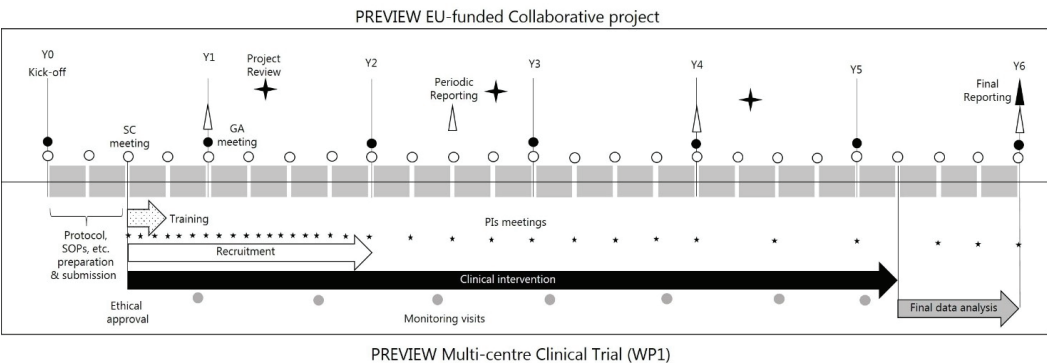
Figure 6. Timeline for the PREVIEW EU-funded Collaborative project (above) and the PREVIEW Multi-centre Clinical Trial (below).

Discussion and Conclusion

PREVIEW was a collaborative EU-funded project that involved a large multi-centre clinical trial (WP1). The Sponsor was a sponsor-investigator, and at the same time, the overall PC. This helped maintaining the overview and compliance with the demands for both contexts.

The tasks associated to the CC for WP1 were shared between Copenhagen and Helsinki centres, where the Sponsor and the CTM belonged, respectively. This approach made sense as the Sponsor and the CTM could complement and collaborate with each other. In addition, this helped balancing the distribution of efforts and responsibilities within the project.

Each of the 8 intervention centres had a PI, as overall responsible, and a daily responsible (CRC). This structure worked well, as the CRCs were in many cases, staff dedicating full-time or a significant part of their time to PREVIEW, in an operative role, while the PIs often could devote part-time to the project, and their role consisted in giving direction and strategy to the intervention.

The CTA role was undertaken by the PM, after receiving appropriate training in GCP. This approach worked well, as the PM was already dealing with the several documents from the project, where the trial belonged. This structure allowed shared use of resources, and helped the PM to acquire new knowledge and skills.

There was no TSC, and a similar role was assumed by the group of the PIs from all centres, counting with the advice from the SAB members. No DSMC was employed, although there was an Ethical Officer, responsible for monitoring and reporting about the safety of the trial. This role was undertaken by one of the members of the SAB. This configuration was cost effective, and made sense given the financial constraints of the project and the trial.

The analyst role in PREVIEW was shared among the sponsor, the CRC in Copenhagen centre, the CTM and the project statistician. The DM was hired by the University of Copenhagen, and was assuming the overall data management of the multi-centre clinical trial. This decision was logical, because of the expertise present at the University, as well as the datahub (placed at UCPH), which needed to aggregate data from all centres.

The monitoring of the trial was done internally by the CC instead of by an external monitor. Although this compromise made sense from the financial point of view, such a task should ideally be done by an external party, not involved in the trial. Therefore, in the future, it is important to include a financial contribution for this in the budget from the start.

Specific WP1 working groups (e.g. for dietary plans, questionnaires and medical issues), with relevant centre representatives were established very early in the project. This was deemed necessary, since WP1 constituted about 75% of the project and a huge workload was put on the WP1 leader and the Sponsor. It would not have been possible to fulfil the WP1 goals without delegation of some the tasks to the other partners. For similar projects in the future, it is advisable to define several thematic working groups for the clinical trial prior to the start date. Clear responsibility needs to be established, or have separate WPs dedicated to each area. It is though

important to ensure that the project does not become unmanageable because of being broken down into too many WPs.

PIs from all WP1 centres met regularly, with high intensity during the recruitment period. An instructors' network formed by the CRCs, together with key hands-on staff from each centre, also met regularly by teleconference, to discuss problems and challenges, as well as to share best practices. Such regular meetings were crucial to enhance collaboration, monitor progress and communicate in a transparent manner among partners.

The coordination of PREVIEW consisted of a combination of centralised and de-centralised project management. The PC, the PM and the PMO formed together the PMT, and jointly ensured that the coordination and administration of the project was done correctly and efficiently, while releasing the PC from some of the administrative burden.

The GA was formed by representatives from all beneficiaries, chaired by the PC, and the SC consisted of all work packages' leaders. The GA and the SC were key with regard to reviewing and implementing decisions. The PC alone would not have been able to undertake these tasks. The SAB was formed by reputed external experts, who provided independent advice.

The project website was the main channel to reach the general public. It served as a resource providing information about project objectives and progress. A password protected private section was used as internal repository, which was very useful to share project related documents among the Consortium members, including those from the TMF from the intervention in WP1. Regular meetings at all levels (WP, SC, GA, other ad-hoc meetings) were key to ensure good communication and collaboration among the project team.

Multi-centre clinical trials have several advantages with respect to single-centre trials, however, the management is more complex. Furthermore, the management of collaborative EU-funded projects is usually regarded as challenging, time consuming and demanding. This article has presented PREVIEW FP7 project, as a combination of those two managerial scenarios. A robust managerial structure and a set of managerial procedures and tools have been designed for each of them, with an optimal use and reutilisation of resources.

PREVIEW is not the first, nor the last EU-funded project that includes a multi-centre clinical trial. The authors hope that the structures, tools, and reflections gathered, described, and proposed in this paper will help future coordinators to plan and manage multi-centre clinical trials in the framework of collaborative EU-funded projects, as well as other multi-partner complex projects, in a successful way.

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References

Andersen, J., Toom, K., Poli, S., & Miller, P. F. (2018). *Research management – Europe and beyond*. Elsevier.

CareSearch Project. (2018, January 11). *Multi-site research*. Australian Government, National Palliative Care Program. Retrieved from https://www.caresearch.com.au/caresearch/tabid/2647/Default.aspx

Clinical Trials Transformation Initiative. (2021). Retrieved October 2021 from https://www.ctti-clinicaltrials.org

Choudhury, O., Fairoza, N., Sylla, I., & Das, A. (2019a) *A blockchain framework for managing and monitoring data in multi-site clinical trials*. https://arxiv.org/abs/1902.03975

Choudhury, O., Sylla, I., Fairoza, N., & Das, A. (2019b). A blockchain framework for ensuring data quality in multi-organizational clinical trials. 2019 *IEEE International Conference on Healthcare Informatics (ICHI)*, Xi'an, China, pp. 1-9.

Christensen, P., Meinert Larsen, T., Westerterp-Plantenga, M., Macdonald, I., Martinez, J. A., Handjiev, S., Poppitt, S., Hansen, S., Ritz, C., Astrup, A., Pastor-Sanz, L., Sandø-Pedersen, F., Pietiläinen K. H., Sundvall, J., Drummen, M., Taylor, M. A., Navas-Carretero, S., Handjieva-Darlenska, T., Brodie, S., Silvestre, M. P., Huttunen-Lenz, M., Brand-Miller, J., Fogelholm, M., & Raben, A. (2018). Men and women respond differently to rapid weight loss: Metabolic outcomes of a multi-centre intervention study after a low-energy diet in 2500 overweight, individuals with pre-diabetes (PREVIEW). *Diabetes Obesity and Metabolism, 20*(12), 2840-2851. https://doi.org/10.1111/dom.13466

Clinical Research Resource Hub (HUB), University of California San Francisco. (2017, March). Clinical trial protocol development. https://hub.ucsf.edu/protocol-development

Dorenbos, E., Drummen, M., Rijks, J., Adam, T., Stouthart, P., Martínez, J. A., Navas-Carretero, S., Stratton, G., Swindell, N., Fogelholm, M., Raben, A., Westerterp-Plantenga, M., & Vreugdenhil, A. (2018). PREVIEW (Prevention of Diabetes Through Lifestyle Intervention and Population Studies in Europe and Around the World) study in children aged 10–17 years: Design, methods, and baseline results. *Diabetes Obesity and Metabolism, 20*(5), 1096-1101. https://doi.org/10.1111/dom.13216

Enspire.Science. (n.d.-a). *The coordination dilemma in Horizon Europe.* https://enspire.science/coordination-dilemma-in-horizon-europe/

Enspire.Science. (n.d.-b). *What it means to be a Horizon Europe Project Coordinator.* https://enspire.science/horizon-europe-project-coordinator/

European Commission. (n.d.-a). *Horizon Europe - The next research and innovation framework programme.* Retrieved October 2021 from https://ec.europa.eu/info/horizon-europe-next-research-and-innovation-framework-programme_en

European Commission. (n.d.-b). The Community Research and Development Information Service (CORDIS), *The PREVIEW project.* Retrieved October 2021 from https://cordis.europa.eu/project/id/312057

European Commission. (n.d.-c). *Before you apply: EU funding for beginners.* Retrieved October 2021 from https://ec.europa.eu/info/funding-tenders/how-apply/you-apply-eu-funding-beginners_en

European Commission. (2007). *FP7 in Brief: How to get involved in FP7 Framework Programme for Research.* Retrieved April 2020 from https://ec.europa.eu/research/fp7/pdf/fp7-inbrief_en.pdf

European Commission. (2019, June 26). Annotated Model Grant Agreement (AMGA). Article 41.2 (b). *Internal Division of roles and Responsibilities. The coordinator.* Retrieved October 2021 from https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf

European Commission. (2021a). Funding and Tenders Opportunities Portal. *Data Management.* Retrieved October 2021 from https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm

European Commission. (2021b). Funding & Tenders Opportunities Portal. *Horizon Dashboard.* Retrieved October 2021 from https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/horizon-dashboard

European Commission. (2020a, January). *H2020 Programme factsheets.* https://ec.europa.eu/research/participants/data/ref/h2020/other/gm/h2020-grant-factsheet_en.pdf

European Commission. (2020b, March 31). *Emergency coronavirus research: Commission selects 18th project to develop rapid diagnostics.* https://ec.europa.eu/info/news/emergency-coronavirus-research-commission-selects-18th-project-develop-rapid-diagnostics-2020-mar-31_en

European Union. (2016). Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). https://eur-lex.europa.eu/legal-content/EN/TXT/ PDF/?uri=CELEX:32016R0679&from=EN

Eurostat. (n.d.). Collaboration in Research and Methodology for Official Statistics (CROS). *Research projects under framework programmes.* Retrieved October 2021 from https://ec.europa.eu/eurostat/cros/content/research-projects-under-framework-programmes-0_en

Fogelholm, M., Larsen, T., Westerterp-Plantenga, M., Macdonald, I., Martinez, J. A., Boyadjieva, N., Poppitt, S., Schlicht, W., Stratton, G., Sundvall, J., Lam, T., Jalo, E., Christensen, P., Drummen, M., Simpson, E., Navas-Carretero, S., Handjieva-Darlenska, T., Muirhead, R., Silvestre, M., Kahlert, D., Pastor-Sanz, L., Brand-Miller, G., & Raben, A. (2017). PREVIEW: Prevention of Diabetes Through Lifestyle Intervention and Population Studies in Europe and Around the World: Design, methods, and baseline participant description of an adult cohort enrolled into a three-year randomised clinical trial. *Nutrients, 9*(6), 632. https://doi.org/10.3390/nu9060632

Forjuoh, S. N., Helduser, J. W., Bolin, J. N., & Ory, M. G. (2015). Challenges associated with multi-institutional multi-site clinical trial collaborations: Lessons from a diabetes self-management interventions study in primary care. *Journal of Clinical Trials, 5*(3), 219. https://doi.org/10.4172/2167-0870.1000219

Friese, C. R., Mendelsohn-Victor, K., Ginex, P., McMahon, C. M., Fauer, A. J., & McCullagh, M. C. (2017). Lessons learned from a practice-based, multi-site intervention study with nurse participants. *Journal of Nursing Scholarship, 49*(2), 194-201. https://doi.org/10.1111/jnu.12279

GCP-Enhederne i Danmark. (2021). Retrieved October 2021 from https://gcp-enhed.dk/

Gist, P., & Langley, D. (2007). Application of standard project management tools to research – A case study from a multi-national clinical trial. *The Journal of Research Administration, 38*(2), 51-58.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (1997, July). General Considerations for Clinical Trials E8. Retrieved October 2021 from https://database.ich.org/sites/default/files/E8_Guideline.pdf

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016, November). Integrated addendum to ICH E6(R1): Guidelines for Good Clinical Practice E6(R2). Retrieved October 2021 from https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

Johns Hopkins Medicine. (2016, April). *Coordinating centre functions and multi-site studies*. https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/coordinating.html

Kahlert, D., Unyi-Reicherz, A., Stratton, G., Larsen, T. M., Fogelholm, M., Raben, A., & Schlicht, W. (2016). PREVIEW Behavior Modification Intervention Toolbox (PREMIT): A study protocol for a psychological element of a multicenter project. *Frontiers in Psychology, 7*, 1136. https://dx.doi.org/10.3389%2Ffpsyg.2016.01136

Kraemer, H. C. (2000). Pitfalls of multi-site randomized clinical trials of efficacy and effectiveness. *Schizophrenia Bulletin, 26*(3), 533-541. https://doi.org/10.1093/oxfordjournals. schbul.a033474

McFadden, E. (2007). *Management of data in Clinical Trials* (2nd ed.). Wiley.

Medium. (2015). Dan Sfera - *What's the difference between A CRO and a sponsor in clinical research?* https://medium.com/@TheRealDanSfera/what-s-the-difference-between-a-cro-and-a-sponsor-in-clinical-research-2a5288f0ed9c

Molloy, S. F., & Henley, P. (2016). Monitoring clinical trials: A practical guide. *Tropical Medicine and International Health, 21*(12), 1602-1611. https://doi.org/10.1111/tmi.12781

Multiregional Clinical Trials Center (MRCT) of Brigham and Women´s Hospital and Harvard (2021). *How we work*. Retrieved October 2021 from https://mrctcenter.org/about-mrct/how-we-work/

Nathanail, E., Adamos, G., & Gogas, M. (2015, July). NOVELOG (G.A. 636626) H2020 project D1.2. *Quality Assurance Framework*. Retrieved October 2021 from https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5a1909162&appId=PPGMS

National Institutes of Health, National Heart, Lung and Blood Institute. (n.d.). *New FOAs for investigator-initiated phase ii and above multi-site clinical trials - Frequently asked questions*. Retrieved October 2021 from https://www.nhlbi.nih.gov/node/83333

National Institutes of Health, U.S. National Library of Medicine. (n.d.). ClinicalTrials. gov. Retrieved October 2021 from https://clinicaltrials.gov/ct2/show/NCT01777893?term=NCT01777893&draw=2&rank=1

OpenClinica. (n.d.). Retrieved October 2021 from https://www.openclinica.com/

PM² Alliance. (2018). PM² project management methodology guide 3.0. https://www.pm2alliance.eu/wp-content/uploads/2019/05/PM%C2%B2-project-management-methodology.pdf

PREVIEW (n.d.). [PREVIEW FP7 project (GA. 312057) website]. Retrieved October 2021 from https://preview.ning.com/

PREVIEW. (2017, June 2). PREVIEW Description of Work (DoW), Grant Agreement no. 312057.

Project Management Institute. (2017). *A guide to the project management body of knowledge (PMBOK® Guide)* (6th ed.).

Raben, A., Fogelholm, M., Feskens, E.,Westerterp-Plantenga, M., Schlicht, W., & Brand-Miller, J. (2013). PREVIEW: PREVention of diabetes through lifestyle intervention and population studies in Europe and around the World: On behalf of the PREVIEW consortium. *Obesity Facts, 6*(Suppl. 1), 194. https://doi.org/10.3390/nu9060632

Rolland, B., Lee, C. P., & Potter, J. D. (2017). Greater than the sum of its parts: A qualitative study for the role of the coordinating centre in facilitating coordinated collaborative science. *The Journal of Research Administration, 48*(1), 65-85.

Tsioutsia, I-M., Keratidis, C. H., Simeonidou, P., & Lafarga, A. (2016, September). RECAP H2020 project (GA. 693171) D.1.2 *Report on Advisory Board Meetings*. https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5acd43f82

ttopstart. (n.d.). *Governance in Horizon Europe projects: Boards and Assemblies explained.* Retrieved October 2021 from https://ttopstart.com/governance-in-horizon-europe-projects-boards-and-assemblies-explained/

U.S. Food & Drug Administration. (n.d.). CFR - *Code of Federal Regulations Title 21, Part 812 – Investigational device exemptions, Subpart A-General Provisions, Sec 812.3 Definitions.* Retrieved October 2021 from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.3

U.S. Food & Drug Administration. (1998, January). *Information sheet: Institutional review boards frequently asked questions, guidance for institutional review boards and clinical investigators.* Content current as for 18 Apr 2019. https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm

Wedekind, G. K., & Philbin, S. P. (2018). Research and grant management: The role of the Project Management Office (PMO) in a European research consortium context. *The Journal of Research Administration, 49*(1), 43-62.

World Health Organization. (2003). *Diabetes factsheet.* https://www.who.int/dietphysicalactivity/media/en/gsfs_diabetes.pdf

World Health Organization. (2005). *Handbook for good clinical research practice (GCP): Guidance for implementation.* https://apps.who.int/iris/handle/10665/43392

Strategies to Obtain Research Funding for Hamamatsu University School of Medicine, a Rural Medical College in Japan

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Abstract: *Japan's operating budget for its national universities has been reduced since 2004 year by year, leaving a tight competition among universities in securing research funding. Urban universities with several prominent researchers can operate by securing competitive funding, joint research with companies, and donations, whereas small rural universities struggle with finances. How should small rural universities survive in the future? The vision and mission of Hamamatsu University School of Medicine (HUSM), a rural medical college, is to play a central role in the local community medicine through medical photonics research and academia-industry-government collaboration. HUSM is a member of the regional industrial cluster, and research administrators (RAs) have promoted the medical photonics filed through activities such as education, matching, funding, research and development support, technology transfer, and sales promotion support to make the university distinctive. RAs collaborate with universities, companies, and local governments in the same region to conduct joint research and commercialize products as though these units were a single organization. As a result, the number of joint research projects and the amount of revenue from joint research have increased every year. The government has recognized this unique approach. Furthermore, university consolidation is being pursued as a cost-saving measure to increase the money spent on research. Consolidation can strengthen the ability of university research, and can result in more joint research with companies and more research funding.*

Introduction

As of 2020, Japan has 86 national, 93 public, and 607 private universities. Until 2004, national universities were internal organizations of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) that allocated a budget to universities each year. MEXT is one of Japan's administrative agencies that promote education, academics, sports, culture, and science and technology. The organization supports operating subsidies to compensate national universities' revenue shortfall due to their incorporation. The Cabinet Office (CAO, 2002) decided in April 1999 that the transformation of national universities into independent administrative institutions would be examined. The CAO of Japan is a collegial body that has executive power and is responsible for planning and coordinating on important policy matters. The CAO believed that by incorporating national universities, they would be able to run them in a top-down management similar to the private sector and train the world's best students in a competitive environment. This examination was part of university reforms while respecting the autonomy of universities. The CAO tried to reinvigorate universities by strengthening university presidents'

authority and including education and research in budget allocations. The National University Corporation Act was enacted in July 2003 and took effect in October 2003. In April 2004, they became independent 89 national university corporations, and 86 corporations were established in April 2020 (MEXT, 2020a). The main research sources of income for national university corporations are operating subsidies and grants-in-aid scientific research (KAKENHI). With the operating subsidies declining every subsequent year, it is imperative that research funding be obtained through KAKENHI funding, other competitive funds, and joint research with private companies. The training project of research administrators (RAs), i.e., to assist in obtaining research funding, was initiated by MEXT in 2011.

Operating Subsidies

Operating subsidies in Japan fall under the "Historically-determined allocation" of block grants (Pruvot et al., 2015). It allocates a fixed amount based on the previous year's amount. MEXT is currently in the third medium-term goal for 2017–2022 (National Institution for Academic Degrees and Quality Enhancement of Higher Education, 2018). Each national university corporation conducts education and research activities based on its medium-term goals and plans. Medium-term goals 6-year targets are set by the minister of MEXT based on national university corporations' opinions. Medium-term plans are prepared by each national university corporation and approved by the minister of MEXT for the achievement of the medium-term goals. Operating subsidy is a fundamental income source for each national university corporation, but its uses are not specified. However, the "Basic Policies for Economic and Fiscal Policy Management and Structural Reform 2006" (Prime Minister's Office of Japan, 2006) indicated that efficiency has to be enhanced and the budgeted amount for each fiscal year (FY) would be decreased by 1% compared with the previous year (Japan Association of National Universities, 2018; Takeuchi, 2019).

In February 2007, a private member of the Council on Economic and Fiscal Policy proposed that the allocation of national university subsidies should be modified "based on effort and results." These expenses had been reduced by 0.8%–1.9% in FY 2010 and were 13% lower in FY 2013 than in FY 2004. The budgeted amount for FY 2019 was $10,158 million (equivalent to 108 JPY). Among other countries, Germany had a 20% increase and the UK saw a 20% reduction in comparison with 2008. In Germany, this is due to an increase in public funding from the federal government as universities that came to be run by each state and the federal government from previously being run by each state. In the UK, this is due to the suspension of operating subsidies for education (Hayashi, 2015; Universities UK, 2016).

Priority Support Quota

Priority support quota (MEXT, 2020b) is the portion of the operating subsidy based on an assessment of the progress of each university's vision and strategy to deliver the selected framework. It is allocated on an evaluation of "based on effort and results," and based on gradient allocation according to the progress of university reforms starting in FY 2016 (Takeuchi, 2019). The amount

started at $926 million, increased to $9,259 million in FY 2019 and will continue to increase. For the third period of the medium-term target from FY 2016, "three priority support frameworks" were created to help each university demonstrate its strengths and characteristics. These three frameworks promote (1) human resource development and research to meet local needs, (2) the formation of outstanding educational and research centers and networks in each field, and (3) education and research excellence at par with the world's top universities (Takeuchi, 2019). Each university would select one of the three frameworks presented by MEXT and create a "vision" and "strategy" to realize their selected framework. The vision and strategy would be based on the medium-term goals for the third term. MEXT evaluates the progress of the strategy annually based on external experts' opinions. A portion of the operating grants would be allocated based on an assessment. A total of 55, 15, and 16 universities selected the first, second, and third priority support, respectively. National universities have proactively set key performance indicators (KPIs) to determine the status of achievement of the strategies and are establishing a plan-do-check-act cycle while implementing initiatives to strengthen their autonomous functions (Otsuka, 2017).

Several study groups of experts in national university corporations have been held to discuss and evaluate the results. The evaluation aims to determine the progress of the KPIs set by the national university corporation. If progress is not identified, then its causes are analyzed and future measures are checked to examine whether they are presented. The evaluation is converted into a score based on a conversion table, and the budget allocation rate is determined. Unlike in Japan, only countries such as the UK and New Zealand have operating subsidies for research. In the UK, the question of the impact on society, economy, and culture, as well as on academia, has been considered. In 1986, the research excellence framework (RAE) was launched. RAE allocates research funding according to three indicators: the number of research projects, a discipline-specific cost index, and weighting by evaluation results (mainstream quality-related research funding) (Hayashi, 2015; Universities UK, 2016). In New Zealand, performance-based research funding (PBRF) began in 2003, based on the UK's RAE. In the PBRF, the evaluation unit is an individual's research results and the funds are allocated in aggregate by the university (Hayashi, 2015; Mizuta, 2007).

Grants-in-Aid for Scientific Research

Grants-in-Aid for Scientific Research (KAKENHI) is a competitive fund that aims to significantly advance all types of academic research, from basic to applied, in all fields, from humanities and social sciences to natural sciences (Japan Society for the Promotion of Science [JSPS], 2020). Its budget was $2,196 million for FY 2019, and it is the national university corporation's primary revenue along with operating subsidies. The number of applications and adoptions were 101,857 and 28,892, respectively, a 28.4% adoption rate. Medical science has a relatively high adoption rate. Universities have been compensating for the annual decrease in operating subsidies by obtaining competitive funds, including KAKENSHI.

Hamamatsu University School of Medicine

Hamamatsu University School of Medicine (HUSM) is a national university corporation located in Hamamatsu City, Shizuoka Prefecture, Japan. HUSM consists of the School of Medicine and School of Nursing, with 120 and 70 students, respectively, every academic year. The Graduate School of Medicine consists of the Department of Medicine (doctoral program), Cooperative Major in Medical Photonics (doctoral program), and Nursing (master's program), with 30, 3, and 16 students, respectively, every academic year. HUSM has 1,402 staff, including researchers, doctors, paramedical workers, and administrative staff, of which 392 researchers and only two are RAs. HUSM's vision and mission is "to play a central role in local community medicine" through medical photonics research and academia-industry-government collaboration.

HUSM has established the Preeminent Medical Photonics Education & Research Center and is conducting research from basic medicine to medical treatment to strengthen the functions of research and development (R&D) and human resource development. Cooperative Major in Medical Photonics was established with the neighboring Shizuoka University (SU) in FY 2018. Moreover, highly specialized personnel in biomedical engineering collaboration based on medical photonics have been developed. Furthermore, the Promotion Center for Medical Collaboration and Intellectual Property (MCIP) has been established in FY 2019 to expand the cooperation between universities, industries, government, finance, and key hospitals in the region. MCIP has two affiliated RAs with diverse functions: (1) discovering the university's medical needs and technical seeds; (2) matching the needs and seeds with companies; (3) reviewing donations and joint and contract research and signing contracts; (4) managing intellectual property, including filing, maintenance, assignment, and licensing; (5) managing research materials; (6) providing supporting for starting a business; (7) lending equipment, such as positron emission computerized tomography, computerized tomography, and magnetic resonance imaging among others, and supporting technically; (8) obtaining and helping to obtain public funding for researchers; and (9) disseminating information inside and outside the university.

HUSM's revenue for FY 2018 was $318 million, of which operating subsidies and research and endowment income (including KAKENHI) accounted for 16.9% and 7.8%, respectively (see Figure 1).
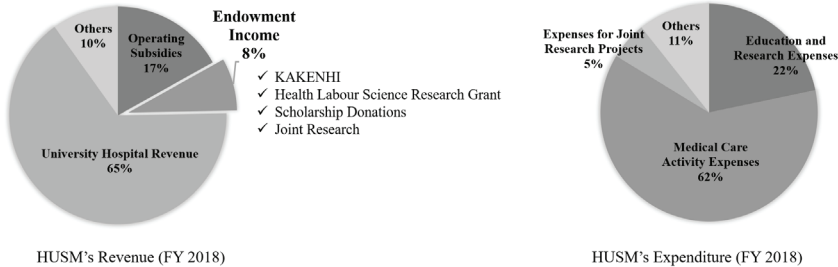
Figure 1. HUSM's Revenue and Expenditure (FY 2018)

The breakdown (in thousands) was $3,929, $5,938, $8,819, and $603 in 205 KAKENHI and Health Labour Sciences Research Grant, 517 scholarship donations, 6,800 funded research, and 87 joint research with private companies and others, respectively. Scholarship donations refer to expenses to encourage education and research, such as academic research expenses. Although 65.4% of the revenue was from the university hospital, medical expenses accounted for 62.0% of the total expenditure. Education and research expenses accounted for 21.7%.

Regional Medical Device Clusters in Japan

Regional industrial clusters in Japan have been established to promote R&D of various products through METI's industrial cluster policy since 2001 and MEXT's knowledge cluster initiative since 2002. These regional industrial clusters include the medical device cluster.

In 2019, the global medical device market was at $479 billion, which will continuously grow because of an aging population and expanding demand from emerging economies. The Japanese global medical device market was at $36.5 billion, which accounted for 7.8% of the world's total. The export value has fallen by 6% year over year (YOY), whereas the import value has a 6% YOY increase. This finding poses a challenge of excess imports. The share of large Japanese companies is also declining annually.

In 2014, the Law on the Promotion of Research, Development, and Dissemination of Medical Devices to Improve the Quality of Medical Care Received by the People was enforced. The law aims to speed up the practical application of effective and safe medical devices; develop clusters on companies, universities, and hospitals; and encourage SMEs with advanced manufacturing technologies to enter the business. Thus, the development of medical devices in clusters was promoted. Medical devices require various elemental technologies and parts. SMEs with unique manufacturing technologies can play an active role because existing high-mix low-volume products may be enhanced.

Shizuoka Prefecture, where Hamamatsu Region is located, is home to several laboratories and manufacturing sites for large- and medium-sized pharmaceutical and medical device companies, including foreign companies. Shizuoka Prefecture accounted for 10% and 18% of the nation's production value for pharmaceuticals and medical devices, respectively, in 2018. Thus far, Shizuoka Prefecture is the highest in the country among other regions and continues to be the first in the country (Shizuoka Prefecture, 2019). Various SMEs also support the production of automobiles, paper, and electrical equipment.

The regional industry clusters constitute an intra-regional network of academia-industry-government, industry, and cross-industry collaborations throughout the country. These collaborations strengthen the international competitiveness of industry and revitalize the local economy. Shizuoka Prefecture also has a Fujinokuni Advanced Medical Care Zone. It has an extremely strong government-driven industrial policy. Each prefecture applies to the national government for funding to form clusters, and the new organization plays a central role as a secretariat.

Objectives and Methods

The objective of this review is to determine ways in which small rural universities survive in the face of declining research funding. The case of HUSM was used as an example.

The operating subsidies received by Japanese national universities, the selection and evaluation of priority support quotas, and the amount of KAKENHI funding received were derived from MEXT and JSPS data. The vision and mission, KPIs, strategies, number of researchers, and income and expenditures of each university were studied from data provided by each university's website and their annual reports. The survey of university and company attitudes was collected through National Institute of Science and Technology Policy (NISTEP) data, while the survey of community attitudes was outsourced to Dentsu Inc. with funding from HUSM.

As a preliminary study, the relationship between the number of researchers at all the national universities and the GDP of the location is presented in Figure 2 (Economic and Social Research Institute, 2019; Japan Association of National Universities, 2019).
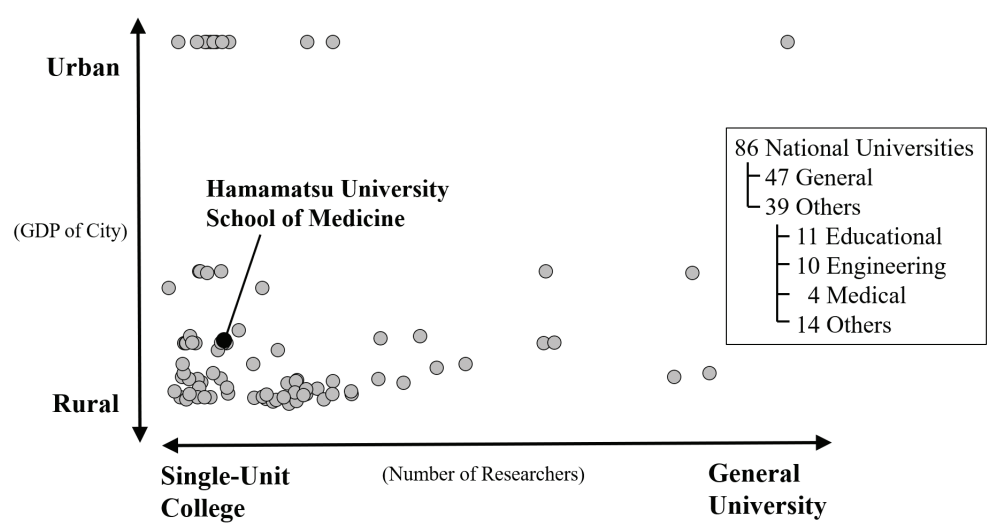
Figure 2. Classification of the National University

The number of researchers indicates whether the institution is generally a large university or a small college, and the GDP of the city indicates whether it is an urban or a rural university. Almost all the universities are small and located in the countryside. Figure 3 shows the correlation between operating subsidies and KAKENHI (MEXT, 2020b; JSPS, 2020).
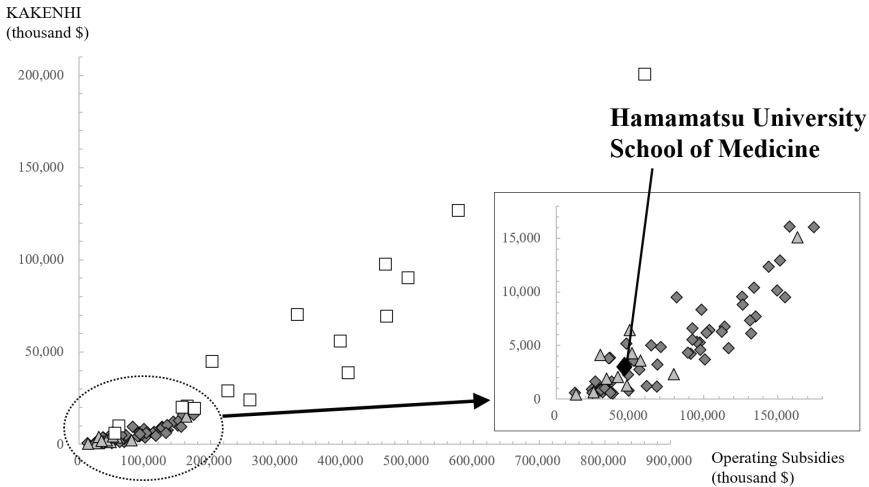
Figure 3. The Correlation between the Two Major Incomes (FY 2018)

Each university selected one of three priority support frameworks;
△ (1) human resource development and research to meet local needs,
◆ (2) the formation of outstanding educational and research centers and networks in each field, and
□ (3) education and research excellence at par with the world's top universities

Regardless of the priority support framework, universities that receive a large amount of operating subsidies also receive more KAKENHI funding. Rural single-unit colleges get less money for both, suggesting that the research environment, including finances, is strained.

Findings and Outcomes

HUSM ranked 56th in operating subsidies awards with $48,898 thousand in FY 2018. HUSM has selected the first-priority support framework of operating subsidies, that is, to promote human resource development and research to meet local needs. The visions are "developing new medical technologies that combine optical technology with other advanced technologies," "training medical photonics leaders and doctors and other medical professionals with medical photonics background," and "partnering with local communities to promote innovation." One of the KPIs is the "number of joint research projects with local companies." Based on KPI evaluation, HUSM received a "b" rating for FY 2019, second in the four-rank evaluation. Moreover, a budget allocation rate was determined based on the evaluation, and total $48,898 thousand were allocated to HUSM (MEXT, 2020a).

Table 1. Operating Subsidies and KAKENHI per Researcher (FY 2018)

Managerial procedures and tools						
	Number of Researchers	Amount Received (TS)	**Per Researcher (TS)**	Adoption Rate (%)	Amount Received (TS)	**Per Researcher (TS)**
HUSM (R-S)	329	48,898	**149**	30.1	3,515	**10.68**
AMU (R-S)	364	48,741	**134**	26.1	2,265	**6.22**
SUMS (R-S)	387	52,370	**135**	33.3	3,592	**9.28**
TMDU (U-S)	884	163,185	**185**	35.8	15,072	**17.05**
SU (R-G)	700	98,167	**140**	22.4	8,332	**11.90**
UT (U-G)	3,858	859,806	**223**	37.4	200,815	**52.05**

HUSM: Hamamatsu University School of Medicine, AMU: Asahikawa Medical University, SUMS: Shiga University of Medical Science, TMDU: Tokyo Medical and Dental University, SU: Shizuoka University, UT: the University of Tokyo, R: Rural, U: Urban, S: Single-Unit College, G: General University

Hamamatsu University School of Medicine ranked 76th in KAKENHI awards with $3.89 million in FY 2018. The average adoption rate was 28.4%, while top-ranking universities had a high adoption rate of more than 60% (JSPS, 2020). Figure 4 shows the amount of KAKENHI funding awarded to each researcher.
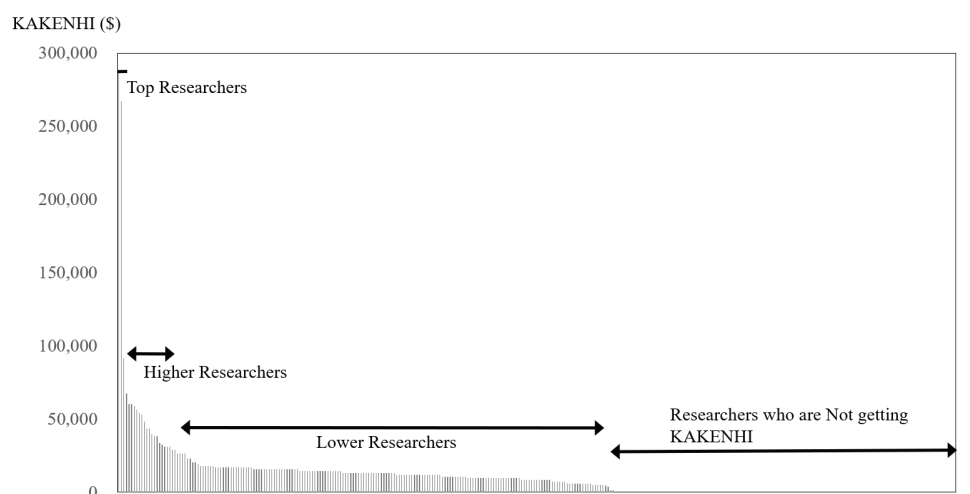
Figure 4. HUSM's KAKENHI per Researcher (FY 2018)

Only two researchers received more than $250,000, and 21 researchers received more than $30,000. Of the remaining 300-plus researchers, 133 received no funding. RAs conduct briefing sessions, document preparation seminars, peer review by top and high-level researchers, and check forms to help researchers obtain KAKENHI funding.

In addition to research funding through operating subsidies and KAKENHI, HUSM increases joint research with local companies, which is consistent with the vision/mission and KPI. HUSM had various collaborations with companies in the same prefecture and SMEs. HUSM works mainly with nearby SMEs in developing medical and assistive devices (MEXT, 2019b). This is because of the RA's efforts in education, matching, funding, R&D support, technology transfer and sales promotion support to SMEs based on HUSM's vision and mission (Amano-Ito, 2020).
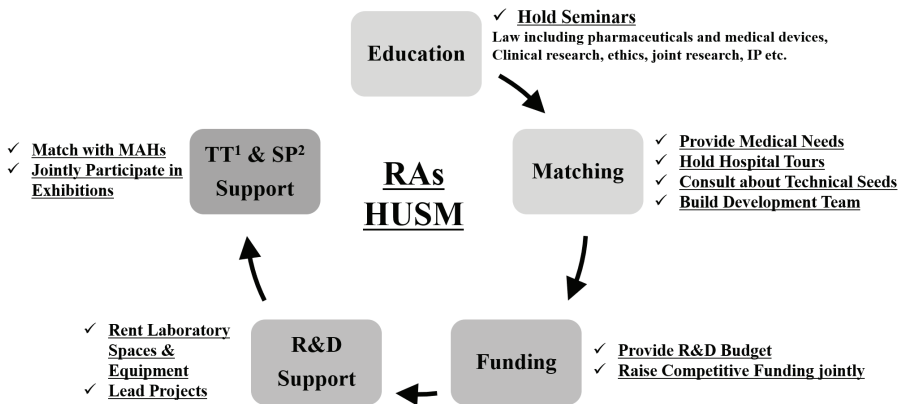
Figure 5. Ecosystem of Medical Device Development (Partial revision of Figure by Amano-Ito, 2020)

[1]technology transfer, [2]sales promotion.

In particular, HUSM provides gap funding for university-industry collaboration in the Hamamatsu Region. GAP funds promote technology transfer from within to outside the university. It differs from the US funds provided autonomously and flexibly by universities to laboratories to promote university technology transfer and create university-born ventures. Although funds similar to the amounts available in the United States have not existed in Japan, local governments and regional banks in the Hamamatsu Region have long been distributing similar funds. Hamamatsu University School of Medicine (HUSM) has been a beneficiary of the fund. As a result, the number of collaborations and the collaboration revenue have also increased over the years. In FY 2019, there were 93 collaborations amounting to $719,000 in revenue. There has also been an annual increase in the number of collaborations with regional companies on "light." There were 38 collaborations in FY 2019.
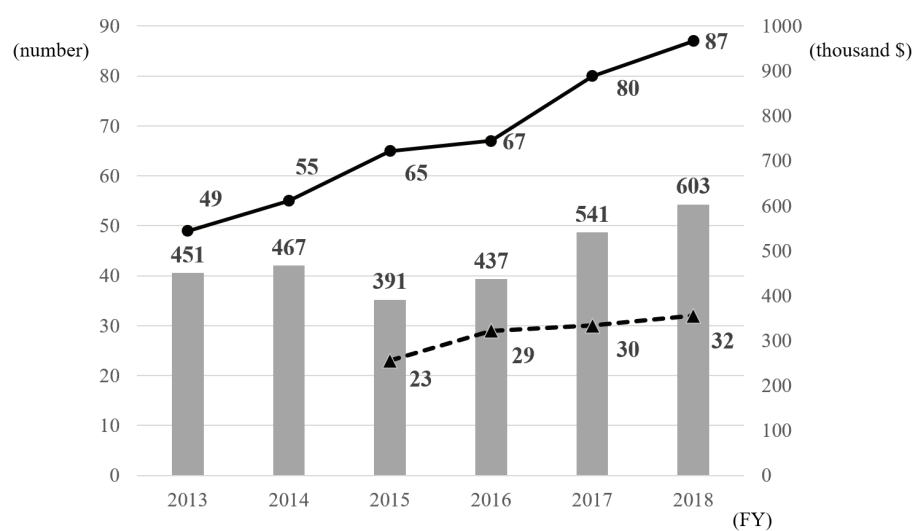
Figure 6. Joint Research with Companies

● Number of Joint Researches, ▲ Number of joint research projects about "light" with local companies, ▮ Joint Research Revenues

Figure 7 shows the relationship between the amount of KAKENHI funding obtained and the amount of joint research provided to researchers who started new collaborative research with companies in FY 2018 (National Institute of Information, 2020). The researchers did not receive a large amount of money for their collaboration, and some of them received no money. The researchers who were aiming to obtain KAKENHI funding were not interested in collaborating with companies, while those who were promoting industry-academia collaboration were not able to focus on pure academic science. None of the findings were related to age or position of researchers. The HUSM's vision/mission, KPIs and the goal of obtaining KAKENHI funding conflict with one another. HUSM researchers make the choice as to which policy to follow, and the RAs support both objectives.
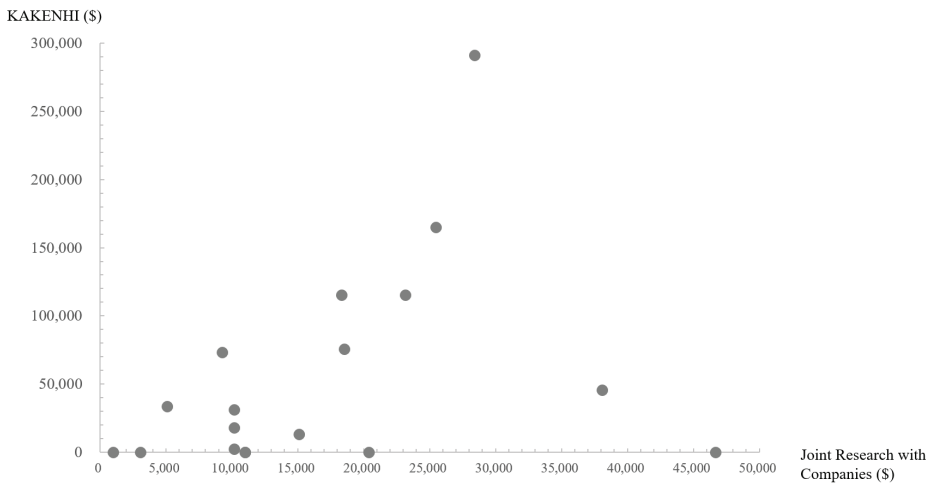
KAKENHI ($)

Figure 7. The Relationship between Joint Research and KAKENHI (FY 2018)

HUSM Status and Comparison with Other Universities

Asahikawa Medical University (AMU) and Shiga University of Medical Science (SUMS) are regional medical colleges similar to HUSM. They have also selected the first-priority support framework of operating subsidies. AMU and SUMS also received a "b" rating and were allocated $48,741 thousand and $52,370 thousand, respectively (see Table 1) (MEXT, 2020). By contrast, Tokyo Medical and Dental University (TMDU) has selected the second-priority support framework of operating subsidies to promote the formation of outstanding educational and research centers and networks in each field. TMDU received a top "a" rating from its evaluation and was allocated $163,185 thousand. KPIs of TMDU are the "number of joint research contracts" and "number of papers in collaboration with other fields." Furthermore, Table 1 presents data from SU, a rural general university in the same region as HUSM, and the University of Tokyo, an urban general university, for comparison. The total amount of operational subsidies is higher in urban areas and supports more researchers, and the amount of money per researcher is also larger. The same is true for KAKENHI funding. Among regional medical colleges, HUSM has one of the largest amounts of operating subsidies and KAKENHI funding per researcher. The regional medical colleges have lower operating subsidies, KAKENHI awards, and research scale than Japanese universities in general. It shows that they need to diversify their financial resources to survive by expanding their funds and income and effectively using and managing their assets instead of relying on operating subsidies and scientific research funds.

Of the 87 joint research projects with private companies, 25 were conducted by companies in Shizuoka Prefecture and 25 by small- and medium-sized enterprises (SMEs). Two of the 27 cases at AMU were from local companies within the prefecture, and 14 were from SMEs, whereas none of the 27 cases at SUMS were from local companies within the prefecture, and 13 were from SMEs (MEXT, 2020b).

According to a survey (NISTEP, 2020a, 2020b), 46% of universities in Japan aimed to work with SMEs, whereas 31% aimed to work with nearby companies. By contrast, 41% of companies aimed to work with nearby universities. Universities and companies aimed to work together in the same region, to a certain extent, regardless of size. The survey showed that universities and companies did not actively develop human resources who can innovate local needs that address problems in the region, and did not actively engage in research that meets local needs that solve problems in the region. The ratings were lower than the results of the FY 2016 survey. Comments about human resource development include "Regional project creations are often transitory, continuity issues exist" and "Researchers have few opportunities to understand regional development needs." Research comments include "The research is not accompanied by a track record" and "Joint research is conducted between universities and companies in the same region but is inconsistent with the region's issues."

HUSM and Regional Medical Device Clusters in Hamamatsu

In the Hamamatsu Region, the optical industry is linked to medical devices to form a university (HUSM)-driven cluster.
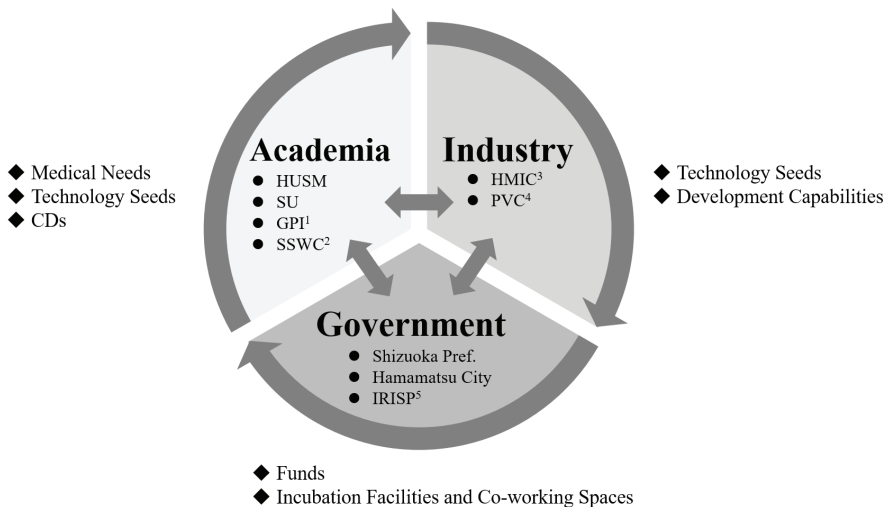
Figure 8.
Medical Device Cluster in the Hamamatsu Region

[1]The Graduate School for the Creation of New Photonics Industries
[2]Seirei Social Welfare Community
[3]Hamamatsu Medical Industry Collaboration Collegium, Hamamatsu Chamber of Commerce and Industry
[4]Photon Valley Center, Hamamatsu Agency for Innovation
[5]Industrial Research Institute of Shizuoka Prefecture

Japan's regional industry clusters (Development Bank of Japan [DBJ], 2017a, 2017b; Kitajima, 2015, 2016, 2017) are established through government project funding and rely on their human resources and funding in 3–5 years when their funds finish (DBJ, 2013, 2017a, 2017b). However, the clusters' independence does not work because of the lack of understanding of the participating companies, universities, and hospitals' situation because clusters are established and operated under local government initiative. The cluster projects end before a good relationship between parties is built. Local government officials are transferred every 2–3 years. Thus, the secretariat is left with no knowledge. This stance is adopted because the participants do not have the initiative and reluctantly cooperate with the local government. The participants perceive that the cluster is free because of the government and municipalities' cluster. Moreover, they cannot perceive that they pay their dues after the government funding ends. Unlike Porter's (2008) definition of cluster, clusters include study groups that do not aim to commercialize and only learn about the medical device industry through seminars. Few major companies participate in the cluster and transferring the knowledge and expertise of corporate personnel to the outside is difficult. In many cases, specific companies' technology seeds are used as a starting point for development instead of being developed by the participants. Therefore, continuous operation of clusters in Japan is difficult. In this context, the cluster led by HUSM stands out as a distinctive feature and provides funding to HUSM because of its continuity and the creation of collaborations between industry, academia, and medical engineering in the field of optics and medical devices.

Medical and Assistive Device Development Cases in the Hamamatsu Region

The Hamamatsu cluster has produced 85 prototypes and launched 12 medical and assistive devices in the past eight years. These included a laryngeal stroboscope, oximeter, bite guard, and periosteum elevator, and assistive devices (Amano-Ito, 2020). RAs in the cluster operated in a unique method where medical doctors and healthcare workers in universities, hospitals, and nursing care facilities present their medical needs and ideas. The Hamamatsu Chamber of Commerce and Industry (HCCI) search for companies that are members of the Hamamatsu Medical-Industrial Cooperative Research Association (HMIC) that match their needs. Universities such as HUSM and others, Shizuoka Prefecture, Hamamatsu City, and local banks subsidize R&D and provide a place of open innovation. Furthermore, hospitals and nursing care facilities provide a place for clinical study and may also be the eventual purchasers. HCCI, together with universities, hospitals, and nursing care facilities, holds seminars about medical and assistive devices and hospital tours for HMIC members. HCCI also supports exhibits at trade shows when selling the products. The Hamamatsu regional cluster could respond immediately to the demand for devices and supplies necessary for controlling the COVID-19 infection (Amano & Makino, 2020; HCCI, 2020).

Other Funding Methods in HUSM

HUSM expects to increase revenues by increasing the indirect cost of research collaborations with companies from 10% to 30% of direct costs, starting in FY 2020. Unlike in the US, salaries, benefits, scholarships, and living expenses among others of researchers in Japan are paid from

indirect cost, not direct cost. The shortfall is covered by each university's operating subsidies. MEXT has issued a notice to raise university indirect cost and income. Big companies frequently complain about the increased ratio and reduce the direct cost.

Other funding methods include continuous acquisition of major government projects and raising funds, such as endowments, donations, and fundraising (crowdfunding). Before fundraising, a survey (unpublished) of the HUSM image was conducted on local companies and residents. The survey "contributed to community health care" and "provided high-level community service." They also approved the use of donations as "educational support to train the next generation of medical professionals." It is possible to fund such uses from local residents.

Universities within the same region could be consolidated to reduce costs and increase revenues. A new national university corporation could be established to manage multiple universities under an "umbrella system" (MEXT, 2019a). Small- and medium-sized universities are believed to be absorbed by large universities in the consolidation. However, this system would allow for rationalization and autonomy in each university.

HUSM and SU, located in HUSM's area, would establish the Shizuoka National University Organization in April 2021. HUSM's School of Medicine and Hospital and the faculty of engineering and informatics on SU's Hamamatsu campus would be integrated. Moreover, medical-engineering and regional cooperation would be further activated. The new university corporation would resolve social issues in cooperation with the region as a "hub of knowledge" for regional development. SU has been promoting a multi-faculty program, that is, the School of Regional Development, and working on regional revitalization in mountainous areas. Solutions to problems such as nursing care and depopulation of medical care in the future would increase because of the population's aging. The integration of universities is expected to bring in medical knowledge that would expand their activities.

HUSM is expected to enhance its effectiveness in education. The content of the general education course and the system for fostering communication skills as a doctor and paramedical worker would be enhanced. Combining SU's technological seeds with medical care would enable us to conduct novel research and explore new fields. However, the integration from SU has persistent opposition, and issues of how to make it converge exist.

Certain colleges also consider consolidating with other single colleges in other regions. For example, the Otaru University of Commerce, Obihiro University of Agriculture and Veterinary Medicine, and Kitami Institute of Technology would establish the Hokkaido United University Corporation in April 2022 to strengthen their education and research functions and thus meet society's needs and contribute to Hokkaido's economic and industrial development, as one of the regional cities. Moreover, the Nara Women's University and the Nara University of Education would establish an engineering joint education program to produce engineering personnel in Nara, one of the regional cities. Thus, Nara National University Corporation would be established in April 2022.

Acquiring Additional Funding across the Region and Future Directions

HUSM has social contribution programs, such as community medicine, public health, and community education. They also allocate research funds to outstanding proposals from university researchers, doctors, and paramedical workers. They hold experimental classes and public lectures for local citizens using awarded research funds. RAs also create an information sharing system with other RAs in the same region. By contrast, SU has launched the "project for promoting research through collaboration in biomedical engineering innovation research" to promote joint research with HUSM.

HUSM has a room and desk for RAs and staff at SU, local governments and regional banks, and vice versa. They are free to come and go with each other. When they hire an RA and staff, they educate and train each other. There are only two RAs in HUSM. It is short-staffed and there are no applicants for new hires. Therefore, RAs and staffs complement each other in the region. RAs in HUSM and SU connect medical researchers, doctors, and paramedical workers at HUSM with engineering and informatics researchers at SU.

RAs from each university list their researchers, and RAs from both universities visit them. They connect researchers with matching needs. They present their researchers to each other in a camp style. HUSM's doctors and paramedical workers are matched with SU's researchers when RAs do not search for companies that embody their medical needs and ideas or when the research is at an early stage. HUSM researchers and SU researchers hold joint research presentations, which can lead to joint research. The product has been successfully commercialized by students of the cooperative major in medical photonics co-founded by HUSM and SU in 2018, and as of 2020 they are working with the Graduate School for the Creation of New Photonics Industries (GPI) in the same region to collaborate, commercialize, and start a business.

No contract is signed in inter-university research collaborations, and researchers are often free to pursue their research. RAs make referrals for public research funding as needed and introduce a regional bank for research funding. When the research has progressed, RAs connect researchers to local companies. Then, HUSM's doctors and paramedical workers collaborate with SU's researchers and regional SMEs on the project. The entire region collaborates to obtain major public research funding. The seeds of research between HUSM and SU continue to emerge constantly and become the research project of the Hamamatsu regional cluster.

Conclusion

Operating subsidies to a national university corporation have been decreasing annually. Although a priority support quota has been established, this system favors general and urban universities and discards regional universities. In the case of the KAKENHI, regional single-department colleges have low application numbers and amount of money adopted. This finding indicates that they cannot receive any indirect costs. These universities are increasingly becoming unattractive because of a lack of facilities, human resources, and funding. Hence, HUSM collaborates with the local community with the keyword "light" to generate income from joint research and sales

of medical and assistive devices. Moreover, they also plan to merge with SU in the same region to reduce costs. The university's brand power is enhanced through unique initiatives.

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References

Amano-Ito, Y. (2020). Introduction of medical device development through industry-academia collaboration by the Hamamatsu Method. *Advanced Biomedical Engineering, 9*, 112-116. https://doi.org/10.14326/abe.9.112

Amano, Y., & Makino, H. (2020). Medical-industry collaboration in an emergency, five days from conception to sale: UMBRELLA to protect you from COVID-19. *Journal of Industry-Academia-Government Collaboration, 6*, 4-6. https://sangakukan.jst.go.jp/journal/journal_contents/2020/06/cover/2006-all.pdf

Cabinet Office. (2002). *US research funding: Direct and indirect costs*. https://www8.cao.go.jp/cstp/project/compe/haihu01/siryo3-1.pdf

Development Bank of Japan. (2013). *The ecosystem for medical device development in Silicon Valley and its implications for Japan*. https://www.dbj.jp/pdf/investigate/etc/pdf/book1309_01.pdf

Development Bank of Japan. (2017a). *Potential for manufacturing companies to enter the medical device industry: The role of the commercialization process and clusters*. https://www.dbj.jp/topics/region/industry/files/0000027138_file2.pdf

Development Bank of Japan. (2017b). *Regional trends toward the formation of medical device clusters: Local initiatives help to strengthen Japan's competitiveness.* https://www.dbj.jp/pdf/investigate/etc/pdf/book1402_03.pdf

Economic and Social Research Institute. (2019). Prefectural economic accounting in FY 2016. https://www.esri.cao.go.jp/jp/sna/data/data_list/kenmin/files/contents/pdf/ gaiyou.pdf

Hamamatsu Chamber of Commerce and Industry. (2020). COVID-19 medical supplies related project. https://www.hamamatsu-cci.or.jp/news/show/1223

Hayashi, T. (2015). *International trends in allocation of operating subsidies based on indicators and evaluation.* Objective committee on the third period of the medium-term target on the role of national universities' operating subsidies. https://www.mext.go.jp/b_menu/shingi/chousa/koutou/062/gijiroku/__icsFiles/afieldfile/2015/02/02/1354813_1.pdf

Japan Association of National Universities. (2018). *Request for enhancement of national university budgets and tax reform in the FY 2019 budget: For national universities to continue contributing to the development of our country.* https://www.janu.jp/news/files/20180807-wnew-giren3.pdf

Japan Association of National Universities. (2019). National university corporation basic data set. https://www.janu.jp/univ/gaiyou/files/20190207-pkisoshiryo-japanese.pdf

Japan Society for the Promotion of Science. (2020). *KAKENHI data.* https://www.jsps.go.jp/j-grantsinaid/index.html

Kitajima, M. (2015). The new business development in small and medium-sized enterprises concentered on Japanese medical equipment clusters: Advantageous competences and required competences. *Japan Society for the Promotion of Machine Industry, 46*, 57-72. http://www.jspmi.or.jp/material/file/eri/pdf/ kikaikeizaikennkyuu/kikaikeizaikennkyuu_46_4.pdf

Kitajima, M. (2016). The characteristics of Japanese medical equipment cluster and the growth conditions for SMEs: The symbiosis of cluster and supply chain. *Japan Society for the Promotion of Machine Industry, 47*, 1-27. http://www.jspmi.or.jp/ material/file/eri/pdf/kikaikeizaikennkyuu/kikaikeizaikennkyuu_47_1kitajima.pdf

Kitajima, M. (2017). Formation of medical device clusters and product development of SMEs: Japanese characteristics of the cluster life cycle model. *The Society for Industrial Studies, Japan, 32*, 155-168. https://www.jstage.jst.go.jp/article/sisj/ 2017/32/2017_155/_pdf/-char/ja

Ministry of Education, Culture, Sports, Science and Technology. (2019a). *Multi-university system for national universities*. https://www.mext.go.jp/b_menu/shingi/chousa/koutou/092/index.htm

Ministry of Education, Culture, Sports, Science and Technology. (2019b). *Status of university-industry collaboration in FY 2018*. https://www.mext.go.jp/a_menu/ shinkou/sangaku/1413730_00005.htm

Ministry of Education, Culture, Sports, Science and Technology. (2020a). *National university corporations*. https://www.mext.go.jp/a_menu/01_d.htm

Ministry of Education, Culture, Sports, Science and Technology. (2020b). *Results of the evaluation of priority support for national university corporation operation subsidies in FY 2019*. https://www.mext.go.jp/content/1417263_01_1.pdf

Mizuta, K. (2007). Reforming higher education funding in New Zealand. T*he Journal of Finance and Management in Colleges and Universities, 4*, 35-74. https://www.niad.ac.jp/media/001/201802/nf005003.pdf

National Institution for Academic Degrees and Quality Enhancement of Higher Education. (2018). *Evaluation of the status of education and research during the third mid-term objectives*. https://www.niad.ac.jp/media/006/201807/01_201807 setsumeikai_siryou1.pdf

National Institute of Information. (2020). *KAKEN database*. https://kaken.nii.ac.jp/ja/

National Institute of Science and Technology Policy. (2020a). *Analytical report for NISTEP expert survey on Japanese S&T and innovation system 2019 (NISTEP TEITEN survey 2019)*. https://nistep.repo.nii.ac.jp/?action=pages_view_ main&active_action=repository_view_main_item_detail&item_id=6682&item_no=1&page_id=13&block_id=21 https://doi.org/10.15108/nr184

National Institute of Science and Technology Policy. (2020b). *Data book for NISTEP expert survey on Japanese S&T and innovation system 2019 (NISTEP TEITEN survey 2019)*. https://nistep.repo.nii.ac.jp/?action=pages_view_main&active _action=repository_view_main_item_detail&item_id=6683&item_no=1&page_id=13&block_id=21 https://doi.org/10.15108/nr185

Otsuka, K. (2017). Structure and aims of the operational subsidies and others for national university corporation. *Obunsya*, May, 1-12. http://eic.obunsha.co.jp/resource/viewpoint-pdf/201705.pdf

Porter, M. E. (2008). *On competition*. Harvard Business Review Book.

Pruvot, E. B., Claeys-Kulik, A. L., & Estermann, T. (2015). Strategies for efficient funding of universities in Europe. In A. Curaj, L. Matei, R. Pricopie, J. Salmi, & P. Scott (Eds.), T*he European Higher Education Area: Between Critical Reflections and Future Policies* (pp. 153-168). Springer International Publishing. https://doi.org/10.1007/978-3-319-20877-0_11

Prime Minister's Office of Japan. (2006). *Basic policies for economic and fiscal policy management and structural reform 2006.* https://www.kantei.go.jp/jp/singi/ keizai/ kakugi/060707honebuto.pdf

Shizuoka Prefecture. (2019). *Manufacturing in Fujinokuni.* http://www.pref.shizuoka.jp/j-no1/iryo_kiki.html

Takeuchi, K. (2019). The future of the operational subsidies for national university corporation operation, on allocation based on assessment. *Rippo to Chosa, 413*, 67-76. https://www.sangiin.go.jp/japanese/annai/chousa/rippou_chousa/backnumber/ 2019pdf/20190603067.pdf

Universities UK. (2016). *University funding explained.* https://www.universitiesuk. ac.uk/ policy-and-analysis/reports/Documents/2016/university-funding-explained.pdf

Examining Employee Retention and Motivation Trends in Research Administration

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Abstract: *The current study examined retention and voluntary turnover intention trends among university research administrators, as well as motivational factors contributing to both retention and voluntary turnover intentions using a mixed-methods survey. The online survey was administered to research administrators using a national listserv and included both qualitative and quantitative questions to explore participants' intent to remain or leave their current place of employment, the motivational factors impacting the decision, and key demographic information. Descriptive statistics and thematic analyses were utilized to analyze the data and to draw both convergences and divergences in participant responses. The study found that retention is high among university research administrators and that perceived supervisor and upper management support were key motivational factors attributed to both retention and voluntary turnover intentions.*

Keywords: *Retention, voluntary turnover intentions, motivation factors*

Introduction

The field of research administration is plagued with understaffed offices and employees that need to perform multiple job roles to increase research capacity within their organizations, while federal regulations cause more oversight in operational practices (Hicks & Monroy-Paz, 2015). Due to ever-evolving research policies and political climates, research administrators face constant change and numerous challenges within their jobs. Employees in research administration may fulfill the roles of business manager, legal counsel, financial administrator, and quasi-researcher all in the same day (Tauginienė, 2009). Given the specialized skill set and need for employees to be nimble, retention is key to retaining institutional knowledge. It is important for managers and directors to understand what factors contribute to employee retention and voluntary turnover intentions to ensure that talented research administrators will continue to stay in the profession. The present study seeks to answer the following research questions: What are the retention and voluntary turnover intention trends among research administrators at universities? What are the top motivation factors for retention identified by those who are not looking for a new place of employment? What are the top motivation factors for voluntary turnover intentions identified by those who are looking for a new place of employment?

Literature Review

The present study seeks to examine retention and voluntary turnover intention trends within research administration, including the associated motivation factors for each. The subsequent literature review will provide an overview of previous research on employee retention, voluntary employee turnover, and motivation factors in the workplace. Literature that heavily focused on the social contract, improving retention, decreasing turnover, and strategies to increase retention were excluded from review. The literature selected for this review focused on retention and voluntary turnover intention as separate phenomena, as well as the underlying factors for each.

Research Administration

Research administration is a fairly recent field and there is a dearth of general social scientific literature on the profession (Hicks & Monroy-Paz, 2015; Huang & Huang, 2018). The field emerged after World War II around 1945 after the United States created federal agencies such as the National Science Foundation, the National Institutes of Health, and the Office of Naval Research to fund basic research (Beasley, 2006). By definition, research administration is the administrative support required to manage and apply for external funding, including but not limited to "the oversight and compliance of the sponsor's management and fiscal requirements as stated in the grant or contract" (Beasley, 2006, p. 9). To date, there is little literature that examines retention and voluntary turnover intention trends within the profession. In a review of the literature, one study was found that examined the psychological contract perceptions of organizational loyalty and commitment among research administrators and focused on generational differences and perceptions of the psychological contract (Hicks & Monroy-Paz, 2015), but not on employment trends.

Landen and McCallister (2006) suggested that formal training and education for a career in research administration is almost nonexistent. A recent survey of research administrators found that roughly 60% of those surveyed chose "skill alignment" as an important factor when entering the profession, while 20% of respondents rated "interest in the field" as an important factor. In addition, roughly 50% of those surveyed responded that a job was available, and they applied without prior experience in research administration. This factor was rated as a high importance factor for entering the field (Kerridge & Scott, 2018). Since research administration is a profession that many find by chance, understanding the underlying motivational factors for both retention and voluntary turnover is of utmost importance to senior leadership.

Research administration can be a demanding and stressful field. Shambrook (2012) compared the 2007 and 2010 Research Administrator Stress Perception Surveys (RASPerS) and found that perceived work stress, number of hours worked, work/family conflict, and sickness presenteeism stress factors were significantly higher in the 2010 survey than the 2007 survey. Data also showed that overall a higher percentage of research administrators perceived high levels of workplace stress in 2010 than 2007. Additionally, Shambrook found that more respondents reported extremely high stress levels than those reporting extremely low stress levels in both survey years. Although the percentage of those who felt appreciated in the workplace increased from 2007 to 2010, 38.2% of those surveyed in 2010 indicated that they did not feel appreciated in the

workplace. Although the present research study did not analyze perceived stress as a motivation factor for retention and voluntary turnover, it is necessary to understand perceived stress and extenuating factors within the field to understand the current climate within the profession.

Retention and Voluntary Turnover

Retaining existing talent is a key concern for most organizations. Literature has indicated that employees no longer stay within an organization for a prolonged period (Acikgoz et al., 2016; Lee et al., 2018), thus making identifying the underlying causes of voluntary turnover extremely important. Lee et al. (2018) puts forward the claim that the traditional view of assuming employees will stay with an organization if they are happy is no longer sufficient. In fact, the researchers identified voluntary employee turnover as the most difficult type of turnover to manage, as opposed to layoffs or company downsizing. It is important to note that intention for turnover does not necessarily lead to voluntary turnover, but that the intention and subsequent behavior are highly correlated (Ertas, 2015).

Motivation Factors

Understanding what motivates employees is crucial for long-term success. A plethora of motivational factors for employee retention and voluntary turnover are mentioned in current literature and a select few of these recurring factors are subsequently outlined. Research has indicated that poor job satisfaction is a major factor for voluntary turnover (Acikgoz et al., 2016; Ertas, 2015; Lee et al., 2008; Lee et al., 2018). While adequate pay and other financial incentives can act as motivational factors to retain employees, studies have found that employee behavioral attitudes within the workplace can prove to be more important (Aguenza & Som, 2012; Ann & Blum, 2020; Honore, 2009; Samuel & Chipunza, 2009). In instances where an employee's pay is fair for their line of work, other factors such as workplace culture can be more powerful in influencing an employee's decision to remain at an organization (Aguenza & Som, 2012; George, 2015). In fact, Honore's (2009) work demonstrates that as an employee's salary increases, financial incentives become less effective as motivating factors.

Studies have also shown that higher-skilled employees are more likely to stay at an organization if their job includes new challenges and opportunities to learn (Aguenza & Som, 2012; Ann & Blum, 2020; Hausknecht et al., 2009; Samuel & Chipunza, 2009). Additionally, considerable research has shown opportunities for career growth and professional development are crucial motivating factors for employee retention (Aguenza & Som, 2012; Cardy & Lengnick-Hall, 2011; Ertas, 2015; George, 2015; Hausknecht et al., 2009; Hicks & Monroy-Paz, 2015; Samuel & Chipunza, 2009). Maintaining an adequate work-life balance, including flexible work schedules, is a key motivational factor shown to influence employee retention (Aguenza & Som, 2012; George, 2015; Hausknecht et al., 2009) and voluntary turnover (Ann & Blum, 2020; Ertas, 2015; Lee et al., 2018). In fact, maintaining a proper work-life balance means that some employees will sacrifice success within their careers or quit in order to allow for more time in the other areas of life outside of work (George, 2015; Lee et al., 2018).

There is growing literature showing that organizational commitment can reduce voluntary

turnover intentions (Acikgoz et al., 2016; Lee et al., 2018), as well as perceived organizational support, or the extent to which an employee feels valued by the organization or supervisors (Acikgoz et al., 2016; Ertas, 2015; Dawley et al., 2010). In other words, the more invested an employee is with an organization, the more valued they feel, and the less likely they will leave. Surprisingly, Ann and Blum (2020) found that relationships with coworkers had no effect on job dissatisfaction and voluntary turnover intentions.

While there is little literature focused specifically on retention and voluntary turnover intentions within research administration, the literature reviewed provides a foundation for the topic. The present study aims to contribute to the research administration community by focusing on the profession as a field of study; borrowing from both educational and human resource research to explore employee retention and voluntary turnover intentions within research administration. A brief overview of the methodology follows.

Methods

The present study utilized a mixed-methods online survey and collected primarily quantitative data. Creswell and Plano Clark (2018) indicated that mixed-methods research is advantageous because it counteracts the weakness of using either qualitative or quantitative research alone by incorporating the strengths of both methods into one design. The survey employed a convergent design, focused primarily on quantitative questions about the participants' desire to stay or leave their current place of employment, the factors that motivated participants to leave or remain in their current positions, and demographic questions. Categorical methods of analysis are best suited for the quantitative data because the data uncovered what kinds of motivational factors for retention and turnover were cited, the frequency of the motivation factors cited for retention and voluntary turnover, and participants' intentions to remain with or leave their current employer (Fraenkel et al., 2019). Emergent coding was used to analyze, reduce, and construct themes based on open-ended survey responses (Charmaz, 2008).

Population and Sample

The target population of this study were university research administrators. Cluster random sampling using the RESADM-L listserv was employed first, obtaining 189 responses. Fraenkel et al. (2019) indicated that cluster random sampling may be advantageous when a listing of the total population cannot be obtained, as is the case in the present study. Purposive sampling was then used to analyze responses from only the self-identified research administrators working in higher education, narrowing the sample size to 154 respondents. Once partially completed responses were removed from the data, the total sample size consisted of 143 respondents.

Instrumentation

Borrowing from similarly designed studies by Ertas (2015), George (2015), and Hicks and Monroy-Paz (2015), the present study used an electronic survey developed in Qualtrics to collect data. Motivation factors identified by previous literature for retention and voluntary turnover intentions were selected and participants were asked to rate each factor using a Likert scale. In

addition, motivation factors identified by previous literature were used as answer choices when participants were asked about motivation factors that influenced them to leave or stay with their current employer. The survey consisted of both closed- and open-ended questions regarding retention and turnover intentions, motivating factors for retention and voluntary turnover intentions, and demographic information including age and position level. To ensure valid and reliable data collection methods, a pilot test of the instrument was conducted with graduate students enrolled in a research course. The present instrument differs from prior research in that both quantitative and qualitative questions were used to obtain a more holistic view of retention and voluntary turnover trends in research administration. Two sample survey questions are included below:

1. Out of the following, please select the top four factors that motivate you to leave your current place of employment:

   Lack of Professional Development Opportunities

   Lack of Support from Supervisor and Upper Management

   Negative Relationship with Coworkers

   Inadequate Compensation and Benefits

   Lack of Intellectual Stimulation with Work Assignments

   Lack of Career Advancement Opportunities

   Disinterest in the Research Administration

   Feeling Undervalued

   Poor Work/Life Balance

   Can Easily Find Another Place of Employment

   Disinterest in Work Assignments

   Other _____

2. Please add any additional information about what has motivated you to leave your current place of employment that may not have already been covered.

Data Collection Procedures

In February 2020, an email invitation to participate in the study was sent to the membership of the RESADM-L listserv. The email described the details of the research study, the risks and benefits of participating in the anonymous survey and sought informed consent. A link to the Qualtrics survey was included at the very end of the email after the informed consent language. Structuring the email and survey this way ensured participants provided their consent before being able to proceed with the survey. Administering the survey online allowed participants to take the survey at a time and location where it is most convenient for them and expand the

geography of the possible participants. To ensure the survey received an adequate response rate the survey remained open for two weeks. Unfortunately, a reminder email was not sent to the listserv due to the COVID-19 pandemic.

Data Analysis

The quantitative data were analyzed using descriptive analysis which were appropriate because the study aims to describe the data collected, but not infer or reach conclusions that extend beyond the immediate data. The analysis relied on measures of central tendency, or averages such as the mean and mode of responses and was best suited because the data uncovered what kinds of motivational factors for retention and voluntary turnover intentions were cited by respondents, the frequency of the motivation factors cited for retention and voluntary turnover intentions, and participants' intentions to remain with or leave their current employer. Therefore, analyses tailored to categorical data such as percentages and frequencies are best suited to make sense of the data collected. The open-ended responses were coded into emerging themes and compared to the quantitative data obtained on motivation factors for retention and voluntary turnover.

Protection of Human Subjects

Institutional Review Board (IRB) approval was obtained on February 3, 2020 before any human subject research was conducted (protocol number 20-1661), thus securing ethical protections for the participants. Content was obtained from participants by way of the cover letter included in the body of the email soliciting participation. The cover letter also described both risks and benefits of participating in the survey so that participants could make an informed decision to take the survey or not.

Results

One hundred eighty-nine people responded to the survey out of a possible 5,736 responses, generating a 3.3% response rate overall. Of the 189 responses, 178 responses were complete. The responses to the survey were further narrowed to 143 when examining only responses from university research administrators (this included colleges, research intensive universities, and predominately undergraduate universities) for the purpose of this survey. Although the response rate for the survey is lower than anticipated, this is a common disadvantage of using online survey research methods (Fan & Yan, 2010; Fraenkel et al., 2019). In addition, the survey was only open for two weeks and reminders were not sent to the listserv due to the early COVID-19 pandemic developments which could have also contributed to the low response rate.

Demographics

Respondents were asked several demographic questions concerning gender, age, ethnicity, level of education, and questions concerning their current place employment. A total of 143 responses were obtained for the demographic questions pertaining to age, level of education, classification of their place of employment, length of time with their current employer, and current position type while 142 responses were obtained for demographic questions relating to gender and ethnicity.

Table 1 summarizes the demographic information.

Research Question 1: What are the retention and voluntary turnover intention trends among research administrators at universities?

Out of the 143 responses, 24 participants, or 17%, indicated that they were looking for a new place of employment and 119 participants, or 83%, indicated that they were not. Out of the 24 participants who indicated they were looking for a new place of employment, 22 participants, or 92% of participants, indicated they were looking for a job within the field of research administration while 2 participants, or 8% of participants, indicated that they were not.

Table 1. Demographics

Characteristic	n	Percent
Gender		
Male	18	13%
Female	122	86%
Nonbinary	2	1%
Age		
25-34	25	17%
35-44	43	30%
45-54	42	30%
55 and Up	29	20%
Prefer Not to Answer	5	3%
Race/Ethnicity		
Asian	4	3%
African American	3	2%
Biracial (text field responses: Asian Pacific Islander, Hispanic, Caucasian, and no text)	3	2%
Caucasian	118	83%
Hispanic	7	5%
Native American or Alaskan Native	1	1%
Prefer not to Answer	6	4%
Level of Education		
High School	1	1%
Some College	5	3%
Associate Degree	2	1%
Bachelor's Degree	40	30%
Master's Degree	84	58%

Table 1. Demographics Continued

Characteristic	n	Percent
Ph.D.	11	7%
Classification of Current Place of Employment		
Private College	25	17.5%
Predominately Undergraduate University	25	17.5%
Research University	93	65%
Length of Time with Current Employer		
Less than 1 Year	12	9%
1-3 Years	39	27%
4-9 Years	40	28%
10+ Years	52	36%

Participants were then directed to three questions, two quantitative and one qualitative pertaining to voluntary turnover intentions or retention based on their above response.

Research Question 2: What are the top motivation factors for retention identified by those who are not looking for a new place of employment?

Participants were asked to rate a list of motivation factors that most aligned with their motivation to remain with their current employer using a Likert scale with answers ranging from Extremely Important (1) to Not at all Important (5). Support from Supervisor/Upper Management was ranked as either Extremely Important or Very Important by 95% of respondents. Other write-in factors ranked included treatment by institution, employer accountability for inadequate managers, the organization valuing employee input, engagement with the mission of the organization, working in an office setting, and the length of time within the current position. Table 2 provides the mean ranking and standard deviation for each motivation factor. The majority of the standard deviations for each motivation factor were under one, meaning that there was not much variance in ranking for each factor from the mean and that there was some consensus among respondents for the ranking.

Table 2. Motivation Factor Ranking for Retention

Motivation Factor	n	Mean	Standard Deviation
Years Committed to the Organization	118	3.01	1.16
Individualized Work Assignments	119	2.48	0.93
Flexible Work Schedule	119	2.13	1.04
Career Advancement Opportunities	119	2.07	0.95
Flexibility in Workload Decisions	119	2.05	0.74
Professional Development Opportunities	119	1.96	0.86
Intellectual Stimulation with Work Assignments	119	1.81	0.70
Adequate Compensation and Benefits	119	1.65	0.63
Positive Relationship with Coworkers	119	1.64	0.64
Good Work/Life Balance	118	1.63	0.77
Support from Supervisor and Upper Management	119	1.31	0.60
Other	8	1.25	0.43

When asked to select the top four factors that best aligned with their own motivation for remaining with their current employer, *support from supervisor and upper management, adequate compensation and benefits, good work/life balance,* and *positive relationship with coworkers* emerged as the most frequent of the top four factors selected by participants, whereas other, *individualized work assignments, flexibility in workload decisions,* and *career advancement opportunities* were selected the least.

Participants were asked to provide additional information about what has motivated them to remain at their current place of employment that had not already been covered. Twenty participants chose to leave qualitative feedback. Each response was analyzed and categorized into several themes. Some of the themes from the qualitative feedback were similar to the motivation factors listed within the quantitative questions. Table 3 shows the emerging themes, the frequency each theme occurred, and supporting excerpts from the qualitative analysis.

Table 3. Emerging Themes Cited for Retention

Theme	Frequency	Supporting Excerpts
Location	6	"Distance to work;" "Easy commute;" "Changing employers would require moving which would have a disruption on other family members."
Good Supervisor	4	"I really like my supervisor and feel that she supports me."
Age	3	"Age has not been an issue yet;" "Close to retirement."
Benefits	3	"…tuition benefits for my high school aged child;" "Retirement benefits…"
Allegiance to Institution	2	"Institutional knowledge can be important… we should keep those folks with institutional knowledge around;" "Allegiance to institution."
Recognition	1	"Appreciation or recognition for a job well done…"
Workload	1	"Workload in general."

Research Question 3: What are the top motivation factors for voluntary turnover intentions identified by those who are looking for a new place of employment?

Participants were asked to rate a list of motivation factors that most aligned with their motivation to leave their current employer using a Likert scale with answers ranging from *Extremely Important* (1) to *Not at all Important* (5). *Lack of support from supervisor and upper management* was ranked as *Extremely Important* by 54% of respondents and *feeling undervalued* was ranked as *Extremely Important* by 48% of respondents. Other write-in factors ranked included relocation costs, heavy workload, toxic work environment, and inept leadership. Table 4 outlines the response size, mean, and standard deviation for each motivation factor. The standard deviations from the mean listed in Table 4 for each motivation factor are higher than the standard deviations found for retention, due to one outlier who consistently rated the motivation factors for voluntary turnover intentions as *Slightly Important* or *Not At All Important*. This individual also left qualitative feedback indicating their desire to leave the field of research administration and work in the private sector doing something completely different. Their responses were inconsistent with the other responses received overall concerning voluntary turnover intentions.

Table 4. Motivation Factor Ranking for Voluntary Turnover Intentions

Motivation Factor	n	Mean	Standard Deviation
Disinterest in Research Administration	23	4.39	1.17
Disinterest in Work Assignments	23	3.65	1.09
Negative Relationship with Coworkers	23	3.24	1.35
Can Easily Find Another Place of Employment	23	3.17	1.13
Poor Work/Life Balance	23	2.91	1.38
Lack of Professional Development Opportunities	23	2.61	1.37
Lack of Intellectual Stimulation with Work Assignments	23	2.61	1.31
Inadequate Compensation and Benefits	24	2.42	1.29
Lack of Career Advancement Opportunities	23	2.09	1.10
Feeling Undervalued	23	2.09	1.35
Lack of Support from Supervisor and Upper Management	24	1.88	1.24
Other	4	1.00	0.00

Participants were asked to select the top four factors that best aligned with their own motivation for leaving their current employer. Out of the twelve motivation factors presented, including the other option, *lack of career advancement opportunities, lack of support from supervisor and upper management, inadequate compensation and benefits,* and *feeling undervalued* emerged as the most frequent of the top four factors selected by participants that best aligned with their own motivation for wanting to leave their current employers. *Disinterest in work assignments, disinterest in research administration, ease in finding a new place of employment,* and *negative relationship with coworkers* were selected as top motivation factors for voluntary turnover intentions the least.

Eight participants provided additional feedback about what has motivated them to look for another place of employment that had not already been covered. As with the feedback left for retention, some of the emerging themes from the feedback for voluntary turnover were similar to the motivation factors provided within the quantitative questions. Table 5 organizes the qualitative data to show the emerging themes, the frequency each theme occurred within the feedback, and sample excerpts for each theme.

Table 5. Emerging Themes Cited for Voluntary Turnover Intentions

Theme	Frequency	Supporting Excerpts
Lack of Career Advancement Opportunities	4	"…I'm ready for a new more senior role, but no one helps me get there or promotes from within." "The job was what I needed at the time and now I'm ready to look for something else."
Feeling Undervalued	2	"…creates tension among existing RAs and feeling undervalued when new hires come in at higher levels than existing RAs fighting for promotions…" "…staff are not seen here as professionals (i.e. – second-class citizens to faculty)…"
Inadequate Compensation	2	"The cost of living and commuting expense… is incredibly high. I do not wish to leave my employer but if I want a home of my own I need to look elsewhere..." "...I plan on leaving to go to private industry, where I can make 40% more in compensation…"
Lack of Strong Leadership	2	"Questionable business ethics." "I have had leadership changes 3 times in the last 18 months."
Demanding Workload	1	"Staffing is minimal, coverage for vacations, sick days, etc. is non-existent so you never really get a break."

Discussion

The purpose of this research was to examine retention and voluntary turnover intention trends and motivation factors among university research administrators by answering the following research questions: What are the retention and voluntary turnover intention trends among research administrators at universities? What are the top motivation factors for retention identified by those who are not looking for a new place of employment? What are the top motivation factors for voluntary turnover intentions identified by those who are looking for a new place of employment? It is promising to see that retention among the field is high and that there is some consensus among the motivation factors for both retention and voluntary turnover intentions identified within this study.

Overview of Results

The key findings from this survey indicated that retention among university research administrators is high, and the majority of those with intentions for voluntary turnover still wish

to remain within the field. In addition, disinterest in research administration and disinterest in work assignments were selected as a top factor for voluntary turnover intentions the least (2% respectively), showing that those who are leaving their employer are not doing so because they dislike the field. This is reassuring data, since the field of research administration is one in which the majority entering the field find it by chance (Kerridge & Scott, 2018).

In terms of motivation factors for retention and voluntary turnover intentions, there were several overlapping factors cited that were uncovered by the present study. Top motivation factors for retention identified by university research administrators include supportive supervisors or upper management, positive relationships with coworkers, adequate compensation, a good work/life balance, and benefits. Top motivation factors for voluntary turnover intentions among university research administrators include lack of support from supervisor or upper management, feeling undervalued, lack of career advancement opportunities, and inadequate pay/benefits.

One overlapping factor included perceived support from supervisor or upper management, perceived support being associated with retention and perceived lack of support associated with voluntary turnover, which is in alignment with previous literature (Ertas, 2015; George, 2015) and was and chosen as a top four factor more than the other choices for both retention and voluntary turnover intentions. Compensation and benefits emerged as another top motivation factor for both retention (adequate compensation and benefits) and voluntary turnover intentions (inadequate compensation and benefits). For retention, benefits were a key theme that occurred within the open-ended feedback question, whereas inadequate compensation was mentioned twice for voluntary turnover intentions.

Prior literature indicated that work/life balance is a key motivating factor for both retention and voluntary turnover intentions (Ann & Blum, 2020; Aguenza & Som, 2012; Ertas, 2015; George, 2015; Hausknecht et al., 2009; Lee et al., 2018) where the present study found that an adequate work/life balance was a key factor for retention only among university research administrators. A prominent motivation factor for voluntary turnover intentions uncovered by this study was feeling undervalued. Previous literature has also uncovered the notion that the degree in which an employee feels supported or valued by the organization is a factor for voluntary turnover (Acikgoz et al., 2016; Ertas, 2015; Dawley et al., 2010). While one open-ended feedback on retention factors specifically mentioned recognition, the study can attribute the factor of feeling undervalued uniquely to voluntary turnover intentions.

Opportunities for advancement and professional development were mentioned in previous literature as extremely important in employee retention (Aguenza & Som, 2012; Cardy & Lengnick-Hall, 2011; Ertas, 2015; George, 2015; Hausknecht et al., 2009; Hicks & Monroy-Paz, 2015; Samuel & Chipunza, 2009). Interestingly, career advancement opportunities was only selected as a top four motivation factor for retention 4% of the time. Lack of career advancement opportunities was an important motivating factor for voluntary turnover intentions among university research administrators, cited as a top motivation factor 18% of the time and averaged a rating of Very Important on a Likert scale. The results from the survey indicated that professional development opportunities did not weigh as high among university research administrators for both retention and voluntary turnover intentions.

Limitations

There are several identified threats and limitations of this study. A major limitation was the low sample size and response rate. Because of the lower than expected samples, the results obtained may not be representative of the entire population. Mortality occurred due to participants neglecting to answer some survey questions and completely skipping over sections of the survey. This study also contained location threat to validity as participants were provided with a survey link for them to take at their convenience. The time and location in which each participant takes the survey may have been completely different. In addition, subject characteristics threat could have arisen from the cluster sampling method, where the participants who subscribe to the listserv may differ in attitudes, motivation, position level, age, and ability than university research administrators who do not subscribe to the listserv.

Implications

The results from the present research have multiple implications for the field of research administration. Organizational leadership in research administration positions can use the findings from this study in making policy decisions within their office concerning hiring from within, publicizing a clear path for advancement, and supporting recognition incentives or programs for current employees. Although some factors may be out of the supervisor's control as they may be more organizational, factors for retention and turnover within their control should be given weight and appropriate steps taken to alleviate any factors for voluntary turnover within their department and strengthen those cited for retention. Given the weight that supervisor support has on retention and voluntary turnover, those in supervisory roles can use the findings from this study to improve their leadership style and create professional development opportunities to cultivate a supportive environment.

Suggestions for Further Research

The present study can be used as a basis for further research in several ways. Within the field of research administration, additional research should compare the retention and voluntary turnover trends and motivation factors among the differing employer types (colleges, predominately undergraduate universities, research-intensive universities, non-profits/foundations, hospitals, etc.) to determine if there are industry specific factors that can contribute to each phenomenon. Determining unique experiences for each employer type can aid the field as a whole and enhance retention efforts among research administrators. Case studies of the different employer types would be especially helpful to obtain preliminary or baseline data and further expand efforts to establish research administration as a science.

While retention and voluntary turnover intentions should be treated as two separate phenomena, it is evident that among university research administrators, there is overlap among some motivation factors relating to both retention and voluntary turnover intentions. Additional research should be conducted to determine the extent of the overlap of motivation factors for retention and voluntary turnover intentions and if voluntary turnover intentions decrease when

overlapping factors for retention and voluntary turnover intention are addressed. The findings of this study can serve as a foundation for future research on retention and voluntary turnover intentions within the field of research administration, as well as contribute to the vast research on both retention and voluntary turnover.

Author's Note

Loralin Welch is a Research Administrator in the Department of Internal Medicine at Virginia Commonwealth University and previously worked as a Grants Specialist at James Madison University. The research presented in this article was conducted in fulfillment for a Master of Science in Education degree under the direction of Dr. Brantmeier. Questions about the research can be directed to Loralin at loralin.welch@vcuhealth.org.

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References

Acikgoz, Y., Sumer, H. C., & Sumer, N. (2016). Do employees leave just because they can? Examining the perceived employability–turnover intentions relationship. T*he Journal of Psychology, 150*(5), 666–683. http://doi.org/10.1080/00223980.2016.1160023

Aguenza, B. B., & Som, A. P. M. (2012). Motivational factors of employee retention and engagement in organizations. *International Journal of Advances in Management and Economics, 1*(6), 88-95. http://managementjournal.info/index.php/IJAME /issue/view/18

Ann, S., & Blum, S. C. (2020). Motivating senior employees in the hospitality industry. *International Journal of Contemporary Hospitality Management, 32*(1), 324-346. http://doi.org/10.1108/IJCHM-08-2018-0685

Beasley, K. (2006). The history of research administration. In E. Kulakowski & L. Chronister(Eds.), *Research administration and management* (pp. 9-29). Jones and Bartlett Publishers.

Cardy, R. L., & Lengnick-Hall, M. L. (2011). Will they stay or will they go? Exploring a customer-oriented approach to employee retention. *Journal of Business and Psychology, 26*(2), 213–217. http://doi.org/10.1007/s10869-011-9223-8

Charmaz, K. (2008). Grounded theory as an emergent method. In S. N. Hesse-Biber & P. Leavy (Eds.), *Handbook of Emergent Methods* (pp. 155-172). The Guilford Press.

Creswell, J. W., & Plano Clark, V. L. (2018). *Designing and conducting mixed-methods research* (3rd ed.). Sage Publications.

Dawley, D., Houghton, J. D., & Bucklew, N. S. (2010). Perceived organizational supportand turnover intention: The mediating effects of personal sacrifice and job fit. *The Journal of Social Psychology, 150*(3), 238-257. http://doi.org/10.1080/002245409033 65463

Ertas, N. (2015). Turnover intentions and work motivations of millennial employees in federal service. *Public Personnel Management, 44*(3), 401-423. http://doi.org/10.1177/0091026015588193

Fraenkel, J. R., Wallen, N. E., & Hyun, H. H. (2019). *How to design and evaluate research in education* (10th ed.). McGraw Hill Education.

George, C. (2015). Retaining professional workers: What makes them stay? *Employee Relations, 37*(1), 102–121. http://doi.org/10.1108/ER-10-2013-0151

Hausknecht, J. P., Rodda, J., & Howard, M. J. (2009). Targeted employee retention: Performance-based and job-related differences in reported reasons for staying. *Human Resource Management, 48*(2), 269–288. http://doi.org/10.1002/hrm.20279

Hicks, M., & Monroy-Paz, J. (2015). Into the looking glass: Psychological contracts in research administration. *The Journal of Research Administration, 46*(1), 77–101. https://www.srainternational.org/resources/journal/journal-archives

Honore, J. (2009). Employee motivation. *Consortium Journal of Hospitality & Tourism, 14*(1), 63–75. http://www.hospitalityhbcu.org/journal.html

Huang, J. S., & Huang, W. L. (2018). Building the science of research management: What can research management learn from education research? *The Journal of Research Administration, 49*(1), 11–30. https://www.srainternational.org/resources/ journal/journal-archives

Kerridge, S., & Scott, S. F. (2018). Research administration around the world. *Research Management Review, 23*(1), 1-34. https://files.eric.ed.gov/fulltext/EJ1187515.pdf

Landen, M. & McCallister, M. (2006). The research administrator as a professional: Training and development. In E. Kulakowski & L. Chronister (Eds.), *Research administration and management* (pp. 75-82). Jones and Bartlett Publishers.

Lee, T. H., Gerhart, B., Weller, I., & Trevor, C. O. (2008). Understanding voluntary turnover: Path-specific job satisfaction effects and the importance of unsolicited job offers. *Academy of Management Journal, 51*(4), 651–671. http://doi.org/10.5465/AMR.2008.33 665124

Lee, T. W., Hom, P., Eberly, M., & Li, J. (2018). Managing employee retention and turnover with 21st century ideas. *Organizational Dynamics, 47*(2), 88–98. http://doi.org/10.1016/j.orgdyn.2017.08.004

Samuel, M. O., & Chipunza, C. (2009). Employee retention and turnover: Using otivational variables as a panacea. *African Journal of Business Management, 3*(9), 410–415. http://doi.org/10.5897/AJBM09.125

Shambrook, J. (2012). Comparison of stress-related factors in the 2007 and 2010 Research Administrator Stress Perception Surveys (RASPerS). *Journal of Research Administration, 43*(2), 107-118.

Tauginienė, L. (2009). The roles of a research administrator at a university. P*ublic Policy and Administration, 30*(1), 45–56

A Proportionate Peer Review Service

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Abstract

Background: The peer review of clinical research projects is an essential step in project preparation. While some projects undergo rigorous review by grant-giving organizations, this does not apply to all clinical research. In many cases, peer review, if undertaken at all, is not rigorous, fully independent, or timely. Depending on their department or institution, many researchers do not have easy access to such review. This can result in delay to ethical and institutional approval, and uncertainty about the quality of individual projects.

Methods: After a two-year pilot study the Peer Review Service (PRS) was established at Imperial College, London in 2009. The aim was to provide an easily accessible and quick service for researchers at all the clinical sites associated with Imperial College. A graded system of review levels was designed which used an algorithm to match the independence and robustness of the review to the ethical weight of each project. The levels ranged from 1—internal review by a supervisor to 5—fully independent review by at least two external individuals. A semi-structured response form for reviewers was generated to facilitate the review process and ensure that all relevant aspects were considered. For each reviewed project, the PRS issued a certificate confirming the quality of the review.

Outcomes: There was a gradual increase in use of the service from the 2009 inception. From January to June 2020, 63 projects underwent peer review commissioned by the service. This represented all of the clinical research projects performed at Imperial sites that required review. The mean time from application to delivery of review was 1.73 weeks. Administrators found the algorithm for determining the peer review level easy to use, occasional queries being managed by members of the supervising committee. Audits demonstrated that researchers, reviewers and ethics committees were satisfied with the service.

Conclusion: A proportionate system of peer review for clinical research projects works well. It produces appropriately robust and independent reviews and can be implemented easily by administrative staff. Close association of a peer review service with university research administration ensures that all projects needing peer review receive it. The centralized service assists researchers in obtaining reviews speedily.

This simple model could be used widely by other clinical research centres.

Keywords: *peer review, proportionate review, centralized review*

Introduction

For clinical research projects to be approved and initiated several regulatory steps are required. One of these is peer review. It is important for a sponsor and/or host organization to be satisfied that a proposed project has sufficient scientific merit. The same applies to the research ethics committee: recruiting participants to a project that is poorly designed is likely to be unethical (NHS Health Research Authority, 2020). The sponsor and ethics committee do not generally have the expertise to determine the scientific validity of a proposed project—hence the requirement for independent peer review.

Many projects are funded by major grant-giving organizations. Examples in the UK are the Medical Research Council, the Wellcome Trust and members of the Association of Medical Research Charities. Such projects undergo robust independent peer review by the funding body—in which case further review is usually unnecessary. Exceptions to this include projects that are proposed under the umbrella of an existing programme grant but which were not specifically considered when the original application was reviewed.

Projects that have funding from other sources may undergo peer review that is not fully independent or robust. Examples include small scale investigator-led research, and studies that are supported by family trusts and similar organizations.

There have been a variety of approaches among organizations to seeking peer review where this is needed (Wood & Wessley, 2003). It is often arranged at department level. However, this can compromise the independence of the reviews, and lead to inconsistency within and between organizations.

At Imperial College, London a more centralized peer review service for clinical research projects was established in 2009 to address these points. It was also recognized that the level of scrutiny required would vary between types of project: for instance, a serological study requiring the donation of a single 10ml blood sample would probably need less extensive review than a two-year interventional drug trial. A centralized, proportionate system of peer review was therefore designed and introduced.

This paper describes the implementation of this system, our experience with it over the first 10 years, and our conclusions regarding its wider adoption.

Methods

Pilot Scheme

From 2007 to 2009 a pilot peer review service was run at Hammersmith Hospitals, two clinical centres that are part of the Imperial College group of hospitals. The service was offered on a voluntary basis to all researchers proposing clinical research projects. It was based on a proportionate review system (see below). At the end of the pilot period a formalized Peer Review Service (PRS) was set up. Experience from the pilot scheme informed the design of the system used by the PRS.

Administration

The Peer Review Service (PRS) was established in 2009. It was closely linked to the Joint Research Compliance Office of Imperial College (JRCO). This manages all the administrative aspects of clinical research at Imperial College and all associated clinical sites. This includes arranging sponsorship and indemnity.

The PRS was designed as an administrator-run service, overseen by a committee. Committee membership includes representatives of major clinical areas (medicine, surgery, women and children's health, nursing, therapies and pharmacy). The committee designed the processes and continues to oversee and review them. The Committee does not carry out peer review itself, but advises on strategic and operational matters and, where necessary, on queries made by researchers.

Use of the Service

The Peer Review Service (PRS) is available for use by all clinical researchers at Imperial College and its associated hospitals. Use of the service is not compulsory; however, it is strongly recommended unless independent peer review has been obtained elsewhere. Even in this situation, confirmation by the PRS that the review is sufficiently robust and independent is advised.

Use of the PRS is widely promoted at Imperial College via its website and through research managers. All clinical research projects need to be registered with the JRCO. Since 2018, it has been possible for details to be passed on directly to the PRS.

Proportionality

A major feature of the PRS process is proportionality of review in relation to the potential burden of the project. The design addresses the specific requirement of providing evidence to research ethics committees and the JRCO.

Five "levels" of review are used. These are summarized in Table 1, together with examples of the type of project at each level, and the minimum review required. A complete list of examples is given in the Appendix. The levels range from 1, for which no review is required, to 5, for which two reviewers independent of the researcher's institution are needed. Most projects fall into Levels 1 to 4. However, projects that are supported by the National Institute for Healthcare Research (NIHR) require a greater number of independent reviewers and are therefore allocated to Level 5.

Table 1. Peer Review Levels.

Level	1	2	3	4	5
Minimum review needed	No review needed	Supervisor/ department colleague	1 internal reviewer independent of researchers	2 reviewers, one independent of institution + researchers	2 reviewers, both independent of institution + researchers
Examples	1a: 10 min questionnaire for patients	Routine history taking	Minor lengthening of procedure	Phase I, II or III drug trial	Study for NIHR adoption
	1b: previous review by major grant-giving body	Spirometry Joint examination	2 blood samples, total up to 100 mls	Use of radiation	

Note: Examples refer to types of project in each category. A complete list is contained in the Appendix.

The minimum requirement for Level 4 was set at one external and one internal reviewer. Both reviewers must be fully independent of the project. The reason why this requirement was chosen is that Imperial College with its ten associated clinical centres is a particularly large institution, and it was therefore felt reasonable for one of the reviewers to come from within. However, if an internal but independent reviewer cannot be identified, a second external reviewer is selected. The same rationale was behind the decision to require one internal reviewer for Level 3.

The administrator determines the level of a project using an algorithm. If necessary, advice is sought from a member of the committee. In the case of Level 1b (research already reviewed by a major grant-giving body), the administrator asks the researcher for evidence that the project in question was specifically considered in the peer review. In some instances a project may be proposed under the umbrella of a programme grant, the application for which did not give specific details of the project. In this case, the project is allocated a level according to the algorithm.

Projects at Level 2 are most commonly student projects. They do not require processing by the PRS, although it can issue a certificate to confirm this. The PRS arranges peer review for projects at Levels 3-5.

Process

The PRS receives applications for peer review, or for confirmation that peer review is not required. All documentation and correspondence is performed electronically.

Researchers submit the protocol, participant information sheet and related supporting documents (e.g. questionnaires). The administrator uses an algorithm to determine if peer review is needed,

and, if so, at what level. If it is not needed, a certificate is issued confirming this.

For projects that need independent review (Levels 3 to 5) the researchers also submit details of two potential reviewers, using a form that asks about their independence from the researchers and the project, and their expertise in the field. Researchers are also invited to submit the names of up to two individuals who they would prefer not to review their projects.

The administrator then selects potential reviewers. They may be identified from the PRS' own database, by using the Web of Science or by members of the committee. If needed reviewers suggested by the researchers may be used. Potential reviewers are contacted and invited to complete a form that asks about their independence and expertise. Once these have been returned they are compared with those submitted by the researchers. If the reviewers are confirmed as suitable, they are sent the project documents, together with a review form template (see *Review Form* below).

When a review form is returned, the administrator checks that all questions have been adequately answered. This is a check on the quality of the review, not the project itself. Once sufficient, adequate reviews have been received, the administrator issues a certificate confirming that the project has undergone appropriate peer review. The certificate is then sent to the researcher, together with the reviews.

The PRS aims for the turnaround time—from receipt of all documents to the issuing of a certificate—to be under four weeks. Members of the committee are available to provide advice to the administrator at any point in the process.

Use of the PRS is free for researchers. Reviewers are not paid but are thanked warmly for their assistance. It is made clear on every certificate—from Level 1 to 5—that it is not a commentary on the quality of the project, but merely confirmation about the status of the project and the quality of the review, if performed.

Review Form

The review form was designed to be easy and quick to use by reviewers. It is semi-structured, with questions requiring yes/no answers, and space for free text. Questions are asked in the following domains: context, research design, sampling, clinical considerations, practicalities, and overall recommendation. It is completed anonymously, although reviewers can ask to have their names revealed to the researchers if they wish.

Quality Assurance

The committee reviews the activity and performance of the PRS biannually. The turnaround time is regularly monitored. Structured forms are used to obtain feedback from researchers and reviewers about the ease of use of the service, and from research ethics committees about the value of the reviews.

Outcomes

General

The peer review system based on the experience in the pilot scheme appeared to work well. In the first three years establishing visibility of the PRS was assisted by meetings with research managers and heads of department. The service was also promoted on the College intranet.

Proportionality

The proportionate system was easily understood by researchers and managers. The definitions of the peer review levels were adjusted by the committee in the first few years, with more examples of projects being added at each level as new studies were considered. Level 5 was introduced in 2013 to take account of the NIHR requirement. Queries about level allocation or the quality of reviews were generally dealt with by committee members outside formal meetings.

Because of the size of Imperial College and its linked hospitals, independent internal reviewers were almost always easy to find for projects at Levels 3 and 4. On some occasions was this not possible, and it became necessary to find an external reviewer.

Activity

In the first year of activity of the PRS the total number of certificates issued at all levels was 34. Thereafter until 2015 between 50 and 70 certificates were issued per year. Following this there was a gradual increase in activity, shown in Table 2. This appeared to be mainly due to the closer connection of the PRS with the JRCO, so that by late 2019 all projects that had not already had adequate peer review were referred directly to the PRS. Also contributory were increasing visibility of the service within Imperial College, and the growing experience of researchers that the PRS process was quick and easy.

Table 2. Number of Certificates Issued (all levels)

Year	Number
2016	56
2017	78
2018	102
2019	161

Table 3 shows activity at the various levels from January to June 2020, measured by the issuing of certificates. Certificates were issued for 115 projects. Of these, 63 underwent peer review commissioned by the service. Cross-referencing with the JRCO database indicated that all of the clinical projects registered by the JRCO in that period which required independent peer review were processed by the PRS.

Table 3. Number of Certificates Issued According to Level, and Time Taken (Weeks, with Mean and Median) From Submission of Full Documentation to Issuing of Certificate: Data for Projects Registered from January to June 2020 (6 Months)

LEVEL	TOTAL	1 week	2 weeks	3 weeks	4 weeks	>4 weeks	Mean	Median
1a	5	5					1.0	1
1b	9	9					1.0	1
2	38	38					1.0	1
3	24	13	7	3	1		1.54	1
4	11	6	4	1			1.54	1
5	28	15	6	5	1	1	1.82	1
Total	**115**	86	17	9	2	1	1.39	1
Levels 3-5	**63**	35	17	9	2	1	1.73	1

Turnaround

Table 3 includes the turnaround times for issuing certificates from the six months from January to June 2020. The results indicate that the target of turnaround of less than 4 weeks was met in almost all cases.

The consistent turnaround time of less than one week for projects at Levels 1 and 2 reflects the fact that no review was commissioned for them by the PRS.

The mean turnaround time for Levels 3 to 5 was 1.73 weeks. Turnaround times greater than two weeks for these levels were all due to reviewers being slow to respond. Nevertheless, only in one case was the target time of less than 4 weeks exceeded. In most cases at Levels 4 and 5 more external reviewers were requested than the minimum required as an insurance against delay. The review process generally occurred in parallel with other regulatory processes and so did not usually delay the progression of the projects.

Quality of Reviews

Because of the design of the review form, the quality of each review could usually be assessed by the administrator. Occasionally the advice of a member of the committee was sought. The vast majority of reviews were found to be sufficient. In 2016-2020 only two reviews were deemed to be inadequate. In these cases, other reviewers were sought.

Quality of Projects

The commissioned reviews gave a full range of opinions, from unconditional support to severe criticism. The majority gave helpful suggestions. Researchers were expected to submit these to the JRCO and to the relevant ethics committees, with an explanation of how these suggestions were addressed.

Feedback

A questionnaire sent to 20 consecutive researchers with projects at Levels 3-5 indicated universal satisfaction with ease-of-access of the PRS, and speed of obtaining reviews. One researcher queried the level allocation if his project. Otherwise there were no adverse comments.

A questionnaire sent to 20 consecutive independent reviewers found satisfaction with the process and the review form. There were no adverse comments.

Questioning ethics committees was more difficult, since it required the researcher to indicate which ethics committee would be considering the project, and then asking the administrator of that committee to request that the committee provide an opinion. Thirty approaches to ethics committees were made using this route; only five responses were obtained. In all cases the reviews supplied were felt by the ethics committee to be of good quality and sufficient for their purposes.

Discussion

Peer review plays an important role in clinical research, notably in the selection of projects for funding and in the assessment of manuscripts for publication (Wood & Wessley, 2003). It is also needed by host organizations and by research ethics committees for confirmation that proposed projects are of sufficient merit. The Imperial College Peer Review Service was set up to address this specific requirement. This paper describes the implementation of the service and its development over the first 10 years.

We found that for an organization with multiple academic sites a centralized system worked well. Researchers had easy access to it, and the turnaround was fast. By the end of the first 10 years all projects within the Imperial group requiring independent review were being processed by the service. Because the review process was commonly performed in parallel with other regulatory processes, it did not usually delay the progress of projects.

A novel proportionate system was used. This was easily understood by all involved. Feedback from researchers, reviewers and ethics committees was good. The minimum requirements for Level 3 (one independent internal reviewer) and Level 4 (one internal and one external reviewer, both

independent) were determined by the size of Imperial College and its associated clinical centres. This appeared to work well and could be replicated in other institutions. Some modifications might be needed: for instance, in smaller organizations it would probably be necessary to raise the requirements, e.g., to one and two external reviewers, respectively.

At its best, peer review can be constructive. Helpful suggestions from reviewers can improve project proposals, and thus raise the overall standard of research (Huisman & Smits, 2017). The short turnaround time of our system meant that this could happen without significantly delaying the approval process.

Independent peer review is a powerful tool that commands great respect. But it is also imperfect (Smith, 2006; Neff & Olden, 2006). Its many drawbacks have been well described. They include the competitive nature of some research, the difficulty in finding truly independent "peers," and the disinclination of many potential reviewers to perform such unpaid work. Nevertheless, most clinical researchers would accept that, when performed to a high standard, it is probably as good a system as we can devise within the limitations of funds and personnel (Jefferson et al., 2002).

Our system uses some reviewers that are suggested by the researchers. Ideally all reviewers would be identified independently of the researchers. However, in some fields this can be difficult. The use of researcher-suggested reviewers is an established practice for many institutions and journals, as is the avoidance of using particular reviewers at the request of researchers (Earnshaw et al., 2007). All potential reviewers are added to our database, and we aim to reduce the use of researcher-suggested reviewers over time.

Most peer review systems are dependent on the willingness of researchers to review the work of their peers without reward. There may be small advantages to being a reviewer, such as maintaining one's profile and learning about the research plans of other units; but most researchers feel a moral imperative to contribute to this aspect of science, from which they also benefit when submitting their own projects. In setting up our system we have been dependent on this goodwill, and are grateful for it.

Conclusion

The Imperial College Peer Review Service offers a proportionate certification method and rapid access to robust, independent peer review. Our experience suggests that this type of centralised system could be replicated or adapted at other centres. This would be of benefit to researchers, host institutions, ethics committees, the quality of research, and therefore, ultimately, patients.

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References

Earnshaw, J. J., Farndon, J. R., Guillou, P. J., Johnson, C. D., Murie, J.A., & Murray, G. D. (2000). A comparison of reports from referees chosen by authors or journal editors in the peer review process. *Annals of the Royal College of Surgeons of England, 82*(4 Suppl), 133-135.

Huisman, J. & Smits, J. (2017). Duration and quality of the peer review process: The author's perspective. *Scientometrics, 113*(1), 633-650. https://doi.org/10.1007/s11192-017-2310-5

Jefferson, T., Wager, E., & Davidoff, F. (2002). Measuring the quality of editorial peer review. *JAMA, 287*(21), 2786-2790. https://doi.org/10.1001/jama. 287.21.2786

Neff, B. D., & Olden, J.D. (2006). Is peer review a game of chance? *BioScience, 56*(4), 333-340. http://dx.doi.org/10.1641/0006-3568(2006)56[333:IPRAGO] 2.0.CO;2

NHS Health Research Authority. (2020, March 26). *Governance arrangements for research ethics committees: 2020 edition*. https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/GAfREC_Final_v2.0_26.03.2020.pdf

Smith, R. (2006). Peer review: A flawed process at the heart of science and journals. *Journal of the Royal Society of Medicine, 99*(4), 178-182. https://dx.doi.org/10.1258%2Fjrsm.99.4.178

Wood, F., & Wessley, S. (2003). Peer review of grant applications: A systematic review. In T. Jefferson & E. Godlee, Eds., *Peer review in health sciences* (pp. 14-44). BMJ Books.

APPENDIX: PEER REVIEW LEVELS

Review requirements and types of project, with examples

Level 1a

Minimum level of review required: None required

Types of project: Studies that involve minimal risk to participants

Examples of projects or procedures:

- Use of data from medical notes by clinician looking after patient
- Short questionnaire studies for use among hospital staff or GPs
- Questionnaires asking participants about the quality of hospital services, or requesting other non-personal data, taking up to 10 minutes for a patient, or 20 minutes for a healthy volunteer

Level 1b

Minimum level of review required: None required

Types of project: Studies that have been specifically peer reviewed by a major grant-giving body or similar organization. These include: UK Research Councils (including the Medical Research Council); the National Institute for Health Research; and Members of the Association of Medical Charities (including the Wellcome Trust and a large number of specialist or disease-specific charities). This exemption does not include projects that are part of a program grant but which have not been specifically considered by the grant-giving body.

Level 2

Minimum level of review required: Departmental colleague or student project supervisor

Types of project: Low-risk projects with minimal patient involvement. Student projects that involve either no patient/participant involvement or only minor involvement

Examples of projects or procedures:

- Routine history taking
- Projects using existing stored data
- Administration of simple questionnaires that do not involve "sensitive" (e.g. psychiatric, sexual, drug or end of life-related) information, unless that information is part of normal clinical practice for the condition under study
- Non-intimate physical examination e.g. joint examination, blood pressure measurement
- Photography if participant is not identifiable
- Venesection involving a single skin puncture: up to 50mls total from healthy volunteers, 20mls total from patients (or pro rata for children)

- Taking of blood via existing cannula or at same time as venesection which is part of normal patient cars: in single or multiple samples, total volumes as above
- Spirometry
- The obtaining or analysis of non-invasive samples, e.g. urine, saliva, faeces
- Histological studies on existing/historical specimens
- Standard MRI scanning

<u>Level 3</u>

Minimum level of review required: Individual within Imperial College or the applicant's hospital trust

Types of project: Involving minor patient or participant risk

Examples of projects or procedures:

- Single-arm study of a drug or device not affecting patient care decisions
- Clinical intervention study or controlled trial with low risk to participants (e.g. a study of an oral nutritional supplement, low vitamin doses, or dietary intervention)
- New acquisition of personal data that are not part of the normal clinical history
- Administration of questionnaires involving "sensitive" information outside normal clinical practice
- Intimate physical examination when appropriate to clinical context
- Photography/recording if participant is identifiable
- Taking of up to two blood samples of no more than 100mls in total from healthy volunteers, 50mls from patients (or pro rata for children)
- Taking of extra biopsies during biopsy procedure that is part of normal care
- A minor lengthening of an invasive procedure (less than 5 minutes or 10% added to a procedure that is part of patient care, whichever is the shorter), with little or no extra risk associated with either the investigation or the lengthening of the procedure
- Investigation that involves a minimal risk procedure (e.g. arterial blood gas analysis)
- DNA analysis with no clinical implication for the participant

Level 4

Minimum level of peer required: Two reviewers, including one individual outside IC or the applicant's hospital trust

Types of project: Projects with greater than minor risk to participants

Examples of projects or procedures:
- Phase I, II and III drug or device trials
- Randomized trials of drugs or devices within their licensed use
- Use of radiation
- Intimate physical examination outside appropriate clinical context
- DNA analysis with potential clinical implication, e.g. for new diagnosis
- Studies involving embryos

Level 5

Minimum level of review required: Two reviewers, both outside Imperial College or the applicant's hospital trust

Types of project: those for which NIHR adoption is sought

A Social Innovation Model as Bridge-Builder Between Academia and Research Management

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Abstract: *Institutional research management (RM) is increasingly seen as a strategic force, not only to raise the research output per academic, but also the quality thereof. RM, therefore, has to attend to researcher development (RD). How RD is achieved, as part of RM, is still viewed as an embryonic field with attendant calls for additional research. Often, criticisms of RM's researcher support efforts come from the academy itself. These drawbacks, perhaps, originate from the nature of research, in that advanced scholars gain strategic research identities through deep positioning within disciplinary specificity, embedded in knowledge-based and methodological originality. This then creates a disjuncture between academia, as researchers, and RM, as support services. Academic staff's perception of the value of RM may be filtered through how well RM speaks to epistemological, academic fields, while inculcating the same in RD. RM's chances of gaining support and traction for their work from the researchers they support, may well be gained through "speaking within the remit of disciplinary languages". Yet, how might this be smartly achieved in the intensely active and respective roles of the two parties? We present a novel RD model, which has been shown to boost credible conversations between researchers and research managers. The research novelty is expressed through a model of social innovation, which brought methodology into the heart of RM's support and received traction from researchers, who perceived RM as "speaking their language", while triggering conceptual thresholds. The findings extend an under-studied area of social innovation within an empirical setting in a mega-university and theorise how conceptual thresholds spur on social innovation.*

Keywords: *Research management, social innovation, researcher development, conceptual thresholds, graduate studies*

Introduction

"Becoming an independent scholar – after years of study or work in other roles – is a major shift in identity and practice. If not well managed, it can be painful and aversive."
(Murray & Cunningham, 2011, p. 831)

Obtaining global recognition is the name of the game for modern universities. The rise of the "world-class university" or "super research university" marks a new era of knowledge production in higher education (Lee, 2013, p. 123; Zhou & Wu, 2016, p. 76). Alongside these existing imperatives, the COVID-19 pandemic also underlined the importance of research-driven solutions for systemic knowledge and quality of life. A world-class university, as such, provides highly sought after, leading-edge researchers and research outcomes, thereby receiving status and coveted resources that enable ongoing success. Altbach (2013, p. 317) is of the opinion that research universities are not only important for national development, but are "the key to gaining entry into the knowledge economy of the twenty-first century". Globally, but in particular in developing countries, there is, therefore, a need for a "quantum leap" in research capacity building, in all disciplines (Nchinda, 2002, p. 1701; Kizza et al., 2010; Merritt et al., 2019).

As a consequence of the increased focus on research quality outputs and the corresponding government funding allocations, universities increasingly support efforts to build research capability (Browning et al., 2014, pp. 123-124; Merritt et al., 2019). Early career academics, who mostly joined academia to teach, have, in many instances, limited research experience and find the pressure to do research difficult, exacting and to be avoided (Belkhir et al., 2019; Murray & Cunningham, 2011, p. 832; Sikes, 2016, p. 555). Many faculties encompass fundamentally technical or vocational disciplines with an original focus on teaching, rather than research (Bai et al., 2008, p. 5; Pratt et al., 1999, p. 43). Yet, systemically and institutionally, publishing research is prized and rewarded. Although institutional support is key to productive research, it is important to look at how institutional goals can be aligned with individual goals of academics as well as to that of a larger discipline-focused community (Nygaard, 2017; SARIMA, n.d.).

Thus, institutional research management (RM) is increasingly seen as a strategic force, not only to raise the research output per staff member, but also the quality thereof. Ironically, however, researcher development (RD), which falls into the remit of the RM, is still viewed as an emerging field (Rospigliosi & Bourner, 2019), with attendant calls for additional research on the matter.

Yet, while perhaps a strategic force, RM's diverse spectrum of services facilitates the fuzzy positioning of the profession. Often, criticisms for the profession come from the academy itself. This could originate from the nature of research, in that advanced scholars gain strategic research identities through their positioning within disciplinary specificity, embedded in knowledge-based and methodological originality. This creates a disjuncture between academia and research management. Academic staff members' perception of the value of research management may be filtered through how well RM speaks to epistemological, academic fields. RM's chances of gaining support and traction for their work, from the researchers they support, may well be gained through "speaking within the remit of disciplinary languages".

Research managers, who might be remote from these discourses, could consider innovatively to bridge the disjuncture through using research methodology tools, provided by knowledgeable mentors, as a unifying language. This translates into a more practical "language" of the research process, as opposed to theories and disciplinary specificity. This may seem to be arguing RM's roles divergently. Notwithstanding this divergence, the article probes the idea that an innovative

construction of a relationship between RM services, on one hand, and researchers, on the other, has thus far been under-conceptualised. The relationship entails sharing methodological commonalities between RM and academics, and in doing so, strengthening RM's third space (Whitchurch, 2008) through bolstering acceptance with academics.

Statement of Problem in Practice

The study, therefore, records the four-year implementation of a researcher development model at a mega distance education (DE) university in Africa. The university, by definition of its mega status, has, in terms of its graduate students, high throughput rates. In terms of rankings, however, its publication and citations statistics, contribute towards its ranking as 1001+ in the world (Times Higher Education, 2021). The higher education sector might consider this a lag in fostering a strong research tradition. While this is felt by the university itself, certain faculties experience it more keenly (Williamson et al., 2020). There are a number of reasons for this lag or lack of research. As previously mentioned, some faculties, for instance those that offer professional qualifications, have been criticised in the literature for adopting a more technical focus, while showing "little appetite" for research (Venter & De Villiers, 2013; Samkin & Schneider, 2014; Verhoef & Samkin, 2017). Another reason, specifically applicable to the illustrative faculty in this case (Faculty A), is that most academics have accredited professional qualifications, with strong professional identities and little research experience. Academia, however, places a premium value on academic research and peer reviewed publications.

Should graduates remain in the academic arena, they are required to pivot their skills set and acumen towards undertaking research for publication in accredited journals. This pivoting starts at master's (M), but mainly doctoral (D) level, and then continues, with increasing pressure during their tenure at universities, should they wish to advance their academic identities and careers. Developing as a researcher may well include virtual support provided by DE and, since 2020, increasingly, also by residential universities, but studies have shown that researcher growth happens through more personalised models (Lamar et al., 2019; Bitzer & van den Bergh, 2014). In DE, the geographical dispersion of M and D students as well as the arms' length virtual learning modalities displace the personalised models. The in-person contact includes experiential guided learning, mentoring, deliberate fostering of research skills, inculcating academic dispositions and proximate interpersonal supervision (Hodza, 2007). The DE orientation, therefore, may well fall short on such models, as has been experienced by Faculty A. Consequentially, this has prompted Faculty A to innovate and to build a research-intensive focus among its M and D candidates, but also, interestingly, among some of its established staff, who also find they need to "play research catch up".

Statement of Research Problem

In response to the problem in practice, Faculty A's RM leadership saw the increasing importance of a deliberate programme for developing researchers (as opposed to teachers or professionals) to achieve graduate throughput, staff academic progression and to improve their publication credentials. Knowing how personal [post-]graduate studies are (Lamar et al., 2019; Bitzer &

van den Bergh, 2014), the leadership desired a shift from the one-size-fits-all institutionalised modalities towards a more innovative, personalised RD model. A broad-based formulation was in place, but no articulated blueprint or precedent existed for the model.

What was in place, however, was the regional Southern African Research & Innovation Management Association (SARIMA) Research Management Professional Competency Framework (PCF) (Williamson et al., 2020). Within this framework, researcher development (RD), as undertaken by RM, was, in part, articulated as: "Support postgraduate [graduate] student and researcher development across the research pipeline within different organisational settings" and included specific competencies, numbered by the authors for convenience: 1) "demonstrate knowledge of the full research cycle"; 2) "develop frameworks to support researchers at different levels of their research careers"; 3) "scan the environment and capitalise on innovative partnerships for researcher development"; 4) "benchmark...initiatives and practices"; and 5) "adapt.. for best practice" (SARIMA, n.d., pp. 13-14). The RM leadership, therefore, was determined to meet these requirements as well as seek a value-adding criterion of innovation.

They also scrutinised the PCF for guidance on RM innovation. The PCF contains a number of cross-cutting competencies, identified across RM, such as communication, negotiation, leveraging of technology, among others. Within this band, innovation was included and expressed as: "questioning conventional approaches, using intuition, experimenting and developing fresh perspectives to resolve challenges with innovative solutions or services" and "forward thinking and doing new things" (SARIMA, n.d., p. 6).

These guidelines thus provided valuable points of departure, but the impetus remained for the model to be home-grown and tailored to disciplinary context (as highlighted in the Introduction). This posed an applied, as well as, research question:

How might RM innovatively implement a model tailored to researcher development needs?

The purpose of this article, therefore, is to report on the genesis and implementation of this model. We reflect on the findings and address theoretical gaps on RD using a confluent theory of social innovation. The remainder of the article is structured as follows: literature review with a conceptual framework; followed by the methodology section; then, the findings are presented and interpreted through a discussion; and, finally, the article concludes the argument and reiterates the contribution of the study.

Literature Review

Conceptualising innovation within RM was underlined by the SARIMA PCF (n.d.). The PCF, like other RM frameworks, was formulated based on international literature and benchmarked against best practices for RM from participatory processes, across public sector RM. Despite innovation being an expected competency, the PCF, as well as the RM literature consulted (see Williamson et al., 2020), did not specifically address the notion of social innovation (hereafter, SI), which is addressed in the current study. Rana et al. (2014, pp. 259, 262), in a systematic analysis of SI in the public sector, indicate such a gap as a "huge" and a neglected area. While these

authors do refer to "operations research management science", they indicate that, within their review, no study had been undertaken on SI, as applied to a model that was founded on empirical practice and, therefore, insufficient primary data had been used. In their introductory views, Rana et al. (2014) show the proliferation of SI research could mainly be attributed to disciplines around business, management and economics (within private sector-bases), and not sufficiently to universities or RM, with nothing addressing RD. Their review also does not sufficiently address a definition of SI, within the public sector, even while noting its intellectual tradition and the plethora of key words, as well as theories associated with the phenomenon (Rana et al., 2014, pp. 259, 263, 265). Other scholars do venture towards definitional spaces, as will our conceptual frameworks, which emanates from this review and practice.

Innovation, and its antecedents of entrepreneurship and disruption, is much touted, in practice, in the field of organisational, management, technology and business domains (Schumpeter, 1934; Christensen, 1997; Adsule et al., 2015), and also as spanning disciplinary boundaries (Dogan, 2019). Scholars had conceptualised innovation studies (see, for instance, Christopher Freeman, Giovanni Dosi, Luc Soete and Ian Miles, in Mulgan [2012, p. 23]), framing specific areas such as innovation ecosystems (de Vasconcelos Gomes et al., 2018), innovation communities (Fichter & Beucker, 2009), innovation universities (see Christensen, 2003 in Mulgan, 2012, p. 24) as well as innovation and creativity in social sciences (Dogan, 2019). In Lepore's view (The New Yorker, 2014), innovation is afforded "gospel status", while getting some things wrong and, perhaps, very obviously so. As Mulgan (2012, p. 20) states: "Not all innovations are good." In developing his argument, he centrally discusses SI, which has gained traction through its links to innovation. Mulgan (2012), however, indicates that, despite innovation being pervasive in societies, SI is "short on theories", with theory needing to "catch up" on practice and each requiring recursively to expand each other (pp. 19-20). This article, in part, addresses this concern.

In his approach to extend SI theory, Mulgan (2012) profiles seven theoretical overviews for nurturing SI. The theories mentioned here do not follow Mulgan's order, but have been recast to support the processes in this study, as underpinned by SI. SI is initiated by: (1) paradoxes and tensions, (2) where previous ways of doing or being appear no longer to suffice, thus incremental, organic change may happen. (3) SI needs to be rooted in contextual circumstances. (4) Additionally, being socially innovative is following communitarian ways of existing, inseparable from collaboration and being more fully, and socially, human. (5) As such, the foundational premises of SI rest on the well-being and development of humanity in the social realm, differentiating it from technological innovation that is hard-wired into test-driven, measurable worlds. Mulgan (2012) advocates, too, that (6) SI seeks to build capabilities towards fully actualised humans, who are able to harness both tacit and explicit knowledge. Given these dimensions, (7) the field remains emergent and less fully formed than other innovation domains; thus, it prompts additional research.

Mulgan's work suggests the boundaries between SI and any system are permeable and intersecting. As such, he defines SI as the capacity to prompt "new ideas (products, services and models) that simultaneously meet socially recognised social needs (more effectively than alternatives) and create new social relationships or collaborations that are both good for society and enhance

society's capacity to act" (Mulgan, 2012, p. 22). Conversely, Avelino et al. (2019) provide working definitions that create a proximity gap between social innovation and wider society. They posit four levels: social, yet, only at the micro level, where people and processes interact to usher in new processes or technologies for "people [to be] doing things differently" (Franz et al., 2012). Moving further from micro views around people, at a more abstract level, systems innovation is described as an organisational sub-system that intersects with society, while game changes are at the macro level, creating mainly global field changes as well as the "rules of the game". As such, narratives of disruptive change are positioned at meta-theoretical and paradigm revision levels, around change and innovation (Avelino et al., 2019).

Mulgan (2012, p. 22) usefully leaves the discussions of social innovation open-ended, by stating that definitions might well clarify what "social innovation is not". He highlights that it is not a subset of techno-economic novelties, but more specifically enables and democratises society. To take a more expansive view, one of the central custodians for achieving such societal advancement is the university, which should be both an incubator for SI theory and a living example of its practice. In short, universities should service a seminal definition of SI that is social "both in ends and means" (Young Foundation and Social Innovation eXchange [SIX], 2010). Based on this review and for this paper, SI, therefore, refers to a co-created model which had not existed before. SI unfolds through in-person, conceptually-challenging interactions shifting graduates' capabilities to engage with research using different or novel ways of thinking, writing and producing academic outcomes.

Paradoxically, however, SI is strongly written about in terms of entrepreneurship, civil society and, increasingly, in socially-conscious businesses (Bayuo et al., 2020, p. 2), yet remains "scattered" and "at the fringes" around RM (as the SARIMA PCF established) policy and the role of higher education therein. Thereto, Bayou et al. (2020, p. 2) conducted a systematic review as a means to offer commentary "on the role of the university" in advancing SI through its core elements of teaching, research and community engagements (the so-called "third mission"). The review covered 61 peer reviewed journals and 7 books from an initial 208 in the search. The review highlights how SI is neglected in universities in terms of its application towards building research acumen through novel teaching and learning innovations. As the authors (2020, p. 8) state, "[there are] growing fields of study but also… large gaps in the knowledge base." Particularly these gaps point to fragmented evidence on SI practice models, such as we present in this paper. The review concludes that SI dominates in works around the third mission—mainly community engagements and social entrepreneurial focal points. This is not surprising, considering that third missions focus on entrepreneurial, technology transfers, consultancies and business engagements, specifically with innovation drivers including "universities as agents for sustainable development and/or technology providers" (Bayuo et al., 2020, p. 8).

In research, while universities are being propelled towards SI, current literature was found to be lacking through being fragmented and casebound. SI is encouraged through being a criterion in grant-funded research and other sponsored initiatives. What appears to be the strongest area of SI, in relation to research, is that which intersects with the third and entrepreneurial mission of technology transfer, with social innovation becoming what Bayuo et al. (2020, p. 6) call

"appendages... with no clear path" for dedicated social innovation philosophy. Within teaching, SI has been taken up through programmes offering curricula and qualifications thereto, with signals that universities currently might be more aspirational in integrating social innovation philosophically in their pedagogies.

Distance education (DE) was singled out as practising SI through necessary technological platforms (Bayou, et al., 2020; de Pretelt & Hoyos, 2015). Wentzel and de Hart (2020, p. 284) endorse this contextual view through arguing that "teaching and learning within DE as a social system has dynamic opportunities for cybernetic learning". Despite recognising DE, which is the setting for this article, the Bayuo et al. (2020) study provided no examples of SI as a model for developing research capability/development to achieve increased and higher quality research. The model, notwithstanding its case base, therefore, integrates two missions, according to Bayou et al. (2020, p. 8): the need for socially innovative thinking as a core epistemological driver, as well as an under-studied topic requiring additional research, while also noting the strengthened potential of DE to provide socially-oriented innovation, especially during complex times, such as the COVID-19 pandemic. Africa, despite possessing a mega-DE university, is tabled for its trailing innovation capabilities.

Kizza et al. (2010, p. 222) argue that African countries, in particular, show inadequate capacity in relation to research and innovation generation, and that developing researchers, through innovative models, is not critical to change this profile. They posit that Africa is, in fact, in a "decline of research and a research culture". While they single out Egypt and South Africa for their better research acumen, their review demonstrates that the African countries do need strategies for research capacity, while also noting that these should increasingly harness "indigenous... expertise". By 2015, Cloete, Bunting and Maasen (2015, p. 29) reiterated that Africa lacked quality PhD quotas and outputs, researcher development and strong research universities, and, therefore, does not possess that "self-generative" capacity to achieve global knowledge production outcomes. While they highlight South Africa as being on the right trajectory to develop more strongly in these areas, South Africa's graduate education efforts (notably, in the apex area of doctoral education) are still not sufficiently intentionally wedded to widespread innovation (Cloete et al., 2015, p. 103).

The review segued from innovation, to universities' SI and, thereto, Africa and South Africa's research deficits. From this review and the problem in practice, which signals how professional qualifications, in many instances, are prized above a research culture, the impetus to create SI and RD becomes stronger. Based on this review and applied practices, the researchers provide the orienting concepts for the study.

Orienting Concepts

Layder (1998, pp. 101, 109) argues that studies may be considered, initially, through orienting concepts, which allow for investigators such as ourselves to seek pertinent issues, in principle, while, at the same time, following inductive means to plumb the data. Orienting concepts are looser than a more structured conceptual framework, allowing for the researchers to explore the data richness with concepts as points of departure, but not necessarily arranged in any structured

relationship. The orienting principles for this study were research management and programmatic researcher development within the SARIMA PCF, which is expressed in the competency framework stating the need for RD to have: "third parties", as a mentoring research methodology in existing supervisor/s-student relationship; and potential for social innovation in a longitudinal model for changing mindsets about undertaking research.

These concepts, as supported by Layder (1998), and MacFarlane and O'Reilly-de Brún (2012), make sense of pre-existing framings (in this case, both the PCF and the empirical model were in existence), while also allowing researchers to keep an open mind to the energy of the data. In this current study, the concepts, therefore, informed the process of the analysis and were then used to crystallise an evidence-informed rendition of the research management model of the study.

Methodology

Context

Englander (2019, p. 6) provides the view that general knowledge claims of qualitative science are provided through context-dependent meaning of a phenomenon, rather than statistical, generalisable findings related to sampling and population. Englander, therefore, questions the necessity for a sample. Given this argument, providing the research context becomes critically important to make our knowledge claims.

The introduction has provided the research setting for this study. The case covers four years, from 2016 to 2020, inclusive of the outlier year of COVID-19. The unit of analysis is a RD model that includes three academic mentors, who are contracted, respectively, for up to 30 hours per month, to support the research and graduate work of the faculty and their master's and doctoral students (who might also be faculty). The faculty's work covers teaching and learning in DE, research, master's and doctoral supervision, and community engagement. The supervisors often have a ratio of 1 supervisor to 10-15 graduate students. There are also punctuated periods to do teaching. Additionally, many members of the faculty are involved with professional associations, based on their registrations with such bodies. They are required to integrate their faculty work with the developments of the profession in the public and private sectors.

The workload of academics and RM in South Africa has been noted as being disproportionately skewed away from concentrating on research and publications, towards teaching, supervision and, sometimes, unwieldy, bureaucratic administrative duties (USAf, 2019). Considerations of this reality, and other dimensions that will be raised in the discussions section, prompted the RM leadership of Faculty A to introduce this model. The model was framed as being part of evolving SI, as discussed in the sections on the literature review and orienting concepts.

The RM office initiated and then integrated the model into Faculty A's strategic cycle. RM also provides relational and administrative support through accepting bookings for the mentors for their hours at the university, promoting supervisors and students' relationships with the mentors, tracking the implementation of the model and, together with the mentors, building on any system enhancements for the model. RM also reports on the model to the Faculty and university

leadership. In doing so, RM fulfils the standards set by the SARIMA PCF (see *Statement of Research Problem* section).

External mentors were contracted for their specific expertise. Each mentor had wide and deep experience in their respective fields of qualitative and quantitative methodology approaches, with the third mentor being highly regarded for disciplinary knowledge. The mentors are widely and well-known nationally in higher education for their work with graduate students and supervisors. Mentors were thus approached to apply to be part of this exploratory process. All mentors thus were well placed to provide advice in recurring, repeat sessions and are consulted for master's or doctoral studies as well as article writing or to discuss any need around the research process. When the members of the Faculty thus have an identified requirement to be addressed, they would make an appointment to see the qualitative, quantitative or discipline-specific mentor for an hour's consultation. Repeat consultations are common and happen from month to month. Written work may or may not be sent beforehand. If written work is sent, the mentor reviews it, before the session, and discusses the feedback in the consultation. Sometimes, on-the-spot advice is requested and the mentor draws on their experience and the discussions happening in the group to consolidate the advice. While the mentor (third party as advised by SARIMA's PCF) is the lead of the session, there is always collective discussion, with the supervisor often co-leading. A session includes mainly advising on methodology, but, often, the study is discussed more broadly, specifically around the coherence of the study, the logic, expectations of academic conventions and the choice of theories.. The practical implementation is best illustrated in terms of the numbered segments and relationships, as depicted in Figure 1, with mentors (segment numbered as 2), as the pivotal anchoring of the model. This model crystallises the orienting concepts, as referred to in the section of the same name.

Figure 1. Practical Display of Research Management Researcher Development Model as Implemented

To add further substance to the context, a sample of enumerated data provides a snapshot to signal that the model is being used. In 2018, as an illustration, 152 community members accessed the model by consulting any or all of the three mentors. Of the 152 consultations, there were often instances of 3 to 4 repeat consultations. Additionally, under the context section of their responses, participants indicated two critical sentiments, in the light of their professional identities, namely, that they found research challenging and that they are currently, as professionals, required to "think in the box", yet research often requires "out of the box" thinking.

Data Gathering

The data were gathered using a qualitative approach, following "a phenomenological theory of science" (Englander, 2019, p. 11). The phenomenon was therefore narratively elicited and analysed for both the textual and sub-textual elements. The study used the self-narrated and recalled experiences of the researchers themselves as well as the consenting members of Faculty A. A limited amount of enumeration of qualitative data (Grbich, 2013) was used in the methodology context to bolster the descriptive setting.

The model is located as an experiential, illustrative phenomenon, shaped by the participants taking into account the meaning-rich assumptions elucidated by the theoretical points of departure (Englander, 2019). As such, following Englander (2019, p. 8), we probe the meaning-making by participants within the "world" of this model. The method used was an adaptation of memory work (Haug, 1992), as experiences were gathered retrospectively over the five years (2016-2020) of the use of the model. Quoting Haug (2008, p. 22), and drawing on other authors, Clift and Clift (2017, p. 606) state that memory work is "not only experience, but work with the experience". In this way, memory work does not recognise memory as truth, but rather as a means of talking around, with and through memory-sharing telling, writing and listening, to produce knowledge about the ways individuals are "made social, [and] are discursively constituted in particular...moments" (Davies & Gannon, 2006, p. 4).

The specific data gathering method used was computer-mediated research (CMR) (Salmons, 2015). CMR, in itself, is an emerging area of methodological innovation, consistent with the theoretical disposition of the article. The COVID-19 pandemic has also validated, through necessity, the use of CMR. The participants were e-mailed a short "e-interview" guideline, to prompt and probe their memories of the consultation sessions in an "asynchronous" manner. The schedule took approximately 15-30 minutes to write up and mail back to the researchers. All the participants responded through a reciprocal e-mail response. The researchers acknowledged each e-mail received and prompted for further additions to the initial recollections. Two members of the group indicated that they would welcome interviews, as they felt they wanted the energy of an oral narrative. The researchers, while respecting these views, indicated that they would keep the data gathering consistent to e-interview responses.

Additionally, the use of e-mail, as a mediated form of data gathering, was deemed useful so as not to have proximate inter-personal relationship cues where the researchers, who are intricately part of the model, could perhaps colour the recollection of the interviews or prompt in-person impression management.

Data Analysis

Data were extracted from the mails, anonymised and then loaded into ATLAS.ti™ Version 8 for methodological systematisation (Smit, 2005). Using inductive content analysis, the researchers first descriptively open coded the data to understand the phenomenon in broader terms. The scope of this first cycle enabled the researchers to use prefixes (see Tables 2-4 for examples of

prefix coding), thereby focusing the coding for two successive coding cycles (Friese, 2019; Saldaña, 2015) so as to arrive at what became four thematic areas, together with a note as to the rationale underpinning the thematic area (as reported in Table 1).

Table 1. Thematic Areas from Codes

No	Thematic area	Note on rationale
1	Professional identity (not research identity)	Context: Disciplinary specificity challenges in relation to research
2	Mentors and why consulted	Context: Consulted for stage of research (PhD, master's, article writing, general research skills); all mentors consulted
3	Researchers themselves	Findings: The model itself and RD specifically
4	Research support model/Metaphors	Findings: The model itself with elements of RD and SI

Thematic areas numbers 1 and 2 verified the context sections of the study. Numbers 3 and 4 were considered substantive to the model itself and are integrated into the narratives with their focused codes tabulated prior to the write-ups. The themes were enriched through using a selection of the researchers' own in-session, handwritten, anonymised jottings of what methodologies, processes and conventions were advised and the mentors' reflections of the session. We adapted Haug's (n.d.) work on how identities (the first person "I") are re-constructed through memories. Haug (n.d.) calls this the "Construction of I", and such devices acknowledge the voice of the narrators, which, in this case, are the researchers. The review of these anonymised jottings appears almost cryptic until memory kicks in. The cues of the jottings enabled memories to manifest in the present (Clift & Clift, 2017) so as to be applied to the narrated themes.

In memory work, these researchers' memories and those e-mailed by the participants may be described as "working backwards into the future" (O'Reilly-Scanlon & Dwyer, 2005, p. 82). Both sources shaped the themes, which are presented in a storyline, with participant quotations to illustrate the themes and the subsequent theorising (Saldaña, 2015).

Quality Criteria for Trustworthiness

To elicit phenomenological knowledge, the researchers are ethically prompted to undertake rich descriptive, reflective and trustworthy research as offered through the qualitative paradigm (Tracy, 2019). Two-level ethics approval was obtained from the Faculty and institution, owing to the data being anchored in both those levels. Within ethics approval, quality criteria for trustworthiness were approved and fulfilled in the study. Inclusive to trustworthiness ATLAS.ti was used for transparency and to systematise for credibility and data organisation. While one researcher coded

the data, the other researcher reviewed the codes for coherence and shared connotative meanings (Barbour, 2001). The study's gaps were verified theoretically and through observation notes in the implementation of the model, as part of the applied faculty operations, thus supporting the pointedness of the research question and the authentic necessity for the study.

Findings

The data provided "memory work" on repeated consultations with all mentors. While the recollections with different mentors were differentiated, the data were aggregated to theme level. The themes are creatively named from participant quotations. With reference to Table 1, each theme integrates researcher development, the research support model and the expressive metaphors used by the participants.

Theme 1: "They did not tell me, but allowed me to figure it out for myself ... I can rely on my (growing) judgement and abilities."

Table 2. Main Codes Informing Theme 1

Codes (with prefixes-capitalized)	Thematic areas
RES stuck	Researchers (RES) themselves
RM space for emotional expression	Researchers (RES) themselves
RM elevated interpretive levels (in session/ afterwards)	Research support model (RM)
RM extended critical thinking and thinking thresholds	**Research support model**
RM_QUAL methodological guidance	Research support model
RM_QUAN methodological guidance	Research support model
RM shared soundboard for research	Research support model
RM theoretical awareness and application	Research support model
MET various	Metaphors

Participants (anonymised, using letters of the alphabet, for instance, Participant O, and then indicated as student or supervisor) used a preponderance of phrases that connoted being "stuck", until they attended sessions with mentors. Some specifically mention the tensions or inadequacies associated with that disposition, evocatively shown in the "before" and "after" reflection below.

> All [my study had] done in the past year was to drain me and at some point made me doubt my abilities. I felt like I was smoking my socks ... (Participant D-Student)

> I remember how nervous I was with my follow up consultation... but she read my updated report, you could see her face light up, I got a bit relaxed, and there it was....I finally got my 'groove back'. Participant R-Student)

I was stuck for quite a long time in my research journey because I needed to find a suitable theoretical lens for my study. Dr L acted like a knight in shining armour and rescued me from my misery. (Participant O-Student)

Predominantly, the data thus showed crossing portals in their thought processes. Students stated that the sessions with the mentors and supervisors stimulated socially situated brainstorming discussions that prompted them to think critically, "there and then" at an interpretive (often new or refined) theoretical level.

… many golden nuggets of wisdom and knowledge get transferred in the mentoring sessions, in words that just sounds amazing. I loved the sessions! There are light-bulb moments while you share ideas with Dr P and then there are other moments while she kindly makes you realise that there are big pieces of the puzzle still missing … (Participant O-Supervisor as well as student)

The sessions also required of them actively to think through their studies, when they had to go back and sit alone with their research work. The details of methodological guidance were also strongly provided in these sessions, increasing their repertoire to address formulating and analysing research projects. They were able to apply the methodological and theoretical ideas gained from these sessions, then, in solo analysis and writing, they built confidence and expanded their ability to integrate their ideas from what they learnt in the model.

Dr X reviewed my research methodology chapter, gave constructive feedback and patiently answered my questions till I was satisfied that I understood everything and could apply it. By nature, I do not simply accept what is told to me, as I have a need to know why it is what it is. It didn't bother her, but bred room for more discussion … I felt confident that my research was based on a solid foundation. (Participant J-Student)

I have a memory regarding methodology [discussions] on a number of occasions with Dr X. Dr P also assisted me intensively to understand the methodological process and the types of theories that are relevant to my study resulting in a very good methodology chapter. (Participant U-Student)

All the participants acknowledge the model for being situated in the social learning of mutual problem solving, both as a means to do better research and to achieve more—or better—research as an end goal. Supervisors, specifically, addressed how welcome it was to get the views of other experts within the context of academic discussion.

Theme 2: Similar to being Greek and other stories….

Table 3. Main Codes Informing Theme 2

Codes (with prefixes-capitalized)	Thematic areas
RM extended critical thinking and thinking thresholds	**Research support model**
RM_AHA moment	Research support model
RM space for emotional expression	Researchers themselves
RM provided intellectual challenges	Research support model
RM motivating and encouraging shared space	Research support model
RM professional and supportive ethos	Research support model
RM think out of the box	Researcher development
MET various	Metaphors

Both the students and the supervisors recall seminal moments of breakthrough—from a place of not knowing to a place of knowing—in the intellectual discussions of the sessions. Likened to feeling as if research was "Greek", in the memorable statement (below) by Participant D, the students could trace their emotional, cognitive and interpersonal engagements during the sessions. As such, they indicate first feeling part of one world and its "languages" and then acknowledge how they entered a different world, using expanded, often, difficult "languages" and moving towards "out of the box" thinking. Their sense-making of the crossover mostly reflects struggle and a feeling of their brain needing to break through. When the "Aha moment" lands, there is a sense of relief and an awareness that they now had a different, yet, irreversible way of viewing their studies. These moments were often reflected metaphorically, indicating the tacit levels of change that complemented the explicit learning.

> [It] was similar to [it] being Greek, having already read a big bunch of studies without understanding the whole 'research' concept with theories … After Dr P asked a few probing questions here and there, she framed the study to be either 'compliance' or 'innovation', where the 'AHA!' moment struck! She provided key words to look up and, all of a sudden, the theories that were relevant and applicable 'came to light'. Without this specific session, I can't imagine what this study would have turned into. I might even say that this was the 'first sign of life' or maybe 'the missing link' (similar to if you were to believe in a fairytale…) in terms of 'RESEARCH' that gave it breath and brought it all together. (Participant D-Student)

Additional to these individualised "Aha moments", there were references to how changes in thinking or viewing of the research happened in the communal energies of a widened academic group and a dedicated space that could be accessed repeatedly, to follow an evolving and cumulative research process and traversing thresholds in thinking and action.

> She was like a living library—always knowing what we needed and ready to share that. After a session with her, I always felt more equipped to guide a student further (knowing that I can consult her again). I do not think we ever thanked her enough for the hours she spent

in finding supporting sources. However, all my students thanked her, by the name, in their dissertations/theses for her contribution to their studies. (Participant F-Supervisor)

Theme 3: "Now to build the puzzle is up to me…"

Table 4. Main Codes Informing Theme 3

Codes (with prefixes-capitalized)	Thematic areas
RM extended critical thinking and thinking thresholds	**Research support model**
RM complete research process	Researcher development
RM completion of high-quality studies	Researcher development
RM love of research/key changes	Researcher development
RM role modelling	Research support model
RM targeted reading	Research support model
RM model indispensable	Research support model
MET various	Metaphors

This theme speaks to the sense of responsibility attained in relation to the development of the researcher facilitated by the model. Multiple reports of how a model, such as this one, impels researchers to work harder and smarter, as a member of the research community, abounded. There was extensive evidence of progressing further across thresholds of learning and being. The enabling environment, provided by Faculty A, in conceiving of a research model such as this one, was repeatedly acknowledged. Fears were even expressed of losing this opportunity, should resources not be available. During the time of COVID-19 lockdowns, when making appointments were not easily effected, researchers took it upon themselves to proactively consult with the mentors, sending completed work in advance, so that online sessions were productively used. The researchers themselves initiated the online platforms, sending out the invite as opposed to expectations that the system would make this happen. Participants did share how they missed the in-person engagements, but stated too that the online adaptation was another dimension to the model, in the sense that they could use the model more flexibly than what the fixed site and days provided. Some initial reservations were expressed about the technology, but, when the participants settled into the "passions" of talking research again, in a supportive online environment, these reservations dwindled as the sessions proceeded.

This changed my life, not only as a researcher, but also on a personal level, allowing me to shift paradigms and, in so doing, start to really love research and appreciate the contribution it can make. (Participant V-Supervisor as well as student)

The session inspired me to do further reading into my methodology of choice in order to produce a chapter of good standard. The discussion made me feel blown away by this passion for and knowledge of research methodology … (Participant H-Student)

> [The model provides] the privilege of receiving much needed methodological support and guidance on theory from [mentors]. (Participant O-Supervisor)

Discussion and Significance of Findings

The study provides distinct findings in respect of initiating a modest contribution to social innovation theory within RM. The model also addresses the call made by Bayuo et al. (2020, p. 8) towards building integrated practice models of SI around research, teaching and learning.

1. Potential for social innovation in programmatic researcher development, assessed over the five years:

With regard to the definition of social innovation (Young Foundation and SIX, 2010; Mulgan, 2012), the data show that the RM model responded to the social needs of supervisors and researchers, who wanted to expand their repertoire of research processes, specifically regarding methodologies and how to use theories. The shift towards supervisors and their students working with mentors created new social relationships, extending beyond the traditional dyadic supervisor-researcher relationship (Wisker, 2012). The strong positive response, narratively and enumerated, shows that individuals felt that the consultations had been productive for their research identity, provided researcher development and research outputs. The impetus to complete their studies and publish, with the knowledge that the support from mentors extended towards publication, also verified that the model provided goodness of fit for Faculty A and the university, as a sub-system of society.

Hughes et al. (2019, pp. 24, 28) posit that conceptual frameworks need to be noteworthy inclusions in publications for their value as contributions. They indicate that the framework graphically demonstrates the main concepts drawn from the literature review, while also providing the "theory-to-experience" hierarchy that the conclusion of a study provides. They also advocate a narrative for the schema. An integrative model was thus developed as a finding of this study.

The schema illustrated in Figure 2 (below) is therefore explained and narrated cohesively. The outer propositions, in the square textboxes, represent the realised "theory" of the framework's hierarchy. The text on the "experience" dimensions of the hierarchy are contained in the inner circle's segments of the figure. The arrows at the core of the model show that all elements are integrative and self-reinforcing. The schema also confirms the orienting concepts which guided this paper. The narrative uses italics to show when the SARIMA PCF framework is applied.
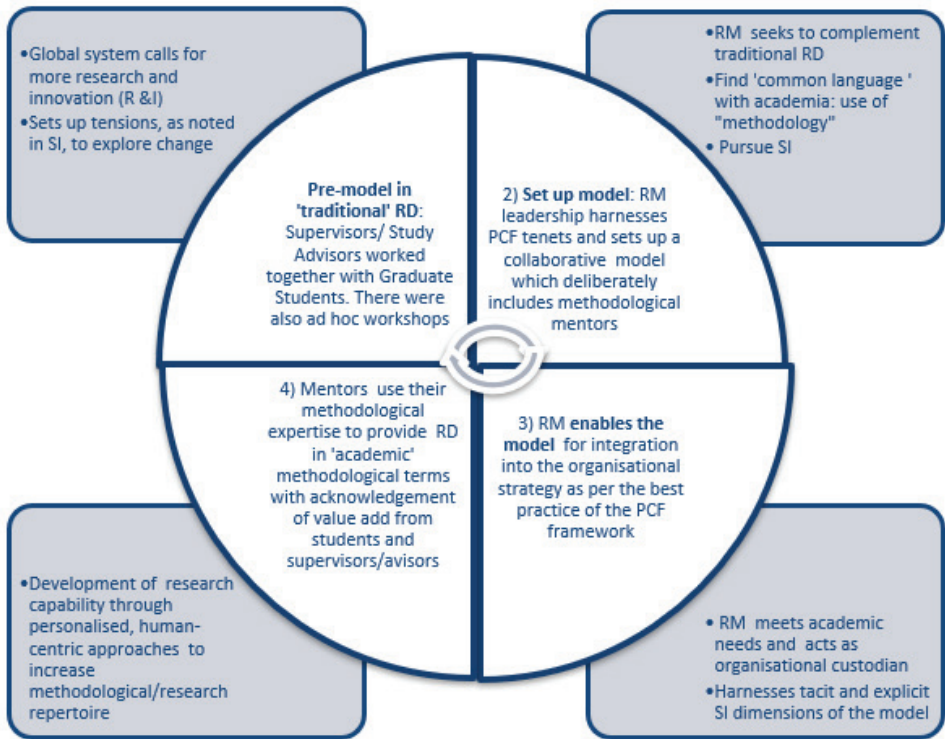
Pre-model in 'traditional' RD: Supervisors/ Study Advisors worked together with Graduate Students. There were also ad hoc workshops

2) **Set up model**: RM leadership harnesses PCF tenets and sets up a collaborative model which deliberately includes methodological mentors

4) Mentors use their methodological expertise to provide RD in 'academic' methodological terms with acknowledgement of value add from students and supervisors/avisors

3) RM **enables the model** for integration into the organisational strategy as per the best practice of the PCF framework

- Global system calls for more research and innovation (R &I)
- Sets up tensions, as noted in SI, to explore change

- RM seeks to complement traditional RD
- Find 'common language ' with academia: use of "methodology"
- Pursue SI

- Development of research capability through personalised, human-centric approaches to increase methodological/research repertoire

- RM meets academic needs and acts as organisational custodian
- Harnesses tacit and explicit SI dimensions of the model

Figure 2. An Integrative Model in response to Research Question and alignment with the SARIMA PCF Researcher Development Competency (SARIMA, 2016)

Worldwide, and now intensified under unusual pandemic systems, there is a need for more research and innovation (R & I), provided by matured and maturing researchers. This group of researchers mature into research, often through traditional supervisor/study-advisor-to-student methods of RD, while also accompanied by RM-driven workshop-based topics; thus, inculcating *the full research cycle*. Yet, there might also be opportunities to *innovate* on a social learning level. RM may conceptualise a *framework* or model that works in a complementary, yet, programmatic fashion to achieve improved R & I and which finds a collaborative, "common language" to *partner* with academia. RM, therefore, hones in on customised teaching of methodologies of qualitative, quantitative and mixed methods research through a sustained mentor-based system. RM, as custodian, devises strategy, which provides the enabling support facilities for such a model, thereby integrating the model into *organizational strategy*. Furthermore, RM also systemically harnesses the SI learning that comes from tacit and explicit dimensions of the model. The model *develops research capability* through the use of *benchmarked mentoring expertise*, to enhance the methodological and research repertoire of students. These mentors are highly versed in this "language" of academia, so that they work in a personalised, customised manner with students'

studies, alongside their supervisors/advisors, with the latter self-declaring the importance of the mentoring for advancing their own and their students' RD.

Based on the discussion above, the dimensions required by the SARIMA PCF (see *Introduction* and italics above) are seen to be achieved.

2. Contribution to Social Innovation Theory

The discussions above serve to provide assenting evidence of social innovation theoretical standpoints and provide an empirical case, as called for by the study of Bayou et al. (2020), in terms of social innovation and university contexts. While the findings presented herein meet the requirements for concurring studies, novel theorising on social innovation is still important for this emergent field. In the extant literature, the tension-driven changes that impel social innovation towards redefining historical circumstances and working collaboratively towards creating change, heightened capability and social good have been conceptualised by Mulgan (2012). Our view is that the substance of these changes has been under-theorised. The researchers' review of the existing literature, for this study, showed broad brushes that did not provide the human-centric manner in which social innovation may translate into practice.

Galle (2011) argues that, while research might start with the foundational conceptual framings, the data often suggest instrumental theory, invoked at the findings stage. An instrumental theory is one that is strongly suggested by the data and not a priori at the initial stages of the research question. For this study, bringing in an instrumental theory was needed because of the defined signals of the data. The strongly grounded code of: "***RM_extended critical thinking and thinking thresholds***", linked to informative quotations, extended the orienting concepts that were anticipated for the study. As may be noted, the latter were thereto covered in the literature and context sections.

The instrumental theory, illumined by the data, is that of threshold concepts and, therefore, these concepts are introduced at this stage, as provided for by Galle (2011, p. 92). He proposed that instrumental theory is akin to providing specific "accent lighting" and thus providing focus through the "drawing [together of] lessons from the case". Our findings posit that social innovation is progressively enabled through critical thresholds (Meyer & Land, 2006), specifically raised in Theme 2, yet also interwoven in the other two themes (as shown through the bold, italicised code in the code summary for each theme). Threshold concepts entail moving beyond an existing, and perhaps even comfortable, conceptual repertoire and transiting to novel lines of sight and worldviews (Meyer & Land, 2006).

Meyer and Land (2006) (with other authors), and Kiley and Wisker (2009) (equally with other authors) provide two bodies of work on threshold concepts (TCs). In applying this theory, the researchers found that it is the experiential, human-activated threshold concepts that might explain the propulsion and translation of social innovation within RM and RD. Meyer and Land (2006) provide the characteristics of threshold concepts (as covered in Table 5, column 1). To demonstrate extending the theory of social innovation through threshold concepts, the researchers juxtapose these characteristics with the theoretical overviews of social innovations (in column 2) and their findings on the RM model (in column 3). Table 5 provides the alignment.

Table 5. Early Theoretical Extension Integrating Threshold Concepts with Social Innovation as Based on the RM Model For RD

1) Characteristics of threshold concepts (TCs) which lead to –>	2) Characteristics of TCs as expressed in the data: Research findings within RM model for RD, which support –>	3) Social innovation theoretical overview, as aligned to columns 1 and 2
Troublesome	Being "stuck" and the need to address different methods to create a more confident research culture	Tensions and paradoxes
Transformative and irreversible	Impetus for change: changed thinking, attitude and improvements in working with theory and methodology	Previous ways of doing or being, appear no longer to suffice; thus, incremental, organic change may happen
Bounded	Contextual, historical circumstances of Faculty, feeling more "at home" in professional qualifications than research; RM in third space role and seeking to find common ground with academics	SI is rooted in contextual circumstances
Integrative and discursive	RM model provides personalised, human-centric means to facilitate researcher development and collaboration	Being socially innovative is following communitarian ways of existing, inseparable from collaboration and being more fully and, socially, human The foundational premises of SI rest on the well-being and development of humanity in the social realm, differentiating it from technological innovation that is hard-wired into test-driven, measurable worlds
Reconstitutive	Model provides researcher development, drawing on tacit and explicit knowledge within the consultations through working collaboratively between the model and traditional supervision	SI seeks to build capabilities towards fully actualised humans, who are able to harness both tacit and explicit knowledge

Transformative and liminality	Model works in an exploratory and incremental manner and is open to emergent dimensions such as the COVID-19 pivoting to online support	The field remains emergent and less fully formed than other innovation domains; thus, it prompts additional research

The alignment constructed within Table 5 provides a starting point to consider social innovation within any sphere, but more specifically how research management's RD role may be better attended to in creating an enabling environment for threshold concepts. As discussed below, this is a summative and modestly provocative finding, which acknowledges its own troublesome basis and impels additional studies.

Implications

The study has provided more intricate details towards how threshold changes instantiate social innovation within the context of a RM model that advanced researcher development in a university setting. The bridge-building between academics, with their knowledge-driven outcomes, and research management, within their support function, was established. RM facilitated that the language of academia could be incorporated systemically into RM service provision. Additionally, the context showed that the SARIMA's PCF's technical requirements and cross-cutting indicator of innovation are also met through this model. The paper which published the SARIMA PCF (Williamson et al., 2020), indicates how different settings and evolutions of dimensions of the PCF need to be replicated. This current paper responded to this call, giving it credence in a mega-university setting. Working with Research and Innovation Management Associations (RIMAs) such as SARIMA and other RIMAS, the model may be replicated or further extended through contextually-relevant customisation. From a DE Faculty and university point of view, the critical thinking capabilities of confident, engaged researchers better place them to deliver to the national system of research and innovation, which is associated with societal benefits. The endeavour has given burgeoning theoretical contours to SI in university settings, while giving impetus to future research and, at the same time, signalling that there are inherent limitations in the current work.

Limitations

With regard to limitations, the human-centred threshold concepts, as boosting social innovation, is only introduced as a theoretical extension and inherently limited herein, and, therefore, this nexus should be further explored. Additional ventures into whether this model has enhancing potential in contrasting research settings, where the research culture is already mature, was not established and is recommended. Concomitantly, it has to be explored whether it has replication potential in comparative, like-minded settings. Methodologically, a follow up longitudinal and/or quantitative approach to studying the research and supervision progress of these participants would also render scholarly benefits. This approach shows only cross-sectional, qualitative memory work, which, while evocative in detail, might be lean on more positivist proofs, which are called for in other academic quarters.

Concluding Remarks

Reflecting on A-ha moments - the metaphors of the researchers, as they articulated their development and experiences - linger from the data, perhaps long after the more formalised principles of scholarship leave. A study should prompt the same in the readers: we extend the wish that the lingering ideas would activate a deepening of, and challenge to, this composition.

Authors' Note

None of the authors have any conflict of interest as it relates to this manuscript.

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References

Adsule, A., Lopez, J., & Kedar, M. S. (2015). Innovation leading the way to revolution. *International Journal of Business and Administration Research Review, 2*(11), 362–371.

Altbach, P.G. (2013). Advancing the national and global knowledge economy: The role of research universities in developing countries. *Studies in Higher Education, 38*(3), 316-330. https://doi.org/10.1080/03075079.2013.773222

Avelino, F., Wittmayer, J. M., Pel, B., Weaver, P., Dumitru, A., Haxeltine, A., & O'Riordan, T. (2019). Transformative social innovation and (dis)empowerment. Technological *Forecasting and Social Change, 145*(August 2019), 195–206. https://doi.org/10.1016/j.techfore.2017.05.002

Bai, L., Millwater, J., & Hudson, P. (2008, May). Building research capacity: Changing roles of universities and academics. In *AARE 2008 International Education Research Conference*, BAI08493. https://www.aare.edu.au/data/publications/ 2008/bai08493.pdf

Barbour, R. S. (2001). Checklists for improving rigour in qualitative research: A case of the tail wagging the dog? BMJ: *British Medical Journal, 322*(7294), 1115–1117. https://doi.org/10.1136/bmj.322.7294.1115

Bayuo, B. B., Chaminade, C., & Göransson, B. (2020). Unpacking the role of universities in the emergence, development and impact of social innovations – A systematic review of the literature. *Technological Forecasting and Social Change, 155*(June), 120030. https://doi.org/10.1016/j.techfore.2020.120030

Belkhir, M., Brouard, M., Brunk, K. H., Dalmoro, M., Ferreira, M. C., Figueiredo, B., Huff, A. D., Scaraboto, D., Sibai, O., & Smith, A. N. (2019). Isolation in globalizing academic fields: A collaborative autoethnography of early career researchers. *Academy of Management Learning & Education, 18*(2), 261-285. https://doi.org/10.5465/amle.2017.0329

Bitzer, E., & Van den Bergh, S. (2014). Doctoral identity change towards researcher autonomy during research journeys across disciplines. *South African Journal of Higher Education, 28*(3), 1047–1068. https://doi.org/10.20853/28-3-369

Browning, L., Thompson, K. & Dawson, D. (2014). Developing future research leaders. *International Journal for Researcher Development, 5*(2), 123-134. https://doi.org/10.1108/IJRD-08-2014-0019

Christensen, C. (2003). *The innovators solution*. Harvard Business School Press.

Clift, B. C., & Clift, R. T. (2017). Toward a "Pedagogy of Reinvention": Memory work, collective biography, self-study, and family. *Qualitative Inquiry, 23*(8), 605-617. https://doi.org/10.1177/1077800417729836

Cloete, N., Bunting, I., & Maassen, P. (2015). Research universities in Africa: An empirical overview of eight flagship universities. In N. Cloete, I. Bunting, & T. Bailey (Eds.) *Knowledge production and contradictory functions in African Higher Education* (pp. 18–31). African Minds. https://doi.org/10.1080/03075079.2010.482204

Davies, B., & Gannon, S. (2006). *Doing collective biography: Investigating the production of subjectivity*. McGraw-Hill Education (UK).

de Pretelt, C. L., & Hoyos, F. (2015). Innovation for social inclusion: Challenges facing the state University System in Colombia. In R. T. Teranishi, L. B. Pazich, M. Knobel, & W. R. Allen (Eds.), *Mitigating inequality: Higher education research, policy, and practice in an era of massification and stratification* (pp. 127–147). Emerald Group Publishing Limited. https://doi.org/10.1108/S1479-358X20150000011008

de Vasconcelos Gomes, L. A., Salerno, M. S., Phaal, R., & Probert, D. R. (2018). How entrepreneurs manage collective uncertainties in innovation ecosystems. *Technological Forecasting and Social Change, 128*, 164-185. https://doi.org/10.1016/j.techfore.2017.11.016

Dogan, M. (2019). *Creative marginality: Innovation at the intersections of social sciences*. Routledge.

Englander, M. (2019). General knowledge claims in qualitative research. *Humanistic Psychologist, 47*(1), 1–14. https://doi.org/10.1037/hum0000107

Fichter, K., & Beucker, S. (Eds.). (2012). *Innovation communities: Teamworking of key persons-a success factor in radical innovation*. Springer Science & Business Media.

Franz, H. W., Hochgerner, J., & Howaldt, J. (Eds.). (2012). *Challenge social innovation: Potentials for business, social entrepreneurship, welfare and civil society*. Springer Science & Business Media.

Friese, S. (2019). *Qualitative data analysis with ATLAS.ti*. SAGE Publications Limited.

Galle, P. (2011). Foundational and instrumental design theory. *Design Issues, 27*(4), 81-94. https://doi.org/10.1162/DESI_a_00107

Grbich, C. (2013). Content analysis of texts. In *Qualitative data analysis: An introduction* (2nd ed., pp. 189-199.) Sage.

Haug, F. (n.d.). Memory work, a research guide: Memory-work as a method of social science research: A detailed rendering of Memory-work Method. http://www.friggahaug.inkrit.de/documents/memorywork-researchguidei7.pdf

Haug, F. (1992). *Beyond female masochism: Memory-work and politics*. Verso.

Haug, F. (2008). Memory-work: A detailed rendering of the method for social science research. In A. E. Hyle, M. S. Ewing, D. Montgomery, & J. S. Kaufman (Eds.), *Dissecting the mundane: International perspectives on memory-work* (pp. 21-41). University Press of America.

Hodza, F. (2007). Managing the student-supervisor relationship for successful postgraduate supervision: A sociological perspective. *South African Journal of Higher Education, 21*(1), 1155-1165. http://dx.doi.org/10.4314/sajhe.v21i8.25767

Hughes, S., Davis, T. E., & Imenda, S. N. (2019). Demystifying theoretical and conceptual frameworks: A guide for students and advisors of educational research. *Journal of the Social Sciences, 58*(1-3), 24-35. https://doi.org/10.31901/24566756.2019/58.1-3.2188

Kiley, M., & Wisker, G. (2009). Threshold concepts in research education and evidence of threshold crossing. *Higher Education Research & Development, 28*(4), 431-441. https://doi.org/10.1080/07294360903067930

Kizza, J., Muchie, M., & Waema, T. (2010). Reaching out: Efforts to build sustainable African research and innovation capacity. *African Journal of Science, Technology (Innovation and Development), 2*(2) 215–229. http://hdl.handle.net/11295/27865

Lamar, M. R., Clemens, E., & Dunbar, A. S. (2019). Promoting doctoral student researcher development through positive research training environments using Self-Concept Theory. *Professional Counselor, 9*(4), 298-309. https://doi.org/10.15241/mrl.9.4.298

Layder, D. (1998). *Sociological practice: Linking theory and social research.* Sage.

Lee, J. (2013). Creating world-class universities: Implications for developing countries. *Prospects, 43*, 233-249. https://doi.org/10.1007/s11125-013-9266-x

Lepore, J. (2014). The disruption machine. *The New Yorker*, 23–45. https://doi.org/10.1177/001452464305400804

MacFarlane, A., & O'Reilly-de Brún, M. (2012). Using a theory-driven conceptual framework in qualitative health research. *Qualitative Health Research, 22*(5), 607-618. https://doi.org/10.1177/1049732311431898

Merritt, C., Jack, H., Mangezi, W., Chibanda, D., & Abas, M. (2019). Positioning for success: Building capacity in academic competencies for early-career researchers in sub-Saharan Africa. *Global Mental Health, 6*, e16. https://doi.org/10.1017/gmh.2019.14

Meyer, J., & Land, R. (2006). *Overcoming barriers to student understanding: Threshold concepts and troublesome knowledge*. Routledge.

Mulgan, G. (2012) Social innovation theories: Can theory catch up with practice? In Franz Hochgerner, J. & Howaldt, J. (Eds.), *Challenge social innovation: Potentials for business, social entrepreneurship, welfare and civil society* (pp. 19-42). Springer Science & Business Media. https://doi.org/10.1007/978-3-642-32879-4_2

Murray, R., & Cunningham, E. (2011). Managing researcher development: 'Drastic transition'? *Studies in Higher Education, 36*(7), 831-845. http://dx.doi.org/10.1080/03075079. 2010.482204

Nchinda, T. C. (2002). Research capacity strengthening in the South. *Social Science & Medicine, 54*(11), 699-1711. https://doi.org/10.1016/s0277-9536(01)00338-0

Nygaard, L. P. (2017). Publishing and perishing: An academic literacies framework for investigating research productivity. *Studies in Higher Education, 42*(3), 519-532. https://doi.org/10.1080/03075079.2015.1058351

O'Reilly-Scanlon, K., & Dwyer, S. C. (2005). Chapter five: Memory-work as a (be) tween research method: The beauty, the splendor, the wonder of my hair. *Counterpoints, 245*, 79-94. https://www.jstor.org/stable/42978693

Pratt, M., Margaritis, D., & Coy, D. (1999). Developing a research culture in a university faculty. *Journal of Higher Education Policy and Management, 21*(1), 43-55. https://doi.org/10.1080/1360080990210104

Rana, N. P., Weerakkody, V., Dwivedi, Y. K., & Piercy, N. C. (2014). Profiling existing research on social innovation in the public sector. *Information Systems Management, 31*(3), 259–273. https://doi.org/10.1080/10580530.2014.923271

Rospigliosi, A., & Bourner, T. (2019). Researcher development in universities: Origins and historical context. *London Review of Education, 17*(2), 206-222. https://doi.org/10.18546/LRE.17.2.08

Saldaña, J. (2015). *The coding manual for qualitative researchers*. Sage.

Salmons, J. E. (2015). *Doing qualitative research online*. Sage.

Samkin, G., & Schneider, A. (2014). Using university websites to profile accounting academics and their research output: A three-country study. *Meditari Accountancy Research, 22*(1), 77-106. https://doi.org/10.1108/MEDAR-05-2014-0038

SARIMA. (no date). Annexure A, Professional Competency Framework [Unpublished]. SARIMA, Pretoria.

Schumpeter, J. (1934). *The theory of economic development: An inquiry into profits, capital, credit, interest and the business cycle*. New Brunswick: Transaction Publishers.

Sikes, P. (2016). Working in a 'new' university: In the shadow of the Research Assessment Exercise? *Studies in Higher Education, 31*(5), 555-568. https://doi.org/10.1080/03075070600922758

Smit, B. (2005). Computer assisted qualitative data software: Friend or foe: Reviewed article. *South African Computer Journal, 2005*(35), 107-111. https://hdl.handle.net/10520/EJC27991

Times Higher Education World University Rankings. (2021). University of South Africa. https://www.timeshighereducation.com/world-university-rankings/university-south-africa

Tracy, S. J. (2019). *Qualitative research methods: Collecting evidence, crafting analysis, communicating impact*. John Wiley & Sons.

USAf. (2019, February 3). *Why emerging researchers need to be supported*. https://www.usaf.ac.za/why-emerging-researchers-need-to-be-supported/

Venter, E. R. & De Villiers, C. (2013). The accounting profession's influence on academe: South African evidence. *Accounting, Auditing & Accountability Journal, 26*(8), 1246-1278. https://doi.org/10.1108/AAAJ-06-2012-01027

Verhoef, G., & Samkin, G. (2017). The accounting profession and education: The development of disengaged scholarly activity in accounting in South Africa. *Accounting, Auditing & Accountability Journal, 30*(6), 1370-1398. https://doi.org/10.1108/AAAJ-08-2015-2192

Wentzel, L., & de Hart, K. (2020). The use of podcasts and videocasts by tertiary accounting students in distance education. *South African Journal of Higher Education, 34*(1), 267-287. http://dx.doi.org/10.20853/34-1-2827

Whitchurch, C. (2008). Shifting identities and blurring boundaries: The emergence of third space professionals in UK higher education. *Higher Education Quarterly, 62*(4), 377-396. https://doi.org/10.1111/j.1468-2273.2008.00387.x

Williamson, C., Dyason, K., & Jackson, J. (2020). Scaling up professionalization of research management in Southern Africa. *Journal of Research Administration, 51*(1), 46–72.

Wisker, G. (2012). *The good supervisor*. New York, Palgrave, Macmillan.

Young Foundation and Social Innovation eXchange [SIX]. (2010). *Study on social innovation*. A paper prepared by the Social Innovation eXchange (SIX) and the Young Foundation for the Bureau of European Policy Advisors. https://youngfoundation.org/wp-content/uploads/2012/10/Study-on-Social-Innovation-for-the-Bureau-of-European-Policy-Advisors-March-2010.pdf

Zhou, Y., & Wu, J. (2016). The game plan: Four contradictions in the development of world class universities from the global south. *Education and Science, 41*(184),75-89. https://doi.org/10.15390/EB.2016.6152

Overhead Rates: Impact on Research Applications Success

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Abstract: *The purpose of this study was to examine the relationship of overhead rates on research application award success. The pressure to maximize overheads to fund the indirect costs associated with operating a research-intensive university and the perception that higher overhead rates disadvantage research proposals create an unhealthy tension between research administrators and faculty. Statistical analyses of four years of banded overhead rates and publicly available funder award data across seven UK universities identified no significant relationship between overhead rates and success by number or value. The results provide objective evidence to inform discussions and decisions regarding adjusting or waiving overheads. The UK results may generalize to the US to the extent comparisons of overhead practices are similar, though further US-focused research is needed. While the study limitations are acknowledged, the empirical examination of overhead rates contribute to the scientific and applied understanding of the relationship with research grant awards.*

Keywords: *research funding, higher education overheads, indirect costs, grant success*

Introduction

University leaders are increasingly required to make difficult decisions to balance the financial requirements to operate a higher education institution and attract external research grant funding to enhance university reputation, support academic careers, and advance scientific knowledge. One factor, overhead rates, that is perceived to impact that balance has been acknowledged in both popular press and trade publications but primarily in opinion editorials (e.g., Aldhous, 1991; Anderson & Schaefer, 1991; Anonymous, 1991a, 1991b; Ledford, 2014; Pells, 2019). While such articles highlight the perception or concern that higher overhead rates may reduce the research grant awards, no empirical evidence was provided regarding the relationship between overhead and grant success rates. Two quantitative examinations of the relationship (Ehrenberg & Mykula, 1999; Sundberg, 1994), while dated, evidence the historical interest in the issue and reported mixed findings. Thus, the objective of this study was to examine the impact of overhead rates on research application success.

Research Overhead Rates

Research overheads are expenses necessary to support research, which may not be attributed to a specific research project. Overheads include costs to support the research environment, including administrative and facilities costs. The United Kingdom (UK) and the United States (US) approach to determining overhead rates, while different, are actually quite similar in effect.

UK Overhead Rates

Transparent Approach to Costing (TRAC)

TRAC is an activity-based costing methodology, introduced across the UK higher education sector to inform research funding in 2004 as a government accountability requirement and to support institutional management through better understanding of costs within individual institutions (Office for Students [OfS], 2020). TRAC is a process of taking institutional expenditure information from consolidated financial statements, adding a Margin for Sustainability and Investment (MSI) to represent the full 'sustainable' cost of delivery, and then adding cost drivers to allocate costs to specific activities and academic departments. The MSI is based on the average of actual financial performance over the previous three years and forecast performance over the next three years. The main activities to which TRAC allocates costs are: Teaching, Research, Other (such as commercial activities, residences, catering), and Support Activities (costed separately but are attributed to the three core activities).

Full Economic Costing (fEC)

Full Economic Costing (fEC), a development of TRAC, is a government-directed standard costing methodology used across the UK Higher Education sector for producing consistent and transparent research project costs. The underlying principle of fEC is to establish the true cost of a research proposal, and for this to inform the amount requested from funders (the price). The price may be below, equal or above the fEC.

There are three fEC Categories:

1. Directly Incurred Costs: project-specific, (i.e. they arise as a direct consequence of the project taking place), actual, and must be auditable at the project level (e.g. supported by supplier invoices).

2. Directly Allocated Costs: not project-specific (i.e. they are incurred whether or not the project takes place),and are estimated at project level (e.g. Investigator time, Technician time [where not directly incurred]), and Estates costs.

3. Indirect Costs: represent the costs of central and distributed services shared by other activities that are not project-specific.

Figure 1 shows Directly Allocated, Estates and Indirect Cost elements.

Directly Allocated	Estates	Indirect

• Technicians who are not working on specific projects but are providing general support services to laboratories	• Rates & Rent
	• Energy, Water & Sewerage
	• Repairs and Maintenance
	• Depreciation (excluding Residences & Catering)
	• Other Expenditures:
	  • Preventative maintenance
	  • Management team
	  • Customer/Business Services
	  • Projects team
	  • Minor works
	  • Contractors & Consultants
	  • Stock write-off
		• Academic Support (RS in TAS)
		• Other Staff
		• Non-Staff
		• Researchers & Associates
		• Estates Costs (PSG)
		• Library
		• IT
		• Business Development
		• DVC AA
		• DVC R&I
		• Business Support
		• Human Resources
		• Marketing
		• Recruitment and Admissions
		• Registrar
		• VC
		• Planning
		• Procurement
		• Finance
		• University Contingencies
		• FRS17 Pension (Staff Costs)
		• USS Pension Movement
		• Holiday Accrual
		• Restructuring
		• Interest Payable
		• Gain/(Loss) on Assets & Investments

Figure 1. Overhead Costs

Research Overheads

TRAC determines the rates UK Research and Innovation (UKRI) allows universities to charge in order to recover the overheads associated with research activity. UKRI, an umbrella organization that brought together seven research councils[1] in 2018, directs research and innovation funding and is funded through the science budget of the Department for Business, Energy and Industry Strategy. Each HEI's Finance is responsible for calculating and coordinating their TRAC approval.

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[1] UK Research Councils include Arts and Humanities Research Council (AHRC), Biotechnology and Biological Sciences Research Council (BBSRC), Economic and Social Research Council (ESRC), Engineering and Physical Sciences Research Council (EPSRC), Innovate UK, Medical Research Council (MRC), and Natural Environment Research Council (NERC). UKRI also monitors National Centre for the Replacement Refinement & Reduction of Animals in Research (NC3Rs) funding activity

Universities applying for research grants from public funders are required to determine the fEC of carrying out the project, regardless if the external funder pays fEC. The aim is to ensure Universities are aware of the true cost of the research and price the work accordingly. Typically, over 80% fEC is expected for competitive commercial projects with industry and 100% fEC for non-competitive research funded by government departments. Research Councils fund at 80% fEC and other funders, such as charities, are often below 80% fEC.

US Overhead Rates

US universities similarly consider infrastructure and operations costs, referred to as facilities and administrative (F&A) costs. F&A costs are calculated based on indirect costs associated with nine facility and administrative cost pools to include buildings, equipment depreciation, utilities, maintenance and library expense, human resources and other central services, as well as research support offices (Office of Management and Budget [OMB], 2014). However, because of the administrative burden associated with costing each research proposal, US universities average the costs by major function, do not adjust for investigator directly allocated costs, and charge a single rate. Large institutions may also employ several rates to reflect the cost at different campuses or without special programs.

While the US Federal Government guidelines drives the F&A calculations and caps administrative costs at the rate of 26%, each university negotiates the facilities portion of their rate with the Division of Financial Advisory Services (DFAS) according to their Cost Accounting Standards (OMB, 2014). As a result, institutional rates vary between institutions, depending on real estate location, construction, and laboratory infrastructure (Cave, 2014). The rate is expressed as a percentage of the direct costs and is negotiated every five years. Policy statements reinforce the rate as appropriate and real for government grants, although agencies can set their own rates for particular programs. In addition, institutions accept a lower indirect cost policy dictated by private and philanthropic funders (National Institutes of Health [NIH], 2019).

A comparison of UK and US overhead procedures and practices highlights differences and similarities between key issues. Examining the governance, calculation methodology and applied rates underscores the procedural differences with establishing and publicizing rates while acknowledging the similarities in practices to include university driven costs and standardized pricing principles. Table 1 summarizes these comparisons of key issues associated with UK and US overheads.

Table 1. Comparison of UK and US Overheads

Key Issues	UK	US
Governance		
• Effective	2004	1966
• Responsible	Office for Students	Dept Health & Human Services
	UK Research & Innovation	Office of Naval Research
• Methodology	TRAC	Nine "Cost Pools"
• Review	Annually	Negotiate 4-5 years
• Visibility	Confidential	Publicly Available
Calculations		
• Terminology	Full Economic Costing (fEC)	Facilities & Administrative (F&A)
• Direct	Cost for conducting Research	Cost for conducting Research
• Overheads	Estates & Indirect Costs	Indirect Costs
	Directly Allocated	
• Limits	None	26% for Administration
• Percentage	% of Project Costs	% of Direct Costs
• Variation	Within HEI Clusters	Across Universities
Rates		
• Government	80% fEC	100% Rate
• Private	> 80% fEC	< 100% Rate
• Philanthropic	< 80% fEC	< 100% Rate

Waiving or Reducing Overheads

In the UK, the methodology for determining the TRAC rates supporting full economic costing is consistent and effectively applies a flat overhead rate to be applied relative to academic time on a project. However, as the factors influencing each university's overhead rates differ, so does this flat rate. As a result, some universities have higher rates than others.

Despite the existence of overhead differences, there is little incentive for a university to waive or reduce the project price by reducing the percent of fEC, as broadly speaking the rates are comparable. Further, grant submission decisions consider the financial contribution required to ensure sufficient funding is available. Universities and Faculties also need to ensure that across their research portfolio of activities, in aggregate, financial recovery targets are achievable and contributions to overheads acceptable.

Moreover, researcher funders are aware of and expect overhead costs and instruct reviewers to focus on the research proposal itself as well as the justification of the resources. When asked to

comment, funders indicated that the project scope or scale is typically the reason a proposal is deemed too expensive. Falk-Krzesinski and Tobin's (2015) comparison of research grant proposal review criteria across US federal agencies substantiated the focus on the research versus the proposal cost. While funders were aware of variation of overheads between universities, reducing prices beyond the percent fEC requirement was acknowledged as not a sustainable practice.

However, principal investigators and senior leaders across the UK protest their institution's overhead rates and request overheads be waived or reduced as the perception that doing so will make research applications more competitive and therefore more likely to be awarded. In universities with relatively higher rates compared to their peer institutions, research offices have reported pressure to coordinate policy to adjust rates to match the TRAC averages, particularly for applications applying to certain funding agencies. Other offices experience requests to waive or reduce overheads, when a project is considered of sufficient strategic interest to 'subsidize' the research. Whether these tactics in massaging the overheads impact application success, though, is not clear.

Impact on Research Grant Awards

Senior HEI leaders, researchers and professional services at United Kingdom Higher Education Institutions (UK HEIs) are interested in the effects of institutional overheads on their grant applications success rates. Preliminary research investigated the relationship of overhead and grant award rates by examining banded overhead rates across multiple UK HEIs and fiscal years with publicly available research funder award data to inform both academic and professional leaders' decisions.

Underlying the request for TRAC, fEC and benchmarking information is the desire to understand the impact of relatively higher overhead rates, if any, on award of research grants. Is there a relationship between overheads and grant award outcomes?

Methods

Participants

A coalition of ten second-tier research-intensive universities representing the 23 TRAC Peer Group B Higher Education Institutions (HEIs) were approached initially by listserv and then follow-up email to participate in the study by providing access to sensitive overhead rates with assurance of confidentiality. Seven of the ten universities provided banded overhead rates from 2013-2018, representing a 70% response rate. The sample of institutions averaged 885 researchers, with 25.6% grant award success rate. The overhead represented the full bands range with average 3.17 with multiple universities reporting different bands across different academic years. Key variable data including the range are shown in Table 2.

Table 2. 2013-2018 HEI Key Variables

Participating HEIs	Min	Max	Average
Universities			
No of Researchers	495	1,150	885
No of Academic Staff	1,115	1,990	1,487
Overhead Bands	1	6	3.7
UKRI Grants[1]			
No Awarded	8	48	29
Value of Awarded	£3.7m	£35.0m	£13.4m
% Success Rate	6%	34%	25.6%
NIHR Grants[2]			
No Awarded[3]	0	3	0.5
£ Awarded	£0	£4m	£477k

Notes.
[1] UK Research Council award per year to include only "Research Grants"
[2] NIHR does not provide the number of applications submitted to calculate % Success Rate
[3] Only 5 of 7 HEIS awarded NIHR Grants between 2014-2018

Measures

Overhead data was collected directly from HEIs and grant award data retrieved from publicly available websites.

Overheads. The annual TRAC Benchmarking analyses reports between 2013-2018 were reviewed with banding data determined by centering the yearly average of awarded projects. The banding then was based on adding or subtracting half the difference between the average and the 1st or 3rd quartile values resulting in six distribution bands, per Table 3. Requesting only banded information provided a means of comparing relative overheads to funder award rates while avoiding confidentiality issues. Each participant shared overhead bands for each of four academic years (AY), as shown in Table 3.

Table 3. Overhead Banding by Academic Year

I +E(Lab)1	2013-2014	2014-2015	2015-2016	2016-2017
Band 1	£48,232	<£50,038	< £52,074	< £55,980
Band 2	£48,233 -£50,798	£50,039 – £53,113	£52,075 - £56.078	£55,981 - £60,499
Band 3	£50,799 -£53,364	£53,114 - £56,189	£56,079 - £60,082	£60,500 - £65,018
Band 4	£53,365 - £54,582	£56,190 - £57,036	£60,083 - £60,628	£65,019 - £68,636
Band 5	£54,583 -£55,799	£57,037 - £57,882	£60,629 - £61,173	£68,637 - £72,254
Band 6	>£55,800	>£57,883	> £61,174	> £72,255

Note.

[1] Indexed rate (£): Indirect + Estates Laboratory TRAC Section D: Research estates charge-out rates per research academic FTE Indirect and Estates: Laboratory ONLY e.g., TRACBenchmarking1617 Group B Average: £65,018 (£52,758 + £12,260)

UKRI Grant Data. UK Research and Innovation (UKRI, 2019) maintains the Gateway to Research (GtR) portal, which the public may access, search and download publicly funded research data. The number of research grant applications submitted and awarded as well as the award value for each responding university was compiled for each research council for five academic years from 2013-2019. The inclusion of AY 2018-2019 accommodates the delay from grant submission to grant award notification. The percent success rate was calculated using the application submission and award data. The number of researchers and academic staff was also collected to examine potential effects of university size.

NIHR Grant Data. The National Institute for Health Research (NIHR, 2019) also hosts a publicly accessible database. The number of research grant applications submitted and awarded as well as the award value for five academic years from 2013-2019 was collected for the seven responding universities.

Analyses

A two-step approach to data analyses included first examining the correlation between overhead bands and number of total research grants awarded, the total value of research grants awarded and the percent success rate for UKRI-only grants to identify the relationship between overhead rates and grant success. NIHR data was not included in the correlation analyses due to the limited and skewed data distribution.

Two tailed T-Tests were employed to identify any significant differences between the lowest and highest overhead rates and award success for UKRI and NIRH grants separately.

In addition, correlation and t-tests were performed to identify potential relationships by UKRI award value and differences accounting for university size.

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[2] Research Grants is one of 30 Project Categories and therefore does not include grants such as Centres, Feasibility Studies, Fellowships, Knowledge Transfer, Studentship, or Training Grants among others,

Results

The correlation analyses indicated no significant relationship between overhead rates and the three measures of award success for UKRI grants: number awarded ($r(26) = 0.21$; n.s.), value awarded ($r(26) = 0.05$, n.s), and percent awarded ($r(26) = 0.22$; n.s.). Further, no significant relationship was identified between overheads and within award values (>£100k ($r(26) = 0.18$; n.s); £100k - £500k ($r(26) = 0.20$; n.s.); £500k - £1m ($r(26) = -0.25$; n.s.); £1m - £10m ($r(26) = 0.38$; $\rho = .05$) and <£10m ($r(26) = -0.25$; n.s)).

No differences were found between overhead bands 1-2 and overhead bands 5-6 by the measures of award success for UKRI (number awarded ($t(19) = 0.50$; n.s.); value awarded ($t(19) = 0.06$; n.s.); percent awarded ($t(19) = 0.85$; n.s.) or NIHR grants (number awarded ($t(11) = -0.53$; n.s.) valued awarded ($t(19) = -0.61$; n.s.). Further, no significant differences were founded adjusting for university size (number awarded ($t(19) = -1.67$; n.s.); value awarded ($t(19) = 0.29$; n.s.); percent awarded ($t(19) = -1.67$; n.s.).

Discussion

The impact of overhead rates on grant awards appears to resonate across the research administrator profession. The systematic investigation provides empirical evidence to help inform university senior leaders with their decisions to waive or reduce overhead rates systematically or in response to ad hoc research grant submissions.

While the difference in UK overheads between similarly research-intensive universities is over £240,000 per full time equivalent academic, the range in rates from less than £48,000 to over £72,000 did not correlate with grant success, which ranged between 8 and 48 grants with values between £3.7 and £35 million. Universities with lower overheads did not experience greater number or value of awarded grants or higher percent success rate. Nor did universities with higher overhead rates experience lower grant award success by number, value or percent submitted.

The lack of a significant relationship between overhead rates and grant success was further confirmed when controlling for university size and within funding values. The latter issue was investigated to avoid speculation that the impact of overheads on grant awards may be less (or stronger) at lower, moderate, or higher award values.

To the extent that UK and US share overhead practices and perceptions, the study results inform understanding of both research offices that overhead rates appear to have no significant relationship to the failure or success of grants being awarded. As funders advise, the merit of research proposal may include consideration of the justification of expenses but are not penalized or rewarded for the university's set indirect costs.

Limitations

Several limitations with this study are acknowledge and should be considered when interpreting the findings. First, the results were based on a limited number of collegial universities with similar characteristics in terms of research focus and do not represent the full complement of UK

universities. While an advantage of such a cohort is the reduced influence of extraneous variables, further research is needed across and between the five TRAC Benchmarking Peer Groups and universities with varying degrees of research ambition.

Second, the measures of research grant awards focused on UK research councils and NIHR public funders. Although UKRI is the single largest university funder by both volume and value, these results may not necessarily translate to other funder types, such as industry or charity. Further, the focus on research specific grants excluded many other types of grants which attract overheads. Future research will need to examine a greater range of funders and grant types to ensure generalizability of these findings.

Third, while the data set was sufficient to meet the assumptions of the analyses required of correlations and t-tests, the relatively small sample size combined with the non-normal distribution must be acknowledged. However, the robustness of the statistical techniques provides confidence that there were no significant differences between low and high overhead success rates and that there was no evidence to indicate overheads affected grant awards.

Finally, further research examining factors that influence grant award success may be useful in not only identifying possible covariates but may inform HEIs on how best to focus their limited resources. Possible factors to consider might include time spent developing applications, quantity and quality of internal peer review, access to successful proposals, size of research support office, and cash and in-kind contributions to applications.

Conclusion

Despite these limitations there are several contributions this article may make to research administrators and researchers. To our knowledge, this is the first publication examining overheads relevant to both UK and US audiences. The overhead comparison sheds light on the similarities and differences between nations. Further, the study provides evidence for research offices to guide internal overhead adjustment decisions, including the need for researchers to provide greater justification for waiving or reducing overheads in publicly funding grant applications. The research also highlights the need to further investigate the issue of overheads across HEIs, funders and grant types as well as to examine empirically other factors that may significantly impact grant award.

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References

Aldhous, P. (1991). Spend more to compete. *Nature, 349*(6306), 183–183. https://doi.org/10.1038/349183a0

Anderson, C., & Schaefer, E. (1991). Showdown over overheads? *Nature, 349*(6308), 361–361. https://doi.org/10.1038/349361a0

Anonymous. (1991a). Overheads cost research dear. *Nature, 351*(6324), 255–255. https://doi.org/10.1038/351255a0

Anonymous. (1991b). Overheads overblown. *Nature, 349*(6308), 355–356. https://doi.org/10.1038/349355b0

Cave, A. (2014, October 20). Taking a hard look at university research. *Stanford Social Innovation Review*. https://ssir.org/articles/entry/taking_a_hard_look_at_university_research

Ehrenberg, R. G., & Mykula, J. K. (1999, February 1). *Do indirect costs rates matter?* National Bureau of Economic Research Working Paper no. 6976. https://doi.org/10.3386/w6976

Falk-Krzesinski, H. J., & Tobin, S. C. (2015). How do I review thee? Let me count the ways: A comparison of research grant proposal review criteria across US federal funding agencies. *The Journal of Research Administration, 46*(2), 79–94

Ledford, H. (2014). Indirect costs: Keeping the lights on. *Nature News, 515*(7527), 326. https://doi.org/10.1038/515326a

National Institute of Health. (2019, December). *NIH grants policy statement: 7.4 Reimbursement of facilities and administrative costs*. https://grants.nih.gov/grants/policy/nihgps/html5/ section_7/7.4_reimbursement_of_facilities_and_administrative_costs.htm

National Institute for Health Research. (2019, October 1). *Funding and awards* [NIHR funding and awards search website]. Retrieved October 30, 2019, from https:// fundingawards. nihr.ac.uk/search

Office of Management and Budget. (2014, April 1). *Indirect (F&A) costs identification and assignment, and rate determination for institutions of higher education (IHEs)*. Code of Federal Regulations, 2 CFR Appendix III to Part 200. https://www.govinfo.gov/app/ details/CFR-2014-title2-vol1/CFR-2014-title2-vol1-part200-appIII/context

Office for Students. (2020). *The Transparent Approach to Costing (TRAC)*. https://www.trac. ac.uk/

Pells, R. (2019, June 18). UK universities 'block funding bids' because of overhead costs. *Times Higher Education*. https://www.timeshighereducation.com/news/uk-universities-block-funding-bids-because-overhead-costs

Sundberg, J. O. (1994). Research grants: Who pays the overhead? *Education Economics, 2*(1), 45–64. https://doi.org/10.1080/09645299400000004

UK Research and Innovation, Gateway to Research. (2019). UKRI gateway to publicly funded research and innovation. Retrieved October 30, 2019, from https://gtr.ukri.org/

Development and Implementation of Work Engagement Strategies in a Clinical Research Consortium During the Coronavirus Disease 2019 (COVID-19) Pandemic: A Reflective Inquiry

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Abbreviations

VA	*Department of Veterans Affairs*
VAMC	*VA Medical Center*
CSP	*Cooperative Studies Program*
ORD	*Office of Research and Development*
NODES	*Network of Dedicated Enrollment Sites*
COVID-19	*Coronavirus Disease 2019*
IT	*Information Technology*

Abstract: *Work engagement is defined as a positive work-related state of mind that is characterized by vigor, dedication, and absorption. The engagement of staff has been associated with their performance and efficiency, productivity, safety, attendance and retention, customer service and satisfaction, and several other organizational success factors. The Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by the most*

recently discovered coronavirus and is now a pandemic that is affecting many countries globally. The literature surrounding the employment of measures and strategies to increase work engagement amongst clinical research staff during pandemics is scarce, and to date, focuses primarily on health care and community health workers.

The Cooperative Studies Program (CSP) Network of Dedicated Enrollment Sites (NODES) is a clinical research consortium of ten medical centers that are embedded within the Department of Veterans Affairs (VA) Health Care System. The consortium developed and implemented strategies during the pandemic that were intended to maintain work engagement amongst clinical research staff at each of the sites within the consortium.

In this manuscript, we describe the development and deployment of these strategies to clinical research study teams in our clinical research consortium. It is our hope that the opportunities, successes, and challenges described here will serve as a useful resource for other clinical research consortia that are working to identify approaches to keep their staff members engaged during the current pandemic, as well as in other potential future situations in which their primary operations may be altered during other times of crises.

Keywords: *Department of Veterans Affairs, CSP, NODES, COVID-19, Work Engagement*

Background

Work engagement is defined as a positive work-related state of mind that is characterized by vigor, dedication, and absorption, and the engagement of staff has been associated with their performance, safety, attendance and retention, customer service and satisfaction, and several other organizational success factors (Schaufeli et al., 2009; Jeve et al., 2015; Johnson & Bullard, 2020; Knight et al., 2017). The Coronavirus Disease 2019 (COVID-19) is an infectious disease caused by the most recently discovered coronavirus and is now a pandemic that is affecting many countries globally (World Health Organization, 2020a, 2020b; Holshue et al., 2020; Centers for Disease Control and Prevention, 2020). People all around the nation have been practicing self-isolation and social distancing to protect the health and well-being of their own and others. The viral outbreak created disruptions in people's routine lives causing increased stress, anxiety, and fear (Lu et al., 2020; Huang & Zhao, 2020; Khan et al., 2020). The literature surrounding the employment of strategies to increase work engagement amongst clinical research staff during pandemics is scarce. To date, the literature in this area focuses primarily on health care and community health workers (Ives et al., 2009; Weber et al., 2020; Boyce et al., 2019).

In this manuscript, we describe the development and deployment of strategies for the work engagement of clinical research study teams in our consortium during the COVID-19 pandemic. It is our hope that the opportunities, successes, and challenges described here will serve as a useful resource for other clinical research consortiums that are working to identify approaches to keep their staff members engaged during the current pandemic and in situations in which their primary operations may be altered during other times of crises.

During the COVID-19 pandemic, there was a growing sentiment of fear, anxiety, and stress across staff in our consortium. This was not surprising as the entire nation and world were grappling with the same feelings of uncertainty. During the spring of 2020, myself and several colleagues from the VA CSP NODES program started developing strategies to keep our staff engaged during the pandemic. Given our role as clinical research administrators, we felt that determining how to both establish and maintain staff engagement across our consortium would be paramount to ensuring the continued success of our program. Establishing a safe and productive way of keeping our staff engaged would also help us fulfil our commitment of providing exceptional health care to our nation's Veterans through research.

Before moving forward it is important that we describe the structure of our program. Having this foundational information will provide you with a better sense of the opportunities and challenges associated with the deployment of these strategies across our consortium. The Cooperative Studies Program (CSP), a division of the Department of Veterans Affairs (VA) Office of Research and Development (ORD), was established as a clinical research infrastructure to provide coordination and enable cooperation on multi-site clinical trials and epidemiological studies that fall within the purview of VA (Huang et al., 2010). Currently the program maintains expertise in multi-site studies through central coordination of activities within VA Central Office, a network of 5 data coordinating centers (CSPCCs) that support clinical trial planning, execution, and analysis; 5 epidemiological research centers that conduct large cohort studies and maintain registries (CSPECs); and a clinical research pharmacy coordinating center (CRPCC) that supports the manufacture (when necessary) and distribution of drugs (including placebos), management of medical devices, and trial monitoring, auditing, and regulatory compliance activities (Huang et al., 2010).

In 2012, CSP also established a consortium of ten VA medical centers (VAMCs) called the Network of Dedicated Enrollment Sites (NODES) that offers innovative approaches in addressing challenges to clinical trial execution (Condon et al., 2017; Johnson et al., 2018; Velarde et al., 2018; Bakaeen et al., 2014). Each Node site is led by a Clinical Director (or team of Clinical Co-/Associate Directors), an Associate Director-Operations (ADO), and other clinical research support staff, e.g. Managers, Clinical Research Nurses, and Clinical Research Assistants (Figure 1). Brief descriptions of these roles can be found in Appendix A. The CSP infrastructure offers support to VAMCs that participate in its clinical trials and studies in the form of the aforementioned support provided by the CSP Centers. NODES also provides an invaluable benefit to both the CSP Centers and the study sites by providing feedback and support as it relates to the numerous "site-level" operational challenges encountered during various phases of a clinical research study (Kutner et al., 2010; Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation, 2010; Fogel, 2018).
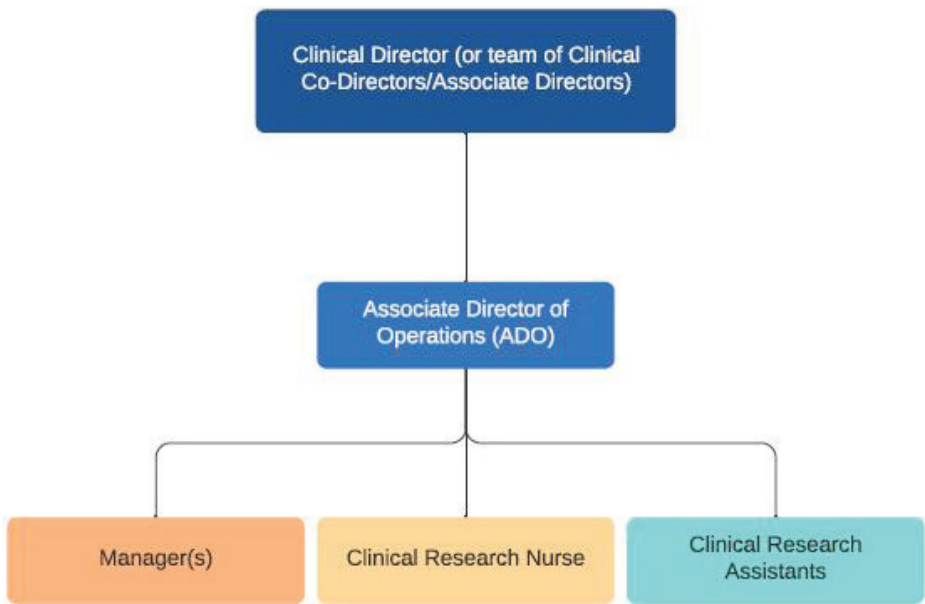
Figure 1. NODES Organizational Structure (Site Level)

Given NODE's role in CSP, we believe that we are well poised to drive innovation and the dissemination of clinical research best practices both within and external to CSP and/or VA. The development and deployment of strategies for the work engagement of clinical research study teams that other groups can use, particularly during times of crises, is also consistent with our program's mission.

Approach

Now that we have established our group's role in CSP and VA, we can further reflect on our experiences during the onset of the COVID-19 outbreak (Spring 2020), and our subsequent actions around staff engagement during that pivotal time. During this period, we observed that in the onset of the COVID-19 outbreak, many state and local government authorities had issued "shelter-in-place" or "stay-at-home" orders to businesses not considered "essential" in order to limit the spread of the infection (Courtemanche et al., 2020; Santoli et al., 2020). Concurrently, on March 17th, 2020, the VA Office of Research & Development (ORD) put an administrative hold on all non-critical, in-person interactions with human research subjects for ORD funded studies. Given these circumstances, the leadership teams at each of the Node sites needed to execute rapid, pragmatic, and strategic steps to ensure the safety of the CSP research personnel at their sites.

The NODES ADOs worked with their local Research and Development (R&D) offices to obtain ad hoc approvals for their CSP research team members to work remotely (off-site). Some R&D leadership teams approved full-time remote work requests while others approved part-time remote work requests for these personnel. A REDCap™ survey (Appendix B) was administered to the ADOs from each of the ten Node sites to glean data on the remote working options that were offered to the personnel, as well as to inquire about the various strategies that were employed at each site to maintain work engagement among their respective workforces during the pandemic (Harris et al., 2019).

Like the rest of the nation and the world, CSP site clinical research personnel had to navigate uncertainties in both their professional and personal lives during the COVID-19 pandemic. The NODES ADOs at each Node site offered opportunities and extended resources to their respective study personnel to keep them engaged in work-related activities, as well as to provide information on coping, wellness, and daily living resources during the current outbreak. It was expected that such work engagement would have a positive psychological impact amongst the workforce, and would also enhance staff knowledge and the skills that are required for their jobs, e.g., good clinical practice (GCP), risk-based monitoring, ethics and human subject protection, patient-centered informed consent, etc. (Vijayananthan & Nawawi, 2008; Agrafiotis et al., 2018; Jaguste, 2019; Department of Health, Education, and Welfare, & National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 2014; Moreno et al., 1998; Krishnamurti & Argo, 2016; Abujarad et al., 2018). These work engagement strategies are highlighted below for your review.

Regular Check-Ins

Each Node established regularly scheduled, open virtual communication channels with their personnel to discuss work-related updates. Conference calls were scheduled on a consistent basis via Microsoft Skype for Business®, Microsoft Teams® and/or Zoom®, and emails between the NODES teams and CSP site study team members were also exchanged on a regular basis. NODES ADOs disseminated general and facility-level updates related to the COVID-19 pandemic and VA ORD guidelines and recommendations to site personnel to keep them abreast of rapidly evolving research policy and operational changes. This approach was implemented as a tool to keep CSP research personnel unified and to create a strong sense of community at each site.

Newsletters

Some VA CSP Node sites have produced and distributed newsletters with information on site- and program-level CSP-related activities to their CSP study team personnel on a quarterly basis since 2014. Two Node sites maintained their ongoing efforts and generated new issues of these newsletters amidst the outbreak to keep their study personnel engaged. These newsletters not only contained updated information about CSP but also incorporated general information related to the COVID-19 outbreak along with self-care tips. The newsletters also included details on accessible research-related training opportunities, COVID-19 related webinars that study personnel could avail and included photos of research staff obtaining their COVID-19 vaccinations to encourage vaccine adoption (Appendices C & D).

Training Opportunities

To make the work experience interesting and productive during the pandemic, VA CSP NODES ADOs advised their CSP site personnel to explore clinical research training opportunities that were available to them. Examples of these training opportunities are noted below:

i.   VA Talent Management System (TMS) Trainings

VA provides virtual training opportunities through its Talent Management System (TMS) in an effort to keep its workforce up to date on their skills and competencies, as well as to make them aware of VA policy and operational changes (Schaa et al., 2014). Most trainings are classified around topic areas that are aimed to enhance the expertise of VA professionals e.g., workplace harassment, contracting, clinical research operations, business compliance, etc. Similarly, mandatory annual trainings are provided to research personnel to refresh their knowledge and skillsets, and to ensure their compliance with Good Clinical Practice (GCP). Recommendations were made that CSP personnel complete their annual mandatory trainings during the time of the pandemic while some research activities were on administrative hold. NODES ADOs also encouraged their site study personnel to explore the TMS online learning catalog for non-mandatory trainings, and to self-assign courses that they found interesting and helpful.

ii.   VA Health Services Research & Development Cyber-seminars

VA Health Services Research & Development (HSR&D) offers state-of-the-art training sessions on various research-related topics via live web conferences (U.S. Department of Veterans Affairs Health Services Research and Development, 2020a). These presentations are then archived and made accessible to VA personnel and the general public. These cyber-seminars select research topics that are current and applicable to the studies conducted within the VA health care system. The CSP team members at each Node site were encouraged to access these valued resources and to think through how they might apply the content in their respective work environments.

iii.   The Association of Clinical Research Professionals eLearning Catalog

CSP has an existing contract with the Association of Clinical Research Professionals (ACRP)™ that secures 200 user accounts to provide free learning and training opportunities for its staff (CSPCCs, CSPECs, NODES) and its clinical research site study teams (Hastings et al., 2012). The ACRP™ offers numerous virtual research-related learning sessions to CSP. Personnel can also use credits from the completed coursework towards a number of Clinical Research Professional certifications, e.g., Clinical Research Associate (CCRA)®, Clinical Research Coordinator (CCRC)®, etc. The NODES ADOs recommended that personnel who were able to access these learning resources utilize them to enhance their knowledge and competencies.

NODES Webinars

At the peak of the current pandemic, many research-related activities (such as study recruitment and enrollment, in-person follow-up visits with study participants, etc.) were on administrative hold to ensure the safety of study participants, providers, and clinical and research personnel. Therefore, it seemed essential to organize events to keep study team members inspired and

motivated through positive work experiences. With that understanding, the NODES ADOs arranged for a series of webinars through Microsoft Skype for Business® and/or Microsoft Teams® for CSP study team personnel at each of the Node sites. Some of the topics that were selected for presentation for these webinars were as follows: 1) General Updates on the COVID-19 Pandemic, 2) Coping Strategies for Stress and Fear During the COVID-19 Pandemic, and 3) An Overview of the CSP Quality Assurance Program.

NODES Virtual Poster Contest

VA celebrates "National VA Research Week (Research Week)" on an annual basis each May. (U.S. Department of Veterans Affairs Office of Research and Development, 2020b). During this month, each VA Medical Center (VAMC) dedicates a week to acknowledge the importance of VA research and its contributions to the VA health care system and the general medical community. The various events that are held during this week are intended to inform Veterans and VA providers/staff about past, current, and upcoming VA research activities. Over recent years, NODES and VA CSP site study teams have organized local/site events during Research Week that showcased and promoted their research work. Because of the COVID-19 pandemic, VA facilities were unable to organize such celebratory research events in 2020. However, to maintain the tradition of Research Week, the VA CSP NODES organized a virtual poster contest amongst their ten sites. The theme of the poster contest was "CSP Culture" and each NODES ADO was asked to organize a poster team comprised of NODES and CSP study team members. These poster teams worked collaboratively to design a poster that demonstrated how NODES and the CSP study site teams defined "CSP Culture" at their site, as well as how they had implemented that culture amongst the CSP study teams at their sites. This activity stimulated excitement amongst the study personnel at each site for a number of reasons including, likely in large part, the fact that the winning site, i.e., the site that had the highest score (as determined by a pre-selected panel of judges), would receive travel funding for all team members to attend a clinical research professional development event (e.g., conference, training, etc.). This effort also provided a sense of community during this time of crisis.

NODES Cookbook

Forming and maintaining social relationships is fundamental to human motivation and well-being (Michalski et al., 2020). The NODES Program took a "community approach" to support and strengthen social relationships across our consortium by developing a cookbook that included selected recipes from NODES and CSP study staff . This effort was an attempt to keep team members energized, engaged, and active through their participation in this extracurricular activity. The cookbook was released in October 2020 and titled, "VA CSP NODES Presents Shelter in Place Recipes." We believe that working on this project provided a strong sense of community to staff members who were working remotely and were not able to have in-person contact with their teammates. This literary product featured more than 100 recipes that included appetizers, entrees, desserts, and beverages, along with pictures of each dish.

Employee work engagement during times of crisis is critical to an organization's productivity and to the well-being of its employees. The creative strategies and required resources extended to the

CSP site personnel at Node sites were intended to keep their workforce engaged in work-related activities. These approaches were executed with the intention of transforming the feelings of stress and anxiety amongst site study personnel into productiveness and constructive vigor.

Lessons Learned

Lessons learned from our collective experiences with deploying these resources are further described in this paper. An increased demand from employees to work from home is among several societal changes the COVID-19 outbreak has become an impetus for. According to the U.S. Bureau of Labor Statistics, only 29% of Americans could work from home in their primary job and 25% did work at home at least occasionally (U.S. Bureau of Labor Statistics, 2020). A recent Gallup poll reported the percentage of workers who say their employer is offering flextime or remote work options has grown from 39% to 57% between March 30 and April 2, 2020 (Gallup, 2020). Many organizations including the VA have undergone creative transitions to allow staff to complete tasks from home that typically would not have been approved for them to do so. Our Node sites have developed remote work contingency plans for staff that take several factors into consideration including VA, ORD, and statewide orders, as well as study-specific contingency plans, and information technology (IT) remote capabilities.

Node sites have an average of 13.2 CSP clinical research study team members at their respective sites. Each of our sites also have CSP study team members that have been offered the flexibility to work remotely for at least some duration of their work schedule. Half of them (Hines, Houston, Minneapolis, Palo Alto, and Portland) have offered their study team members the option to work from home entirely, though only two of these sites reported that 100% of their study team staff members chose to do so. Most Node sites have varied remote work schedules among the CSP personnel at their sites and have transitioned all CSP site personnel at their respective locations to work remotely on a periodic basis. One site (San Diego) offered only a select number of staff members any option to work remotely.

The transition to working from home has caused a shift in daily tasks for CSP site personnel at our sites. Opportunities for participating in TMS trainings, VA cyber-seminars, ACRP™ learning sessions, NODES webinars, the creation of a group cookbook, and a virtual research poster contest have encouraged staff to stay engaged with our organization during a time of uncertainty. Professional development has always been a primary focus of NODES, including during the ORD administrative hold. The NODES webinars have had regular attendance of approximately 75–100 attendees. Among CSP Node site personnel (9/10 Node sites), 44 individuals have obtained ACRP™ accounts through CSP's existing contract. Due to a limited number of available accounts at the program-level (CSP), and subsequently at the NODES consortium level, there are plans to determine the feasibility of increasing the number of ACRP™ accounts available to CSP staff in future revisions to the existing contract.

In addition to the trainings and webinars staff are actively involved with taking, most of the Node sites (80%) reported that they had staff members that were reassigned by their respective VAMCs and/or facility research leadership to work on COVID-19 study-related activities.

These tasks included coordination and management of new COVID-19 clinical trials and studies, research programs, and study planning activities (study feasibility surveys, preparation for new study proposal submissions, protocol feasibility reviews, etc.). Moreover, the VA has implemented resource labor pools in which staff at a given facility may be mandatorily reassigned for a designated period to new positions that the facility determines as high priority. Depending on the staff position held (clinical versus non-clinical), labor pool duties may include new unit/floor assignments, facility entrance screening, and scrubs/personal protective equipment (PPE) collection and distribution.

Discussion

Work engagement has been demonstrated as being positively associated with several organizational and staff characteristics such as productivity, human error in the workplace, low sickness absence frequency, good service quality, and innovativeness (Okazaki et al., 2019; Shimazu et al., 2018). While the concept of work engagement is not unique, our creation and implementation of strategies to keep staff engaged across a clinical research consortium during a time of crises was novel. We hope that our work will serve as a useful resource for other clinical research consortia, and other groups, as those entities work to identify approaches for staff work engagement during the current pandemic and in other situations where disruptions in the general public's routine lives might cause increased stress, anxiety, and fear. The NODES consortium was successful in developing and deploying these strategies with our staff.

The VA health care system is somewhat nuanced in that different VAMCs within the health system often have variability in their general healthcare operations, which subsequently leads to inconsistency in how clinical research operations are conducted at any given site. For example, over the course of the current pandemic, some VAMCs have established policies that allow a significant number of personnel to work remotely due to considerations such as patient and employee safety, and "shelter in place orders" that were implemented within the various states in which these facilities are located. Other VAMCs have maintained the "status quo" in terms of their day-to-day operations, with staff continuing to come into work at their respective facilities. Therefore, the sites in our consortium vary with regards to whether the clinical research teams at those locations are working at their VAMCs as they would during normal day-to-day operations or are working from home due to the guidance provided by leadership at their respective medical center. NODES' "boots-on-the-ground" approach to solving operational issues and challenges at the clinical research site-level (VAMC) puts the program in an ideal position to develop strategies aimed at maintaining work engagement amongst clinical research staff during the COVID-19 pandemic at each of the Node sites within the consortium. Although the impact of the pandemic on day-to-day operations varied across the NODES consortium, the work engagement strategies that were employed across its sites demonstrates a convincing connection between employee engagement and the cultural characteristics of well-being, communication practices, professional development, and organizational resilience.

Working remotely can induce feelings of professional isolation, but using the strategy of regular

check-ins (phone, email, video chats, texts, Skype, etc.) enforces connections with teammates whereby staff are able to participate in brainstorming activities, assign and breakdown project tasks, and share quick tips for completing work remotely (Golden et al., 2008; Martin et al., 2019; Wakerman et al., 2019). In the absence of staff gatherings, e.g., in-person meetings, social outings, etc., staff were able to share family news related to celebrations and announcements, and/or exchange shared and personal feelings around the pandemic to reduce anxiety. Sites that produced newsletters communicated their organizational or team culture, as well as their sense of empathy and community at their respective locations. These newsletters were also used to honor fellow colleagues' contributions to their facility labor pools (or in healthcare roles) and participation in the treatment of COVID-19 patients. Implementing work engagement strategies that promote sharing and participating in group dynamics, the opportunity to talk with colleagues, the continuation of personal relationships, and opportunities to address difficulties or successes enables individuals to increase job resources, such as social support and influence in decision-making, leading to positive outcomes (Knight et al., 2017).

The creative strategy to engage staff in designing and presenting a virtual poster for Research Week created synergy, enthusiasm, a sense of healthy competitiveness, and feelings of significance amongst teammates who previously may not have had opportunities to work together on a shared project. Competitive behavior has been defined as the actual actions people take, or are inclined to take, in a specific job or life environment to compete for resources or succeed over others (Wang et al., 2018). Literature suggests that it is closely related to job behavior and performance, i.e., people showing more competitive behavior tend to outperform others and are more likely to do their best at work, thereby potentially resulting in better job performance (Wang et al., 2018). The poster contest and the prize for the first-place winner generated a competitive climate that allowed participants to demonstrate competitive behavior, which potentially resulted in better job performance in this instance.

Previous work has demonstrated a positive relationship between the job resources that are offered by an organization (for example, support from supervisors, learning opportunities, etc.) and employees' work engagement levels (Van den Broeck et al., 2017). By providing staff with study-specific contingency plans, direct communication and guidance from ORD, and the option to transition to remote work, staff were able to remain engaged and productive in study-related activities. Training opportunities from the VA Talent Management System (TMS) kept staff involved in learning opportunities, while NODES educational webinars and VA Health Services Research and Development (HSR&D) cyber-seminars provided avenues for advanced research education and professional development by research staff.

There are several potential limitations related to this effort that may impact the generalizability of our work. Until the onset of the current pandemic, the option for remote work at most Node sites had been non-existent. The REDCap™ survey that was disseminated across Node sites gathered data on remote working options and strategies that were being employed to maintain employee work engagement. Although most staff have welcomed the opportunity to work remotely, our survey did not query how research study staff viewed the opportunity to transition to remote work under the associated circumstances, therefore we were not able to effectively tailor our strategies

for staff based on their attitudes around remote work. The data that could be potentially gleaned from the inclusion of this type of survey question might have allowed us to create and employ higher-intensity engagement strategies for those staff that had strong feelings of opposition to remote work. Alternatively, we could have potentially created lower-intensity engagement strategies for those staff who demonstrated an appreciation for remote work and may have had higher existing levels of engagement due to their attitudes around remote work settings. Informal communication to staff members highlighted that they experienced varying levels of frustration and difficulties with remote access and other IT issues, including obtaining access to various study SharePoint™ sites, study files, and study contact information. While working through these challenges, they were also dealing with suboptimal workspaces at home, unexpected parental responsibilities, and fear and anxiety associated with the COVID-19 pandemic itself (Watkins, 2013). Although our intent was that these strategies would encourage workplace engagement, we do not know if research staff felt they were effective. Having additional input from staff on what approaches they felt might help to keep staff engaged during this difficult time may provide useful suggestions that could be employed at some point in the future.

In summary, we have been able to successfully implement several approaches that were designed to maintain staff work engagement in the NODES consortium during the COVID-19 pandemic. Additional work is needed to assess the impact of these strategies in terms of their potential ability to improve the level of work engagement amongst staff. It is anticipated that surveys administered to staff both pre- and post-implementation of similar strategies might provide insight into their benefit and would allow for formal evaluation of these methods. We have confidence that the work presented in this manuscript will benefit other clinical research consortia that are striving to maintain work engagement amongst their staff during the current pandemic. Furthermore, these strategies may be beneficial to organizations during other potential future national and/or global crises that warrant the development and implementation of mitigation strategies to decrease the impact of these situations on their operational activities.

Disclaimer

The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the government of the United States.

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Conflicts of Interest
The authors report no conflicts of interest.

References

Abujarad, F., Alfano, S., Bright, T. J., Kannoth, S., Grant, N., Gueble, M., Peduzzi, P., & Chupp, G. (2018). Building an informed consent tool starting with the patient: The patient-centered Virtual Multimedia Interactive Informed Consent (VIC). In *AMIA Annual Symposium Proceedings* (Vol. 2017, pp. 374–383). American Medical Informatics Association.

Agrafiotis, D. K., Lobanov, V. S., Farnum, M. A., Yang, E., Ciervo, J., Walega, M., Baumgart, A., & Mackey, A. J. (2018). Risk-based monitoring of clinical trials: An integrative approach. *Clinical Therapeutics, 40*(7), 1204–1212. https://doi.org/10.1016/j.clinthera.2018.04.020

Bakaeen, F. G., Reda, D. J., Gelijns, A. C., Cornwell, L., Omer, S., Al Jurdi, R., Kougias, P., Anaya, D., Berger, D., & Huang, G. D. (2014). Department of Veterans Affairs Cooperative Studies Program Network of Dedicated Enrollment Sites: Implications for surgical trials. *JAMA Surgery, 149*(6), 507-513. https://doi.org/10.1001/jamasurg.20134150

Boyce, M. R., & Katz, R. (2019). Community health workers and pandemic preparedness: Current and prospective roles. *Frontiers in Public Health, 7*, 62. https://doi.org/10.3389/fpubh.2019.00062

Centers for Disease Control and Prevention. (2020, June 3). Coronavirus (COVID-19): Coping with stress. Retrieved July 6, 2020, from https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/managing-stress-anxiety.html

Condon, D. L., Beck, D., Kenworthy-Heinige, T., Bratcher, K., O'Leary, M., Asghar, A., Willis, C., Johnson, M., & Huang, G. D. (2017). A cross-cutting approach to enhancing clinical trial site success: The Department of Veterans Affairs' Network of Dedicated Enrollment Sites (NODES) model. *Contemporary Clinical Trials Communications, 6*, 78–84. https://doi.org/10.1016/j.conctc.2017.03.006

Courtemanche, C., Garuccio, J., Le, A., Pinkston, J., & Yelowitz, A. (2020). Strong social distancing measures in the United States reduced the COVID-19 growth rate. *Health Affairs* (Millwood), 14. https://doi.org/10.1377/hlthaff.2020.00608 [Epub ahead of print.]

Department of Health, Education, and Welfare, & National Commission for the Protection

of Human Subjects of Biomedical and Behavioral Research. (2014). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. *The Journal of the American College of Dentists, 81*(3), 4–13.

Fogel, D. B. (2018). Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review. *Contemporary Clinical Trials Communications, 11*, 156–164. https://doi.org/10.1016/j.conctc.2018.08.001

Gallup. (2020, May 19). U.S. workers discovering affinity for remote work. https://news.gallup.com/poll/306695/workers-discovering-affinity-remote-work.aspx

Golden, T. D., Veiga, J. F., & Dino, R. N. (2008). The impact of professional isolation on teleworker job performance and turnover intentions: Does time spent teleworking, interacting face-to-face, or having access to communication-enhancing technology matter? *The Journal of Applied Psychology, 93*(6), 1412–1421. https://doi.org/10.1037/a0012722

Harris, P. A., Taylor, R., Minor, B. L., Elliott, V., Fernandez, M., O'Neal, L., McLeod, L., Delacqua, G., Delacqua, F., Kirby, J., Duda, S. N., & REDCap Consortium. (2019). The REDCap Consortium: Building an international community of software platform partners. *Journal of Biomedical Informatics, 95*, 103208. https://doi.org/10.1016/j.jbi.2019.103208

Hastings, C. E., Fisher, C. A., McCabe, M. A., National Clinical Research Nursing Consortium, Allison, J., Brassil, D., Offenhartz, M., Browning, S., DeCandia, E., Medina, R., Duer-Hefele, J., McClary, K., Mullen, N., Ottosen, M., Britt, S., Sanchez, T., & Turbini, V. (2012). Clinical research nursing: A critical resource in the national research enterprise. *Nursing Outlook, 60*(3), 149–156.e1563. https://doi.org/10.1016/j.outlook.2011.10.003

Holshue, M. L., DeBolt, C., Lindquist, S., Lofy, K. H., Wiesman, J., Bruce, H., Spitters, C., Ericson, K., Wilkerson, S., Tural, A., Diaz, G., Cohn, A., Fox, L., Patel, A., Gerber, S. I., Kim, L., Tong, S., Lu, X., Lindstrom, S., Pallansch, M. A., Weldon, W. C., Biggs, H. M., Uyeki, T. M., & Pillai, S. K. [for the Washington State 2019-nCoV Case Investigation Team]. (2020). First case of 2019 Novel Coronavirus in the United States. *The New England Journal of Medicine, 382*(10), 929–936. https://doi.org/10.1056/NEJMoa2001191

Huang, G. D., Ferguson, R. E., Peduzzi, P. N., & O'Leary, T. J. (2010). Scientific and organizational collaboration in comparative effectiveness research: The VA Cooperative Studies Program Model. *The American Journal of Medicine, 123*(12 Suppl 1), e24-31. https://doi.org/10.1016/j.amjmed.2010.10.005

Huang, Y., & Zhao, N. (2020). Generalized anxiety disorder, depressive symptoms and

sleep quality during COVID-19 outbreak in China: A web-based cross-sectional survey. *Psychiatry Research, 288*, 112954. https://doi.org/10.1016/j.psychres.2020.112954

Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. (2010). Transforming clinical research in the United States: Challenges and opportunities:Workshop summary. In *Challenges in clinical research* (pp. 19–36). Washington DC: National Academies Press. https://www.ncbi.nlm.nih.gov/books/NBK50888/

Ives, J., Greenfield, S., Parry, J. M., Draper, H., Gratus, C., Petts, J. I., Sorell, T., & Wilson, S. (2009). Healthcare workers' attitudes to working during pandemic influenza: A qualitative study. B*MC Public Health, 9*, 56. https://doi.org/10.1186/1471-2458-9-56

Jaguste, V. S. (2019). Risk-based monitoring: Review of the current perceptions and toward effective implementation. *Perspectives in Clinical Research, 10*(2), 57–61. https://doi.org/10.4103/picr.PICR_18_18

Jeve, Y. B., Oppenheimer, C., & Konje, J. (2015). Employee engagement within the NHS: Across-sectional study. *International Journal of Health Policy and Management, 4*(2), 85–90. https://doi.org/10.15171/ijhpm.2015.12

Johnson, M. R., & Bullard, A. J. (2020). Creation of a structured performance-based assessment tool in a clinical research center setting. *Journal of Research Administration, 51*(1). https://www.srainternational.org/blogs/srai-jra1/2020/05/02/creation-of-a-structured-performance-based-assessm

Johnson, M. R., Kenworthy-Heinige, T., Beck, D. J., Asghar, A., Broussard, E. B., Bratcher, K., Tommessilli, L. M., Antonelli, M., & Planeta, B. M. (2018). Research site mentoring: A novel approach to improving study recruitment. *Contemporary Clinical Trials Communications, 9*, 172–177. https://doi.org/10.1016/j.conctc.2018.01.011

Khan, S., Siddique, R., Li, H., Ali, A., Shereen, M. A., Bashir, N., & Xue, M. (2020). Impact of coronavirus outbreak on psychological health. *Journal of Global Health, 10*(1), 010331. https://doi.org/10.7189/jogh.10.010331

Knight, C., Patterson, M., & Dawson, J. (2017). Building work engagement: A systematic review and meta-analysis investigating the effectiveness of work engagement interventions. *Journal of Organizational Behavior, 38*(6), 792–812. https://doi.org/10.1002/job.2167

Krishnamurti, T., & Argo, N. (2016). A patient-centered approach to informed consent:

Results from a survey and randomized trial. *Medical Decision Making: An International Journal of The Society For Medical Decision Making, 36*(6), 726–740. https://doi.org/10.1177/0272989X16636844

Kutner, J., Smith, M., Mellis, K., Felton, S., Yamashita, T., & Corbin, L. (2010). Methodological challenges in conducting a multi-site randomized clinical trial of massage therapy in hospice. *Journal of Palliative Medicine, 13*(6), 739–744. https://doi.org/10.1089/jpm.2009.0408

Lu, W., Wang, H., Lin, Y., & Li, L. (2020). Psychological status of medical workforce during the COVID-19 pandemic: A cross-sectional study. *Psychiatry Research, 288*, 112936. https://doi.org/10.1016/j.psychres.2020.112936

Martin, P., Kumar, S., Lizarondo, L., & Baldock, K. (2019). Debriefing about the challenges of working in a remote area: A qualitative study of Australian allied health professionals' perspectives on clinical supervision. *PloS one, 14*(3), e0213613. https://doi.org/10.1371/journal.pone.0213613

Michalski, C.A., Diemert, L.M., Helliwell, J.F., Goel, V., Rosella, L.C. Relationship between sense of community belonging and self-rated health across life stages. *SSM - Population Health*. 2020 Dec;12:100676. DOI: 10.1016/j.ssmph.2020.100676.

Moreno, J., Caplan, A. L., & Wolpe, P. R. (1998). Updating protections for human subjects involved in research. Project on Informed Consent, Human Research Ethics Group. *JAMA, 280*(22), 1951–1958. https://doi.org/10.1001/jama.280.22.1951

Okazaki, E., Nishi, D., Susukida, R., Inoue, A., Shimazu, A., & Tsutsumi, A. (2019). Association between working hours, work engagement, and work productivity in employees: A cross-sectional study of the Japanese Study of Health, Occupation, and Psychosocial Factors Relates Equity. *Journal of Occupational Health, 61*(2), 182–188. https://doi.org/10.1002/1348-9585.12023

Santoli, J. M., Lindley, M. C., DeSilva, M. B., Kharbanda, E. O., Daley, M. F., Galloway, L., Gee, J., Glover, M., Herring, B., Kang, Y., Lucas, P., Noblit, C., Tropper, J., Vogt, T., & Weintraub, E. (2020, May 15). Effects of the COVID-19 Pandemic on routine pediatric vaccine ordering and administration—United States, 2020. *Morbidity and Mortality Weekly Report*, 69(19), 591-593. https://doi.org/10.15585/mmwr.mm6919e2

Schaa, K., Anderson, G., Alt-White, A, Kasper, C., & Boyd, A. (2014). Genomics education for Veterans Affairs nurses. *Genetics in Medicine, 16*, 984–985. https://doi.org/10.1038/gim.2014.142

Schaufeli, W. B., Bakker, A. B., & Van Rhenen, W. (2009). How changes in job demands

and resources predict burnout, work engagement, and sickness absenteeism. *Journal of Organizational Behavior, 30*, 893–917. https://psycnet.apa.org/doi/10.1002/job.595

Shimazu, A., Schaufeli, W. B., Kubota, K., Watanabe, K., & Kawakami, N. (2018). Is too much work engagement detrimental? Linear or curvilinear effects on mental health and job performance. *PloS one, 13*(12), e0208684. https://doi.org/10.1371/journal.pone.0208684

U.S. Bureau of Labor Statistics. (2020, May 19). Economic News Release Table 1. Workers who could work at home, did work at home, and were paid for work at home, by selected characteristics, averages for the period 2017-2018. https://www.bls.gov/news.release/flex2.t01.htm

U.S. Department of Veterans Affairs Health Services Research and Development. (2020a, May 18). VA HSR&D Cyberseminars. Retrieved May 18, 2020 from https://www.hsrd.research.va.gov/cyberseminars/.

U.S. Department of Veterans Affairs Office of Research and Development. (2020b). Research Week: May 11-15, 2020: "Empowering veterans through research". Retrieved May 18, 2020 from https://www.research.va.gov/researchweek/default.cfm

Van den Broeck, A., Elst, T. V., Baillien, E., Sercu, M., Schouteden, M., De Witte, H., & Godderis, L. (2017). Job demands, job resources, burnout, work engagement, and their relationships: An analysis across sectors. *Journal of Occupational and Environmental Medicine, 59*(4), 369–376. https://doi.org/10.1097/JOM.0000000000000964

Velarde, K. E., Romesser, J. M., Johnson, M. R., Clegg, D. O., Efimova, O., Oostema, S. J., Scehnet, J. S., DuVall, S. L., & Huang, G. D. (2018). An initiative using informatics to facilitate clinical research planning and recruitment in the VA health care system. *Contemporary Clinical Trials Communications, 11*, 107–112. https://doi.org/10.1016/j.conctc.2018.07.001

Vijayananthan, A., & Nawawi, O. (2008). The importance of Good Clinical Practice guidelines and its role in clinical trials. *Biomedical Imaging and Intervention Journal, 4*(1), e5. https://doi.org/10.2349/biij.4.1.e5

Wakerman, J., Humphreys, J., Russell, D., Guthridge, S., Bourke, L., Dunbar, T., Zhao, Y., Ramjan, M., Murakami-Gold, L., & Jones, M. P. (2019). Remote health workforce turnover and retention: What are the policy and practice priorities? *Human Resources for Health, 17*(1), 99. https://doi.org/10.1186/s12960-019-0432-y

Wang, H., Wang, L., & Liu, C. (2018). Employee competitive attitude and competitive

behavior promote job-crafting and performance: A two-component dynamic model. *Frontiers in Psychology, 9*, 2223. https://doi.org/10.3389/fpsyg.2018.02223

Watkins, M. D. (2013). *Making virtual teams work: Ten basic principles*. Harvard Business Review. https://hbr.org/2013/06/making-virtual-teams-work-ten

Weber Lebrun, E. E., Moawad, N. S., Rosenberg, E. L., Morey, T. E., Davies, L., Collins, W. O., & Smulian, J. C. (2020). COVID-19 Pandemic: Staged management of surgical services for gynecology and obstetrics. *American Journal of Obstetrics and Gynecology,* 2020 Apr 3. https://doi.org/10.1016/j.ajog.2020.03.038 [Epub ahead of print.]

World Health Organization. (2020a, April 17). Q&A on coronaviruses (COVID-19). Retrieved July 6, 2020, from https://www.who.int/news-room/q-a-detail/q-a-coronaviruses

World Health Organization. (2020b). WHO Coronavirus disease (COVID-19) Dashboard. Retrieved July 6, 2020, from https://covid19.who.int/
[a] – Required Position

Appellix A. NODES Position Descriptions	
Role	**Responsibilities**
Clinical Director (or team of Clinical Co-Directors/Associate Directors) [a]	*Provides oversight, leadership and mentorship to local Node and CSP study teams and ensures the successful conduct of CSP studies at the local Node site *Identifies, mentors and collaborates with prospective and existing Site Investigators *Works closely with medical center leadership at the site to promote and encourage clinical trial efforts throughout the institution *Ensures appropriate resources and support for CSP research efforts including space requests, laboratory needs, or study specific needs *Works with the NODES Associate Director-Operations to develop the Node site budget *Ensures CSP and NODES research procedures, process improvements, initiatives and projects are successfully executed at the site *Strengthens connections within the CSP network to provide greater opportunities for interdisciplinary research *Collaborates with local and national stakeholders to achieve CSP objectives *Engages with CSP Coordinating Centers in the feasibility, planning, and implementation of CSP trials *Participate in programmatic strategic planning of CSP and NODES

	*Provides mentorship for non-Node Sites, new Node Sites/NODES Expansion efforts * Facilitates the submission of CSP study Letters of Intent (LOI) from the site for review and potential funding
Associate Director-Operations [a]	*Provides supervision, leadership and mentorship to local Node and CSP study teams *Identifies, mentors and collaborates with prospective and existing Site Coordinators and other CSP study team members *Works with the NODES Director to develop the Node site budget *Works with study team members to develop site study budgets for each site's respective studies *Ensures appropriate resources and support for CSP and NODES research efforts *Ensures research process improvement initiatives and projects are successfully executed *Strengthens connections within the CSP network to provide greater opportunities for interdisciplinary research *Collaborates with local and national stakeholders to achieve CSP objectives *Engages with CSP Coordinating Centers in the feasibility, planning, and implementation of CSP trials *Participates in programmatic strategic planning of CSP and NODES

	*Provides mentorship for non-Node Sites, new Node Sites/NODES Expansion efforts *Provides mentorship and support for CSP study team members *Provides/arranges for back-up coverage for study team members that are on planned and unexpected leave *Human Resources: Facilitates job posting, interviewing, hiring, and training for study staff (study coordinators, research nurses, study research assistants, etc.) *Conducts meetings with site study teams to share best practices, deliver education and training, and to discuss successes/challenges as it relates to clinical trial execution *Completes local and national study auditing, as well as data and adverse event reporting *Assists with special projects/workgroups locally & nationally
Manager(s) [b]	*Provides oversight, direction and guidance to local CSP study teams on all clinical trial related activities *Collaborates with local and national stakeholders to achieve CSP objectives *Assists Director and Associate Director-Operations in engagement with CSP Coordinating Centers in the feasibility, planning, and implementation of CSP trials *Human Resources: Facilitates job posting, interviewing, hiring, and training for study staff (study coordinators, research nurses, study research assistants, etc.)

	*Provides back-up coverage for study team members that are on planned and unexpected leave *Completes local and national study auditing, as well as data and adverse event reporting *Assists with coordinating and executing meetings with site study teams to share best practices, deliver education and training, and to discuss successes/challenges as it relates to clinical trial execution *Assists with special projects/workgroups locally & nationally
Clinical Research Nurse[b]	*Provides back-up coverage for study team members that are on planned and unexpected leave (for all studies) *Provides medical informatics expertise as it relates to the Electronic Medical Record. *Assists with lab alerts, CPRS required documentation into CPRS, creation of CPRS templates and study progress notes/templates. *Assists with special projects/workgroups locally & nationally *Administers investigational drug products or vaccines. Provides education on study drug administration and anticipated adverse effects. *Activates/triggers pharmacy orders following randomizations

	*Performs and assists other research personnel with medical tests, biometric measurements, venipunctures, and medical procedures within the RN scope of practice and competency. Obtains samples during infusion studies, processes and aliquots samples as appropriate.
	* Initiates lab order entries and scheduling of diagnostic tests; creates pre-set study lab orders.
	*Provides guidance and knowledge to non-clinical research staff of hospital organization and hospital services in managing research participants in various study settings, including ambulatory care, specialty areas, inpatient and critical care.
	*Provides clinical expertise for study adverse events and query resolution, eligibility, data collection activities, adjudications, and drug accountability.
	* Completes R&D submissions for non-clinical CSP staff in sections regarding safety, scientific review, and impact statements for clinical services/pharmacy/ pathology services.
	*Identifies to the LSI any problems that arise during conduct of the trials and assists in their solutions.
	*Provides mentorship and in-services to clinic/hospital staff on the clinical aspects of studies and clinical roles of staff for those studies conducted outside of the outpatient setting (inpatient units, OR, radiology)
	*Initiates lab order entries and scheduling of diagnostic tests; creates pre-set study lab orders.

Clinical Research Administrator[b]	*Provides back-up coverage for study team members that are on planned and unexpected leave (for studies not requiring an RN) *Coordinates required performance data submissions for program evaluation efforts *Produces Bi-Annual local NODES Newsletter *Schedules meetings, prepares agendas, & minutes *Organizes/Plans/Arranges travel *Maintains Director's calendar *Assists with special projects/workgroups locally & nationally
NODES Assistant (Clinical Research Assistant)[b]	* Coordinates monthly meetings with site study teams to share best practices, deliver education and training, and to discuss successes/challenges as it relates to clinical trial execution * Assists site teams with travel coordination for CSP-related study kick-off/annual meetings *Assists site teams with CSP related purchase orders *Assists new hires with completion of VA trainings

[b] – Optional Position depending on the site's determination of what its needed resources are to meet program and site metrics as defined in the NODES FY21-22 OKRs.

Appendix B. NODES Survey

NODES Study Teams Work Engagement Survey

Please complete the survey below.

Thank you!

NODE Site: _____
                     (e.g., Salt Lake City)

1. How many CSP staff (FTE) does your site have working
    with NODES (do not include MVP staff)?   _____
                                                              (e.g., 7.5)

2. a) How many of those staff members are working remotely
      for their entire tour of duty (TOD) due to COVID-19?   _____

2. b) How many are working remotely for part of their TOD
      due to COVID-19?   _____

3. What tasks have your staff been working on during the
    pandemic?
                                                              _____
                                                              (Please specify any training, new projects,
                                                              assignments etc.)

4. a) Have staff been working on any COVID-19 related   ○ Yes
      research studies (CSP or non-CSP) ? Please do not   ○ No
      include educational training (i.e. webinars, reading
      daily updates etc.).

4. b) Please specify COVID-19 studies:

                                                              _____

5. a) Have any of your staff been reassigned to general   ○ Yes
      labor pool duties?   ○ No

5. b) How many RNs have been reassigned to the labor
      pool?   _____

5. c) Please state newly assigned role/
      position(s):   _____

5. d) How many non-clinical staff have been reassigned to
      the labor pool?   _____

5. e) Please state newly assigned role/position(s):
                                                              _____

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Appendix C. CSP Houston NODES Newsletter

CSP RESEARCH
# HOUSTON NEWSLETTER

FEBRUARY 2021

CSP and COVID-19

It was shortly after the presidential election in November 2020 that the first vaccine trial results were released to the general public. And the results were promising. With measures of effectiveness in the 90th percentile, a new hope blossomed for an end to the COVID-19 pandemic. Our question changed from can we be vaccinated to when can we be vaccinated. And it turns out the answer was soon.

Hardly a month later we received the first emails assessing interests in receiving the vaccine from the VA. By mid-December, the first vaccines were being administered to frontline personnel with RSL employees soon to follow. Those of us who chose to receive the vaccine will recall a hopeful, almost giddy atmosphere when they entered the 4th floor auditorium. From the nurses administering the shots to the staff running the check-in, everyone seemed eager to be a part of this historic vaccination effort.

Needless to say, we're all very grateful to everyone involved in the process to get us vaccinated. These men and women's professionalism and compassion does great credit to the VA. Let's also not forget to give thanks to our co-workers in the Research Service Line who took the time and effort to assess our levels of interest in receiving the COVID-19 vaccine and get us scheduled in an efficient, timely manner.

The following page is a snapshot of the vaccination effort in our CSP community. Thanks to all who sent a picture of themselves receiving the vaccine. We are nearly as happy to have a picture of you getting your vaccine as you were to receive the it!

As a final note, please report any side-effects you may have experienced after receiving the vaccine to VHA-HOUSCOVID19AdverseEvent@va.gov. Understanding the negative side effects that may occur as a result of receiving the vaccine is a crucial part of the vaccination effort, so please don't hesitate to report your own post-vaccine experience!
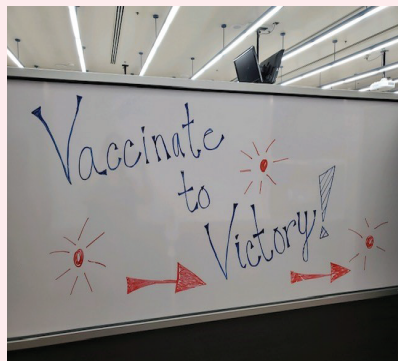
Appendix D. CSP Minneapolis NODES Newsletter

IN
THE NODE
DURING COVID-19

NODES: Rise Up to COVID-19 Challenges

Volume 7 Issue 1

April 2020

The COVID-19 pandemic imposed several new challenges to research including mitigating risks to staff, participants and study data integrity. On March 4th, 2020 the first COVID+ veteran was reported at the Palo Alto VAMC which was our catalyst for the opportunities for action. Simultaneously, national and local research departments and study teams rose up to these obstacles and began preparation of the Continuity of Operations Plans (COOP). The Minneapolis VA CSP-NODES team worked on a multi-factor COOP to address risks.

While some CSP studies had already implemented holds on recruitment, the VA ORD Administrative hold directive was not officially released until March 17th, 2020. The first challenge noted was mitigation of risk of our CSP Staff. Due to VA policies and local standard operating procedures, our research staff was not authorized to telework until March 17th. NODES worked with local Research ACOS to advocate for telework and to field questions from CSP staff to set up and prepare telework agreements. Preparation included NODES assessing current CSP staff capabilities, guiding in the

process to obtain the correct access, equipment and authorization. Staff facing extra challenges with telework ability due to COVID-19 were addressed Individually and back up plans were created between study teams and NODES as required. Due to steps taken by NODES, CSP staff and LSIs, the majority of our local, telework eligible, CSP team staff were able to telework by March 18th. To date, 100% of Minneapolis CSP research staff are telework eligible under the COOP.

A second risk to address was the risk to CSP participants. The administrative hold halted in person visits and new consents for all local CSP trials. NODES as a support team engaged with local CSP staff to compile direction from CSP study chairs offices, local and national directives. By answering questions, guiding logistics and providing coverage as needed, the NODES team was able to assist with the transition to no-contact visits.

Mitigating risk to CSP study data integrity helped to guarantee the

reduction of missing data and capture of serious adverse events and primary outcomes. Telework was the primary factor in maintaining our ability to obtain this data. In addition, the CSP cross training contributes to the available pool of trained staff to ensure study coverage in the event the primary staff is unavailable. The second tier back up NODES staff is also a safety net ensuring there are no lapses in coverage.

Teams and departments worked together to RISE UP to the challenges of COVID-19. The persistent advocacy for staff and patient safety while maintaining our study data integrity reiterates the amazing team of Minneapolis VA CSP Research.

Special points of interest:

- COVID-19 Challenges
- COVID-19 Opportunities

In The Spotlight: COVID-19 Research Opportunities

COVID-19 has provided opportunities for Minneapolis to reassess our abilities to quickly mobilize study start up and address potential obstacles prior to them creating barriers to research. The NODES Director collaborated with the Infectious Disease team to assess the availability of potential LSIs if selected for a CSP trial. The NODES Assistant Director of Operations communicated directly with local R&D to assess abilities to streamline approval of CSP research

VA COOPERATIVE STUDY #2027

- Randomized, Placebo-Controlled Trial to Evaluate the Efficacy of Hydroxychloroquine to Prevent SARS-CoV-2 Infection in Exposed Persons
- Study proponents: Sanjay Mehta, MD, Davey Smith, MD MAS VA San Diego HCS
  – CSP Coordinating Centers: West Haven, Albuquerque
- LOI received Feb 2020; currently in planning

directly related to COVID-19. The NODES team assessed the status of current study, cross training and ability of current staff to shift to cover an expedited start up. CSP teams were surveyed to address staff ability and desire to work on a COVID trial. The results were overwhelming at >90% of respondents ready to participate in COVID research. Opportunities are available for COVID-19 proposals prompting several of our local CSP coordinators to dedicate time assisting LSIs in these expedited submissions.

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