Australasian Research Management Society

RESEARCH MANAGEMENT PROFESSIONALS IMPACT CASE STUDIES

ARMS Strategic Plan 'Towards 2025' has as one of its priorities the promotion of the profession of research management (Strategic Priority 2). One way ARMS plans to achieve this in the timeframe 2019-2021 is to develop case studies that demonstrate the value and contribution of research management professionals (Implementation Priority 2.2).

A template has been developed to help describe your research management impact. ARMS hopes to use many of the impact case studies to demonstrate to our stakeholders the value of our profession to the research enterprise. The impact could be felt by researchers, funders, institutions, collaborators, students, the community, governments or industry.

A Research Management Impact Case study should be a narrative (maximum 1,000 words) around the following questions:

1.Please tell us about the research enterprise, and your role in it. What was the situation/project; what were the challenges that were faced; what was your role it; and why did you do what you did?

University of Sydney is sponsor of approximately 450 active clinical trials and site or coordinating centre for a further 150. Management of clinical trial governance and oversight activities are carried out by the Clinical Trials Support Office (CTSO) DVCR Research Portfolio on behalf of the University. The CTSO makes recommendations to the University Delegates (authorised decision makers) regarding trial conduct.

The COVID-19 pandemic brought significant challenges to stakeholders. CTSO needed to be agile in an evolving space and conversant with current government and institutional requirements. University researchers needed information in an accessible and timely manner.

The CTSO developed a guideline tailored to researcher needs. The guideline content was updated contemporaneously and linked to Government websites.

Aligned with local public health organisation directions, the University recommended clinical trials involving face-to-face participant-researcher contact or requiring public health resources (including use of clinic space, clinicians, ethics committees, allied healthcare workers) cease recruiting new participants during the pandemic. Certain trials were identified as exempt, for example:

- clinical trials of COVID-19 treatments.
- clinical trials investigating life-threatening or serious conditions with no alternative treatments.
- where discontinuation of treatment would adversely affect participants.

As the pandemic situation evolved locally, some trials previously not exempted became eligible to recommence participant involvement. From March to August 2020 CTSO logged 114 researcher COVID-19-related queries involving over 160 individual trials. More than 30% of the queries

required protocol amendments with ethics and site-specific assessment (SSA) review and approval.

2.How did you add value, improve outcomes and/or otherwise positively impact the research enterprise?

How was this impact measured?

Researchers predominantly sought advice about how current guidelines and University expectations applied to their trial and how to safely continue their research.

Initially, significant time was spent managing correspondence between researchers and CTSO as the parties worked to obtain a complete understanding of the situation for each trial.

To streamline the process, CTSO developed:

- a COVID-19 specific trial exemption application form which guided researchers on what should be considered to safely resume their research, documentation of risk mitigation initiatives and required supporting documentation.
- a supplementary consent form template for researcher use compliant with Federal government requirements to obtain explicit consent from participants to continue as part of the trial during the pandemic.

Operationally, CTSO:

- implemented a process to log and track researcher enquiries
- prioritised COVID-19 related queries.
- developed a template Delegate briefing paper that provided Delegates with the information for each application.

These initiatives enabled researchers whose trials had implemented appropriate risk-mitigation measures to obtain expeditiously the necessary approvals to recommence or continue participant activities during the pandemic.

3. Who were the key stakeholders in the research enterprise and how did you work with them to achieve a common goal? Please include any testimonials you have from those key stakeholders.

The key stakeholders in any trial are participants and researchers. However, due to community safety concerns arising from the pandemic, contacts and potential contacts of participants and researchers (the wider community) also became stakeholders.

One of the first research teams the CTSO worked with early in the pandemic involved an intervention administered as a comprehensive home-based rehabilitation program for people living with mild to moderate dementia. This trial led by Professor Yun-Hee Jeon aims to recruit 256 participants with the goal to enable this vulnerable population to remain in their own homes and out of institutional care.

The researchers initially applied for and had approved a protocol change to switch home visits to telehealth and video conferencing visits. This proved difficult for the participants and their carers due to hearing and sight impairment as well as low technology literacy. The researchers

approached CTSO for support and advice on how to safely resume home visits. Safety and risk mitigation were developed by the researchers, approved by ethics and governance, and home visits resumed with those measures in place.

Recommencement of the research impacted positively on the study participants. A Registered Nurse involved in this study shared some comments from participants and carers that support the importance of physical presence to people with dementia:

> A participant living alone and her daughter (her off-site carer) were both grateful for option of home visit when the daughter was sick and unable to visit. "It's really nice to have someone visit in person rather than see them via Zoom," said the mother.
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> A participant living alone missed her routine and daily outings due to COVID-19 restrictions. She stated during the home visit, "It's so good to see a friendly face, have someone come into my home. It really cheers me up."
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> Another participant joined the study with a face-to-face home visit. The second visit was via telehealth, where the participant was quiet, not as engaged. His wife stated she felt her husband was not sure who the nurse was. The third visit was face-to-face and the participant commented to the nurse, "I know you are familiar to me, happy to see you."

4.What lessons did you learn that you would like to share with your fellow research managers?

e.g. better communication protocols; tips for negotiating successful industry partnerships; more transparent reporting of research expenditure

In high-stress situations such as the COVID-19 pandemic, identifying common goals – which in this example was to continue conduct of a high quality clinical trial in a manner that maintains participant, researcher and community safety – then implementing a planned, collaborative and adaptive approach to problem solving is essential to achieve these goals. The CTSO found this strengthened relationships with researchers as highlighted in the testimonial below from the Professor Yun-Hee Jeon.

> *"The COVID-19 pandemic has made us realise the importance of working closely and collaboratively with the Clinical Trials Support Office more than ever. During the early phase of the pandemic lockdown we were able to discuss benefits and risks of continuing the trial with face-to-face home visits. After a number of long discussions, we agreed on a plan that has allowed our team to continue home visits and new enrolments.*
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> *"Our team has been working hard to ensure the agreed safety and risk mitigation measures are in place. Our participants highly appreciate continued face-to-face home visits, especially after having difficulties with telehealth.*
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> *"I believe this partnership has worked in such difficult times thanks to the trust and respect of all parties and a shared understanding that the wellbeing of our trial participants comes first. We are continuing our trial steadily and slowly, knowing we cannot be complacent, and hoping to achieve our trial objectives in due course."*

Templates must be submitted to the ARMS Executive Office by COB 5 PM on the 30th of September 2020 to arms.adminofficer@flinders.edu.au Where possible, applicants are encouraged to submit any images to support their case. Please ensure that all approvals to use such images are obtained prior to submitting your case study template.