Australian and New Zealand

Intensive Care Research Coordinator Interest Group (IRCIG)

Incorporating the Paediatric Intensive Care Research Coordinator Group (PIRCIG)

Pandemic Research Coordinator Guide

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Disclaimer

The Australian and New Zealand Intensive Care Research Coordinator Interest Group (IRCIG) Pandemic Research Coordinator Guide has been developed to assist intensive care research coordinators to prepare and plan in the event of a pandemic. The authors have made considerable effort to ensure the information contained within the recommendations is correct at the time of publication. Further iterations of this guide will be published as new information comes to hand. IRCIG accepts no responsibility for any inaccuracies, information perceived as misleading, or the success or failure of any of the recommendations detailed in the document. The Australian and New Zealand Intensive Care Research Coordinator Interest Group (IRCIG) is not liable for the accuracy or completeness of the information in this document. The information in this document cannot replace professional advice.

1. Preamble

The Intensive Care Research Coordinator Interest Group was formalised in 2000 as an endorsed working group of the Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG). Specific aims of the group include providing peer support, assisting with communication and providing a forum of discussion of issues relevant for intensive care research coordinators (RCs). The emergence of COVID-19 (SARS-CoV-2) pandemic and its impact on the global society will have significant impact on critical care services. This document has been produced by members of the IRCIG executive group to provide support and guidance for research coordinators navigating research programs during this pandemic. Research coordinators should use the themes and ideas discussed in this document as a reference for further discussions within their own working environments in collaboration with their colleagues.

Within the context of government legislation and local health district mandates, all research departments should ensure appropriate contingency plans are put in place to ensure the safety and wellbeing of trial participants during this time as well as prioritising pandemic research and support of research staff.

2. Working environment & clinical capacity support

If at all possible, consideration needs to be given to research priorities. The ANZICS COVID-19 Guidelines V1 dated 16th March 2020, specifically states on page 31 that *"research involving therapies for COVID-19 remains a high priority. Wherever possible research staff engaged in COVID-19 related research should be protected from redeployment".* IRCIG strongly endorse this recommendation. However, we also recognise that it may be difficult for RCs to negotiate this position if pressure is applied to assist in a clinical capacity from nursing workforce executive. Support from medical colleagues (& principal investigators) would be extremely useful for the RC. Consideration should be given to the most urgent priority whenever needed.

Many RCs have an extensive background and training in intensive care nursing. It is anticipated that Intensive Care Units (ICUs) will look for staffing support outside the current pool of ICU nurses and many RCs may be asked to assist clinically at the bedside to cover clinical demand.

If clinical cover is being asked of the RC, we recommend you consider the following:

- Clinical shifts worked should be attributed to the cost centre where the shift is worked. This will protect research finances, especially in a time of potential low recruitment where research income generation may be impacted due to prioritisation of other needs.

- RCs should consider their scope of practice and qualifications if required to undertake clinical duties.
- The RC should actively seek support and training from ICU educators or senior staff to assist with clinical transition. Consider the following: supernumery shifts to re-familiarise at the bedside, BLS & ALS reassessment, ICU specific mandatory competencies, and other more formal refresher courses (ventilator management, renal replacement therapy etc.)
- RCs should undertake specific training on personal protective equipment (PPE), donning and doffing procedures.
- If the RC is not able to undertake clinical duties, they could consider offering non-clinical support to ICU. RCs have an extensive skill set to offer.
- If RCs *are able* to continue working in a research capacity, consider the ability to work from home and put in place IT requests to facilitate remote access. RCs should maintain patient privacy as per usual Good Clinical Practice (GCP) guidelines when working remotely and should follow organisational guidelines.

RCs share a sense of camaraderie with nursing colleagues and may experience a torn sense of obligation between working clinically and/or in a research role. If RCs *are able* to continue working in a research capacity, consider carefully navigating the opportunity to educate nurse/medical colleagues on research activity, and of the specific role and research data being collected.

3. Managing research activity

If individual organisations have issued a directive regarding research activity, RCs should adhere to these guidelines. RCs should hold discussions with appropriate intensivists and investigators about research priorities and capacity. Consider which current trials will be suspended, continued, and commenced. Priority should be given to COVID-19 research activity, such as SPRINT-SARI, REMAP-CAP, EXCEL, ECMO CARD, SAGE-ANZ and others focusing on influenza, community acquired pneumonia, ECMO and adjunctive therapies. Demand may emerge for research on novel pharmaceutical therapies.

RCs should consider the following:

- Communicate with trial sponsors, method centres, project managers and Clinical Research Associates (CRAs) to indicate their contingency to either support, suspend or slow recruitment to current trials. Any interruption to supply of trial drugs, kits and study supplies should be communicated. Consider and discuss possible protocol breaches that may occur.
- On-site, in-person planned monitoring visits should not occur. If necessary, remote monitoring visits could be considered. RC capacity to comply with remote monitoring demands should be considered, as it is likely RCs will not have time or capacity to attend to requests. Trial sponsors should understand that maintenance of site investigator files and obligations for regulatory requirements will not be prioritised by

RCs. Trial sponsors could communicate with ethics/research governance offices on site behalf if they have capacity to support sites in this manner.

- Obligations for safety should remain an important aspect of research conduct. Particularly if new, novel therapies are tested. All data entry will be reduced and priority should be given to safety reporting. In lieu of reporting individual non-serious safety breaches, consider submitting a post COVID-19 deviation report after the pandemic situation has subsided, including summary details of number of participants impacted, changes to medication dosing due to supply/dispensing issues, protocol breaches due to unforeseen events, and missing or delayed data.
- Discussions should be held with supporting departments about capacity to support and continue research work in the ICU. Clinical trial pharmacy staff may be redeployed to other pharmacy duties and be unavailable. Pathology services may not be able to prioritise above standard-care research requests. Capacity and workload across all areas of the hospital will be particularly strained and RCs should initiate contingency plans to work around this.
- Ethical and local governance submissions for new trials may need to be delayed or not accepted at this time. Protocol amendment submissions may be delayed, unless it relates directly to impact of COVID-19 research (eg. adaptive platform trials such as REMAP-CAP). Trial sponsors should support RCs and sites in administration of these amendments as much as possible.
- Data lock timelines may not be able to be met.
- Patient follow-ups may have to be delayed or conducted via other telecommunication means if approved. Communicate this with trial sponsors as you are able to, or consider asking other discipline RCs to assist (see discussion in next section).
- Seek support from administrative staff to assist with photocopying of blank paper CRF forms. If working remotely, consider asking ICU ward clerks to send a list of all ICU patients admitted each day which may help identify patients eligible for COVID-19 audits.
- ICU patients may be cared for outside of ICU environments. Monitoring and documentation may be different to usual and patients may be cared for by unskilled staff who have little experience in ICU environments. Documentation for data collection may be challenging and varied depending on circumstance. Consider drafting a COVID-19 pandemic file note template. This could be used to record physically sighted data that wasn't recorded accurately, explained aberrances in data or other random occurrences if you know they occurred.
- Research equipment and supplies may need to be removed or fit for purpose to cope with the pandemic. Clinical trial medication fridges may need to be utilised to house extra pharmacy medication. Shelving units storing research trial kits or equipment and resources may need to be repurposed. Consider removing research stock from clinical areas to reduce possible contamination and free up space in the ICU for other urgent equipment.
- Communication with colleagues is important. Communicate openly, simplify where possible and remember that everyone is operating under difficult circumstances.

4. Consent & GCP

Many ICU trials recruit patients using a variety of consent processes and approaches. Consent models vary from state to state and country to country. The following points should be considered:

- Clinical staff may continue to recruit patients to existing trials using the current approved consent model. If patients are intubated and sedated and a person responsible/substitute decision maker/medical treatment decision maker needs to be approached for consent, this may be difficult to obtain. Visitor restrictions to hospitals may mean it is not possible to approach substitute decision makers in person at the bedside. If approved by the Human Research Ethics Committee (HREC), approach via phone and conduct a verbal consent conversation, followed by posting or emailing the information and consent form. If posting, make sure to include a stamped, self-addressed envelope to help ensure return of the document.
- Consider discussions with trial sponsors about how to manage alternative approaches to consent, noting HREC requirements and obligations. Seek support from trial sponsors to submit an amendment to HRECs for rapid approval of alternative methods of consent (such as verbal telephone consent). Trial sponsors should support administrative approach to HREC to facilitate this and relieve the burden from sites. However, it should be noted that HRECs will also be operating under difficult circumstances and may not be able to process amendment requests for alternative consent approaches promptly.
- Breaches relating to GCP protocol and consent may occur but should be mitigated as much as possible. Document any approach to consent, particularly detailing difficult circumstances surrounding consent. Ensure clear communication with the coordinating centre/trial sponsor/HREC.
- Research staff should consider their own safety when seeking in-person consent. We do not recommend RCs don PPE gear specifically to enter a room to discuss consent. Where possible, it is recommended the discussion be held later when the patient has recovered from COVID-19.

5. Sustainment of research programs

Healthcare costs to support the pandemic will be substantial. Financial circumstances to support research may be difficult and income generation may be severely impacted. Consider discussions with trial sponsors about invoicing timelines for current trials. Where possible, consider discussions with hospital executives and finance departments about extensions of timelines for business case and contract renewals. Consider reviewing individual research program portfolios at each site and consider incorporating & prioritising industry-sponsored trials if able to. Please communicate with the IRCIG executive group about any financial difficulties this pandemic may create as we may be able to offer advice and assist in advocating for research funding.

6. RC safety & well-being

RCs may be personally impacted by COVID-19 and unable to continue in research duties. Important research activity during periods of RC absence will need to be prioritised. Consider seeking help from RCs in other clinical disciplines who may be able to step in and support any urgent work. Examples include other established research coordinator groups such as The Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA CTN) Anaesthesia Research Coordinator Network (ARCN). Alternatively, consider RCs from other disciplines such as department of surgery, renal, oncology, haematology, cardiology, endocrinology or infectious diseases.

Look after your own mental health and well-being. Adhere to social distancing and the latest government and local health district pandemic advice. Consider the impact your role will have on your family. Although it may be difficult, try not to feel overwhelmed. If work commitments become too much, reduce research activity. Only do what can conceivably be managed.

Lastly, consider RC research projects as a result of this pandemic. Learning opportunities can be taken from this pandemic and nurse-led research is vitally important. IRCIG can help you formulate and implement your ideas.

7. Conclusion

Research coordinators are highly skilled professionals who have a lot to offer our colleagues, our patients, and wider community. These are challenging and unprecedented times. We sincerely hope this guide has been helpful in providing guidance to RCs during this current pandemic.

Acknowledgments

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References

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