Project Continuation Guidance

Contents

Overview

RBWH has established an approach to research activity during the COVID-19 pandemic, which has the following elements:

- **Project evaluation and assessment**: considering the implications and risks that affect a research project in the context of COVID-19 prevalence in the community
- **Adaptation**: making changes that do not detract from the aims of research but minimise risks and optimise feasibility in the presence of COVID-19
- **Opportunity**: Identifying new research topics, evidence gaps and opportunities for meaningful research

This Guidance is intended to support researchers and departments in following these principles and optimise research activity. It supports a vision of retaining an active portfolio of RBWH research through the COVID-19 pandemic and contributing to the global body of new research on the far-reaching consequences of the pandemic.
The Guidance aims to:

- Assist those overseeing, conducting, and reviewing research activities to continue work and maximise the safety and minimise risk to research patients, the community, researchers, and institutional staff
- To guide the commencement of new RBWH research activities
- To provide guidance for existing projects that are significantly impacted or unable to continue due to COVID-19.

National and International Context

This Guidance is designed to support current thinking and best practice that reflects the shared views of state and territory Departments of Health, National Health and Medical Research Council, and the Therapeutic Goods Administration.

Project Evaluation and Assessment

Key Points

- **An assessment should be carried out for all projects of the potential implications of COVID prevalence in the community**
- **Assessments should be shared with Heads of Clinical Departments, to determine if there are any service implications or requirements that should apply to research activity in clinical areas**

Individual chief investigators (CIs) should undertake contingency planning to address the potential impact of COVID-19 and responses to the pandemic on current and future research. Clinical departments and services should consider the nature and procedures of each research project and determine if changes are required.

Considering the fluidity of the COVID-19 situation and the variable levels of capacity and readiness for non-COVID research, an assessment of potential project impacts, including associated impact mitigation strategies, and project feasibility, should be incorporated into all active and future research activities as part of comprehensive facility governance procedures.

Project assessments should reflect the RBWH COVID-19 response planning and consider the potential implications of the current or evolving situation on the feasibility or prioritisation of clinical research, especially clinical trials or research embedded within clinical service delivery. Such considerations may include:

- Departmental priorities
- Availability of patients and families or participants who may be unable or unwilling to attend clinical research visits
- Clinical research, administration, and support staff unavailable to perform assessments or enrol and monitor patients
- Clinical staff in research positions re-called to perform clinical duties in the event of staff shortages or pandemic response
- Access to clinical space, administration and meeting rooms limited or restricted to provide essential services for the management of pandemic response
- Impact of the project delay or cessation on patients

The first part of **COVID-19 – Project Assessment and Adaptation** lists key information that will support clinical directors in considering whether changes are needed in the conduct of research.
This form should be completed for each project and provided to Heads of Department/ Clinical Directors.

Adaptation and Project Amendments

Key Points

- **RBWH HREC will support a rapid review process for COVID-19 related amendments. Wherever possible, decisions on amendments will be made within 48 hours of submission.**

Researchers should also consider novel approaches to the conduct of research and clinical trials, such as decentralised trials, tele -trials and hybrid models in which participants can be recruited and participate remotely and data can be captured via available technology. The second part of **COVID-19 – Project Assessment and Adaptation** prompts some considerations about study conduct and adaptation.
This planning should include:

- Assessment of the importance of and the risks associated with the research as designed or with necessary modifications, such as continuing in the current/proposed form, conducting the research activities in a modified form, suspending the research or ending the research.
- Assessment of the ability of participants to participate in the research activities in accordance with protocol requirements and consideration of alternative models for participation that would not compromise the integrity of the research.
- Assessment of the resources available for alternative models of research, including equipment and facilities for telehealth follow-up or remote data collection.

If a decision is made to alter the conduct of a study, investigators will need to decide if the change requires approval by the approving HREC. Some examples of changes requiring, or not requiring, HREC approval are provided below:
Examples of changes requiring approval:

- A material change to a protocol, for example:
    - A new element to the protocol e.g., new survey, additional tests
    - Reduction or increase in proposed recruitment
- Accessing personal information where this was not originally included

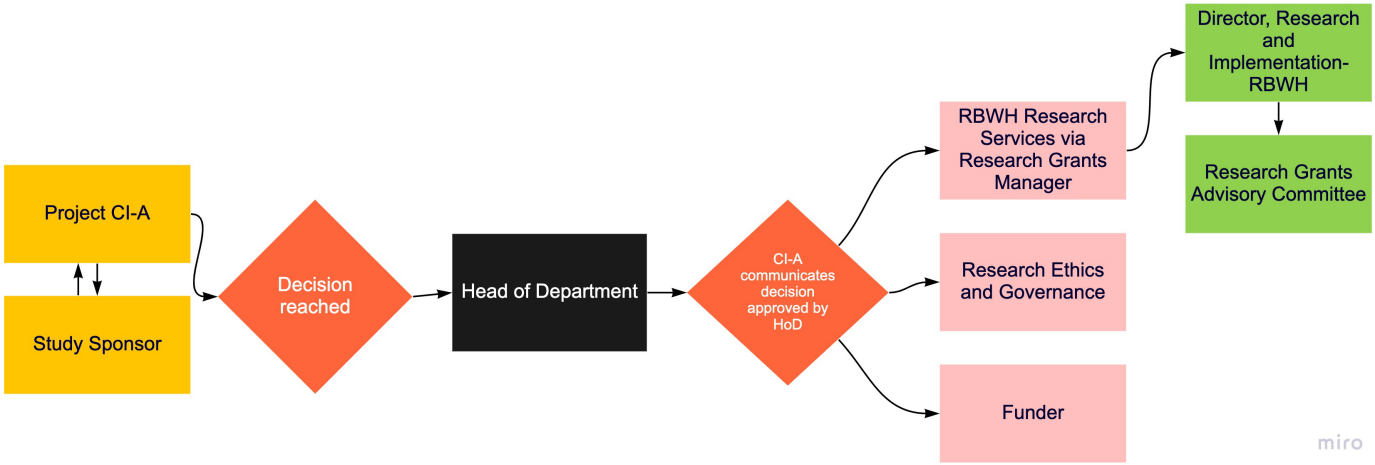
Examples of changes not requiring approval include:

- The use of telehealth approaches rather than in person approaches (if such changes are explained to participants)

- A change to a consenting process as long as the process is valid (i.e., the person has capacity, the consent is specific; the consent is informed; and the consent is voluntary). Note that where verbal consent is obtained, this should be recorded in medical records and where possible witnessed.
- Additional analysis of data for which consent was already provided.

Deciding to Pause Activity or Recruitment

In some cases, circumstances may mean that a decision is made, in consultation with sponsor, to pause recruitment or to pause all study activity. The chart below provides a guide to notification requirements if a decision is made to pause research activity.
If RBWH is the funder (Project Grant or Scholarship), you should also notify the RBWH Research Grants Manager, who will offer guidance on management of the award moving forwards.



Clinical Trial Monitoring

Key Points

- **All monitoring of clinical trials at RBWH should be performed remotely while we remain at Tier 2/3 level of response**
- **If there are exceptional circumstances which justify on-site monitoring activities, principal investigators will need to request an exemption from the above requirement**

Monitoring arrangements should be considered as part of the assessment of study procedures. It will often be possible for sponsor oversight responsibilities, including monitoring and quality assurance activities, to take place remotely. When possible, to reduce the number of visitors to the hospital campus during a period of visitor restrictions, a switch to remote monitoring would be encouraged.

If it is necessary for monitors to visit the hospital campus to undertake monitoring activities, they will need to abide by the relevant directives for contractors on hospital sites, including the need to be vaccinated.
In considering sponsor oversight of trials and studies, the leading principle must be to protect the rights, safety and well-being of trial participants. The European Medicines Agency articulate this in their guidance to conduct of trials in the context of COVID-19:

> *"…. a risk-based approach to monitoring should be taken, focusing on certain sites, certain data points and certain processes that are critical to ensure the rights, safety and well-being of trial participants and the integrity of the trial (and trial data). The sponsor should consider the extent and nature of monitoring that would be eligible in each specific trial under this exceptional situation, and weigh this against the extra burden that introduction of any alternative measures would put on site staff and*

facilities. The monitoring plan should then be revised in accordance with these considerations, in order to strike an acceptable balance between appropriate oversight and the capacity of the trial site."

Further Information and FAQs

Detailed guidance on the conduct of clinical trials is available from both the European Medicines Agency and the US Dept of Health and Human Services Food and Drug Administration (FDA). See the links below:

1. Conduct of Clinical Trials of Medical Products During COVID-19 Public Health Emergency (fda.gov)
2. EMA. 2020. Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic. Available at: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf