GUIDELINES FOR COMPLETING THE MQ HEALTH CLINICAL RESEARCH GOVERNANCE APPLICATION FORM

PROJECT RELATED INFORMATION

WHO IS CONDUCTING THE RESEARCH?

• *Is the Principal Investigator a Macquarie University staff member for indemnity purposes?*

Note: The Principal Investigator should be either be a staff member or an honorary. Some Honorary appointments are not automatically covered by the MQ insurance for the purposes of conducting of clinical research. Even if you have Macquarie OneID and email address, you might still not be eligible to conduct research. This information needs to be verified with the Macquarie insurance office.

If you don't have any Macquarie University appointment (either staff member or honorary), you are not covered for liability and insurance purposes and can't conduct research at MQU. Contact Clinical Research Manager at clinical.research@mqhealth.org.au to discuss this further.

• *Do the investigator/s have the necessary expertise and training to conduct clinical research (e.g. Good Clinical Practice (GCP) training, research expertise)?*

Good Clinical Practice *(*GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human participants. Compliance with this standard provides public assurance that the rights, safety and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

In Australia, we work under the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) annotated with Therapeutic Goods Administration (TGA) comments which details how Australia implements the international guideline. (Ref: UTAS http://www.utas.edu.au/research-admin/research-integrity-and-ethics-unit-rieu/clinical-trial-governance)

It is expected that all Principal/Chief Investigators of clinical trials will have GCP training.

ARE THERE ANY CONFLICTS OF INTEREST TO BE DECLARED?

Conflict of interest may arise from relationships, professional or personal with associated clinicians, medical companies or any other significant party involved in the research financially or otherwise.

If you are unsure how to answer this question, contact the Clinical Research Manager for help at: clinical.research@mqhealth.org.au or phone: +61 2 9850 2834.

WHAT IS THE PROJECT ABOUT?

You will need to determine if the project proposal is a clinical trial, non-clinical trial research, or Quality assurance or audit activity.

• For **investigator-initiated clinical trials or other clinical research projects**, the investigator should submit a project synopsis or full protocol, which includes a summary of the project and an estimate of budget using the MQ Health template.

There are several budget calculators specific to different funding schemes available on the Research Office website. You can use those as a guide to develop your budget.

https://www.mq.edu.au/research/research-opportunities-at-macquarie/funding-fellowships-and-partnerships/training-and-support

- If you need help with completing the budget section, you can seek advice from the Clinical Research Manager (clinical.research@mqhealth.org.au)

- For **fully sponsored clinical trials**, there is a simplified version of the Clinical Research Governance application form, which should be completed by the principal investigator or the Clinical Trials Unit.
- For help with sponsored clinical trial related budget, you should contact the Clinical Trials Unit at clinicaltrials@mq.edu.au
- You need to clearly indicate in the application form who the sponsor is and how many sites are involved.

RISK, INSURANCE AND DATA MANAGEMENT

WHAT IS THE LEVEL OF RISK OF THIS RESEARCH?

Risk assessment is an integral part of the institution/sponsor's responsibility to ensure the rights and safety of subjects taking part in clinical research are protected.

- *Does your research involve direct interaction with human participants?*

If the research involves direct interaction with human participants, the risk level of the project will be determined by the Clinical Research Executive during the governance assessment process.

- *How many participants are you intending on recruiting at the Macquarie University site and how many overall for the project (if multisite study)?*

It is very important to provide the anticipated number of participants which you are planning to recruit at Macquarie University Hospital or Clinics, as his will inform the risk assessment for your project.
The overall number of participants for multisite studies is required for insurance purposes.

INSURANCE

If your project involves any of the below categories, it will require additional insurance risk assessment:

- o First-in-human Phase 1 trial;
- o Medical intervention on pregnant women;
- o Children 5 years of age or under;
- o Interventions involving blood plasma or whole blood products and exchange, apart from simple blood collection;
- o Clinical trial which is to be undertaken outside of Australia;

The additional risk assessment is conducted by the University insurance team and will involve request for a specific study related documentation.

DATA COLLECTION, ACCESS AND STORAGE

- o Data collection, storage, access and management are integral part of any research project. In your application, you need to make it clear how are you going to collect or access the data, where are you going to store it and how will you keep it secure.

o If you intend on collection of sensitive patient data **directly** from the patients, you need to ensure you have relevant permissions to access the patient pool and have patient consent in place.

o If you are planning to access stored medical information (database) of individual participants for your research project, you will need to seek a permission from the custodian (the owner) of the database.

Tip: An important aspect to check is, if the patients have consented for the use of their medical information for research purposes.

o If you are accessing **stored tissue samples**, it is important to seek permission from the custodian of the tissue sample collection, e.g researcher, Head of Department, CEO of the hospital.

o Refer to Macquarie University research data management toolkit at https://staff.mq.edu.au/research/project-management/systems-and-data-management for detailed guidance on research data planning and management.

Informed consent by research participants is essential for the collection, use and sharing of sensitive data. Storage, access, de-identification and plans for sharing are very important considerations.

The Australian National Data Service (ANDS) have developed and made available the following Health and Medical data resources

- ANDS Health and Medical data resources

- ANDS Publishing and Sharing Sensitive Data Guide

- ANDS Data Sharing Considerations for Human Research Ethics Committees Guide

- ANDS De-identification Guide

- 10 Health and Medical Research Data Things

- ANDS Health and Medical YouTube playlist

FUNDING AND MQ HEALTH RESOURCES

BUDGET AND RESOURCING
For the smooth running of your research project, you will need to have enough funding available. Any project involves some cost. It might be direct (e.g. consumables, equipment) or indirect (e.g. staff time, IT support).

This could be from a grant, fellowship, industry sponsorship, pharmaceutical industry, etc. For the purposes of the governance assessment, you need to provide any sources of funding (if more than one) and the total amount of money available.

If you haven't obtained any funding, you need to explain how are you going to cover the costs of running of the project.

There are several budget calculators specific to different funding schemes available on the Research Office website. You can use those as a guide to develop your budget.

https://www.mq.edu.au/research/research-opportunities-at-macquarie/funding-fellowships-and-partnerships/training-and-support

WILL THE PROPOSED RESEARCH USE ANY MQ HEALTH FACILITIES AND RESOURCES?

If you require any hospital, clinic or laboratory space or resources for the conduct of your research project, you will need to describe what these resources are and obtain approval from the relevant Head of Department or Clinical Program Head.

- *Will research subjects be admitted to the **Macquarie University hospital** for the purposes of the study?*

If the answer to this question is yes, you need to indicate how many people is estimated to be admitted to MUH and to contact the Patient Services Manager at Ben.Lewis@muh.org.au and estimates@muh.org.au for estimate of hospital charges.

- *Will hospital employees be utilised in collecting research data or conducting other research activities?*

If you answered yes, you need to provide details about estimate hours of nurse or allied health staff time, or any other relevant information. This is essential for resource and workload allocation purposes.

- *Will any other resources located in the hospital be used, e.g. operating room, equipment, storage space, Macquarie Medical Imaging (MMI), etc.*

Please specify.

- *Who from the Macquarie University Hospital or MMI (if applicable) was this discussed with? Please provide names.*

You need to provide a list what hospital resources that will be required for your project and the people you have discussed your needs.

- *Are there any other clinical resources to be used, e.g. MUCA clinics? Please list them below.*

If you need to use any of the Clinics, e.g. Eye clinic, GP clinic, you need to indicate what kind of resources you will require.

- *List the resources of the **Faculty of Medicine and Health Sciences** that will be used (if applicable), e.g. PC2 laboratory access, equipment, consumables, etc.*

To address this question, you will need to describe what type of work you are proposing to do in the laboratory, the volume of the work, how often, how long, and what equipment and consumables you will require. Please note: to access the PC2 lab space, you will need to undergo a general laboratory induction. For more details about the lab induction and for planning of lab related work, please contact the lab operations team at: lab.operations@mq.ed.au