**Clinical Research Governance Application form**

**Investigator-Initiated Clinical Trial (IICT) – MQ as sponsor or MQ as a site**

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| The purpose of this form is to capture the governance aspects of your proposed Investigator-Initiated Clinical Trial (IICT). Governance review should be undertaken before you seek ethics approval. Researchers must refer to the [MQ IICT webpage](https://mqoutlook.sharepoint.com/sites/MQHealth/CR/Shared%20Documents/CRE%20reviews/Forms%20and%20templates/Application%20forms/3dmorphichttps%3A/staff.mq.edu.au/research/resources-and-support/fmhs-research-resources/clinical-research-governance/governance-for-maquarie-sponsored-investigator-initiated-clinical-trials-iicts) prior to completing the application for guidance on completion of relevant documentation. You can find the application form and PI agreement form on this webpage. The Principal Investigator needs to complete the IICT application form, obtaining **all relevant signatures**. Please submit the application form, the clinical trial protocol, signed MQ PI agreement, CVs, and copies of current Good Clinical Practice (GCP) certificates for the PI and the research team, along with any other supporting documentation relevant to the project in the one project submission to: clinical.research@mqhealth.org.au. |

**Trial information:**

*Please provide a brief but complete answer to each question and supply all support documentation as required.*

1. **My trial is: Select type:**

**Where MQ is a site:**

* 1. **Please provide the name of the sponsor of the clinical trial**

*(eg:* ***Commercial, Institutional, Collaborative Group or Cooperative Research****)*

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* 1. **Has your research been scientifically reviewed?**

[ ]  Yes *(if yes, please submit the review documents with your application submission)* [ ]  No

1. **Please indicate the type of trial - drug or device: Select trial type**  ***Other:***
2. **Please indicate the phase: Select the phase**
3. **If phase 0/I is selected, list PI’s relevant qualifications/research experience for leading this IICT**

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|  **Click to enter date.**  |

1. **Anticipated start date of the clinical trial**
2. **Clinical trial title**

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1. **Principal Investigator (PI) name and contact details**

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| Title | **Select your title:** | ***Other:*** |
| First name: |  |
| Surname: |  |
| MQ One ID: |  |
| Position: |  |
| Clinical program or FMHHS department: | **Select your clinical program:** ***Other:*** |
| MQ Health clinical discipline  | **Select your clinical discipline:** ***Other:*** |
| Type of Macquarie University affiliation | **Select your appointment:** **Select your Macquarie affiliation:** ***Other:*** |
| Macquarie Email:  |   |
| Phone No: |  | Mobile No: |  |
| Qualifications and clinical research experience **relevant to this trial:**  |

***Please note:*** *A Macquarie University affiliation (staff or honorary of FMHHS, or staff of MQ Health Pty Ltd) is required for all activities, for liability and insurance purposes.* ***Hospital accreditation is not sufficient; an honorary appointment with the FMHHS is required.***

* 1. **Name, appointment, and contact details of Co-Investigator/s.** (*Insert rows as required)*

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| **Full name** |  **Macquarie affiliation** |  **Email** | **Mobile No.** |
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1. **Are there any conflicts of interest to be declared?** (*e.g.,* ***professional or personal relationships with associated clinicians, medical companies or any other significant party involved in the research financially or otherwise?****)*(If you are uncertain, please contact clinical.research@mqhealth.org.au)

[ ]  Yes *(if* ***YES****, please provide details below).* [ ]  No

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**Risk, insurance, and data management**

1. **What type of site will be involved in the trial? Select a site category:**
2. **If multi-site, is Macquarie University the lead site?**

[ ]  Yes [ ]  No

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1. **How many participants do you intend to recruit at the Macquarie University site?**

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1. **If a multi-site study, how many participants are intended to be recruited** **overall?**
2. **For insurance purposes, please indicate if your research is: Select a research category:**

***Note:*** *Any of the above categories listed will require additional insurance risk assessment. The Clinical Research Manager will contact you directly to request further documentation as required.*

1. **Please confirm the named sponsor is responsible for the clinical trials insurance and covers Macquarie University as a site.**

[ ]  Yes [ ]  No

1. **Does the study require administration of unapproved radiopharmaceuticals or radiopharmaceutical active ingredients (RAI)?**

[ ]  Yes *(If yes, please provide details below for* ***each tracer/RAI*** *- insert rows as required)*[ ]  No

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| Name of unapproved tracer/RAI: |  |
| Name of SUPPLIER of tracer/RAI: |  |
| Confirmation of supplier agreement with MMI: ***(Confirmation email from Marg Pardey or MMI delegate for each tracer/RAI must be sent with the application).*** |  |

1. **Please explain how you intend to collect confidential patient data or access stored samples/stored medical information of individual patients for this research project.** *Please provide details of* ***where*** *(eg. location) and* ***how*** *data/samples will be stored. If you are accessing a database or samples,* ***describe below how you will obtain access***

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**Funding and MQ Health resources**

1. **Do you have funding for your trial?**

[ ]  Yes *(please provide details of* ***funding sources and total amount****)*

[ ]  No *(please details of how you* ***plan to cover the costs of running the trial?****)*

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1. **Will research subjects be admitted to Macquarie University Hospital for the purposes of the study?**

[ ]  Yes [ ]  No

1. **Will any other MQ Health resources be used?**

[ ]  Yes[ ]  No

*(If* ***YES****, provide details,* ***e.g., MUH operating rooms, wards, equipment, MQ Health clinic consulting rooms, Macquarie Medical Imaging (MMI) facilities, etc****.)* ***Note: Sign off from relevant Head or delegate respectively is required.***

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1. **Will any resources of the Faculty of Medicine, Health and Human Sciences be used?**

[ ] Yes *(If* ***YES****, please provide details, e.g.,* ***PC2 laboratory access, equipment.****)*[ ]  No

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**Principal Investigator declaration**

[ ]  I declare that all information provided in this application and relevant attachments is true and correct.

[ ]  I have read and I am familiar with the requirements of the [Australian Code for the Responsible Conduct of Research (2018)](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018), the [Macquarie Code](https://staff.mq.edu.au/work/strategy-planning-and-governance/university-policies-and-procedures/policies/responsible-conduct-of-research) and the [National Statement on Ethical Conduct in Human Research (2018)](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018).

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| **Principal Investigator Name** | **Signature** | **Date** |
|  |  | **Click to enter date.** |

**Clinical Program Head/Head of Department (FMHHS) or delegate declaration**

[ ]  I confirm that I am comfortable with this clinical trial being done within my Clinical Program and that there are the necessary space and resources available for the work.

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| **Name of Clinical Program Head/ Head of Department (FMHHS),** **or delegate respectively** | **Signature** | **Date** |
|  |  | **Click to enter date.** |

**Will any MQ Health nursing or allied health staff help collect research data or conduct other research activities related to the clinical trial? *Routine clinical care is excluded.***

[ ]  Yes [ ]  No

*(If* ***YES****, please provide details, e.g.,* ***estimate hours of nurse or allied health staff time, etc.)***

***Note: Sign off from Nursing Line Manager or Director of Allied Health, or*** ***delegate respectively, is required.***

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**Nursing Line Manager or Director of Allied Health or delegate declaration**

[ ]  I confirm I am comfortable with nurses/allied health staff being involved in this clinical research project.

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| **Name of Nursing Line Manager,** **or Director of Allied Health, or delegate respectively** | **Signature** | **Date**  |
|  |  | **Click to enter date.** |

***Note:*** *If your project involves the use of any other MQ Health units or facilities not mentioned above, additional sign-off may be required**. Please contact the Clinical Research Team for further guidance:* *clinical.research@mqhealth.org.au**.*

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| **Name of other MQ Health Unit Head, or delegate respectively** | **Signature** | **Date** |
|  |  | **Click to enter date.** |

**PI document submission checklist:**

[ ]  Completed and signed MQ Health Clinical Research Governance IICT application form

[ ]  Complete and signed [MQ IICT PI agreement](https://staff.mq.edu.au/research/resources-and-support/fmhs-research-resources/media-and-documents/IICT-Principal-Investigator-Agreement.pdf) where MQ is a sponsor or a site

[ ]  Clinical trial protocol

[ ]  Itemised study budget/funding information *(if applicable*)

[ ]  Investigator brochure (*if relevant*)

[ ]  Current CVs for the PI and the research team

[ ]  Current GCP certificates for the PI and the research team

[ ]  Scientific review documentation if MQ is a site

[ ]  Any other supporting documentation relevant to the project