

**Clinical Research Governance Application form (fully sponsored clinical trials only)**

*This form is for* ***fully sponsored*** *clinical trials only and is to be completed by the Clinical Trials Unit (CTU) and emailed to* *clinical.research@mqhealth.org.au*, *with the project synopsis or full protocol for review.*

**Trial information**

1. **Trial title and protocol number**

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1. **Clinical trial phase: Select your clinical trial phase:**

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| ***Other:*** |

1. **Disease type**: **Select the disease type:**
2. **Principal Investigator (PI) name and contact details**

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| Title: | **Select your title:** | ***Other:***  |
| First name: |  |
| Surname: |  |
| MQ Staff no. |  |
| Macquarie University position and affiliation | **Select your appointment:** **Select your Macquarie affiliation:** ***Other:*** |
| Macquarie email:  |   |
| Phone no: |  | Mobile no: |  |
| **Relevant** qualifications and clinical research experience: |

***Please note:*** *A Macquarie University affiliation (staff or honorary of FMHHS, 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. **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 the Clinical Research Manager to discuss *+61-2-9850-2834*).

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

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

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**Risk, insurance, and data management**

1. **What type of site will be involved in the research? 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. **Does the study** **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 Margery (Marg) Pardey or MMI delegate for each tracer/RAI).* |  |

**MQ Health resources**

1. **Will any MQ Health resources outside the CTU standard resource arrangements** **be used** ***(e.g., extra PC2 laboratory space, Macquarie Medical Imaging (MMI) facilities, extra MQ Health clinic consulting rooms, MUH operating rooms, wards etc.)? Note: Sign-off from relevant Head or delegate respectively is required.***

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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), the Macquarie Code and the National Statement on Ethical Conduct in Human Research (2018).

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

**Clinical Trials Director or delegate declaration**

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

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| **Name CTU Director, or delegate respectively**  | **Signature** | **Date** |
|  |  | **Click to enter date.** |

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

[ ]  Yes *(if* ***YES****, please provide details, e.g.* ***estimate hours of nurse or allied health staff time)*** [ ]  No

***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 that 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.** |