|  |  |
| --- | --- |
| **Office Use Only** | |
| Ref. No. |  |
| Rec. Date |  |
| Rec. By |  |

# Mater Health Services Site-Specific Assessment (SSA) Form

Site-Specific Assessment (SSA) is a key component of research governance and involves assessment of the suitability of the site and the Investigator(s) for the proposed research. The SSA is the mechanism for professional, legal and financial accountability and transparency and is consistent with the NHMRC’s “Australian Code for the Responsible Conduct of Research” 2007 (the Code).

**The SSA process considers the following elements of Research Governance:**

* Ethical Approval
* Compliance with legislation, regulations, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, biosafety, radiation safety and professional standards.
* Financial management and site-specific requirements (adequate resources - financial, human, equipment and infrastructure) for the research to proceed at the site
* Legal and Insurance – consent, indemnity and contracts
* Researchers have the necessary expertise and experience; if not relevant training is planned before carrying out their research study
* Monitoring of research throughout the life of the project

**Instructions for the Principal Investigator:**

* This form must be completed by the Principal Investigator (PI) responsible for the research project at this site.
* Applicants should begin negotiations with relevant Mater Health Services (MHS) personnel responsible for resources that will be required for the study, e.g. Heads of Departments or Managing Accountant, as early as possible.
* The completed form must be submitted to the Mater Research Governance Office for review prior to final Authorisation by the Mater Health Services Chief Executive Officer or delegate, before the research can begin.
* All aspects of the form are to be completed and the required associated documents attached.
* The checklist on the back of the SSA form must be reviewed prior to submission and will assist to ensure a full submission is completed before forwarding to the Mater Research Governance Office.

**Please note** – this form is designed to be completed in Microsoft Word and includes selectable tick boxes and dropdown options. Textboxes will expand as necessary.

This form is based on the Queensland Health SSA Form.

Components of the SSA form

**Note:** This table of contents may be used to link directly to a specific section of the SSA form. However, all sections of the form must be completed.

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[3. Research team 6](#_Toc417553992)

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[11. Clinical trials information 16](#_Toc417554027)

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[13. Indemnity and insurance 18](#_Toc417554037)

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## 1. Project details

### 1.1 Formal title of research project:

|  |
| --- |
| Click here and replace text with project title. |

### 1.2 Short title/acronym of research project (if applicable):

|  |
| --- |
| Click here to enter text. |

### 1.3 Mater Research Hub Project ID (e.g. MR-2015-xx):

|  |
| --- |
| Click here to enter text. |

### 1.4 Name of Human Research Ethics Committee (HREC) reviewing the research project:

|  |
| --- |
| Click here to enter text. |

### 1.5 HREC application reference number:

|  |
| --- |
| Click here and replace text with HREC Reference Number. |

**1.6 Review type (as determined by the reviewing HREC):**

|  |
| --- |
| Choose an item. |

**1.7 Mater sites at which the research project will be undertaken (select all that apply):**

|  |  |
| --- | --- |
| Mater Hospital Brisbane | Mater Private Hospital, South Brisbane |
| Mater Children’s Private Hospital, South Brisbane | Mater Private Hospital, Redlands |
| Mater Mothers’ Hospitals, South Brisbane | Mater Research, South Brisbane |
| Mater Research, Translational Research Institute | Other |

### If Other, please provide details:

|  |
| --- |
| Click here to enter text. |

1.8 Is this a single site or multi-centre study?

|  |
| --- |
| Choose an item. |

**1.9 Non-Mater Sites: List all locations at which study-related activities are conducted. Please indicate activity at each site. E.g. Recruitment only, data collection**

|  |
| --- |
| Click here to enter text. |

### 1.10 Mater Research Theme/Centre to which this research project belongs (select one only):

*If you are unsure about which Theme you or your project belong to, please contact the* [*Research Development Team*](mailto:research.development@mater.uq.edu.au)*.*

|  |
| --- |
| Choose an item. |

### 1.11 Select study type:

|  |
| --- |
| Choose an item. |

## 2. Lay summary

Provide a brief description (half page) of the aims and methods of the research project, including the nature of the research project at Mater. Include information on how the conduct of this research will impact on the Mater site (department or service) and the resources required.

|  |
| --- |
| Click here to enter text. |

## 3. Research team

### 3.1 Research personnel relevant to Mater

Provide details below for each researcher involved with the conduct of the research project at this site. This includes anybody who will be accessing the Mater participants’ data or Mater resources.

All research personnel involved with the research at Mater must sign the SSA form (see [Section 16a](#_a)_Declaration_by)).

***Note: Space has been provided for up to nine (9) researchers. If your study involves additional research personnel please download the “Additional research personnel” template from the Research Governance*** [***webpage***](http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee/HREC-and-RGO-Resources)***.***

a) Principal Investigator at Mater site

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | |
| Full Name: | | | | | Click here and replace text with full name of Mater Principal Investigator | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | | |  | |  |
| **Clinical staff only:** | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  |  | |  |  |

b) Other research personnel relevant to Mater

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

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| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

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| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

### 

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Project Role: | | | | | Choose an item. | | | | | | | | | |
| Title: | | | | | Choose an item. | | | | | | | | | |
| Full Name: | | | | | Click here to enter text. | | | | | | | | | |
| Position: | | | | | Click here to enter text. | | | | | | | | | |
| Department: | | | | | Click here to enter text. | | | | | | | | | |
| Organisation: | | | | | Click here to enter text. | | | | | | | | | |
| Mailing Address: | | | | | Click here to enter text. | | | | | | | | | |
| Phone: | | | | | Click here to enter text. | | | | | | | | | |
| Email: | | | | | Click here to enter text. | | | | | | | | | |
| Qualifications (relevant to this project): | | | | | Click here to enter text. | | | | | | | | | |
| Key responsibilities in project: | | | | | Click here to enter text. | | | | | | | | | |
| *A CV for each researcher must be provided with your application, unless a CV has been provided to the Research Governance Office in the past 2 years.* | | | | | | | | | | | | | | |
| Is a (short) CV attached? | | | | Yes | | | | N/A | |  | | |  | |
| **Clinical staff only:** | | | | | | | | | | | | | | |
| Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study? | | | | | | | | | | | | | | |
|  |  | Yes | No | | | N/A |  | |  | |  |  | |  |

### 3.2 Project Contact Person at Mater:

The PI will be responsible for ensuring there is a contact person (Mater Sponsor) at the site who will liaise with the site Research Governance Officer. The contact person may be the PI or a person nominated by the PI however they must be located at Mater.

**Please complete the table below if the contact person is not already listed in section 3.1.**

**If the details of the contact person have been completed in section 3.1, enter their name here:**

|  |
| --- |
| Click here to enter text. |

|  |  |
| --- | --- |
| Title: | Choose an item. |
| Full Name: | Click here to enter text. |
| Position: | Click here to enter text. |
| Department: | Click here to enter text. |
| Organisation: | Click here to enter text. |
| Mailing Address: | Click here to enter text. |
| Phone (Work): | Click here to enter text. |
| Phone (Mobile): | Click here to enter text. |
| Email: | Click here to enter text. |

### 

**Optional: If the project has a coordinator/contact person who is external to Mater who should be included in correspondence about the application, provide their details below.**

|  |  |
| --- | --- |
| Title: | Choose an item. |
| Full Name: | Click here to enter text. |
| Position: | Click here to enter text. |
| Department: | Click here to enter text. |
| Organisation: | Click here to enter text. |
| Mailing Address: | Click here to enter text. |
| Phone (Work): | Click here to enter text. |
| Phone (Mobile): | Click here to enter text. |
| Email: | Click here to enter text. |

### 3.3 Additional information required for studies involving non-Mater researchers and/or students:

|  |  |
| --- | --- |
| a) Will non-Mater researchers be accessing the Mater site for purposes of this research? | |
| Yes | No |
| If yes, please provide details: | |
| Click here to enter text. | |
|  | |
| b) Will non-Mater researchers be approaching Mater participants for purposes of this research (e.g. providing project-related information, undertaking informed consent procedures)? | |
| Yes | No |
| If yes, please provide details: | |
| Click here to enter text. | |
|  | |
| c) Will non-Mater researchers be accessing identifiable or re-identifiable Mater participant data? | |
| Yes | No |
| If yes, please provide details: | |
| Click here to enter text. | |
|  | |
| d) Will non-Mater researchers be storing identifiable or re-identifiable Mater participant data at a non-Mater site? | |
| Yes | No |
| If yes, please provide details: | |
| Click here to enter text. | |
|  | |
| e) Are students involved in the conduct of this research at the Mater site? | |
| Yes | No |
| If yes, please provide details for each student (including student name/s, supervisor/s, name of university (and course) the student is enrolled in, and student qualifications): | |
| Click here to enter text. | |

### 3.4 Training

a) Will any of the researchers at Mater require extra training to enable their participation in this project?

|  |  |
| --- | --- |
| Yes | No |

If yes, complete the table below.

|  |  |  |
| --- | --- | --- |
| Researcher | Training required | Who will provide training? |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

b) Are any members of the research team certified in Good Clinical Practice (GCP)?

|  |  |
| --- | --- |
| Yes | No |

If yes, complete the table below.

|  |  |  |
| --- | --- | --- |
| Researcher | Level of GCP training  (e.g. Online course, half-day course, 2-day course etc.) | Year training was undertaken? |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Click here to enter text. |

## 4. Recruitment

### 4.1 Participants

a) Does this project require prospective recruitment of human participants at Mater?

|  |  |
| --- | --- |
| Yes | No |

If yes, what is the proposed number of participants to be recruited at Mater?

|  |
| --- |
| Click here to enter text. |

b) Does this project use existing collections of retrospective clinical data?

|  |  |
| --- | --- |
| Yes | No |

If yes, what is the planned number of Mater patient records to be reviewed?

|  |
| --- |
| Click here to enter text. |

### 4.2 Recruitment process

a) What process will be used to identify potential participants at Mater?

|  |
| --- |
| Click here to enter text. |

b) How will initial contact be made with potential participants at Mater?

|  |
| --- |
| Click here to enter text. |

## 5. Vulnerable participant groups at Mater

### 5.1 Participant details

a) At Mater, does the study include recruitment of participants whose primary language is other than English (LOTE)?

|  |  |
| --- | --- |
| Yes | No |

If yes, are the costs for interpreter services included in the study budget?

|  |  |
| --- | --- |
| Yes | No |

b) At Mater, does the study include recruitment of women who are pregnant and the human foetus?

|  |  |
| --- | --- |
| Yes | No |

c) At Mater, does the study include recruitment of children and/or young people (i.e. <18 years)?

|  |  |
| --- | --- |
| Yes | No |

d) At Mater, does the study include recruitment of people with a cognitive impairment, an intellectual disability or a mental illness?

|  |  |
| --- | --- |
| Yes | No |

**5.2 Research involving adults with impaired capacity to consent** Where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken.

For further information please refer to the [Queensland Civil and Administrative Tribunal website.](http://www.qcat.qld.gov.au/using-qcat/forms)

### Does this study involve adults with impaired capacity to consent?

|  |  |
| --- | --- |
| Yes | No |

### 5.3 Research into the health of Indigenous Australians

If the study involves recruitment of Aboriginal and Torres Strait Islander people at Mater (including coincidental recruitment), have the researchers had relevant community engagement with Aboriginal and Torres Strait Islander individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results for this study, and/or consulted with the Australian and Torres Strait Islander Liaison Officer/s at Mater?

|  |  |  |
| --- | --- | --- |
| Yes | No | N/A |

Provide an explanation.

|  |
| --- |
| Click here to enter text. |

### 5.4 Research involving access to coronial material

Research involving access to coronial material must be referred to the Queensland Health Forensic and Scientific Services Human Ethics Committee (FSS-HEC) for ethical and legal approvals. This also applies to clinical research projects where there is a component involving coronial material. In this context, examples of coronial material include tissues from coronial autopsies, slides and blocks, blood samples, autopsy reports and other documents and data relating to coronial autopsies.

For further information please refer to [Accessing Coronial Materials for Research](http://www.health.qld.gov.au/hsq/research/coronial-materials.asp).

Does this study require access to coronial material?

|  |  |
| --- | --- |
| Yes | No |

## 6. Access to confidential information

If researchers require access to confidential information (e.g. patient records, databases, departmental records) to conduct their research then approval must be obtained from Mater Health Information Services Privacy Office. This is to determine whether the project complies with all Privacy Laws and that the data required for the study is collected and accessible for the research project.

**Please note:** Approval from the Privacy Office is required even if the information required for the purpose of the research is readily available to the researchers for clinical purposes.

Instructions on how to obtain Privacy Office Approval are provided on the [Mater Research Governance Webpage](http://www.mater.org.au/Home/Research/Human-Research-Governance).

Please contact the Mater Contact/Sponsor or the [Research Governance Office](mailto:research.governance@mmri.mater.org.au) for further details.

### Does this project require access to confidential information held by Mater Health Services?

|  |  |
| --- | --- |
| Yes | No |

If No, please give an explanation:

|  |
| --- |
| Click here to enter text. |

## 7. Compliance with requirements of a Catholic organisation

All policies are accessible to Mater staff from the [Mater Document Centre](http://quality.mater.org.au/docs/default.aspx).

Researchers external to Mater should liaise with their Mater Contact/Sponsor for a copy of relevant policies.

Please note: A selected number of Mater research policies are available on the [Mater Research Governance Webpage](http://www.mater.org.au/Home/Research/Human-Research-Governance).

### 

### Does the research comply with requirements of the [Catholic Health Australia "Code of Ethical Standards for Catholic Health and Aged Care Services in Australia" 2001](http://www.cha.org.au/code-of-ethical-standards.html), particularly regarding the following types of research?

### (i) Use of embryos in human research

### (ii) Clinical trials where pregnancy must be avoided

### For further information regarding acceptable wording in participant information and consent forms (PICF) suggested by Mater, please refer to the PICF guidelines available on the [Mater HREC and Research Governance Office Resources Webpage](http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee/HREC-and-RGO-Resources) .

|  |  |
| --- | --- |
| Yes | No |

If No, please give an explanation:

|  |
| --- |
| Click here to enter text. |

## 8. Timeline

### Provide the anticipated start and finish dates for the research project at Mater.

|  |  |
| --- | --- |
| Recruitment start date\* : | Click here to enter text. |
| Finish date#: | Click here to enter text. |
| Duration (Months): | Click here to enter text. |

\*Start date refers to the anticipated first point of recruitment i.e. the date when the advertising or screening for participants begins, or first access to data.

#Finish date refers to the date when no further contact with participants/data source, including data analysis and reporting period, is foreseen.

## 9. Resource and budget information

### Instructions for researchers:

Mater may incur costs in providing support for your research over and above those costs associated with standard care. Any additional routine care costs to be met by Mater are to be clearly identified and detailed. This includes both the ‘actual monetary’ costs and ‘in kind’ support.

**Confirmation of cost estimates, and agreement as to a funding source, is to be provided by the Managing Accountant in the first instance before approvals are obtained from the Head/s of Department/s and Executive Director/s of the relevant hospital/s and/or support service.**

### 9.1 Departments and services involved in the research project at Mater

A signed declaration from the Head of Department must be attached with a completed SSA before Authorisation to begin the research project is given (see [Section 16b](#_b)_Declaration_by)).

|  |  |
| --- | --- |
| **Department/location** | **Name of responsible person contacted** |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |

### 9.2 Funding source/s

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of funding** | **Name of funding organisation/source** | **Amount for this site (either $/year or $/participant)** | **Sought or Approved** |
| Overseas sources | Click here to enter text. | Click here to enter text. | Choose an item. |
| Business (commercially sponsored) | Click here to enter text. | Click here to enter text. | Choose an item. |
| Private Non-profit Organisations (e.g. collaborative groups) | Click here to enter text. | Click here to enter text. | Choose an item. |
| Donations/Bequests | Click here to enter text. | Click here to enter text. | Choose an item. |
| Australian Government (e.g. NHMRC, ARC) | Click here to enter text. | Click here to enter text. | Choose an item. |
| Joint Business/Government | Click here to enter text. | Click here to enter text. | Choose an item. |
| Non QLD state/local government | Click here to enter text. | Click here to enter text. | Choose an item. |
| University | Click here to enter text. | Click here to enter text. | Choose an item. |
| Other QLD Government Department (e.g. Treasury) | Click here to enter text. | Click here to enter text. | Choose an item. |
| Internal Institutional Competitive Research Grants | Click here to enter text. | Click here to enter text. | Choose an item. |
| Internal Department Funds | Click here to enter text. | Click here to enter text. | Choose an item. |
| Other Australian Sources | Click here to enter text. | Click here to enter text. | Choose an item. |
| Other (e.g. Researcher Self-Funded) | Click here to enter text. | Click here to enter text. | Choose an item. |

### 9.3 Study budget (site-specific)

Instructions for researchers:

* Document only those items which are above the usual standard care and are particular to the research study, e.g. extra documentation, extra tests.
* If actual monetary costs are involved, dollar values are to be supplied. If seeking in-kind support, please provide details of resources required, e.g. Mater investigator time, time of any other Mater staff involved (e.g. as participants), use of infrastructure, administrative support.
* The monetary costs need to be covered by a funds source /s which may be an existing source or new funds.
* If required by the RGO, attach the relevant site-specific departmental budgets.
* **Please provide quotes from any department/s which may be supplying services.**

Note: If a budget item does not fit under any of the categories listed in the first column, please choose the “Other” option at the bottom of the table and complete the relevant details.

**If a detailed budget worksheet has already been prepared for the Mater site, this may be attached to the application instead of completing Section 9.3. If the budget is provided as an attachment please ensure that any requested ‘in kind’ support is listed below.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item/s** | **Budget for the site ($ where appropriate, or relevant details)** | **In kind costs** | **Cost covered by sponsor or funder** |
| Supply of drugs and/or other therapies | Click here to enter text. | Yes No | Yes No |
| Radiology  *(e.g. MRI brain scan x 10)* | Click here to enter text. | Yes No | Yes No |
| Pathology  *(e.g. 4 x venepuncture per patient x 10 patients)* | Click here to enter text. | Yes No | Yes No |
| Pharmacy | Click here to enter text. | Yes No | Yes No |
| Diagnostics – other  *(e.g. 3 x ECGs per patient x 10 patients)* | Click here to enter text. | Yes No | Yes No |
| Principal Investigator  *(e.g. 3 hours/patient, and corresponding $ value if known)* | Click here to enter text. | Yes No | Yes No |
| Co-investigators  *(e.g. 6 hours/patient, and corresponding $ value if known)* | Click here to enter text. | Yes No | Yes No |
| Clinical Study Coordinator  *(e.g. 16 hours/fortnight, and corresponding $ value if known)* | Click here to enter text. | Yes No | Yes No |
| Administrative Support | Click here to enter text. | Yes No | Yes No |
| Other Infrastructure  *(E.g. computers, printing, office space, stationery etc.)* | Click here to enter text. | Yes No | Yes No |
| Use of Equipment | Click here to enter text. | Yes No | Yes No |
| Patient Travel and Accommodation Costs | Click here to enter text. | Yes No | Yes No |
| Staff Travel and Accommodation Costs | Click here to enter text. | Yes No | Yes No |
| Archiving | Click here to enter text. | Yes No | Yes No |
| Other, please state:  Click here to enter text. | Click here to enter text. | Yes No | Yes No |
| Other, please state:  Click here to enter text. | Click here to enter text. | Yes No | Yes No |
| Other, please state:  Click here to enter text. | Click here to enter text. | Yes No | Yes No |
| **TOTAL** | Click here to enter text. |  |  |

If costs are not covered by the sponsor or funding body please explain how the costs will be covered or explain how Mater will benefit from this research.

|  |
| --- |
| Click here to enter text. |

### 9.4 Finance authorisation

Confirmation of cost estimates, and agreement as to a funding source, is to be provided by the Managing Accountant in the first instance beforeapprovals are obtained from the Head/s of Department/s and Executive Director/s of the relevant hospital/s.

Cost allocations and sources as described within the SSA form have been agreed by:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Managing Accountant Name |  | Signature |  | Date |
|  |  |  |  |  |
|  |  |  |  |  |
| Principal Investigator Name |  | Signature |  | Date |

## 10. Funds management

### Where the research is funded, Mater has a responsibility to ensure appropriate financial management processes are in place. Additionally, the site PI must have a Mater cost centre set up for the study.

### 10.1 Cost centre details

|  |  |
| --- | --- |
| Mater/Mater Research Cost Centre Code | Click here to enter text. |

### 10.2 Externally managed funding

### Complete Section 10.2 only if the research project is funded by external sources and funds are not being managed by Mater. If not applicable to the study, continue to [Section 11.](#_131._Clinical_trials)

a) Name the organisation administering the funding:

|  |
| --- |
| Click here to enter text. |

b) Explain the process for funds management at Mater (i.e., funds to be paid in regular instalments OR Mater will be required to raise invoices. If the latter, how often will this occur.) Has this process been discussed with the relevant Mater Management Accountant?

|  |
| --- |
| Click here to enter text. |

## 11. Clinical trials information

### 11.1 Is the study a clinical trial?

|  |  |
| --- | --- |
| Yes | If yes, please complete this section |
| No | If no, please proceed to [Section 12](#_124._Research_study) |

### 11.2 Select the study phase

|  |
| --- |
| Choose an item. |

### 11.3 Is the research project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?

|  |  |  |
| --- | --- | --- |
| CTN | CTX | N/A |

Attach the relevant TGA form (with relevant sections signed by the Principal Investigator and HREC chair) for CEO/Research Delegate authorisation.

### 11.4 Clinical trials registry

Section 19 of the [Declaration of Helsinki (2008)](http://www.wma.net/en/30publications/10policies/b3/17c.pdf) states:

**“*Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.”***

In addition, it is an essential criterion for publication of a trial in journals of the [International Committee of Medical Journal Editors (ICMJE)](http://www.icmje.org/) that the details of a trial should be publicly available in a clinical trials registry.

1. Is the clinical trial registered on a publicly accessible clinical trials registry database?

|  |  |
| --- | --- |
| Yes | No |

1. If yes, please provide detail (name of registry, registry number).

If no, please explain why the study is not registered on a publicly accessible clinical trials registry database.

|  |
| --- |
| Click here to enter text. |

### 11.5 Industry Sponsored/Contract Research Organisation (CRO) trials

If the study is not industry sponsored, please proceed to [Section 11.7](#_113.7_Clinical_trial).

1. Sponsor details

|  |  |
| --- | --- |
| Organisation name: | Click here to enter text. |
| Contact person: | Click here to enter text. |
| Title: | Choose an item. |
| Full Name: | Click here to enter text. |
| Position: | Click here to enter text. |
| Department: | Click here to enter text. |
| Mailing address: | Click here to enter text. |
| Business phone no.: | Click here to enter text. |
| Mobile no.: | Click here to enter text. |
| Fax no.: | Click here to enter text. |
| Email address: | Click here to enter text. |
| Account details: | Click here to enter text. |
| ABN: | Click here to enter text. |

1. Contract Research Organisation (CRO) details

|  |  |
| --- | --- |
| Organisation name: | Click here to enter text. |
| Contact person: | Click here to enter text. |
| Title: | Choose an item. |
| Full Name: | Click here to enter text. |
| Position: | Click here to enter text. |
| Department: | Click here to enter text. |
| Mailing address: | Click here to enter text. |
| Business phone no.: | Click here to enter text. |
| Mobile no.: | Click here to enter text. |
| Fax no.: | Click here to enter text. |
| Email address: | Click here to enter text. |
| Account details: | Click here to enter text. |
| ABN: | Click here to enter text. |

1. Invoicing details for Research Governance review fees

The Mater Research Governance Office has established a schedule of fees for SSA submissions. Refer to the [schedule of fees](http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee/old-docs/ScheduleOfFees) located on the [Mater Research Governance website](http://www.mater.org.au/Home/Research/Human-Research-Governance).

Please note that these fees are in line with other hospitals and universities in Brisbane.

Select the organisation that should be invoiced for Research Governance review fees:

|  |
| --- |
| Choose an item. |

**11.6 Is the fully executed Medicines Australia Standard Indemnity Form attached?**

Please liaise with the [Research Compliance Officer](mailto:research.agreements@mater.uq.edu.au) regarding signing of this form by Mater.

|  |  |  |
| --- | --- | --- |
| Yes | No | N/A |

If No or N/A please give an explanation:

|  |
| --- |
| Click here to enter text. |

### 11.7 Clinical trial agreement

A copy of the fully executed Clinical Trial Agreement (CTA) must be supplied to the Mater Research Governance office when available. Mater Research Governance Authorisation cannot occur until all agreement requirements are in place.

a) Is the Medicines Australia Standard CTA attached?

|  |  |
| --- | --- |
| Yes | No |

If no, please give an explanation:

|  |
| --- |
| Click here to enter text. |

b) Has the CTA been reviewed by the Mater legal office?

|  |  |
| --- | --- |
| Yes | No |

If no, please contact the [Research Compliance Officer](mailto:research.agreements@mater.uq.edu.au).

**For Mater – the delegated authority to sign ALL research agreements (including clinical trial agreements) is the Mater Health Services CEO/Research Delegate.**

***If the study is a clinical trial and the CTA is provided or in progress please proceed to*** [***Section 13***](#_135._Indemnity_and)***.***

## 12. Research study agreement/s

All collaborative research studies involving entities external to Mater require a study agreement. In addition, some studies involving multiple entities within Mater require a study agreement.

All agreements must be processed by the [Research Compliance Officer](mailto:research.agreements@mater.uq.edu.au). If you are unsure if an agreement is required, please seek advice from the Research Compliance Officer.

**Please note:** An SSA application can be submitted at any time, however please note that if an agreement is required, the Research Governance Office must receive a copy of the fully executed agreement before review of the application can be finalised. Mater Research Governance Authorisation cannot occur until all agreement requirements are in place.

Is there a written research study agreement, signed by all relevant parties attached?

|  |  |  |
| --- | --- | --- |
| Yes | No | N/A |

If no or N/A please give an explanation:

|  |
| --- |
| Click here to enter text. |

**For Mater – the delegated authority to sign ALL research agreements (including collaborative research agreements) is the Mater Health Services CEO/Research Delegate.**

## 13. Indemnity and insurance

If the research project is a clinical trial or if non-Mater investigators are accessing the Mater site for the purposes of this research, evidence of insurance is required (e.g. Certificates of Currency for Clinical Trial Insurance and/or Product and Public Liability and/or Professional Indemnity).

Is evidence of adequate insurance cover attached?

|  |  |  |
| --- | --- | --- |
| Yes | No | N/A |

If no or N/A please give an explanation:

|  |
| --- |
| Click here to enter text. |

## 14. Intellectual Property considerations

### 14.1 Is there a possibility of new commercial intellectual property to be developed from this project?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### 14.2 Has a patent search been undertaken?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### 14.3 Does the research agreement include arrangements for the use of existing property and the parties’ rights in relation to ownership?

|  |  |  |
| --- | --- | --- |
| Yes | No | N/A |

### 14.4 Does the research agreement include arrangements for the use of all new intellectual property developed through the research project?

|  |  |  |
| --- | --- | --- |
| Yes | No | N/A |

If the answer is ‘yes’ to any of the above questions then you should discuss the issue of incorporating intellectual property terms in the research agreement with your collaborators and any lawyer assisting with development of the research agreement.

**Please contact the** [**Research Compliance Officer**](mailto:research.agreements@mater.uq.edu.au) **if you are unsure about intellectual property considerations.**

## 15. Biosafety, chemical and radiation safety

It may be necessary for research organisations to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation.

If ‘yes’ is ticked below, appropriate documentation of approval must be attached or forwarded to the Research Governance Officer.

### 15.1 For projects where ARPANSA Code compliance is required, is additional state-specific radiation safety approval and registration required?

### Section 2.1.6 of the [Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code on Exposure of Humans to Ionizing Radiation for Research (2005)](http://www.arpansa.gov.au/publications/codes/rps8.cfm) states that a researcher must obtain an independent assessment or verification by a Medical Physicist of the total effective dose and relevant organ doses for those radiological procedures that are performed specifically for the research protocol.

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### 15.2 Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### 15.3 Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) or CTAC (Cellular Therapies Advisory Committee) assessment?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

### 15.4 Will the project require application for a license to the NHMRC Licensing Committee to conduct embryo research?

|  |  |  |
| --- | --- | --- |
| Yes | No |  |

## 16. Declarations

### a) Declaration by the Principal Investigator and all other research personnel involved with the project at Mater (as listed in [Section 3.1](#_3.1_Research_personnel))

|  |  |
| --- | --- |
| HREC application reference no.: | Click here to insert HREC Reference Number. |
| Project title (in full): | Click here and replace text with project title. |
| Principal Investigator: | Click here and replace text with full name of Mater Principal Investigator |

1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take responsibility for the conduct of the study at this site.
2. I will only start this research project after obtaining authorisation from the site and approval from the lead Human Research Ethics Committee (HREC).
3. I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (2007), the Australian Code for the Responsible Conduct of Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and Catholic Health Australia “Code of Ethical Standards for Catholic Health and Aged Care Services in Australia” (2001).
4. I agree to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.
5. I agree to conduct this research in accordance with Mater and Mater Research policies.
6. I agree to conduct this research in accordance with relevant legislation and regulations.
7. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
8. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
9. I will inform the HREC and the research governance officer if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
10. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.
11. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, research governance officer, the sponsor or an independent body for audit and monitoring purposes.
12. I understand that information relating to this research, and about me as a researcher, will be held on file and in the research databases of the HREC and the Research Governance Office. This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

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| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

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| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

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| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | |  |  |  |  |
| Print Name | |  | Signature |  | Date |
|  | |  |  |  |  |
| Role in Project: |  | | | | |

### b) Declaration by Head of Department/s at this site where the Principal Investigator will do the research (as per departments/services listed in [Section 9.1](#_911.1_Departments_and))

**NOTE:** Where an investigator is also Head of Department, a counter-signature must be sought from the person/position to whom the Head of Department reports (this may by the Executive Director who will then need to sign in 16b and 16c).

*Where more than one Mater department or service area is involved, extra space has been provided to obtain multiple relevant signatures.*

|  |  |
| --- | --- |
| HREC application reference no.: | Click here to insert HREC Reference Number. |
| Project title (in full): | Click here and replace text with project title. |
| Principal Investigator: | Click here and replace text with full name of Mater Principal Investigator |

1. I certify that I have read the research project application named above.
2. I certify that I have discussed this research project and the resource implications for this department with the Principal Investigator.
3. I certify that all researchers/students from my department involved in the research project have the skills, training and experience necessary to undertake their role.
4. I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This includes ‘actual costs’ and ‘in kind costs’.
5. My signature indicates that I support this research project being carried out using such resources.
6. I have determined, following discussions with the investigators of this study, that all professional groups within the hospital / department (e.g. senior - medical, nursing/midwifery, allied health, etc.) who may be impacted by the conduct of this project have been consulted about the implications of this research.

**Please list name and position of senior medical, nursing/midwifery, allied health staff consulted regarding this project:**

|  |  |
| --- | --- |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. |
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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
|  | | | |  |  | |
| Signature |  | | | Date | |  |

**To be completed only if Head of Department is an investigator on the study:**

**Declaration by Executive Director at the relevant hospital**

1. I have liaised with the Head of Department who is an investigator on this study and confirm that the resources can be used as detailed in this application.

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| Name of alternate signatory: | | |  | | |
| Position: | |  | | | |
|  |  | | |  | |
| Signature |  | | | Date |  |

*Where more than one Mater department or service area is involved, please use this page to obtain additional relevant signatures:*

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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
|  | | | |  |  | |
| Signature |  | | | Date | |  |

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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
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| Signature |  | | | Date | |  |

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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
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| Signature |  | | | Date | |  |

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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
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| Signature |  | | | Date | |  |

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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
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| Signature |  | | | Date | |  |

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| Name of department: | |  | | | | |
| Name of Head of Department (or appropriate person): | | |  | | | |
|  | | | |  |  | |
| Signature |  | | | Date | |  |

### c) Declaration by Executive Director at the relevant hospital (NOT REQUIRED FOR LNR STUDIES)

To be completed by the Executive Director providing support or services to the research project – [must not have any direct staff member(s) on the research team]

*Where more than one Mater hospital is involved, extra space has been provided to obtain multiple relevant signatures.*

|  |
| --- |
| HREC application reference no.:  Click here to insert HREC Reference Number. |
| Project title (in full):  Click here and replace text with project title. |
| Principal Investigator:  Click here and replace text with full name of Mater Principal Investigator |

I have discussed this project with the Principal Investigator and have confirmed that: *(tick whichever applies)*

🞏 the investigations/services indicated are able to be performed within the present resources of the listed department/s

🞏 the investigations/services indicated are able to be performed if the following financial assistance is provided:

🞏 the investigations/services indicated are unable to be undertaken on the following grounds:

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| Name: |  | | | | | |
| Hospital: | |  | | | | |
|  | | | |  |  | |
| Signature | | |  | Date | |  |

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| --- | --- | --- | --- | --- | --- | --- |
| Name: |  | | | | | |
| Hospital: | |  | | | | |
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| Signature | | |  | Date | |  |

## 17. Checklist

## Please complete this checklist to ensure you have provided all the required items and documentation in your SSA Application to the Mater Research Governance Office (RGO). Failure to do so will delay the review process of your application.

**SSA Submission Requirements:**

**All Studies:** The SSA application will consist of the completed signed Mater SSA form, all SSA supporting documentation and a full copy of all documents submitted to the reviewing HREC.

**Full-SSA application –** 1 hard copy and an electronic copy of all documentation is required.

**LNR-SSA application –** only electronic copies are required.

|  |  |  |  |
| --- | --- | --- | --- |
| **FOR ALL RESEARCH GOVERNANCE APPLICATIONS** | Yes | No | N/A |
| Has a cover letter, signed by the PI, been provided? Cover letter should include the project title, a list of supporting documents, and a brief description of the proposed study relevant to conduct at the Mater site. |  |  |  |
| Have all declarations (Section 16) been signed? |  |  |  |
| Has a CV been attached for each investigator? *(If not supplied to the RGO within the past 2 years)* |  |  |  |
| Is proof of Medical Registration attached? *(Not applicable for clinicians based in NSW and Queensland)* |  |  |  |
| Has a Mater Sponsor/Contact been appointed to this study (Section 3.2)? The PI is responsible for ensuring there is a contact person at the site who will liaise with Research Governance Office. |  |  |  |
| Have all financial details in Section 9 been completed? |  |  |  |
| Have signed quotes for required services from MHS or Mater Research, been supplied? |  |  |  |
| Has Finance authorisation from the relevant Managing Accountant been obtained? |  |  |  |
| Has a copy of the HREC Approval letter been provided (if this approval has been granted)? |  |  |  |
| Has a copy of the research protocol been provided? |  |  |  |
| Are all Participant Information Sheet(s) and Consent Form(s) provided?  For Multi-centre studies with HREC approval under the single ethical review process: BOTH a Site Specific version of the Participant Information Sheet and Consent Form, and the HREC Approved MASTER, on which the site version is based, are required.  The site specific documents must include:   * Mater Version number and date followed by MASTER version number and date, as listed on the HREC Approval letter (NOTE: the Mater version MUST make reference to the HREC-approved MASTER document). **For example only:**   *MHS Participant Information & Consent Form, Version 1.0, 20 January 2015; based on Master Participant Information & Consent Form, Version 2.0, 10 December 2014*   * Mater Research Letterhead or Logo to be used on all documents to be supplied to Mater participants (contact RGO for a copy of logo if required) * The following sentence containing Research Governance Office contact details is to be included in the Complaints/Concerns section, immediately following the contact details of the reviewing HREC (this section is usually found on the last page of the Participant Information Sheet): *‘If you wish to speak to someone at the Mater please contact the Research Governance Officer on 07 3163 8836 or email: research.governance@mmri.mater.org.au’.* |  |  |  |
| Has a copy of all documents submitted to the HREC been provided (e.g. advertising material, questionnaires, ethics application form etc.)? |  |  |  |
| If relevant to the research project:  Has evidence of biosafety, chemical and/or radiation approvals been provided? (Section 15) |  |  |  |
| **ADDITIONAL REQUIREMENTS FOR INDUSTRY-SPONSORED CLINICAL TRIALS** | Yes | No | N/A |
| Is a CTN/CTX form, signed by the Chair of the reviewing HREC and the Site Principal Investigator, attached? |  |  |  |
| Are Certificates of Currency, for all project-appropriate Insurances, provided (e.g. Clinical Trials Insurance, Product and Public Liability, Professional Indemnity)? |  |  |  |
| Has the Medicines Australia Standard Clinical Trial Agreement been provided to the Research Compliance Officer for review by Mater Legal?  Note: a copy of the fully executed agreement will be required by the RGO prior to study authorisation. |  |  |  |
| Has the Medicines Australia standard indemnity form been provided to the Research Compliance Officer for review by Mater Legal?  Note: a copy of the fully executed document will be required by the RGO prior to study authorisation. |  |  |  |
| **Additional Requirements For Investigator-Initiated Clinical Trials/Collaborative Research Studies** | Yes | No | N/A |
| If applicable: Is a CTN/CTX form, signed by the Chair of the reviewing HREC and the Site Principal Investigator, attached? |  |  |  |
| Has the Clinical Trial Agreement/Collaborative Research Agreement been provided to the Research Compliance Officer for review by Mater Legal?  Note: a copy of the fully executed agreement will be required by the RGO prior to study authorisation. |  |  |  |
| Are Certificates of Currency, for all project-appropriate Insurances, provided? (E.g. Clinical Trials Insurance, Product and Public Liability, Professional Indemnity). |  |  |  |
| **Checklist 4: ADDITIONAL REQUIREMENTS For Student Researchers** | Yes | No | N/A |
| Are the name, contact details and a current CV of your research supervisor/s attached? |  |  |  |
| If the research is for the purpose of obtaining a degree or other educational qualification, has this been clearly stated in the cover letter to the Research Governance Office and in the Participant Information Sheet? |  |  |  |
| It is possible an agreement will be required for studies involving student researchers. Has the Research Compliance Officer been consulted to determine any legal requirements? |  |  |  |

### For internal use only – not to be completed by the researcher

***For full SSA (more than low or negligible risk*):**

**Recommendation by the Research Governance Officer**

|  |
| --- |
| HREC application reference no.:  Click here to insert HREC Reference Number. |
| Project title (in full):  Click here and replace text with project title. |
| Principal Investigator:  Click here and replace text with full name of Mater Principal Investigator |

The Site-Specific Assessment (SSA) form for the above research project has been completed (with all attachments).

SSA Authorisation is:

🞏 Recommended

🞏 Not recommended

🞏 Requires Chief Executive/delegate consideration

If not recommended or requires Chief Executive/delegate consideration, give reasons.

Research Governance Officer (or equivalent)

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| Name: |  | | | | |
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| Signature | |  | Date | |  |

***For LNR SSA (low or negligible risk):***

The application has been reviewed and all Mater Research Governance requirements have been met.

Study Authorised, under delegation from the MHS CEO, by the Research Governance Officer (or equivalent)

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| Name: |  | | | | |
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| Signature | |  | Date | |  |

### Authorisation by Chief Executive Officer/Delegate – in case of litigation

|  |
| --- |
| HREC application reference no.:  Click here to insert HREC Reference Number. |
| Project title (in full):  Click here and replace text with project title. |
| Principal Investigator:  Click here and replace text with full name of Mater Principal Investigator |

This research is:

🞏 Authorised

🞏 Not authorised

Specify, conditions applying to authorisation or reasons for not authorising.

My signature indicates that I authorise/do not authorise this research project to commence at this site.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name of Chief Executive Officer: | | |  | | | |
| Name of Organisation: | |  | | | | |
|  | | | |  |  | |
| Signature |  | | | Date | |  |