**Advice regarding negligible and low risk review processes and current application form**

A low-risk activity is defined by the National Health and Medical Research Council (NHMRC) “National Statement on Ethical Conduct in Human Research 2007 (updated 2018) as one *where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort, the research is not low risk.*

 *Research is “negligible risk” where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is not more than inconvenience. Where the risk, even if unlikely, is more than inconvenience, the research is not negligible risk.”*

***Note:***

*Risk includes both potential and actual risks*

*Risks are not confined to physical risk but can include psychological, devaluation of a person’s worth, social, financial, cultural and legal risk.*

Research that involves the risk of harm or the likelihood of harm must be reviewed by a fully constituted HREC.

**Applicants must review Checklist 1 below to determine whether the activity is suitable for low-risk review.**

**This application form should only be used by researchers seeking low risk ethical approval for human research projects at Mercy Health.**

|  |  |  |
| --- | --- | --- |
| Does the research project involve **any** of the following?  | Yes | No |
| 1 | Use of *any* interventions. Examples include testing, drugs, surgical procedures, therapeutic procedures, therapeutic devices, preventative procedures, collection of fresh biospecimens from donors where risks associated with collection are more serious than discomfort, diagnostic devices or diagnostic procedures. | [ ]  | [ ]  |
| 3 | Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care. | [ ]  | [ ]  |
| 4 | Invasive procedures outside of routine clinical care. | [ ]  | [ ]  |
| 5 | Targeted recruitment of Aboriginal or Torres Strait Islander people | [ ]  | [ ]  |
| 6 | Targeted inclusion of vulnerable participants where competence to provide consent is diminished. Examples include, ventilated patients, those dependent on care, those with a mental health condition, and cognitively or intellectually impaired persons. | [ ]  | [ ]  |
| 7 | Use of biospecimens or establishment of a biobank. Projects involving individual biospecimens where the potential information discovered or generated may be of potential importance to the health of the individual, their blood relatives, or their community. | [ ]  | [ ]  |
| 8 | Genetic testing or use of stem cells  | [ ]  | [ ]  |
| 9 | Use of Assisted Reproductive Technology; Xenotransplantation; Genetically Modified Organisms | [ ]  | [ ]  |
| 10 | Examining potentially sensitive or contentious issues or deception of participants, concealment, or covert observation. Examples include research of sensitive personal or cultural issues, grief, death or serious/traumatic loss, substance abuse suicide and illegal activity.  | [ ]  | [ ]  |
| 12 | External research teams. The research is being conducted by a person not associated with Mercy Health and there is no one on the research team from Mercy Health Staff.  | [ ]  | [ ]  |
| 13 | External research teams. The research is being conducted by a person not associated with Mercy Health and there is minimal supervision by Mercy Health Staff and there is a request for waiving the requirement of obtaining consent to access/collect/use or disclose identifying information and/or biospecimens. | [ ]  | [ ]  |
| If you ticked YES to any item above, then full HREC review is required. Do not proceed with this low-risk application form. |
| If you ticked NO to ALL items above, please proceed with the HREC low-risk application below.  |

**Checklist 1. Eligibility HREC Review of Low-Risk Research**

**Completing the Form:**

**Required attachments:**

1. Complete research protocol
2. CV from the principal researcher (plus the senior investigator if the principal researcher is a student or an inexperienced researcher)
3. [Pre-submission peer-review proforma (where applicable, see section 1.5)](file://MHWFS01/Users/roxanneh/OneDrive%20-%20The%20University%20of%20Melbourne/Research%20Manager/Ethics/Low_risk_Peer%20Review%20proforma_.docx)
4. [Victorian Specific Module (VSM) Section 2; to be completed for proposals involving the collection, use or disclosure of information.](file://MHWFS01/Users/roxanneh/Downloads/SECTION-2.docx)
5. ALL participant information and consent forms i.e. advertisements, questionnaires, surveys, letters etc

**Submissions:**

Please use clear, simple and accessible language when completing this form

Applications that use complex and inaccessible language will be required to resubmit their application. This is a common reason for delays, so write it well and check your application carefully. (Re-read, check grammar and spelling before submitting). Applications must be peer reviewed by an experienced researcher prior to submission.

Please submit this, and all attachments to:

HREC Administration Officer, ethics@mercy.com.au

**Do not commence research until written approval has been received by the Principal Researcher or Project Co-ordinator from Mercy Health HREC.**

**Application for HREC Review of Low Risk Research**

**SECTION 1: RESEARCHERS**

|  |  |
| --- | --- |
| **PRINCIPAL INVESTIGATOR** |  |
| **Position Title** |  |
| **Department / Group** |  |
| **Institution** |  |
| **Phone**  |  |
| **Email** |  |

**1.1 Student/Other Researcher/s:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title** |  | **Title** |  | **Title** |  |
| **Name**  |  | **Name**  |  | **Name**  |  |
| **Phone**  |  | **Phone**  |  | **Phone**  |  |
| **Email** |  | **Email** |  | **Email** |  |

**1.2 Mercy Health Site Lead (only applicable if the PI is not a Mercy Health Employee/Honorary)**

|  |  |
| --- | --- |
| **Position Title** |  |
| **Name** |  |
| **Department / Group** |  |
| **Phone**  |  |
| **Email** |  |

**1.3 Departmental/Faculty Head (undertaking work in the hospital)**

|  |  |
| --- | --- |
| **Position Title** |  |
| **Name** |  |
| **Department / Group** |  |
| **Phone**  |  |
| **Email** |  |

**1.4 Researcher/s Qualification, Experience and Skills:**

*List academic qualifications and outline experience and skills relevant to project that researcher/s and any supporting staff have in carrying out the research. (100 words max)*

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**1.5 Pre-submission peer review**

*Mercy Health HREC requires peer review prior to project submission. The peer reviewer must be an experienced researcher. A completed peer review proforma must be attached with the application.*

*Peer review will not be required for projects where the principal investigator 1) holds 3 or more first or senior authored peer review publications, 2) holds a PhD or MD or 3) the project has received external funding following a peer review process (evidence to be attached).*

|  |  |
| --- | --- |
| **Has this research undergone peer review?** | [ ]  Yes [ ]  No[ ]  Not applicable, please provide reason: |
| **Is the completed, signed and dated Pre-submission (Peer) Review Proforma (or equivalent) attached?** | [ ]  Yes [ ]  No, please explain:  |

**SECTION 2: Project Details:**

[***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)”, section 1)***](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)

**Project Title:**

|  |
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**2.1 Lay Description:**

*Briefly outline in* ***clear and plain language*** *what the project aims to do and how this will be done, include project’s aim(s), justification, participant group(s), method and possible outcomes. (150 words max.)*

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**2.2 Research Aims:**

*State the aims, research objectives and key research questions. Where relevant, state the specific hypothesis to be tested. (200 words max.)*

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**2.3 Research Methodology:**

*Outline the proposed method, including study design, data collection techniques, tasks participants will be asked to complete; estimated time commitment required of them; and how data will be analysed. Give a justification of your proposed sample size, including details of statistical power of the sample where appropriate. (1000 words max.)*

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**2.4 Significance**

*Provide a brief description of the relevance of your proposed project to current research, a justification as to why your research should proceed and an explanation of any expected benefits to the community. Comment on and it potential to contribute to existing knowledge, treatment, disease prevention, health promotion or social improvement. (150 words max.)*

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**2.5 Ethical Justification:**

*Outline what ethical issues this study may encounter and why this project is ethically justified. (200 words max)*

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**2.6 What is the anticipated duration of the research project (include start and finish dates)?**

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**SECTION 3: Funding and Finance**

***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)” Chapter 5.4)***

**3.2 Sources of funding**

|  |  |
| --- | --- |
| **Has this protocol received research funding or is this submission being made as part of an application for research funding?** | [ ]  Yes [ ]  No |
| **Funding source** |  |
| **Approval number** |  |
| **Duration of funding** |  |

**3.2 Will the researcher receive any remuneration and/or in-kind funding to perform this research?**

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**3.3 Will participants receive any payment or expenses for participation in the research? If yes, give details.**

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**SECTION 4: Other Approvals?**

***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)”, Chapter 5.3)***

*The Principal Researcher is responsible for informing Mercy Health HREC of all other Australian sites at which the research is being proposed or conducted, at the time of submission of the research project; and of any previous decisions regarding the research made by another HREC; and informing of whether the protocol is presently before another HREC.*

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| --- | --- |
| **Is this protocol being submitted or has it been previously submitted to another ethics committee?** | [ ]  Yes [ ]  No |
| **Centres and approval status of each**  |  |
| **Details of any required amendments**  |  |

**SECTION 5: Recruitment of Participants**

***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)”, Chapter 2.2)***

**5.1 Participant Details:**

*Provide eligibility details, study numbers, age range and source of participants. This explanation should also include how potential participants will be identified and how initial contact will be made.*

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**5.2 What is the expected number of participants?**

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**5.3 What is the proposed method of recruitment of participants?**

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**SECTION 6: Consent**

***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)”, Chapter 2.2, 2.3)***

**6.1 Informing Participants: Participant Information Sheet and Consent Form**

*The potential participant must be provided with information at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results).*

**Will the research involve informed consent of participants?**

|  |  |
| --- | --- |
| [ ]  Yes, provide detail of how informed consent will be obtained and recorded  |  |
| **If yes, participant information sheet and consent forms must be attached.**  |
| [ ]  No, justify why consent will not be obtained  |  |
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***N.B.*** *If this study is using health, personal or sensitive data already collected/retrospective study and there is no patient contact then the researcher must also fill in Section 2 of the Victorian Specific Module (privacy)*

**SECTION 7: Information Protection (Confidentiality, Data Storage and Security)**

***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)”, section 1 and NHMRC, Universities Australia “Australian Code for the Responsible Conduct of Research 2018, R22”)***

**Confidentiality:**

***7.1 Explain what methods will be used to guarantee confidentiality/anonymity of participant data****.*

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**7.2 Data Storage and Security.**

**N.B useful guide** [**(**Management of Data and Information in Research**)**](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf)

**Explain how and where data will be held, including any arrangements for data security and access? N.B.** The principal researcher must ensure all local, state, and national data storage and retention requirements are met. In general, the minimum period for retention of research data is 5 years from the date of last publication.

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**7.3 Please explain how long the data will be kept? Note, data must be securely held within the clinical or research department during this time.**

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**7.4 How will data be disposed of?**

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**SECTION 8: Impact on clinical services**

**List the clinical services that may be involved and the anticipated level of impact on those clinical services**

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| **For HREC review only: if clinical services are impacted, please advise the HREC Office to forward to relevant clinical service and program director for signed endorsement after final review.**  |

**SECTION 9: Dissemination of Results**

***(NHMRC “National Statement on Ethical Conduct in Human Research 2007 (updated 2018)”, Section 1 and NHMRC, Universities Australia “Australian Code for the Responsible Conduct of Research 2018, R23”,)***

**Explain when, how, where and to whom results will be disseminated, including whether participants will be provided with information on the findings or outcomes of the project.**

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| Ensure ALL documents have version numbers, dates and page numbers (other than copyright material)Ensure ALL required Signatures are provided |
| **Name of document** | **Included**  | **Date** |
| **1** | Completed research protocol  | [ ]  Yes  |  |
| **2** | CV from the principal researcher (plus the senior investigator if the principal researcher is a student or an inexperienced researcher)  | [ ]  Yes  |  |
| **3** | Peer-review proforma  | [ ]  Yes [ ]  N/a |  |
| **4** | Include ALL participant information and consent forms i.e. advertisements, questionnaires, surveys, letters etc | [ ]  Yes [ ]  N/A |  |
| **5** | Victorian Specific Module (VSM) Section 2; For research Involving the Collection/Use/Disclosure of health, personal or sensitive Information | [ ]  Yes [ ]  N/A |  |

**SECTION 10: ALL required attachments must be included with the application. NB incomplete applications will not be reviewed and returned to the PI.**

**SECTION 11: Declarations**

**NB:**

* Digital signatures are accepted and encouraged
* Please sign in the Applicant/Principal Researchers and Site Sponsor (if required)
* Where necessary Clinical Service Director and Program Director signatures will be obtained by the HREC Office following review
* The CEO signature will be collected by the HREC Office for your convenience

**Applicant/Principal Researchers (including Students and Supervisors where permitted)**

I/we, the researcher(s) certify and agree:

* All information is correct and complete as possible.
* To only start this research project after obtaining final approval from the Institution’s Human Research Ethics Committee (HREC);
* To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
* To provide additional information as requested by the HREC;
* To provide annual progress reports to the HREC as requested, including a final report and a copy of any published material at the end of the research project;
* To maintain the confidentiality of all data collected from or about project participants;
* To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;
* To notify the HREC in writing immediately of any unforeseen events that might affect continued ethical acceptability of the project and await approval before continuing
* To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;
* To agree to an audit if requested by the HREC;
* To only use data and any tissue samples collected for the study for which approval has been given;
* To only grant access to data to authorised persons;
* To maintain security procedures for the protection of privacy, including (but not restricted to): removal of identifying information from data collection forms and computer files, storage of linkage codes in a locked cabinet and password control for access to identified data on computer files;
* I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these;
* I/we have attempted to identify all the risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of participants;
* I/we will not continue the research if ethical approval or site authorisation is withdrawn and will comply with any special conditions required by the HREC, including;
	+ Conditions of approval stipulated by the HREC
	+ Cooperate with monitoring requirements.
* I/we have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise;
* I/we have read the NH&MRC National Statement on Ethical Conduct in Research Involving Humans 2007 (updated 2018)
* This project complies with the Mercy Health guidelines for submission for Low Risk Research review.

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| --- |
| ………………     ………………..(Principal Researcher)……………………     …………………….(Print Name in block letters)Date:      /     /      |

|  |  |
| --- | --- |
| …………………     ………………(Other Researcher)………………………     …………………….(Print Name in block letters)Date:      /     /      | …………………     ………………(Other Researcher)………………………     …………………….(Print Name in block letters)Date:      /     /      |

**Mercy Health Site Lead (if required):**

I certify that:

* I am familiar with this project and endorse its undertaking;
* I am familiar with and agree to comply with the roles and responsibilities of the “Site lead” as outlined in the QH Research Management Policy;
* The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

|  |
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| **Title:** **Name:** **Position:** **Signature:** **Date:**  |

**Heads of Departments/Divisional Director:**

**Departmental signatures must be obtained before submission to HREC Office**

I/we certify that:

* I/we are familiar with this project and endorse its undertaking;
* The resources required to undertake this project are available;
* The researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

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| **Mercy Site Department Head** **Date**  |

**If clinical services or programs will be utilized or impacted (Section 8) appropriate signatures will be obtained by HREC Office after final review**

**Clinical Services Director (Mercy Health Services) Date**

**Program Director (Mercy Health Services) Date**

**Note: CMO signature will be obtained by HREC Office after submission**

|  |
| --- |
| **Chief Medical Officer Health Services      Date****Dr Jeffrey Kirwan** |

**Return to: Administration Officer**

 **Human Research Ethics Committee**

 **C/o Mercy Hospital for Women**

 **163 Studley Road, Heidelberg**

 **VIC 3084**

 **Tel: 8458 4808: Fax: 8458 4818**

 **Email:** **ethics@mercy.com.au**