Purpose

The form is the be used for addition of research personnel to research projects submitted to the Royal Melbourne Hospital Human Research Ethics Committee

Procedure

Complete the relevant sections of this form (Sections are reproduced from the Human Research Ethics Application Form) and submit along with an Amendment Request form and any other affected documents. Forms can be found on the RMH Research website at: <https://www.thermh.org.au/research/ethics-governance/post-approval-project-management/submit-amendment/>.

Provide a justification of the personnel changes i.e. staff member no longer employed at Melbourne Health on the Amendment Request from.

Other Related Documents

Complete an **Investigator Curriculum Vitae** for any personnel that are new to research at RMH and existing researchers if they have not submitted an updated CV within the past 3 years.

Completed CVs should be emailed to CVsFolder@mh.org.au. Hardcopy CVs will not be retained. It is the responsibility of investigators to inform the Office for Research should a researcher’s position or registration change in a manner that affects the conduct of the study.

**Tips for completing the form**

**For the instruction “Describe the research activities this person will be responsible for”**

* Briefly describe the research activities the person will be undertaking in relation to the research project. For example, participant recruitment, obtaining consent, data collection, sample collection or data analysis.
* If this person is responsible for directly supervising students this activity should be recorded here.

**For the instruction “Describe the person’s expertise relevant to the research activity”**

* [The National Statement 1.1](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) states: “Research that has merit is …conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research.”
* Consider the research activities that this person will be responsible for and explain how their qualifications, training, experience, skills, experience, qualifications and competence make them appropriate for their role in the research project.

1. RESEARCHERS AND CONTACT INFORMATION

List all the *NEW* researchers involved in this project in the relevant sections below

1.1 Complete the table below and repeat for each *new* **Principal Researcher only**

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment |  |
| Organisation  |  |
| Department |  |
| Address |  |
| Telephone |  |
| Email |  |
| Describe the research activities this person will be responsible for |  |
| Describe the person’s expertise relevant to the research activity |  |
| Has the new Researcher submitted a CV to the Office for Research within the last three years? If no, complete and submit an **Investigator Curriculum Vitae Form** | Yes [ ]  No [ ]   |

1.2 Copy this table and repeat for each *new* **Associate Researcher**

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment |  |
| Department |  |
| Organisation  |  |
| Address |  |
| Telephone |  |
| Email |  |
| Describe the research activities this person will be responsible for |  |
| Describe the person’s expertise relevant to the research activity |  |
| Has the new Researcher submitted a CV to the Office for Research within the last three years? If no, complete and submit an **Investigator Curriculum Vitae Form** | Yes [ ]  No [ ]   |

1.3 Copy this table and repeat for each *new* **Student Researcher**.

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment |  |
| Department |  |
| Organisation  |  |
| Address |  |
| Telephone |  |
| Email |  |
| Describe the research activities this person will be responsible for |  |
| Describe the person’s expertise relevant to the research activity |  |
| Has the new Researcher submitted a CV to the Office for Research within the last three years? If no, complete and submit an **Investigator Curriculum Vitae Form** | Yes [ ]  No [ ]   |

2. TRAINING

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

Yes [ ]  No [ ]

If *Yes*, list the researchers, describe the training that is required and who will provide this training.

|  |  |  |
| --- | --- | --- |
| **Researcher** | **Training required** | **Who will provide training?** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

3. OTHER NEW PERSONNEL

3.1 Research Coordinator (if not named as a co-researcher):

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment |  |
| Department |  |
| Organisation  |  |
| Address |  |
| Telephone |  |
| Email |  |
| Describe the research activities this person will be responsible for |  |
| Describe the person’s expertise relevant to the research activity |  |

3.2 New Person to whom the HREC should forward correspondence (if not the Principal Researcher)

|  |  |
| --- | --- |
| Title and Name |  |
| Appointment |  |
| Department |  |
| Organisation |  |
| Mailing address |  |
| Telephone |  |
| Email |  |

4. DECLARATION BY RESEARCHERS AND RESEARCH COORDINATORS

Project Title:

I/WE, the researcher(s) agree:

* To only start this research project after obtaining final approval from the Institution’s Human Research Ethics Committee (HREC);
* To conduct this research project in accordance with the protocols and procedures as approved by the 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 maintain the confidentiality of all data collected from or about project participants;
* 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; and
* 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 read the NHMRC’s [National Statement on Ethical Conduct in Human Research (2007) Updated 2018](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) and will observe the principles set out in that document and in the [Declaration of Helsinki](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/).

|  |  |
| --- | --- |
| Name of Principal Researcher |  |
| Signature |  |
| Date |  |

*[Repeat signature section below for each new researcher added]*

|  |  |
| --- | --- |
| Name of Researcher |  |
| Signature |  |
| Date |  |

|  |  |
| --- | --- |
| Name of Research Coordinator |  |
| Signature |  |
| Date |  |