**Alfred Health**

**Ethics & Research Governance**

**Change to Research Personnel Form**

* *Submit this form and other required documents, with changes tracked, as an amendment through ERA.*
* *Refer to the ERA* [*“instructions for researchers”*](https://www.alfredhealth.org.au/research/ethics-research-governance/research-training/era-online-submission-review-system)
* *If the project is not in ERA, email the form and attachments to* [*research@alfred.org.au*](mailto:research@alfred.org.au)
* *Include all relevant signatures. Signature pages can be scanned and emailed/uploaded.*
* *Attach/upload brief CVs for each new personnel (unless provided within the last two years).*
* *Attach/upload tracked-change versions of any documents updated to reflect the changes to personnel (e.g. PICF, participant information sheet, letters, advertising material, HIS Resource Centre Declaration for medical records access). Clean versions are not required.*
* *If there is a change to the Principal Researcher an amendment or addendum to the Clinical Trial Research Agreement (CTRA), CTN and/or indemnity may be required. Please attach/upload the amended documents, and provide hard copies to the Ethics & Research Governance Office. At least two hard copies are required in the case of the CTRA and indemnity.*
* *Refer to “*[*Being a researcher at Alfred Health*](https://www.alfredhealth.org.au/research/ethics-research-governance/essential-elements-for-research-applications/being-a-researcher-at-Alfred-Health/)*” for information about adding student researchers*
* *The Principal Researcher and Head(s) of Department are responsible for ensuring that all researchers and other personnel involved in this project are appropriately qualified, undertaking research activities in line with their employment contracts/experience or will undergo appropriate training to fulfil their role in this project.*

|  |  |
| --- | --- |
| **Alfred Health Project No:** |  |
| **Project Title:** |  |
| **Principal Researcher:** |  |
| **Contact Person:** | Name:  Email:  Phone:  Department/Organisation: |
| **Date** |  |

|  |  |  |
| --- | --- | --- |
| **1.** | **List personnel who have left the study** |  |
| **2.** | **List personnel whose role is changing, stating the changed role** |  |
| **3.** | **List the names of new personnel** |  |
| **4.** | **How will the personnel changes impact on the study?** |  |
| **5.** | **Do any documents need amending to reflect the personnel changes?**  *e.g. PICF, participant information sheet, letters, advertising material, HIS Resource Centre Declaration for medical records access.* | Yes *If Yes, attach the tracked-change version/s*  No *If No, provide an explanation:* |

**6.****New Personnel:**

*[Copy this table and repeat for each person]*

|  |  |
| --- | --- |
| Name and Appointment/Position title |  |
| Department |  |
| Institution |  |
| Phone/pager |  |
| Email |  |
| Role on research team | Principal Investigator  Associate/Co-Investigator  Research Coordinator/Assistant  Student on placement  Other: *Please specify* |
| For students, provide course code & title |  |
| Will this person be accessing Alfred Health medical records for this study? | Yes  No  *If Yes, provide details:*  **Access type:**  Alfred Health staff member  Honorary Alfred Health appointment (*provide letter of appointment*)  Undertaking a student placement at Alfred Health |
| Will this person be the contact person for this project? |  |
| Does this person require access to the project on ERA? |  |
| Date joined project |  |
| Describe what this person will do in the context of this project |  |
| Include a brief summary of relevant experience for this project |  |

**7. Will any of the above personnel require extra training to enable their participation** **in this project?** Yes  No  *If Yes, provide brief details below*

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

8. Declaration by Research Personnel

**I/We agree:**

1. To conduct this research project in accordance with the protocol and procedures as approved by the reviewing Ethics Committee and authorised by Alfred Health;
2. To maintain the confidentiality of all data collected from or about project participants;
3. To only use data and biospecimens collected for the study for which approval has been given;
4. To only grant access to data to authorised persons; and
5. 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, secure storage of linkage codes and password control for access to identified data on computer files.

**I/We will observe the principles set out in the NHMRC *National Statement on Ethical Conduct in Human Research* (2007) and in the *Declaration of Helsinki*.**

Name of Principal Researcher:

Signature: Date:

New personnel or personnel whose role has changed:

Name:

Signature: Date:

Name:

Signature: Date:

Name:

Signature: Date:

*[Insert more names and signatures on a separate page if necessary]*

**9. Certification by Principal Researcher**

**I accept responsibility for the conduct of this research project according to the principles of the *National Statement on Ethical Conduct in Human Research* (2007).**

As Principal Researcher, I will ensure that

* Progress reports are provided to the reviewing Ethics Committee and Alfred Health, including a final report and a copy of any published material at the end of the research project;
* The reviewing Ethics Committee is notified in writing immediately if any change to the project is proposed, and approval is received before proceeding with the proposed change (except for urgent safety measures);
* The safety monitoring and reporting requirements of Alfred Health and the reviewing Ethics Committee are adhered to;
* This research project will only be conducted where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
* Research records will be maintained confidentially as required by Alfred Health; and
* Audit requests from the reviewing Ethics Committee or Alfred Health are complied with.

Name of Principal Researcher:

Signature: Date:

**10. Acceptance by Head of Department/Divisional Director/Authorised   
 Institutional Official\***

*[Only complete this section if there has been a change of Principal Researcher]*

**I certify that I have read the research project application named above.**

**My signature indicates that I support this research project.**

Name of Head of Department (or appropriate person):

Name of Department (or relevant section):

Signature: Date:

*\*Where a researcher is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible. Researchers who are also Department Heads or Divisional Directors must not approve their own research on behalf of the Institution.*