**OFFICE FOR RESEARCH**

**Quality Assurance (QA) or Minimal Risk Research (MRR)**

**Change of Personnel Form**

This form is to be used for reporting changes to personnel for Western Health (WH) QA/MRR projects approved by the Office for Research or Low Risk Ethics Panel (LREP).

**An addition of personnel to a project must not be implemented until it has been acknowledged by the WH Office for Research.**

1. *Complete this form and get it signed by all relevant parties.*
2. *On Ethics Review Manager (ERM) utilise the Correspond Tab under the Action Tabs within the QA/MRR project (on the left-hand side of the work area) and upload a signed copy of this form and all relevant documents as outlined below:*
	* *Upload a signed WH CV template for each additional person being added to the project.*
	* *Upload evidence of current ICH GCP Training for each additional person being added to the project.*
	* *Upload a copy of any updated Project documents that have the new personnel listed. E.g. Participant Information and Consent Form.*
3. *If ERM help or guidance is required please contact helpdesk@infonetica.net*

***PLEASE NOTE: This form must be signed by all relevant personnel and will not be processed without the requisite signatures.***

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| 1. **RESEARCH PROJECT DETAILS**
 |
| **Date of completing this Form:** | Enter date  |
| **QA and ERM Project Number:** | E.g. 41234; HREC/18/WH/123; QA2018.123 |
| **Project Title:** | Enter text |
| **Principal Investigator:** | Enter text |
| 1. **CONTACT PERSON**
 |
| **Name:** | Enter text |
| **Email:** | Enter email address |
| **Phone:** | Enter contact number |
| **WH Department:** | Enter text |
| 1. **SUMMARY OF CHANGES**
 |
| **Please list personnel who have left the study** | Enter text |
| **Please list the names of new personnel** | Enter text |
| **Please list personnel whose role is changing, stating the changed role** | Enter text |
| **How will the personnel changes impact on the study?** | Enter text |
| **Does the PICF need to be amended to reflect the personnel changes?** | [ ]  Yes – *attach the tracked and clean version/s*[ ]  No – *please provide an explanation below:* |
| Enter text |
| 1. **TRAINING**
 |
| **Will any new personnel require extra training to enable their participation in this project** | [ ]  No [ ]  YesIf Yes, please provide brief details below. |
| **Name** | **Training required** | **Who will provide training?** |
| Enter text | Enter text | Enter text |
| Enter text | Enter text | Enter text |
| Enter text | Enter text | Enter text |
| Enter text | Enter text | Enter text |
| Enter text | Enter text | Enter text |

**Duplicate this Page for each personnel being added**

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| 1. **INVESTIGATOR/RESEACHER DETAILS**
 |
| **Title:**  | Enter text |
| **First Name:** | Enter text |
| **Surname:** | Enter text |
| **Role: (i.e. Principal/Associate Investigator, Student Researcher, Research Coordinator)** | Enter text |
| **Honorary Researcher Appointment at the WH****This is required for all external/non-WH personnel***(Please contact the Office for Research if unsure)* | [ ]  Yes – please attach Honorary Researcher Application Form[ ]  No, new personnel is a WH employee |
| **Will this person be the contact person for this project?** | [ ]  Yes [ ]  No  |
| **Date joined/joining project:** | Enter date |
| **Appointment period:** | Enter text |
| **Department & Organisation:** | Enter text |
| **Work Mailing address:** | Enter mailing address  |
| **Phone:** | Enter phone number |
| **Mobile/pager:** | Enter mobile/pager number |
| **Email:** | Enter email address |
| **Describe what this person will do in the context of this project:** | Enter text |
| **Include a brief summary of relevant experience for this project:** | Enter text |
| **Which sites will the personnel be working at? Select all that apply.** | [ ]  Sunshine Hospital[ ]  Footscray Hospital[ ]  Williamstown Hospital[ ]  Sunbury Day Hospital[ ]  Hazeldean Transition Care[ ]  Drug Health Service |
| **Curriculum Vitae attached** | [ ]  Yes [ ]  No *If no, please give reason:* Enter text |

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| 1. DECLARATION BY RESEARCH PERSONNEL
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| * 1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief.
	2. I will only commence on this QA/MRR project after obtaining acknowledgement from WH Office for Research/ LREP).
	3. I accept responsibility for the conduct of this QA/MRR project according to the principles of the NHMRC National Statement on Ethical Conduct in Research (2023 and updates) and abide by the Western Health Research Code of Conduct (2020).
	4. I undertake to conduct this QA/MRR project in accordance with the protocols and procedures as approved by the WH Office for Research or LREP.
	5. I undertake to conduct this research in accordance with relevant legislation and regulations.
	6. I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the WH Office for Research/LREP and NHMRC.
	7. I will adhere to the conditions of approval stipulated by the WH Office for Research/LREP and will cooperate with WH Office for Research/LREP monitoring requirements.
	8. I will inform the WH Office for Research/LREP if the project ceases before the expected date and I will discontinue the project if the WH Office for Research/LREP withdraws the approval.
	9. I understand and agree that QA/MRR project files, documents and QA/MRR project records and data may be subject to inspection by the WH LREP/Office for Research for audit and monitoring purposes.
	10. I understand that information relating to this QA/MRR project, and about me as a researcher, will be held by the WH Office for Research/WH LREP and on the Ethical Review Manager (ERM). 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.
 |
| **New personnel or personnel whose role has changed:** |
| Name: | Enter text |
| Signature: | Date: |
| Name:  | Enter text |
| Signature: | Date: |
| Name:  | Enter text |
| Signature: | **Date:** |
| Name:  | Enter text |
| Signature: | Date: |

*If necessary, please duplicate page for more names and signatures.*

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| 1. CERTIFICATION BY PRINCIPAL RESEARCHER
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| I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on Ethical Conduct in Human Research (2023 and updates)I certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training to fulfil their role in this project.As principal researcher, I will ensure that * A Final report and a copy of any published material is provided to Western Health at the end of the QA/MRR project.
* The Office for Research is notified in writing immediately if any change to the project is proposed, and approval is received before proceeding with the proposed change.
* The Office for Research is notified in writing immediately if any adverse event occurs after the approval of the Reviewing HREC/WH LREP has been obtained.

As principal researcher, I will take responsibility for the confidential maintenance of records as required by the Western Health Office for Research. |
| Name of Principal Researcher: | Enter text |
| Signature: | Date: |

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| 1. **FOR CHANGE IN PRINCIPAL INVESTIGATOR ONLY**

**ENDORSEMENT BY HEAD OF DEPARTMENT/DIVISIONAL DIRECTOR/AUTHORISED INSTITUTIONAL OFFICIAL\*** |
| **I certify that I have read the ERM application and associated documentation for the QA/MRR project named on this form.****My signature indicates that I support the continuance of this QA/MRR project and this change to the Principal Investigator as outlined on this form.** |
| Name of Head of Department/delegate: | Enter text |
| Name of Department (or relevant section): | Enter text |
| 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/endorse their own research on behalf of the Institution.*

**Useful link to WH GCP SOPS, Guidelines and policies:** <http://www.westernhealth.org.au/EducationandResearch/Research/General%20Information/Pages/Standard-Operating-Procedures.aspx>

**Mandatory electronic file name convention:**

To ensure the electronic copies submitted are easily identifiable, the format outlined below must be used for all electronic files. As shown in example below, include version numbers (if applicable) and dates in the file name.

PLEASE NOTE: Change of Personnel Submissions that contain documents that do not follow the naming convention/format below will not be processed. The researcher will be notified to revise the document names and this may delay the acknowledgement of the submission and subsequently the smooth conduct of the project.

**Convention**: [Reference Number/ERM Project ID] [Document Name] [version number] [Date DDMMMYY]

E.g. ERM 41234 Change of Personnel Form 01Jan25; or QA2020.123\_ERM12345 Change of Personnel Form 01Jan25