

**WESTERN HEALTH SITE SPECIFIC ASSESSMENT FORM**

Research Excellence Ethical Review Process (Rex)/University Projects

* *Please email this form and all attachments, to* *ethics@wh.org.au* *with the project number included in the subject line and send one hard copy with original signatures to the Office for Research.*
* *Please include all relevant original signatures*

|  |
| --- |
| 1. **RESEARCH PROJECT DETAILS**
 |
| **Date of this Form:** | Enter Date |
| **Project Number/Reference:** | Enter HREC Reference Number |
| **Project Title:** | Insert Title |
| **Principal Investigator:** | Enter Name |
| **Anticipated start date:** | Enter date | **Anticipated finish date:** | Enter date |
| 1. **PROJECT SUMMARY**

Provide a brief summary of the project, including a brief statement of the main objective of the project and the methodologies (not more than 400 words) |
| Enter Text |

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| 1. **INVESTIGATOR DETAILS**
 |
| **Title:**  | Enter Text |
| **First Name:** | Enter Text |
| **Surname:** | Enter Text |
| **Honorary Researcher Appointment at the Western****This is required for all external/non-Western Health personnel** | [ ]  Yes – please attach Honorary Researcher Application Form[ ] No, Investigator is a WH employee[ ] No, other please specify: Enter Text |
| **Role: (i.e. Principal/Associate Investigator, Student Researcher, Research Coordinator)** | Enter Text |
| **Will this person be the contact person for this project?** | [ ] Yes [ ]  No  |
| **Department & Organisation:** | Enter Text |
| **Work Mailing address:** | Enter Text |
| **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 |
| **Phone:** | Enter number |
| **Mobile/pager:** | Enter number |
| **Email:** | Enter work email address |
| **Curriculum Vitae attached** | [ ] Yes [ ] No *If no, please give reason:* Enter Text |
|  |
| **Title:**  | Enter Text |
| **First Name:** | Enter Text |
| **Surname:** | Enter Text |
| **Honorary Researcher Appointment at the Western****This is required for all external/non-Western Health personnel** | [ ]  Yes – please attach Honorary Researcher Application Form[ ] No, Investigator is a WH employee[ ] No, other please specify: Enter Text |
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| **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 |
| **Phone:** | Enter number |
| **Mobile/pager:** | Enter number |
| **Email:** | Enter work email address |
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|  |
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| **Phone:** | Enter number |
| **Mobile/pager:** | Enter number |
| **Email:** | Enter work email address |
| **Curriculum Vitae attached** | [ ] Yes [ ] No *If no, please give reason:* Enter Text |
|  |
| **Title:**  | Enter Text |
| **First Name:** | Enter Text |
| **Surname:** | Enter Text |
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| **Will this person be the contact person for this project?** | [ ] Yes [ ]  No  |
| **Department & Organisation:** | Enter Text |
| **Work Mailing address:** | Enter Text |
| **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 |
| **Phone:** | Enter number |
| **Mobile/pager:** | Enter number |
| **Email:** | Enter work email address |
| **Curriculum Vitae attached** | [ ] Yes [ ] No *If no, please give reason:* Enter Text |

Use separate Investigator’s details page to add more Investigators

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| 1. **SITE DETAILS**
 |
| **Site** | **Department** | **Number of Participants** |
| [ ] Footscray Hospital | Enter Text | Enter number |
| [ ] Sunshine Hospital  | Enter Text | Enter number |
| [ ] Williamstown Hospital  | Enter Text | Enter number |
| [ ] Sunbury Day Hospital | Enter Text | Enter number |
| [ ] Drug and Alcohol Services | Enter Text | Enter number |
| [ ] Hazeldean Transition Care | Enter Text | Enter number |
| [ ] Reg Geary House | Enter Text | Enter number |
| 1. **HOSPITAL/NETWORK SERVICES REQUIRED FOR THIS RESEARCH PROJECT**

Indicate (please tick) which hospital services will be required (**including host department**) to undertake this research: |

|  |  |
| --- | --- |
| **Emergency, Medicine and Cancer Services** | **Perioperative and Critical Care Services** |
| [ ]  Acute Ambulatory Care | [ ]  Anaesthetics and Pain Management |
| [ ]  Addiction Medicine | [ ]  Cardiology |
| [ ]  Dermatology | [ ]  Central Sterilising Services |
| [ ]  Endocrinology & Diabetes | [ ]  Elective Booking Service |
| [ ]  Emergency Medicine | [ ]  Facio-Maxillary Surgery |
| [ ]  Gastroenterology | [ ]  General and Breast Surgery |
| [ ]  General Medicine | [ ]  General and Colorectal Surgery |
| [ ]  Haematology | [ ]  General and Endocrine Surgery |
| [ ]  Hospital In The Home | [ ]  General and Upper Gastrointestinal Surgery |
| [ ]  Immunology | [ ]  Intensive Care Services |
| [ ]  Infectious Diseases | [ ]  Neurosurgery |
| [ ]  Medical Oncology | [ ]  Ophthalmology |
| [ ]  Medical Staff | [ ]  Orthopaedic Surgery |
| [ ]  Nephrology | [ ]  Otolaryngology, Head, Neck Surgery |
| [ ]  Neurology | [ ]  Paediatric Surgery |
| [ ]  Renal Dialysis | [ ]  Plastic, Reconstructive and Facio Maxillary Surgery |
| [ ]  Respiratory and Sleep Disorders | [ ]  Thoracic Surgery |
| [ ]  Rheumatology | [ ]  Urology Surgery |
| [ ]  Palliative Care | [ ]  Vascular Surgery |
| [ ]  Stroke Service | **Subacute & Aged Care Services** |
| **Clinical Support and Specialist Clinic Services** | [ ]  Acute Aged Care |
| [ ]  Bone Density Unit | [ ]  Cardio-geriatric Service |
| [ ]  Health Information Services/Medical Records | [ ]  Dementia Management Unit |
| [ ]  Interventional Radiology | [ ]  Geriatric Evaluation and Management |
| [ ]  Medicine Imaging | [ ]  Inpatient Rehabilitation |
| [ ]  Nursing Services | [ ]  Transition Care Program |
| [ ]  Pathology | [ ]  Ortho-Geriatric Service |
| [ ]  Performance Unit | [ ]  Palliative Care (Inpatient) |
| [ ]  Pharmacy | [ ]  Subacute and Non acute Access and Pathways  |
| [ ]  Specialist Clinics (Adult) | [ ]  Wellcare Program |
| **Allied Health** | **Women’s and Children’s Services** |
| [ ]  Audiology | [ ]  Gynaecology |
| [ ]  Exercise Physiology | [ ]  Obstetric Services |
| [ ]  Language Services | [ ]  Maternal Fetal Medicine |
| [ ]  Neuropsychology | [ ]  Special Care Nursery |
| [ ]  Nutrition and Dietetics | [ ]  Paediatric Medicine |
| [ ]  Occupational Therapy | **Drug Health Services** |
| [ ]  Pastoral Care | [ ]  Adolescent Community Programs |
| [ ]  Physiotherapy | [ ]  Adult Specialist Services |
| [ ]  Podiatry | [ ]  Community Residential Drug Withdrawal Units |
| [ ]  Psychology | [ ]  Dual Diagnosis Residential Rehabilitation Centre |
| [ ]  Social Work | [ ]  Nurse Practitioner Clinics |
| [ ]  Speech Pathology | [ ]  Psychology Clinics |
| **Community Services** | [ ]  Women’s Therapeutic Day Rehabilitation Program |
| Aboriginal Health, Policy & Planning | **Other** |
| ACE (Advice, Coordination and Expertise) | [ ]  Enter Text |
| Aged Care Assessment Service | [ ]  Enter Text |
| Central Access Unit (CAU) | [ ]  Enter Text |
| Children’s Allied Health Service | [ ]  Enter Text |
| Community Based Rehabilitation | [ ]  Enter Text |
| Community Transition Care Program | [ ]  Enter Text |
| Falls & Fracture Clinic | [ ]  Enter Text |
| GP Integration Unit | [ ]  Enter Text |
| Health Independence Programs Community Services | [ ]  Enter Text |
| Hospital Admission Risk Program | [ ]  Enter Text |
| Subacute Ambulatory Care Services | [ ]  Enter Text |

**Statement of Approval Forms**

* For each department ticked above, a separate Statement of Approval Form must be completed for every Service/Host Department involved in this research project. The Service Department Head and the Principal Researcher must sign each form.
* Requirements for research projects should be discussed with service/department heads as required. Researchers must provide a copy of each signed and completed form to the relevant service/department for their records.
* The above requirements also apply to research projects that are engaging Service Departments for procedures considered “Standard of Care”.
* Medical Records/Health Info Services (HIS); Statement of Approval Form for HIS is only required if Physical Records are being retrieved. If researchers are collecting information from BOSSNET (electronic records) only, then a Statement of Approval is not required except when researchers are collecting patient data prior to 24 November 2011
* \*Medical Imaging & Pathology; please review additional information and requirements on the website as they require separate forms.

**WESTERN HEALTH – Office for Research**

*(Please provide a separate Statement of Approval Form for all departments involved or accessed.)*

**STATEMENT OF APPROVAL FORM**

*If the project is to be undertaken in the same department at more than one site, complete a separate form for relevant departments at each site.*

|  |  |
| --- | --- |
| Service Department: | Insert Service Department name |
| Project No: | Enter Number | Expected Commencement Date: | Enter Date |
| Title of project: |
| Insert Title |
| Principal Researcher: | Enter Name |

I have discussed this study with the Principal Researcher having seen the application and protocol and I am:

|  |
| --- |
|[ ]  Able to do the investigations indicated with the present resources of the Insert Service Department name \* and/or support the conduct of this project. |
|[ ]  Unable to do the investigations within the present resources of the Department but would be willing to undertake them with financial assistance for: [ ] Staff [ ] Equipment  [ ] Maintenance [ ] Other (Please specify below) |

Comment (Please specify nature of assistance and estimated costs)

|  |
| --- |
| Enter text |
| Service Department Cost Centre to be Credited: | Insert Cost Centre Code |
| Charges - select one option only | 1. [ ] Charge to Western Health cost centre Enter Code *or*
2. [ ] Provide Billing details below

Contact name: Enter textCompany name: Enter textBilling address : Enter text |

I am unable to undertake the investigations on the following grounds:

|  |
| --- |
| Enter text |

|  |  |  |  |
| --- | --- | --- | --- |
| [Insert Name of Department Head signatory e.g. Dr John Smith]Signature(Head of Service Department) |  | Date: |  |

*(****Note:*** *If an Investigator is also the Head of Department, sign off should be obtained from the next line of reporting e.g. Divisional Director/Clinical Director)*

*I have discussed this project with* Name of Head of Service Department signatory, Insert Service Department name *and appropriate arrangements have been made for this service/department to assist with this project as outlined above.*

|  |  |  |  |
| --- | --- | --- | --- |
| PI name Signature (Principal Investigator) |  | Date: |  |

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| 1. DECLARATIONS
 |
| * 1. I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.
	2. I will only start this research project after obtaining authorisation from the site and approval from the responsible 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 Ethical Conduct in Research and abide by the Western Health Researcher’s Code of Conduct (2012).
	4. I undertake 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 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 HREC and NHMRC
	7. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements.
	8. 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.
	9. 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.
	10. 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.
	11. I understand that information relating to this research, and about me as a researcher, will be held by the HREC, research governance officer, and on the Research Ethics Database (RED). 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.
 |
| **Principal Investigator:** | Name: | Enter Name |
| Signature: | Date: |
| **Associate Investigator:** | Name: | Enter Name |
| Signature: | Date: |
| **Associate Investigator:** | Name: | Enter Name |
| Signature: | Date: |
| **Associate Investigator:** | Name: | Enter Name |
| Signature: | Date: |
| **Associate Investigator:** | Name: | Enter Name |
| Signature: | Date: |

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

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| 1. **DECLARATION BY HEAD OF DEPARTMENT\* (OR DIVISIONAL DIRECTOR OR OTHER AUTHORITY) WHERE THE PRINCIPAL INVESTIGATORWILL DO THE RESEARCH**
 |
| * I certify that I have read the research project application named above.
* I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator.
* 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.
* I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
* My signature indicates that I support this research project being carried out using such resources.
 |
| Name of Head of Department/delegate: | Enter Name e.g. Dr John Smith |
| Name of Department (or relevant section): | Enter Department Name |
| 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.*

***Office for Research to complete:***

|  |
| --- |
| 1. **Western Health Site Specific Authorisation by Chief Executive (or delegate)**
 |
| This project is: [ ] Authorised [ ]  Not authorisedSpecify any conditions applying to authorization or reasons for not authorising: Enter textMy Signature indicates that I authorise/do not authorise tis research project to commence at this site. |
| Name of Chief Executive/delegate: | Enter Name |
| Signature: | Date: |

SITE-SPECIFIC REQUIREMENTS CHECKLIST

Please check each of the following before you submit the application, otherwise approval may be delayed. Include one copy of this checklist (completed and signed) with the original application.

|  |  |  |
| --- | --- | --- |
| **FORMS INCLUDED** | **YES** | **NA** |
| * Statement of Approval Forms foreach department whose services are required (Section 5)
 |[ ]   |
| * Research Agreement
 |[ ] [ ]
| * Curriculum Vitae (for all investigators)
 |[ ]   |
| * GCP Certificate for Principal Investigator
 |[ ]   |
| * Honorary Researcher Application Form
 |[ ] [ ]
| * Application Fee & Compliant Tax Invoice
 |[ ]   |
| * HREC Approval letter
 |[ ]   |

Principal Investigator Signature:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Enter Name Date

Both Electronic and Hardcopy submissions must be made. See instructions for both below:

**Electronic Copy:**

Applicants must submit both the ethics application via Ethics Review Manager (ERM) and email (ethics@wh.org.au)

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 and dates in the file name.

Projects submitted with documents that do not follow the below naming convention/format will not be considered and will be returned via email to sender.

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

E.g. 41234 Protocol v1 01Jan19

**One Hardcopy:**

**By post/drop-off:**
Manager
Office for Research​
Level 3 Western Health Centre for Health Research & Education – Sunshine Hospital,
Furlong Road, St Albans VIC 3021

**Drop-off/after hours:**
A drop off box is located in the Ground Level Staircase (right of the elevators) of the Western Health Centre for Health Research & Education Building, Sunshine Hospital, Furlong Road, St Albans VIC 3021.