# APPROVAL TO EXAMINE RECORDS FOR MONITORING

This approval is valid only for the project specified below. Approval is valid for the duration of the study, it is the responsibility of the Prinicpal Investigator (PI) to ensure the WH Office for Research is notified of any changes to external monitors. Please submit completed form electronically to ethics@wh.org.au for acknowledgement before commencement.

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| **PROJECT NO:** Project reference number**PROJECT TITLE:** Project title |

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| Principal Investigator (PI): | Principal Investigator name |
| WH Supervisor (if not PI): | Click here to enter name |
| Expected Commencement Date: | Click here to enter a date |

**EXTERNAL MONITOR NAME**

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| --- | --- |
| Name: | External Monitor name |
| Position Title: | Click here to enter text |
| Organisation: | Click here to enter text |
| Contact number: | Click here to enter text |
| Email: | Click here to enter text |

Review of Medical Records in Research Studies by Monitors or other persons not affiliated with the Western Health Service.

The policy of Western Health with respect to outside monitors is as follows:

1. The designated monitor for any registered project is to be a person with appropriate tertiary, biomedical or scientific qualifications and with appropriate appreciation of the ethical issues involved with respect to confidentiality.
2. In each case the monitor undertakes to fill in the “Approval to Examine Records for the Purpose of Research” Form and to observe the confidentiality of the records examined.
3. If the Principal Investigator is not a staff member of Western Health, the monitor must be approved by a WH Investigator/supervisor associated with the project.
4. Direct copies of the patient’s notes should not be taken. Transcribed data must be identified by patient ID code only (non-identifiable). Hospital Unique/Unit Record Number (UR Number), Names and/or addresses should not be recorded.
5. In the case of participants who are not registered patients of Western Health - e.g. volunteers, or patients from elsewhere - the complete record should be kept solely in the care of the investigator as required by the NHMRC guidelines, and any transcription of the record by the monitor is to follow the same rules as for registered patients of the Western Health.

**DECLARATION**

* I undertake to preserve the confidentiality of all information concerning any individual taking part in this project.
* I agree that I shall only view and not make any direct copy of participant’s records, and shall identify transcribed data by patient ID code only (non-identifiable form).
* I agree to access only the hospital record numbers of study participants as provided to me by the site research staff.

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| External Monitor nameExternal Monitor Signature:  |  | Date: |  |
| Principal Investigator namePrincipal Investigator’s Signature: |  | Date: |  |