EMHS Research Hub

Low and Negligible Risk (LNR) Ethical Review

EMHS Research Hub
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Introduction

The National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007, Updated 2018 (NS)* makes provision for the establishment of procedures for the ethical review of human research according to the degree of risk involved in the research. Research involving no more than low risk may be reviewed under non-Human Research Ethics Committee (HREC) processes provided certain conditions are met (NS s5.1.18-5.1.21).

EMHS has implemented an area wide approach to research ethics and governance coordinated by its Research Hub. The Hub provides support for the ethical review of research, including managing non-HREC review and monitoring of low or negligible risk research.

EMHS has a non-HREC low and negligible risk (LNR) review panel for the ethical review of research that is of low (NS 2.1.7) or negligible risk (NS 2.1.6). The operations of the LNR Review Panel are describe in the EMHS Research Governance SOPS (SOP105).

Low and Negligible Risk (LNR) Panel

The function of the LNR Panel is to complete ethical reviews (including scientific appraisal) that are both comprehensive and expeditious (NS s5.1.18 and 5.1.20b) and to monitor approved projects to completion.

The EMHS Research Hub maintains a roster of inducted LNR Panel members drawn from staff and current or former HREC members experienced and trained in the ethical review of research proposals and the application of relevant local and national guidelines and legislation (including the NS and Privacy regulations).

LNR Panel members receive the same induction documents as RPH HREC members and are invited to HREC member training opportunities. Members receive a formal appointment letter.

LNR Panels are convened when required to review an application, with each panel comprising:

- The EMHS Ethics Coordinator
- 2 x LNR Panel members

Submitting research for review by the LNR Panel

The requirements for submission to the LNR Panel are the same as for HREC review. The Coordinating Principal Investigator (CPI) must submit the following documents via the Research Governance Service (RGS):

- Application form (e.g. WA Health Ethics Application Form) ***mandatory**
- Protocol ***mandatory**
- Recruitment documents (letters, posters, advertisements etc)
- Participant Information Sheet and Consent Form (PICF)
- Questionnaires, surveys, interview outlines etc
- Other participant documents (identification card, diaries)
- Any other study documents or relevant material

Review by LNR Panel

On receipt of a submission where the CPI has identified the project as being of low or negligible risk the EMHS Ethics Coordinator will pre-review the application to confirm the project meets NS criteria and is eligible for LNR Panel review.

The CPI's judgement as to whether their project is suitable for non-HREC review is considered but the decision is ultimately made by the Ethics Coordinator and, if required, the LNR Panel.

Two critical factors should be considered when allocating a project for LNR review:

- Low risk research projects involving access to patient records or samples without consent require a waiver of consent that can only be granted by a fully constituted HREC (NS 2.3.9). These projects must be reviewed at an HREC meeting.

- An external funding body may require HREC review, even if the project meets the NS low or negligible risk definitions. It is also important to remember that the ethical review provided may be relied upon by multiple sites and so must satisfy the respective research governance offices. This is especially relevant for multi-jurisdictional projects. *Because processes for low risk review vary greatly across the country, it is often expedient and safer in the long run to proceed to HREC review for such projects. This should be discussed with the CPI (see Site Authorisation below).*

Where an application is determined to be 'more than low risk' the submission will be allocated to the next available HREC agenda. The CPI will be informed of the decision by email with an explanation for why the research is not suitable for LNR review.

Referral to HREC review can also occur at any time during LNR review, if additional information arises (NS 5.1.21).

As with HREC submissions, the Ethics Coordinator will complete a standard pre-review of the research and contact the CPI if further information or clarifications are required. This constitutes the beginning of the LNR review.

LNR Panel members will be notified by email that there is a submission for review and the following documents will be made available electronically:

- Submission documents
- LNR Review Template, including the low risk checklist and the Ethics Coordinator's review

LNR Panel members will complete their reviews and recommendations within 2 working days of being notified that there is a submission for review.

LNR Panel members can make one of the following recommendations:

- that the research be approved
- that the research be approved subject to further information being provided
- that the research is not approved.

Member's responses will be collated by the Ethics Coordinator and the consensus recommendation recorded in the review template.

The CPI will be advised in writing of the outcome of the panel decision including links to the relevant section/chapter/paragraph of the NS.

If further information is requested, the Ethics Coordinator will expedite resolution of any queries or document edits using direct phone and email communication between the panel and the CPI.

On finalisation of the approval, the CPI will be sent an approval letter via the RGS signed by the EMHS Ethics Coordinator.

Site Authorisation

All communication with the CPI must re-iterate that ethical review by an alternative non-HREC pathway does *not* change any other aspect of the governance of research within WA health services.

Before the research commences at any site for which the LNR Panel is providing ethical approval, a site authorisation must be obtained following research governance review by the relevant research governance office/s.

As with HREC review, the site research governance applications can be submitted and reviewed independently and in parallel to the ethical review (either by the LNR Panel or an HREC), but the ethical approval must be obtained prior to site authorisation being granted.

When submitting a multi-site or multi-jurisdictional project for low risk ethical review, it is essential that the CPI discusses the acceptability of a non-HREC review with each site's respective research governance office. The EMHS Ethics Coordinator will discuss this with the CPI as part of their pre-review and, if required, liaise with the site research governance office/s.

Monitoring

Ethical approval by the LNR Panel in no way changes the post-approval monitoring obligations for research. All projects must be monitored through to completion, with progress reports being submitted at least annually and any protocol or study document or process amendments being approved prior to implementation.

The following monitoring reports must be submitted via the RGS:

- Progress Report - A progress report annually at the anniversary of approval, or more frequently if requested by the LNR Panel.
- Final Report - A final report on completion of the project, including the results, and logging of any publications, presentations or translation eventuating in the RGS.
- Protocol Amendment – Any changes to the study documentation, including the Study Protocol and/or participant informed consent documents, if required.
- Protocol Deviation / Violation - Any deviation from, or violation of, the study protocol.
- Protocol Withdrawal / Termination / Suspension - If the research project is withdrawn, terminated or suspended before the expected date of completion, providing reasons for this.
- Reporting of Adverse / Serious Adverse Events - any reports of adverse / serious adverse events in accordance with the Reporting Guidelines

Review of low or negligible risk projects is completed with the expectation that, on average, these projects will require less frequent and substantial reporting than those projects deemed to be of 'more than low risk'. They are typically, although not always, of shorter duration and less methodologically complex and are, of course, expected to require significantly less safety reporting.

Monitoring submissions will be reviewed by the EMHS Ethics Coordinator in the first instance. If required, an LNR Panel will be convened to review substantial amendments, or serious safety reports.