

## **POLICYI016 LOW OR NEGLIGIBLE RISK (LNR) REVIEW POLICY**

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### **PURPOSE**

To describe the Bellberry procedures regarding requests for Low or Negligible Risk (LNR) review.

LNR review is defined as out of session review of research applications for negligible or low risk research. This review is conducted by the Committee Chair and/or the LNR Review Sub-Committee.

Responsibility for reviewing research involving no more than low risk has been delegated to the Committee Chair, per National Statement 5.1.18 – 5.1.23.

Requests for LNR review may be submitted by an Investigator and addressed to the Committee Chair in the following circumstances:

- When research is 'low risk' where the only foreseeable risk is one of discomfort (per National Statement 2.1.6).
- When research is 'negligible risk' where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience (per National Statement 2.1.7).

Review procedure:

1. The Operations Manager or delegate will review the study in conjunction with a Committee Chair to determine the level of risk, and the potential for the study to be satisfactorily reviewed outside of a meeting, subject to the Committee Chair's discretion.
2. When risk is more than negligible or low risk, the Investigator will be advised that LNR review will not be undertaken.
3. Where it is determined that the study can be considered for LNR review, the application will be submitted through the eProtocol application form.
4. The Operations Manager or delegate, in conjunction with the Committee Chair, will determine the appropriate level of review; Committee Chair alone or Sub-Committee, and relevant composition of the Sub-Committee. This will be a person or persons with appropriate expertise selected from the entire panel of Bellberry HREC members. An external party or parties with relevant expertise may be co-opted as required.
5. Where LNR review has been undertaken, the Investigator will receive comments or letter noting the outcome through eProtocol.
6. Where the Sub-Committee determines that further review will be required, the Investigator will be notified, and arrangements made for the study to be allocated to a relevant full

HREC meeting. The Sub-Committee will provide their report to the HREC to form a part of their consideration. The Investigator will receive comments or approval through eProtocol.

7. Following approval, the following will be required to be submitted; any amendment to the project protocol or associated study documentation, an annual progress report, a Final Report at the completion of the project.

Bellberry will provide a six monthly report of LNR review activities to its HRECs.