POLICYI029 NATIONAL APPROACH TO SINGLE ETHICAL REVIEW OF MULTI-CENTRE RESEARCH (NATIONAL APPROACH)

Manual:	Policies	**Document ID:**	PI029	**Date Created:**	May 13
Section:	Investigator	**No. Pages:**	2	**Review Date:**	Jun 17
				Future Review Date:	Jun 19

PURPOSE

To outline the requirements for all applications submitted under The National Approach, which is a national system where the single ethical review by an HREC would be recognized by all institutions participating in a collaborative research project. The National Approach aims to reduce the duplication of ethics review and improve timelines for research start-up.

Bellberry has been granted certification for ethical review processes relating to Bellberry Human Research Ethics Committees A, B, C and D.

For applications submitted under the National Approach, Bellberry has the following responsibilities:

- Review a multi-centre human research proposal to form a view on its ethical acceptability (in accordance with the National Statement).
- Ensure the project is compliant with relevant guidelines, regulations and legislation (institutional, State and Federal).
- Provide the Coordinating Principal Investigator, and/or the Principal Investigator, with the outcome of the ethical review of the multicentre human research project.
- Advise and receive reports from institutions regarding complaints or reports of research misconduct arising out of the conduct of approved multi-centre human research.
- Monitor research for which it has given approval, through the receipt of safety, progress and any other required reports in conjunction with the participating institutions and their research governance offices.

All applicants should refer to the NHMRC Research Governance Handbook: Guidance for the National Approach to Single Ethical Review. This Handbook provides investigators engaged in multi-centre human research an understanding of governance activities that the institution must address before, during and after research, as well as how the relationship between the Coordinating Principal Investigator (CPI) and the ethical review process supports these activities.

When submitting an application, the following is required:

1. The application is required to be submitted by the Coordinating Principal Investigator (CPI) from the lead site, who is responsible for coordinating and overseeing the other sites.

2. The application is required to be submitted via eProtocol, completing the eProtocol application form, and attaching all relevant documentation.

3. It is a requirement that the Human Research Ethics Application (HREA) be completed and attached to the application. This is also satisfied via the eProtocol application form, and is to be attached under the relevant heading in the Attachments section.

4. All Principal Investigators must be listed in the application. The name and physical location of each and the site where they will conduct the study must also be listed in the application.

   Bellberry will correspond with the Coordinating Principal Investigator.

5. A generic Participant Information Sheet and Consent Form (PICF) is attached to the application. Once Bellberry approves the generic template (PICF) with the approval of the lead site, the CPI will submit the site specific PICF for each site.

6. The application must indicate any state specific legislation and administrative policies that apply to the application. These will be outlined in each of the relevant sections of the HREA.

7. Sponsor/Site Indemnities, HREC Indemnities and Certificates of Currency for all sites and investigators involved in the study will also be required to be submitted.

The Lead Site is also responsible for:

Coordinating Submissions

As the lead site is responsible for responding on behalf of the other sites, then the questions/comments raised by the committee are sent to the Coordinating Principal Investigator only.

Amendments and other Reports

The lead site will complete the Amendment form in eProtocol. The approval letter will note all the National Approach sites for which the amendment applies.

All other reports including Progress Reports, Protocol Violations, Safety Reports, SAEs and SUSARs will also be submitted in eProtocol by the Coordinating Principal Investigator on behalf of all sites.

Final Reports

The Final Report will be submitted by the Coordinating Principal Investigator, and will not be accepted until the study has closed at all sites.

References and Acknowledgements:

NHMRC Research Governance Handbook: Guidance for the National Approach to Single Ethical Review (December 2011)

www.health.nsw.gov.au/ethics/research

www.health.vic.gov.au/ethics

National & State Statutory and Administrative Frameworks for Ethical Review of Multi-centre Studies.