Purpose

To give an overview of the review pathways available for human research that involves lower risk or higher risk.

Definitions

ARTG: Australian Register of Therapeutic Goods.

Identifiable data: When the identity of a specific individual can reasonably be ascertained the data is referred to as "identifiable data". Examples of identifiers may include name, date of birth, address, postcode (particularly small sets of data or small districts).

IVD: In vitro diagnostic device.

Non-identifiable data: Data that has never been labelled with individual identifiers or; data that has had the identifiers permanently removed in such a way as to ensure no specific individual can be identified.

***Re-identifiable* data (potentially identifiable data):** Data that may have identifiers removed and replaced by a code (including but not limited to UR numbers). In such cases it is possible to use the code to re-identify the person to whom the data relates. In these cases, the data are referred to as "potentially identifiable".

TGA: Therapeutic Goods Administration.

Therapeutic goods: Include drugs, devices, and biologics, and are broadly defined as products for use in humans in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury
- influencing, inhibiting or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling or preventing conception
- testing for pregnancy.

Unapproved therapeutic good:

- Any medicine not included in the ARTG or any medicine already in the ARTG involving a new formulation, strength or size, dosage form, name, indication(s), directions for use, or type of container.
- Any medical device (including an in vitro diagnostic device (IVD)) not included in the ARTG, such as any new sponsor, manufacturer, device nomenclature system code, classification or unique product identifier (for certain classes of medical devices only) of a medical device already in the ARTG.
- Any in-house IVD medical device used for a clinical trial, where the laboratory providing the in-house IVD is unable to comply with the regulatory requirements for in-house IVDs.
- Any biological not included in the ARTG such as:
    - any new applicable standards, intended clinical use, or principal manufacturer of a Class 1 or 2 biological already in the ARTG.
    - any new product name, dosage form, formulation or composition, therapeutic indication, type of container or principal manufacturer of a Class 3 or 4 biological already in the ARTG
    - any use of a therapeutic good already included in the ARTG not covered by the existing entry in the ARTG.

Guidance

Human research is conducted with or about people, or their data or tissue. Human participation in research may include the involvement of humans through:

- participating in surveys, interviews or focus groups
- psychological, physiological, or medical testing or treatment
- researchers observing their responses, actions or behaviour
- researchers having access to their personal documents or other materials
- the collection and use of their body organs, tissues, or fluids (e.g., skin, blood, urine, saliva, hair, bones, tumour or other biopsy specimens) or their exhaled breath
- access to their information (in individually identifiable, re-identifiable or non-identifiable form) in an existing published or unpublished source or database.

The National Statement on Ethical Conduct in Human Research (2025) is the principal reference for research involving humans in Australia. Relevant chapters and paragraphs from the National Statement are cited throughout this document, for example as (3.2).

Clinical trials

A clinical trial is a research study designed to assess the safety and/or effectiveness of a therapeutic product. In trials regulated by the TGA, “research” refers to any use of an unapproved therapeutic product. When participants are given a therapeutic product to evaluate its safety and/or efficacy, the research must include objectives measures, meaning the outcomes cannot be based on subjective interpretation.

Retrospective review

As per the National Statement Chapter 5.1.6, Bellberry does not provide counterfactual opinions or retrospective reviews for any work already undertaken.

Exempted research

Bellberry does not provide letters stating that research is exempt from ethical review. Institutions are responsible for assessing a research project to determine if ethical review is required in consultation with the National Statement, Chapter 5.1. Bellberry HREC will only accept submissions for either lower risk review or full HREC review.

Assessment of risk level

To determine the level of ethical review required, an assessment of the level of risk involved in the research project must be conducted, referring to the *National Statement on Ethical Conduct in Human Research (2025)* Chapter 2.1.

The risk profile of an individual research project falls somewhere along a continuum. Risk assessment should be based on the following categories.

Lower risk		Higher risk (Individual, group, community, societal or global)	
Minimal	**Low**	**Greater than low**	**High**
No risk of harm or discomfort; potential for minor burden or inconvenience*	No risk of harm; risk of discomfort (+/- foreseeable burden)	Risk of harm (+/- foreseeable burden)	Risk of significant harm (+/- foreseeable burden)

Higher risk research

Higher risk research describes research in which the risk for participants or others is greater than discomfort and carries risk of harm. Higher risk research requires full ethics review by an HREC (National Statement Chapter 2.1).

The National Statement Chapter 2.1 identifies the types of potential harms that could occur in or from research.

Review by the full HREC is required for the following types of research as identified by the relevant chapters of the National Statement.

- Opt-out Consent: Research proposals using opt-out consent and where s95 or 95A Privacy Act guidelines apply (2.3).
- Active concealment or planned deception or aims to expose illegal activity (2.3.4)
- Waiver of consent: requested for research using personal information in medical research, or personal health information (2.3.9)
- Prospective collection of biospecimens for research purposes (3.2.1).
- Genetic testing: however, where information used cannot identify an individual and no linkage of data is planned, the research may be determined to carry lower risk (3.3).
- Animal-to-human xenotransplantation (3.4).

The National Statement no longer assumes that particular participant groups must always be excluded from research. Instead, it recognises that involvement is possible where the research is ethically justifiable and the risks are appropriate. Research in the following areas may require full HREC review; however, the risk level will be considered within the context of the research in determining the appropriate pathway:

- Pregnancy, the human fetus and human fetal tissue (Chapter 4.2)
- Children and young people under 18 years of age (Chapter 4.3). In particular, lower risk research could potentially include young people between 14/15-17 based on the National Statement 4.3. If researchers wish to take this approach, a justification will need to be provided using National Statement 4.3.8.
- People experiencing physical or mental ill-health, or disability (Chapter 4.5)
- Research involving Aboriginal and Torres Strait Islander peoples and communities (Chapter 4.7)
- Research that may uncover illegal activity (Chapter 4.9)

The following research is excluded from review via the Bellberry Lower Risk pathway and must be reviewed by a full HREC.

- Research that involves Artificial Intelligence (AI) technologies as a central component of the research (e.g., tool development, evaluation, or deployment in health or behavioural contexts).

General guidance for full HREC review

Bellberry HRECs meet each Wednesday evening. Our submission timelines are as follows:

- An application and documents are required 10 working days prior to the meeting day with submission cut off 5pm every Wednesday. A complete application will usually be considered at a HREC meeting on the Wednesday two weeks following the submission cut off. Incomplete applications may delay the study's review.
- Generally, three meetings are held each week, except between Christmas and New Year.
- An investigator can expect to receive comments detailing the HREC's deliberations 2 working days following the HREC meeting.
- All responses to the HREC's requests/comments are reviewed outside of the meetings and a response will be received generally within a week.
- This meeting date to application decision timeline is dependent on the complexity of the study being reviewed and response time for an investigator to respond to the HREC's questions.

Principal Investigator's/researchers may be invited by the HREC to attend review meetings to present their study, or answer concerns in regard to specific issues either in person or via telephone.

Where issues remain unresolved following HREC review, the HREC Chair will consider a teleconference upon request from the Principal Investigator. The Principal Investigator must be present and there must be no more than three attendees from the sponsor and site combined. In the event issues are unresolved, the complaints procedure may be followed.

Lower risk review

Lower risk research describes research in which the only foreseeable risk for participants or others is no greater than discomfort (2.1). Lower risk research may be reviewed by the Bellberry Lower Risk Sub-committee (5.1.12).

Discomfort is considered less serious than harm. It can involve physical or psychological impacts, for example, minor side-effects of medication, discomfort related to non-invasive examinations or tests (such as measuring blood pressure), and mild anxiety associated with an interview. Where a person's reactions might exceed discomfort and become distress, this should be viewed as the potential for harm (2.1).

Please refer to the Higher Risk review section for a list of exclusions from Lower Risk review.

General guidance for lower risk review

Responsibility for reviewing research involving lower levels of risk has been delegated to the HREC Chair and/or the Lower Risk Sub-Committee (5.1.12).

Our submission timelines and processes are as follows:

- An investigator may request Lower Risk review of their research proposal by submitting an application through the eProtocol online platform with the completed LER F1.1.16 Application for Lower Risk Review form. Applications that do not include this completed form will be returned to the Investigator.
- Applications can be submitted at any time but submission by close of business each Wednesday will allow for addition to that week's meeting agenda for full HREC review if the research is reassessed as high risk. The investigator will be notified of any outcomes/comments via eProtocol. Ongoing cycles of comments and responses will continue until an outcome has been reached.
- The Operations Manager or delegate and HREC Chair will review the study to determine the level of risk and determine the appropriate level of review and, if necessary, the composition of the Sub-

Committee. The Sub-Committee will be a person or persons with appropriate expertise selected from all Bellberry HREC members, with external expertise sought if needed.

- If the Sub-Committee decides that a full HREC review is required, the investigator will be notified that the project will need to be redirected to the full ethical review process. Upon confirmation from the investigator, the study will be assigned to an HREC meeting.
- After approval, the investigator must submit any amendments to the project protocol or study documentation, serious breaches, safety reports, an annual progress report, and a report when the project is completed.

Taking over ethical oversight of approved research

Any request by a Principal Investigator for Bellberry to take over ethical oversight of a research study which has been approved by another HREC will be treated as a new application. Bellberry will require a full submission via eProtocol to be reviewed by the full HREC. Approval by Bellberry will not be guaranteed. Transfer of the study cannot take place until Bellberry has provided ethics approval.

Please refer to LER F1.1.13 Transfer of Ethical Oversight Guidance.

Review fees

Please refer to BA G6 Application Fees.

References

National Statement on Ethical Conduct in Human Research (2025)
NHMRC Guidelines under section 95 of the Privacy Act 1988
NHMRC Guidelines under section 95A of the Privacy Act 1988
LER F1.1.13 Taking over ethical oversight checklist

Appendix 1. Review flowchart