Purpose

To outline the monitoring activities Bellberry undertakes as part of its external auditing processes in accordance with section 3.1.9 and Chapter 5.4 of the *National Statement on Ethical Conduct in Human Research (2025)*.

Definitions

Auditing: The process of verifying that the conduct of research conforms to the approved proposal. Bellberry undertakes auditing in one of two ways:

- Site monitoring: completed face to face at the research site by Bellberry staff.
- Desktop auditing: remote monitoring completed by a member of the research team at Bellberry's request, using the Bellberry provided Desktop Audit form.

HREC: Human Research Ethics Committee.

ISF: Investigator Site File.

NTF: Note to File.

PI: Principal Investigator.

Research governance: Refers to the processes used by institutions to ensure that they are accountable for the research conducted under their auspices. Elements of research governance include compliance with legislation, regulations, guidelines and codes of practice; legal matters, including contracts, and indemnity/insurance frameworks; financial management, risk management and site-specific assessment; institutional policies and procedures for responsible research conduct and managing research misconduct; management of collaborative research; and reporting requirements.

RGO: Research Governance Office.

Guidance

Bellberry staff will undertake desktop auditing or site monitoring:

- on a routine basis,
- to confirm compliance when reporting obligations have not been met,
- after receiving a complaint of ethical concern,
- 'for cause', at the Human Research Ethics Committee's (HRECs) request or recommendation, or
- to review corrective or preventative strategies identified through a previous audit.

Bellberry has prepared audit readiness checklists to assist sites in preparing for an ethics audit. Please see Appendix 1 for the checklist for clinical studies and Appendix 2 for non-clinical studies.

Desktop Auditing

From time to time, research sites will be requested to complete a Desktop Audit. The Principal Investigator (PI) and nominated contact(s) will be emailed the relevant materials and supporting documents. Bellberry will generally limit distribution of the Desktop Audit material to the study's PI and nominated contact(s).

The PI/nominated contact(s) will be provided with seven calendar days from initial audit request to acknowledge receipt of the Desktop Audit request. If there are delays in the PI/nominated contact(s) acknowledging receipt of the Desktop Audit request or completing the Desktop Audit, their access to eProtocol may be limited until the requested information is provided. If access to eProtocol is to be made limited, Bellberry will notify affected site personnel.

Following the research site's completion and submission of the audit form, Bellberry will review the responses and associated information provided. Bellberry staff will correspond with research site personnel to rectify any identified issues. If required, Bellberry may request the provision of additional information. If no additional information is required, the site will receive an audit close out report.

Where inadequate information is received, the site may be placed on a higher frequency for desktop auditing or may be included on Bellberry's site monitoring schedule.

In addition to the above, Bellberry may request sites to complete desktop audits prior to a site monitoring visit to ensure approved studies are being conducted within the parameters of HREC approval.

Site Monitoring

Site Monitoring by Bellberry staff ensures approved studies are being conducted consistently within HREC approval parameters. When required, the HREC Chair may be involved in the site visit.

The PI will be notified of Bellberry's intention to conduct Site Monitoring and a mutually convenient time to attend will be arranged. Once confirmed, the PI will receive confirmation of the impending visit, the name of the attendee(s) required to be present, and any other information relevant to the Site Monitoring visit.

Bellberry does not routinely require the PI, Sub-Investigators or research participants to be present during the audit. If required, Bellberry staff will confirm these requirements during the initial scheduling stage.

Following the Site Monitoring visit, the PI will receive an outcome letter outlining any findings of note. If any action is required, the PI will be notified and advised of the timeframe to respond to or implement these actions. If no action is required, the site will receive an audit close out report.

Site Monitoring Responsibilities

The auditor(s) will:

- contact the site outlining the reason for a visit and who the auditors will be,
- notify the PI in writing of the confirmed date and time of the visit,
- if required, request that some study documentation be provided prior to the visit,
- attend the site,
- conduct opening and closing meetings, in which the site will be informed about the visit and outcomes,
- if required, auditors have the authority to observe the consent process. Observing the consent process may be a requirement at a 'for cause' monitoring visit but generally does not apply to routine monitoring visits,
- review all documentation, including study records, consent forms, participant files, staff training files and standard operating procedures,
- inform the HREC Chair, Bellberry CEO and Director of Operations of any items of concern,
- provide an outcome letter to the PI, outlining any required actions and timeframes, as soon as possible after the visit,
- follow up any identified actions with the site.

The investigator(s) will:

- if applicable, inform the sponsor and the institution's RGO of the audit request,
- assist with arranging the site visit,
- provide space for the auditors and other resources for the visit,
- ensure all relevant personnel are available for the visit, including participants if the HREC has asked to speak to one or more,
- be available during the audit or nominate a suitable delegate to be available as the site representative (this is usually the trial unit manager or study coordinator). The site representative should be available for the opening and closing meetings as a minimum, but can be absent during the body of the audit,
- ensure all relevant documentation is available for inspection, including study files and records, consent forms, participant files, staff training files and standard operating procedures,
- if applicable, inform the sponsor and the institution's RGO of the audit findings and recommendations,
- rectify any issues and implement identified actions within the time frames requested by the HREC.

References

National Statement on Ethical Conduct in Human Research (2025)
The Australian code for the responsible conduct of research (2018)

Appendix 1: Audit Readiness Checklist – Clinical Study

Bellberry recommends considering the following requirements when preparing for a clinical study ethics audit.

Terms and conditions of ethical approval	
Review your HREC approval letter to ensure all conditions have been adhered to.	☐

Take appropriate corrective action if you identify non-compliance with the terms and conditions outlined on your approval letter; this may include, for example:
• submission of an Amendment form to inform the HREC of:
  ○ a change in study personnel,
  ○ the outcomes of any audit by a regulator or organisation/body,
  ○ any other changes to study documents,
• submission of progress reports via a Progress Report form,
• submission of HREC reportable safety events via a Safety Report form,
• submission of serious breaches via a Serious Breach Report form.
	☐

Ensure all records are available and appropriately filed; this may include, for example: • HREC approval letters, other applicable HREC documents, • RGO approval letters, • Notes to File (NTF) for records located outside of Investigator Site Files (ISFs), • fully executed insurance certificates, indemnities, and clinical trial research agreements (CTRAs), • medical registration certificates, clinical trial notifications (CTNs), financial disclosure forms (FDFs).	☐
eProtocol application is current and accurate	
Review your eProtocol application to ensure all sections are current and accurate.	☐
If you need to rectify any discrepancies, ensure you submit an amendment to make the appropriate updates; this may include, for example: • addition or removal of research personnel, • update to contact information, etc.	☐
Training and delegation	
Review your delegation logs. Ensure: • handwriting is legible, • study personnel have been appropriately trained and delegated, ○ in clinical trials, those delegated authority to complete the informed consent process must be a medical doctor with appropriate knowledge and experience. • the end date is recorded for personnel no longer involved in the study.	☐
Review your training logs. Ensure relevant documents (e.g. curriculum vitae (CV), good clinical practice (GCP) certificates, International Air Transport Association (IATA) certificates, etc.) are available, appropriately filed, and training has been completed in appropriate timeframes.	☐
Include a NTF for records located outside of ISFs.	
Essential documents	
Perform a comprehensive revision of essential documents, confirming that local superseding processes have been followed.	☐
Include a NTF for essential documents located outside of the ISF.	☐

Informed consent	
Review your informed consent processes and documentation. Ensure that all participants provided ongoing informed consent and that the documentation is complete, including: • participants are consented using current HREC and RGO approved PICFs, • site specific documents are based on current approved master documentation, • completed consent forms include participant signature, name of consenting investigator, date of consent, etc., • records documenting the informed consent discussion are available.	☐
Standard operating procedures (SOPs)	
SOPs are available relevant to the type and nature of the research conducted. A research institution should have the following SOPs for clinical studies, as a minimum: • obtaining informed consent, • complaints management and resolution, • data management, privacy, and confidentiality, • specimen handling and shipping, • IP dispensing, • drug destruction on-site, • laboratory, • use of personal protective equipment (PPE), • conflict of interest management and resolution, • training on study documents, • archiving, • study termination – study close out.	☐
Legislation and guidelines	
The research is conducted in accordance with the Guideline for Good Clinical Practice (GCP) (with TGA annotations), local regulatory and governance requirements, other applicable industry codes and guidelines, and in accordance with the NHMRC's: • National Statement on Ethical Conduct in Human Research, • Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods, • Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods, and • The Australian Code for the Responsible Conduct of Research.	☐

Appendix 2: Audit Readiness Checklist – Non-Clinical Study

Bellberry recommends considering the following requirements when preparing for a non-clinical study ethics audit.

Terms and conditions of ethical approval	
Review your HREC approval letter to ensure all conditions have been adhered to.	☐

Take appropriate corrective action if you identify non-compliance with the terms and conditions outlined on your approval letter; this may include, for example:
• submission of an Amendment form to inform the HREC of:
  ○ a change in study personnel,
  ○ any other changes to study documents,
• submission of progress reports via a Progress Report form,
• submission of serious breaches via a Serious Breach Report form.
	☐

Ensure all records are available and appropriately filed; this may include, for example: • HREC approval letters, other applicable HREC documents, • Notes to File (NTF) for records located outside of study files, • fully executed insurance certificates and indemnities.	☐
eProtocol application is current and accurate	
Review your eProtocol application to ensure all sections are current and accurate.	☐
If you need to rectify any discrepancies, ensure you submit an amendment to make the appropriate updates; this may include, for example: • addition or removal of research personnel, • update to contact information, etc.	☐
Essential documents	
Perform a comprehensive revision of essential documents, confirming that local superseding processes have been followed.	☐
Include a NTF for essential documents located outside of the study file.	☐
Informed consent	
If applicable for the study, review your informed consent processes and documentation. Ensure that all participants provided ongoing informed consent and that the documentation is complete, including: • participants are consented using current HREC approved PICFs, • site specific documents are based on current approved master documentation, • completed consent forms include participant signature, name of consenting investigator, date of consent, etc. • records documenting the informed consent discussion are available.	☐

Standard operating procedures (SOPs)	
SOPs are available relevant to the type and nature of the research conducted. A research institution should have the following SOPs for non-clinical studies, as a minimum: • obtaining informed consent, • complaints management and resolution, • data management, privacy, and confidentiality, • conflict of interest management and resolution, • training on study documents, • archiving, • study termination – study close out.	☐
Legislation and guidelines	
The research is conducted in accordance with local regulatory requirements, other applicable industry codes and guidelines, and in accordance with the NHMRC's: • National Statement on Ethical Conduct in Human Research, and • The Australian Code for the Responsible Conduct of Research.	☐