Purpose

This document outlines the monitoring activities Bellberry undertakes as part of its auditing processes in accordance with *section 3.1.9 and chapter 5.4* of the *National Statement on Ethical Conduct in Human Research (2023)*.

Definitions

Auditing: is 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 tool.

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 random basis,
- to confirm compliance when reporting obligations have not been met,
- after receiving a complaint,
- 'for cause', at the HREC's request or recommendation, or
- to review corrective or preventative strategies identified through a previous audit.

Bellberry recognises that some sites have a formalised governance process. To avoid duplication, Bellberry encourages collaboration between the HREC and local RGO, where one exists.

As an independent HREC, Bellberry will seek confirmation that governance processes are in place throughout the duration of a study. This will primarily occur through desktop auditing and site monitoring.

Desktop auditing

From time to time, research sites will be requested to complete a desktop audit. The PI and nominated contact(s) will be emailed the relevant materials and supporting documents. Bellberry will limit distribution of the desktop audit material to the study's PI and nominated contact(s). If necessary, to circulate further, the PI/nominated contact(s) must first update the personnel information page.

The PI/nominated contact(s) will be provided with seven calendar days from initial audit request to acknowledge receipt of the desktop audit.

If the PI/nominated contact fails to acknowledge receipt of the desktop audit within seven calendar days, a reminder will be generated advising the PI that access to eProtocol will be limited until the requested information is provided.

Following completion and submission of the audit form, Bellberry will review the responses and associated information provided, and confirm that the responsibilities and accountabilities for individuals and groups are understood, enacted, and maintained. If required, Bellberry may request the provision of additional information. If no additional information is required, the site will receive an acknowledgement letter.

Following fourteen calendar days with no response, access to eProtocol will be limited until the requested information is provided. A letter will be generated advising the PI that this has occurred, and the action required to be taken.

Bellberry staff will correspond with site personnel to rectify identified issues. 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.

When the PI provides contact information for the institution's RGO (or representative responsible for research governance oversight) by way of the desktop audit form, the RGO will also receive a copy of the outcome letter and completed desktop audit form. It is the responsibility of the PI/research team to check any local governance requirements regarding the initial RGO notification of the audit.

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, co-investigators, or research participants to be present during the audit. Bellberry staff will confirm these requirements during the initial scheduling discussion, if required.

Responsibilities

Site monitor responsibilities

The site monitor(s) will:

- contact the site outlining the reason for a visit and who will inspect the site,
- notify the PI in writing of the confirmed date and time of the visit,
- conduct opening and closing meetings, in which the site will be informed about the visit and outcomes,
- if required, site monitors 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 random basis monitoring visits,

- review all documentation, including study records, consent forms, participant files, staff training files, equipment servicing records, policies, and standard operating procedures,
- inform the HREC Chair, Bellberry CEO and Operations Manager of any items of concern,
- provide an outcomes 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.
- If identified, Bellberry may communicate any significant outcomes to the sponsor and institution's RGO (if applicable).

Investigator responsibilities

The investigator(s) will:

- help arrange the site visit, if required;
- provide space and other resources for the site inspection;
- 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, participant files, staff training files, equipment servicing records, policies and standard operating procedures;
- rectify any issues and implement identified actions within the time frames the HREC requests;
- inform the sponsor of the audit and its findings.

Please review the audit readiness checklist provided at the end of this document. While it is not compulsory to use, this checklist is designed to assist you in preparing for a site monitoring visit or a desktop audit, ensuring all necessary items are addressed

Following the site monitoring visit, the PI will receive an outcomes letter outlining any findings of note. If any action is required, the PI will be notified.

References

National Statement on Ethical Conduct in Human Research (2023)
The Australian code for the responsible conduct of research (2018)

Audit readiness checklist

Bellberry recommends considering the following requirements when preparing for an 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 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 a progress report,
• submission of HREC reportable safety events via a safety report,
• submission of serious breaches.
	☐

Ensure all records are available and appropriately filed; this may include, for example: • HREC approval letters, HREC composition lists, other applicable HREC documents, • RGO approval letters, • NTFs for records located outside of ISFs, • fully executed insurance certificates, indemnities, and clinical trial research agreements (CTRAs), • medical registration certificates, clinical trial notifications (CTNs), financial disclosure forms (FDFs), etc.	☐
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, if anything has changed, 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,
  ○ in social science projects, those delegated authority must be study personnel with appropriate knowledge and experience relevant to the research area,
• the end date is recorded for personnel no longer involved in the project.
	☐

Review your training logs. Ensure relevant documents (e.g. curriculum vitae, 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, 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 resolution, • archiving, • study termination – study close out.	☐

Laboratory and pharmacy	
Records are available, as appropriate, for: • drug receipt and shipping, • drug accountability logs and reconciliation, • temperature logs, • calibration records.	☐

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.	☐