Purpose

This document outlines the monitoring activities Bellberry undertakes as part of its auditing processes in accordance with section 3.1.9 and chapter 5.5 of the *National Statement on Ethical Conduct in Human Research (2007, incorporating all updates)*.

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: is 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.

NC: Nominated Contact.

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 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 using *MAR F6.2.1 Desktop audit.* The Principal Investigator (PI) and nominated contact(s) (NC) will be emailed MAR G6 and a template of MAR F6.2.1 for each study selected to be audited.

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/NC must first update the personnel information page.

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

If the PI/NC 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.

The PI and nominated contact(s) will be provided with a link to upload audit materials to Bellberry's secure remote monitoring portal. Access to this portal will lapse after 14 calendar days from the initial audit request.

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 Principal Investigator 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 Principal Investigator 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.

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.

Bellberry staff will undertake site monitoring:

- on a random basis, or
- 'for cause', at the HREC's request or recommendation, or
- to review corrective or preventative strategies identified as necessary at a previous site visit.

The Principal Investigator 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.

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 Principal Investigator 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 of any items of concern,
- provide a full (internal) report to the Bellberry CEO and an outcomes letter to the Principal Investigator, 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 research governance office (if applicable).

Investigator responsibilities

The investigator(s) will:

- help arrange the site visit,
- 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,
- 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.
- The PI/delegate is responsible for informing the sponsor of the audit and its findings.

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 (2007 incorporating all updates)

The Australian code for the responsible conduct of research 2018

MAR F6.2.1 Desktop audit – clinical

MAR F6.2.2 Desktop audit – non-clinical