POLICYI009a SITE MONITORING

Manual:	Policies	**Document ID:**	PI009a	**Date Created:**	Jul 04
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PURPOSE

The primary purpose of conducting site monitoring is to ensure approved studies are being conducted consistently within the parameters given under the HREC's approval, pursuant to the National Statement on Ethical Conduct in Human Research Chapter 5.5 and Section 3.3.5.

This procedure outlines the process for undertaking site monitoring.

1. Bellberry Human Research Ethics Committees will undertake site monitoring:
- on a routine and random basis, and
- 'for cause' monitoring may be undertaken at other times at the request and/or recommendation from the Bellberry HREC's, and
- to review corrective and/or preventative risk management strategies implemented following identification at a previous Bellberry site monitoring visit.

2. The monitoring of sites will be conducted by experienced Bellberry HREC personnel and/or by a third party with delegated responsibility to undertake the work on behalf of Bellberry.

3. Bellberry will provide the Bellberry Site Monitor with a complete list of studies requiring review at the site, and advise the Principal Investigator in writing of the basis for the visit and the name of the person who will conduct the site monitoring.

4. The Site Monitor will provide a full report to Bellberry for reporting to the relevant HREC or delegate.

5. Investigator responsibilities:
- Assist with reaching a mutually agreeable time for the monitoring to take place.
- Ensure all relevant personnel are available at the time of the visit.
- Ensure all relevant organisational documentation, study records and files are available for review e.g. study files, participant files, staff training files, equipment servicing records, policies and Standard Operating Procedures.
- Provide access to space for the review to take place for the provision of interviews with site personnel and study participants plus to impart feedback as necessary.

6. The Chair of each Bellberry HREC or delegate will review all Site Monitor reports.

7. If any follow-up is required, the investigator will be informed regarding the HREC's decision, in writing, and as soon as possible following the visit. The recommended corrective action required will be identified in writing with time frames given in which to rectify the matter.

8. Copies of site visit reports will not be made available to Sponsors or sites.

9. All site information will remain confidential. Any third party engaged to conduct site monitoring on behalf of Bellberry HREC's will sign and be bound by a confidentiality agreement.

Refer Policy PI009 – Monitoring of Approved Trials

Note: The Bellberry Site Monitor refers to the person with the delegated responsibility to undertake the site monitoring on behalf of the Bellberry HREC's.

This policy should be read in conjunction with the following documents:

The National Statement for Ethical Conduct in Human Research 2007
The Australian Code for the Responsible Conduct of Research 2007

And the following Bellberry Policies

SOPI004	Informed Consent
PolicyI002	Participant Payment and Reimbursement
PolicyI003	Conflicts of Interest
PolicyI004	Serious Adverse Event Reports
PolicyI005	Complaints relating to Research
PolciyI007	Ionising Radiation
PolicyI008	Advertising
PolicyI010	Monitoring - Progress Reports
PolicyI011	Data Storage and Retention
PolicyI012	Bisphosphonates Policy
PolicyI013	Pregnancy and Sexual Health Policy
PolicyI014	Compensation Policy
PolicyI015	Investigator Qualifications Policy
PolicyI018	Adult photographic release form
PolicyI019	Protocol Violations

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