

SOPC006 SITE MONITORING

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PURPOSE

To outline the process for undertaking site monitoring as per **Section 5.5 (d)** of the National Statement.

1. BELLBERRY COMMITTEE MANAGER RESPONSIBILITIES

- Liaise with Chief Executive and Operations Manager about selection of sites to be monitored.
- Liaise with Site Monitor about sites to be monitored and required timeframes.
- When a third party conducts Site Monitoring on behalf of Bellberry, advise the Principal Investigator in writing of the basis for the visit and the name of the person who will conduct the site monitoring (refer letter to PI template).
- Provide the Bellberry Site Monitor with a list of studies requiring review at the site (When external third party conducts monitoring refer template Summary Information for Site Monitor & instructions therein).
- Provide third party Site Monitor with template Site Visit Monitoring Checklists – Study Specific and Site Specific to be completed for each site and study.
- Ensure copies of all correspondence between third party Site Monitor and study site are provided to Bellberry.
- Provide Site Monitor's full report to the relevant HREC or delegate.
- Upload relevant information and save site/study reports on eProtocol (per SOPA023).
- Upload Site Reports to Committee Member pages of Bellberry website.
- Collate relevant information to be included in annual report to Policy Committee (per SOPA023).

2. BELLBERRY SITE MONITOR RESPONSIBILITIES

- Contact the site and arrange a mutually agreeable time for the visit to take place.
- Ensure the meeting date and time is confirmed in writing with the investigator.
- Negotiate the use of office space to enable the review of documentation, for meeting with personnel and to provide feedback with the investigator.
- Negotiate with the investigator to ensure all relevant study records and files are available for review at the time of the visit eg study files, participant files, staff training files, position descriptions, equipment servicing records.
- Confirm with the investigator if a participant is required for interview at the time of the visit.
- Informal feedback will be given to the site by the Bellberry Site Monitor prior to the end of the visit.
- Provide a full report to the Bellberry Operations Manager/Committee Manager for reporting to the relevant HREC or delegate.

- Report is to include any recommendation for a follow-up visit to observe implementation of any corrective and/or preventative risk management strategies required when a site is not meeting relevant guidelines which is or has the potential to put participants at risk.
- All correspondence between the Bellberry Site Monitor and investigators must be copied to the Committee Manager, Bellberry Limited.

3. 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.

4. HREC (OR DELEGATE) RESPONSIBILITIES

- Review Site Monitor reports and prepare response to Investigators.
- Determine if any follow-up is required, and inform the Investigator regarding the HREC's decision, in writing, as soon as possible following the visit. Recommended corrective action will be identified in writing with time frames given in which to rectify the matter.

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