

POLICYI009 MONITORING OF APPROVED TRIALS

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PURPOSE

Bellberry HRECs will monitor approved trials in the following ways as per the National Statement **Chapter 5.5:**

- Serious Adverse Events Reports
 - Protocol Violations
 - Progress Reports
 - Site visits
1. Serious Adverse Events Reports – see Policy PI004
 2. Protocol Violations – see Policy PI019
 3. Progress Reports – see Policy PI010
 4. Site Monitoring – see Policy PI009a
- Bellberry HRECs or a third party may undertake site visits to assess on-site monitoring and compliance with regard to consent procedures, verification of data sources, study protocol and documentation procedures.
 - Sites will receive a site visit confirmation notice advising of the impending visit and the name of the attendee. If any follow up is required the Investigator will be notified. Copies of site visit reports will not be made available to sponsors or sites.
 - A request may be made to interview willing participants at this time.