

POLICYI010 MONITORING – PROGRESS REPORTS

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PURPOSE

To explain the monitoring requirements for research projects to ensure continued approval as per the National Statement **Chapter 5.5**.

Continued approval of a research protocol is dependent on the receipt of an annual progress report from the Principal Investigator.

- 1.** The first report is to be no later than twelve months from commencement of the research (or on completion of the trial if sooner) and annually thereafter. If a request for an annual progress report is not received within sixty (60) days, ongoing approval of the project by the Bellberry HREC will automatically lapse.
- 2.** The progress report must be completed via eProtocol and includes the following information:
 - Compliance of the trial with the approved protocol, consent procedures and documentation
 - Any new information which may have an impact on the continued ethical acceptability of the trial or that may indicate the need for amendments
 - Reasons for lack of result in any area or if the trial is discontinued before the expected completion date.
 - Security of records
- 3.** An annual review of project is to be undertaken to determine the ongoing validity.
- 4.** A Final Report must be submitted once the research is completed.

For National Approach (HoMER) applications, the Final Report should be submitted by the Coordinating Principal Investigator only once the research is completed at all sites.