

## **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**.

Annual review of a research project is to be undertaken to determine the ongoing validity and continued approval of a research project. This is dependent on the receipt of an annual progress report from the Principal Investigator.

- 1.** The first report is required no later than twelve months from commencement of the research (or within three months of completion of the project if sooner) and annually thereafter, for ongoing projects. If not received, then it will be requested by Bellberry. If a requested annual progress report is not received within sixty (60) days, ongoing approval of the project by the Bellberry HREC will automatically lapse.
- 2.** Phase I studies  
In line with the National Statement sections 5.5.2 and 5.5.5, reflecting the increased degree of risk, and duration of Phase I trials, upon review of the study, the Committee will make a determination on whether more regular Progress Reporting will be required. The reporting requirements for the study will be outlined in the study Approval Letter. Approval of trials beyond Phase I will usually be contingent on receipt of the Phase I report.
- 3.** The progress report must be completed via eProtocol.
- 4.** A Final Report must be submitted within three months of completion of participant involvement.

For National Approach applications, the Final Report should be submitted by the Coordinating Principal Investigator only, within three months of completion of participant involvement at all sites.