Guidance: Materials Required for IRB Review and Approval

This document outlines the materials investigators should include with submissions for IRB review in order to provide sufficient information for the IRB and HRPP Office to make specific determinations.

Initial Review
The following materials are required for initial review:
- Clinical Research Trial Questionnaire
- Questionnaires, surveys, flyers, posters, advertisements, recruitment materials, etc.
- Informed Consent Forms or, as applicable, Request for Waiver or Waiver of Documentation with applicable Information Sheet
- Protocol
- Investigator’s Brochure (if applicable)
- Data Collection Sheets
- Investigator Financial Disclosure and Agreement for all investigators
- CVs and Completion of CITI for all research staff (reports automatically sent to HRPP)
- Patient materials (ID cards, diaries, dosing or appointment schedules, brochures, etc)
- Other study related documents

Continuing Review
The following materials are required for continuing review as applicable:
- Completed Continuing Review Report
- Serious Adverse Event (SAE) Summary Log (only if study is not overseen by Central Safety Monitoring Committee)
- Deviation Log (if applicable)
- Most recent DSMB Report
- Most recent literature
- Summary of Participant Complaints
- Any relevant reports

Amendments to Previously Approved Research
The following materials are required for amendments:
- Completed Amendment to Previously Approved Research form
- Relevant modified study documents (tracked copies, if available)
- Tracked informed consent forms (if applicable)
- Any additional pertinent documentation (Investigator forms and/or agreements, etc.)

Reports of Unanticipated Problems and Serious or Continuing Noncompliance
The following materials are required for these reports:
- Completed Adverse Event/Non-Adverse Event Incident Report or Protocol Violation Report
- Relevant associated reports (i.e. Suspect Adverse Reaction reports, Case Summary documents etc.)
- Relevant modified study documents (e.g. protocol, consent form, etc.)

Study Information Report
The following materials are required:
- Completed Study Information Report
- Relevant materials associated with the information

Study Closure Report
The following materials are required:
- Completed Study Closure Report
- Relevant materials associated with the closure, such as sponsor closure notification.