IRB Guidance: Regulatory File/Binder Contents

All IRB-approved projects should maintain a Regulatory File or Binder. All FDA regulated projects must maintain a Regulatory File/Binder. This document provides a list of the required documents to be included in the file or binder. The Regulatory File/Binder can be maintained in paper form or electronically. Not all items on the list may apply to your project.

Each IRB-approved project file/binder should list the Principal Investigator, IRB Protocol #, Title of the Project, and Sponsor, if applicable.

All Projects:

- All IRB-approved versions of the Research Plan
- All IRB-approved consent forms with watermark/date
- All IRB submission forms (New Protocol, Amendment, Progress or Continuing Review Report, Closure and Reportable Events)
- All IRB approval/determination letters
- IRB-approved advertisements/recruitment materials (flyers, brochures, social media posts, etc.)
- Written information provided to subjects (pain scales, diaries, questionnaires, etc.)
- All supplementary documentation included with all types of submissions (translation documentation, ancillary approvals, etc.)
- CVs and any relevant licenses of PI and Co-PIs (update every 2 years/license annually)
- Copy of Medical licenses, if applicable
- Conflict of Interest documentation and management plan, if applicable
- Site responsibility/staff signature log, if applicable
- Subject screening/enrollment log, if applicable
- Retained body fluids/tissue sample logs, if applicable
- Adverse Event, if applicable, and/or Protocol Deviation Log
- Human Subject Research Protection Training certification of PI and project team members
- DSMB reports, if applicable
- Sponsor correspondence, if applicable
- Registration of clinical trial, if applicable
- Copy of grant or funding proposal, if applicable

Multi-site Project in which Campbell is the IRB of Record:
(In addition to the documents listed above in All Projects)

- All IRB approval/determination letters from collaborating/subcontracting sites
- All IRB stamped consent forms from collaborating/subcontracting sites
- All IRB approved versions of the protocol/research plan from collaborating/subcontracting sites
- Reliance Agreement (IAA or IIA), if applicable

- Letters of Support, if applicable
- Data Use Agreement/Material Transfer Agreement, if applicable

Multi-site Project in which Campbell has deferred to the External site:

- Subcontract agreement (defines scope of work, responsibilities, etc.
- Documents listed above as required by the external IRB policy and procedures.

NIH sponsored Projects:
(Including all documents listed in All Projects and Multi-site projects as applicable)

- Copy of the NIH grant application
- All progress reports submitted to NIH
- NIH correspondence