Study Regulatory Binder: Instructions

Per CHB policy *Principal Investigator Responsibilities*, the PI is responsible to create, maintain and properly store a current protocol file or binder that contains, at a minimum, required study documents as outlined in the policy.

This Study Regulatory Binder was created to help PIs and research staff identify, maintain and organize all required and other useful study documents and correspondence in one central location, with the goal to help manage studies more efficiently, and minimize the chance of procedural errors.

The Study Regulatory Binder includes:

- 20 pre-labeled dividers (listed in Table of Contents) and 5 blank dividers for additional sections
- On each pre-labeled divider, a description of what documents should be stored within that section as well as other recommended documents depending on the type of study; links to applicable regulations and policies; and useful hints, reminders and definitions
- Blue dividers are relevant for studies that fall under FDA regulations.
- Contact information and description of pertinent CHB resources and departments

Guidelines for Using the Study Regulatory Binder

- Tailor the binder to practically meet the needs of your protocol:
  - Only include sections pertinent to the protocol – omit unused sections and add sections as needed.
  - Organize and order the sections to facilitate easy use and reference (e.g. file most used and referenced sections in the front of the binder for easy location and access).
  - Add additional documents to each section as needed.
- Keep the Study Regulatory Binder current and up-to-date.
- List person(s) responsible for maintaining the binder as an Additional Contact with the CCI/IRB to ensure correspondence and documents are received and filed in a timely manner.
  - It is recommended to designate one (or two) person to maintain the binder, update documents as necessary, and inform staff of approved changes.
- Store binder in a safe and secure location, but that is accessible by research staff at all times.
- The entire research team should agree upon how the binder is organized and maintained.
- Subject specific documents and information, such as signed consent forms, test results and completed case report forms should be maintained separately in a subject specific binder/file.

Study Regulatory Binder Key

EQuIP Hint	Useful tips to help with study management
REMINDER	Helpful reminders or updates on CHB/CCI policies and procedures
Definitions	Descriptions of regulatory terms that may require clarification