

Regulatory Binders

The regulatory binder is a compilation of materials you'll use, or refer to, as your study progresses. Most regulatory binder documents are not subject-specific. Instead, regulatory binders contain documents that relate to the overall conduct of the study.

Section 8 of the Guideline for Good Clinical Practice (ICH E6) is entitled **ESSENTIAL DOCUMENTS FOR THE CONDUCT OF A CLINICAL TRIAL** and contains a list of documents that may be generated during a study. This Section is an excellent resource for study staff to use when deciding what items need to be placed in a regulatory binder.

There are 3 phases to consider when you are compiling a regulatory binder: before the study formally begins, during the conduct of the study, and after the study is completed. The ICH E6 guidelines list documents that should be generated and filed during each of these phases. Not every study will be expected to have every document on the Guidelines list, but the list may be used to determine those documents you will need for your study. Note also that while the ICH E6 guidelines are written for clinical research studies, they contain excellent guidance for all types of research, including behavioral and social research.

It takes some time and effort to gather the documents required for your study, but if all necessary documents are prepared and filed in the binder at the appropriate time, you'll find that essential study records will be much easier to find when you need them, and that will make it easier to run your study.

Why do I need a Regulatory Binder?

Research findings cannot be proven to be valid without solid data from good records. The Regulatory Binder assists study staff in organizing the records necessary to operate a good study.

What does a Regulatory Binder look like?

The Regulatory Binder is usually one or more 3-ring binders, which help keep all your regulatory material secure. Material in the binder is usually separated by tabs.

What tabs must I have in my Regulatory Binder?

There are no rules telling you what divisions or tabs you must have in your binder. Those separations are generally study-specific as not all studies will have the same regulatory material. As mentioned above, the ICH E6 guidelines contain good information about what should be included. Another resource can be found here: <http://www.partners.org/phsqi/vrb/files/index.htm>. Remember that not all studies will have all of these items. For example, if your study does not involve a drug or device, items related to drugs/devices won't be required.

What are some examples of Regulatory Binder material?

Examples of items common to all Regulatory Binders would include the current protocol, the current informed consent form, copies of all IRB approval letters, training records for all study personnel, CVs and licensure for all investigators, signature/delegation of responsibility logs, and subject enrollment logs. Examples of additional material that may be needed for a study would include the Investigator's Brochure, copies of all sponsor correspondence, copies of regulatory body correspondence, samples of data-recording forms, laboratory certifications and normal values, and SOPs.

Where should I keep my Regulatory Binder?

The regulatory binder needs to be stored somewhere that's accessible to study staff who need to refer to the material in it. But it shouldn't be overly accessible – some of the material it contains might be confidential (e.g. industry-sponsored study protocols), and you want to make sure that only the people who need to use can get into it.

My department is involved in several studies. Does each of these studies require its own, complete regulatory binder?

Not necessarily, if there's some overlap in the records. For example, if the same study personnel and investigators work on multiple studies, training records and CVs/licensure may be kept in one central location. Then, each separate study's regulatory binder will contain a note stating where these records may be found. The same is true for laboratory certifications and normal values. If more than one study uses the same laboratory, these items may be kept in one central location, too, with a note in each study's regulatory binder stating where those records may be found.

Is there anything that should not be filed in the Regulatory Binder?

Yes. Items such as financial records, records related to other studies, non-study related personnel records, and auditing/monitoring reports should not be placed with study records. Store these separately as they are usually not open to regulatory agencies.

Questions? Call Karen Barnwell at the UAMS Research Compliance office at 686-5186.