When is a Full Protocol Required with an IRB Submission?

With the new update to ERICA in January 2012, a separate Protocol/Research Summary is no longer required as part of the IRB application process, because the information formerly collected in the Protocol/Research Summary is now collected in the IRB new study application.

Even though the Protocol/Research Summary is no longer used for the IRB, it is still important that each study have a written protocol to follow as part of the conduct of research. A full written protocol will also allow for easier completion of the IRB application. In the majority of cases, it is **not** required that the full protocol be submitted as part of the IRB application.

The IRB requires that a full, written protocol be submitted in the following situations:

- The study is industry-sponsored and a company or sponsor protocol is provided to the study team.
- The study is an investigator-initiated investigational drug or device trial, and the PI (or other member of the study team) is the sponsor-investigator and holds an IND or IDE (click here for the definition of a sponsor-investigator).
- The study is part of a multi-centered trial and a full protocol for all sites is provided to the study team.

If you need to create a full protocol, the many protocol templates are available online through a number of research agencies. The IRB also provides a sample of protocol templates on the Health Sciences Forms menu on the IRB website under “Full Protocol Documents”.

Full protocols must be attached under the “Full Protocol” section of the Documents and Attachments page of the new/update study application.