PREPARING IRB SUBMISSIONS
BEST PRACTICES
Help Us Help You More Quickly

IRB submissions have been prepared and submitted electronically in Insight since 2009. As of April 8, 2013, the IRB has been reviewing submissions electronically and maintaining only electronic records. IRB submissions and IRB reviews are stored in Insight and can be viewed and printed from the system. We strongly recommend that you follow the instructions below to speed the review process and allow us to help you more quickly.

1. Document Version Dates and Pagination: Version dates on documents must be updated when changes are made and the version date of the Protocol Summary and the Detailed Protocol must be entered on the Attachments page. The date entered on the Attachments page and the date on the actual document must be consistent or the submission will be declined and returned for changes. The Research Consent Form also includes a field for version date at the end of the form. Documents should always be paginated. The Detailed Protocol version date on the Attachments page will appear in the approval letter.

2. Amendments and Description of Proposed Changes: Clearly identify all proposed changes in the amendment form, or, reference a specific document containing a detailed list of changes (i.e., a sponsor document detailing all changes). Don't inadvertently "sneak things into" a consent form or protocol document if they are not listed/ discussed as proposed changes in the amendment. We need to be sure all components of an amendment are considered and approved. Some changes may require full panel review, and we wish to identify such immediately. Also, provide **your** assessment of how the amendment alters, or does not alter the risks and benefits of the study.

3. Identification of Changes to Documents: Use ~~red strike-through~~ for all deletions and yellow highlighting for additions to all "tracked changes" versions of documents. These are most easily seen on screen. Be sure to identify deletions **and** additions in all "tracked changes" versions of documents!

4. Amendments and Updated Protocol Documents: Update all documents in real time with amendments, submitting "tracked changes" and "clean" versions, identifying changes as above. Use the Add New Version functionality on the Attachments page to add the updated "tracked changes" version followed by the "clean" version of the document.

5. Continuing Review and Protocol Documents: Continuing review submissions must include current versions of documents originally submitted to obtain approval. On the Attachments page of the continuing review submission, check the box "Include with Submission" at the end of the row of all protocol documents relevant to ongoing approval of the research; for example, the Protocol Summary, Detailed Protocol, Consent Form(s), Instruments and Questionnaires, Recruitment Material, Drug Brochure. When submitting an amendment to be reviewed with the continuing review, do not click "Include with Submission" on the row of documents that are updated and attached to the amendment. For completeness of the electronic record, all questionnaires and instruments must be included in the submission. A list of questionnaires/instruments is no longer required. Add a new row on the Attachments page for updated minor deviations or other logs and updated DSMB/DMC reports.

6. Point-by-Point, Self-Contained Responses: Complete the Response to Review form on the Forms page. Add responses to questions in this format with a 1:1 concordance, i.e., a question followed immediately by a complete response in another font/color. The point of this formatting (which is the standard expected by the FDA and other regulatory bodies and most journals) is to provide a self-contained Response to Review document that minimizes the need for a reviewer to "flip back and forth" between documents. For example:

   Query 1: Why is a CT scan needed?
   Answer 1: A CT is the standard approach for diagnosis of porcelain overload in 2013.... etc. A consent form change has been made as follows on page 2 to clarify for subjects: "You will have a CT scan to look for..etc."

7. Financial Disclosure Forms: Completed and signed Financial Disclosure Forms may be scanned and uploaded to the Attachments page of the submission or emailed to the Partners IRB mailbox, or, faxed to 617-424-4199. These may contain financial information; the choice is yours. If you have nothing to disclose, you need only complete the first 4 pages; the appendices do not need to be submitted.