



UNIVERSITY OF CALIFORNIA, SAN DIEGO HUMAN RESEARCH PROTECTIONS PROGRAM

Frequently Asked Questions—Common Qs

Q. What is Expedited Review?

- A. Expedited review is a type of review that can be used for review of study projects and amendments when the project and/or amendment is minimal risk and can be appropriately reviewed by the IRB Chair or the Chair's designee. It does not mean the review will be done "faster" or will be put before other review requests.

Q. What do all the red boxes mean on the application Facesheets?

- A. The application Facesheets are not considered complete by the HRPP database unless an appropriate response is provided in each of the boxes that are outlined in red. This very much includes the boxes regarding participant accrual numbers and where the accrual will take place, both current and expected.

Q. When I put a response in the box outlined in red, it still stays red. Why?

- A. The boxes remain red to provide a visual cue so that you can review the Facesheets quickly to ensure a response is provided within boxes outlined in red.

Q. Can I use a Mac to upload the application Facesheets?

- A. Macs can be used to upload the application Facesheets. You will need the latest version of Adobe Acrobat/Reader, X, and the latest version of Firefox or Chrome. For instructions, please see the top of the Forms page on the web.

Q. When do I need to include a cover letter with my submission?

- A. All submissions to the HRPP require a cover letter that clearly and specifically states why

the submission is being provided for review. When submitting an amendment, please ensure that the cover letter states why the amendment is being requested, what the amendment includes, what effect the amendment has on the study including any effect to the risk to subjects, risk/management procedures, etc. In addition, two copies of any document that has been revised are required. One that "highlights" the changes and one "clean" copy. Not providing sufficient information and documentation for review will cause a delay in the review of the submission.

Q. The "Upload Document Files" page in My Protocols at a Glance includes a request to select the type of document and format of file that is being submitted. Is it important that I select the correct type and format?

- A. When uploading documents, please ensure the appropriate type of document and format is selected. If you are uploading an Adult consent, please select the Adult consent checkbox. If the format of the document you are uploading is a Word document, please ensure the MS Word for Windows checkbox is selected.

Q. Are there specific requirements regarding the font and font size for consent/assent and recruitment documents provided for review?

- A. Yes. These documents must use the same font type throughout and for documents that will be signed by participants/parents, the font size must be at least 12 point. For all documents, the font type must be either Times New Roman or Arial.

Q. Can amendment requests be included with a Continuing Review submission?

A. No, as noted on the Continuing Review Facepages, a request to amend a study must be completed as a separate request. If such a request is provided with a Continuing Review submission, it may not be reviewed, and the PI would be required to re-submit the request as a *separate* request.

Q. Can Microsoft “X” documents be uploaded?

A. Do not upload Microsoft “X” documents, such as docx, xlsx, pptx as these are not easily converted by the HRPP database. In addition, “clean” consent/assent documents provided as part of a continuing review submission must be provided as Word for Windows (*.doc) documents so that they may be stamped electronically. Consent/assent and recruitment documents provided as pdf files cannot be stamped.

Q. Why can’t I see documents I have uploaded?

A. Because of security procedures, if you remain logged on without activity for more than approximately 10 minutes and then upload a document, that document will not be available for viewing by you.

Q. Does the HRPP accept documents by e-mail?

A. The HRPP does not accept e-mailed documents. All documents must be uploaded through eIRB services or provided hard copy if the document is part of the hard copy documents accepted list (see below).

Q. What documents will still be accepted by the HRPP as hard copy?

A. The list of documents that will still be accepted in hard copy form include documents that require the signature of the PI, Department Chair, VA Service Chief, and Submitter. These documents include the application Facesheets, Continuing Review Facepages, Report of Unanticipated Problem Involving Risk to Subjects or Others. In addition, as requested for continuing review, a copy of the stamped, approved consent/assent documents currently in use may also be provided hard copy. If the PI has the appropriate means to convert these each document into a PDF, such as a document scanner, then each document can be submitted via the web using eIRB services.

Q. Can a CD or DVD that includes an electronic copy of study documents or “Zipped” files be submitted?

A. No. The HRPP will accept only individual documents uploaded via the web using eIRB services.

Q. What will be done if I cannot provide study documents as either “Word for Windows” files or PDFs?

A. After July 14, 2010, provision of such documents will cause the submission to be considered incomplete, and no review of the documents will be done.

Q. What will happen if I provide hard copy documents that are not on the list of hard copy documents that will be accepted?

A. The HRPP will not accept any hard copy documents that are not on the list. These documents will be returned to the sender and no review of the documents will be done.

Q. Who can I talk with if I have questions?

A. If you have questions, please contact the HRPP Office at 858-455-5050.