Frequently Asked Questions about the HRPP Push→2→Paperless (P→2→P)

Q. How will the HRPP P→2→P affect me?

A. *For many of you, the HRPP P→2→P will have little if any affect. Many PIs and study staff currently provide their study documents electronically via the web through eIRB services. However, the "new" procedures regarding the submission of documents that would require the HRPP stamp-of-approval (see item 8 below) may affect some of you.*

Q. Why is the HRPP doing this?

A. *The HRPP is going "paperless" for many reasons including reduction of paper consumption and costs; to increase the ease of document submission, control, security and sharing; quicker access to information; and the ability to have copies of documents viewed by multiple users.*

Q. What documents will still be accepted 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. What about cover letters submitted to the HRPP?

A. *Cover letters should be "electronically" signed by the PI, as is done with HRPP letters to the PI, and uploaded or the signed cover letter can be scanned by the PI and uploaded as a PDF.*

Q. After what date will the HRPP no longer accept hard copy documents with the exception of those listed above?

A. *July 14, 2010.*

Q. Step 3 on the "Upload Document Files" page in My Protocols at a Glance includes a request to select the format of file that is being submitted. Is it important that I select the correct format?

A. Yes, vitally. When a document is uploaded to the HRPP database, the format type selected must be accurate. If a Word document "DOC" is indicated as a PowerPoint document "PPT" or a "PDF," the file cannot be appropriately read by the HRPP database, and therefore, cannot be appropriately reviewed by the HRPP/IRB. Please be very careful to select the "correct" file format when uploading your documents.

Q. Is it still required that two copies of revised study documents be uploaded?

A. Yes. Per current guidelines, when study documents are revised, two copies of the document must be submitted—one copy that "highlights" the changes and one "clean" copy. If these documents are not provided, the submission is considered incomplete, and no review of the documents can be done. Note the "clean" copy must have all boxes unchecked under "Track Changes."

Q. Will anything "special" need to be done to documents that will require the HRPP stamp-of-approval such as consent/assent/permission and locally created recruitment materials for the HRPP P→2→P?

A. Yes. For consent/assent/permission documents, a 2-inch by 2-inch "content free" space must be placed on the upper left-hand corner of the first page of the document and the lower right-hand corner on the remaining pages. This "free" space will be used to place the HRPP stamp-of-approval. For recruitment material, sufficient "content free" space to place the stamp must be provided. These documents must be provided as "Word for Windows" documents.

Q. Are there specific requirements regarding the font and font size for these documents?

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. The font type must be either Times New Roman or Arial.

Q. If documents that require the stamp-of-approval are provided without this "content free" space, what will happen?

A. Without the free space, the document will not be stamped approved, and a letter will be sent to the PI noting that the document cannot be stamped approved. This will cause a delay in the approval of the document.

Q. Can the HRPP accept "password" protected documents even if the password is provided?

A. No. The database cannot convert documents that require a password to open. If a document is provided that requires a password, the submission will be considered incomplete and no review of the submission can be done.

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 858-657-5100.