



March 31, 2021

MEMO RE: IRB Procedures Update - Determination Letter Format

To Whom It May Concern:

This memo serves as formal notice that as of May 2017, IRB administrator signature is no longer be required on IRB determination letters. Please see IRB SOP Section GA 107 for full details of the policy.

Additionally the IRB staff no longer develop document lists for IRB determination letters. Instead, the following procedures have been implemented:

For Greater Than Minimal Risk Research:

Any submission for Greater Than Minimal Risk protocols (Initial, Modification, Continuing Review, Deviation, Exception, and Reportable Event) must include a full list of documents being submitted for review. This list must reflect the Document Name, Version #, and Date for every document as it should appear in the determination letter. The IRB staff will copy the list provided by the study team into the determination letter.

If upon receipt of a submission a document list appears to be incorrect (i.e. number or description of attachments does not match the number or description of documents listed) the study team will be asked via email to provide a corrected list.

If any documents are submitted via email, the email from the study team should include the text to add this document to the existing list.

The IRB staff will continue to list the HSERA application with appropriate confirmation code and date of receipt as usual. The IRB staff will also list any email correspondence that includes information pertinent to the determination being made. These correspondences will be listed as "IRB Email Correspondence RE: (a brief description of the main issue raised), Dated (the most recent date on the email thread)"

For Minimal Risk Research:

The IRB will no longer include document listings in letters for any actions reviewed for Minimal Risk research (Initial, Modification, Continuing Review, Deviation, Exception, and Reportable Event). As such, study teams who submit this type of research do not have to include a list in any of their submissions. The IRB staff will continue to list only the HSERA application with appropriate confirmation code and date of receipt and the IRB letter will make reference to "the submitted documents" included with the associated confirmation code.

Any study team submitting minimal risk research who requires a specific document listing in a letter, for whatever reason, must clearly state so in a cover letter and provide the list of documents for that submission in alignment with the guidelines noted above for greater than minimal risk research.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available on our website:
<https://irb.upenn.edu>.

Sincerely,

Jessica L. Yoos, MA, M.Phil., CIP
Director, Human Research Protections