

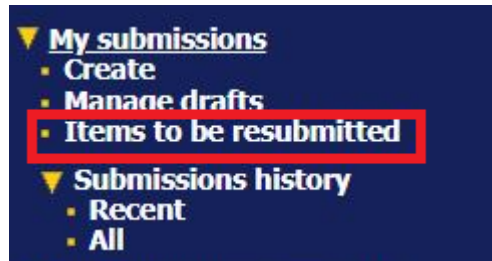


Guidance for Responding to Initial Convened Board Review

How to Respond to IRB Stipulations

The submission will be returned to you in HSERA with a determination letter within approximately 3 business days of the IRB meeting. Please download and review the IRB letter. See: <https://irb.upenn.edu/mission-institutional-review-board-irb/irb-member-toolbox> for a description of IRB determinations (e.g., Tabled, Withheld approval, etc.).

You can find the submission under My Submissions in HSERA. Click on “Items to be resubmitted” to work on a submission that the IRB sent back to your team after performing a review.



1. Please make all requested revisions to the HS-ERA Application pages when applicable.

Additionally, please include **one copy** of the following documents:

2. A **response cover letter** that includes:

- A. Point by point responses to IRB stipulations that are *requests for clarification*.

- Requests for document changes do not require a response if they have been completed as directed.
- If any directive stipulations from the IRB will not be followed, please state that clearly in your response and provide rationale for not doing so.

Please follow these steps to improve the IRB’s ability to quickly process your response:

- Please ensure that the cover letter is **in a format that may be copied and pasted by the IRB**. Please do not provide a scanned copy of the signed cover letter because signatures are not required in HSERA.
- The response cover letter should clearly demonstrate the IRB’s stipulations and the study team’s responses. Alternating colors are not required but are often helpful. For example:

1. Stipulation as phrased by the IRB

Response:

2. Stipulation as phrased by the IRB

Response:

... etc

- B. If the response includes additional modifications that were not requested by the IRB (e.g., the Sponsor released a new version of the protocol), the cover letter should include a detailed summary of the changes
 - Substantive changes should also be summarized for EVERY document revised. Clarifications should also be summarized.
 - If not provided by the sponsor, then a physician investigator should provide the summary of substantive changes to the protocol (i.e., changes that may affect the risk benefit ratio and/or subjects willingness to participate), along with rationale for each substantial change.

- Administrative / editorial changes do not need to be summarized, but should be tracked in the documents.
- If new documents are being submitted that were not reviewed previously, then this should be clarified in the cover letter.

Note: The IRB does not recommend including new changes when responding to stipulations as it may further delay the approval of the protocol.

3. A document listing that includes **only the documents being submitted with the response**. There is no need to relist documents that were reviewed at initial submission and are listed in the initial IRB letter.

Document listings should **not** be a copy and paste of the list reflected on the confirmation page of HSERA, such as:

- *Informed consent form (consent-hipaaquestionsform_clean_3.29.18.doc) Date uploaded: 04/16/2018 10:38:34 AM*
- *Informed consent form (consent-hipaaquestionsform_tracked_3.29.18.doc) Date uploaded: 04/16/2018 10:38:34 AM*
- *Full sponsor's protocol (protocol_v1_clean_02.19.2018.doc) Date uploaded: 04/16/2018 10:37:10 AM*
- *Full sponsor's protocol (protocol_v1_tracked_02.19.2018.doc) Date uploaded: 04/16/2018 10:37:10 AM*
- *Cover Letter (irb_cover_letter.doc) Date uploaded: 05/01/2018 12:57:01 PM*

An example of an appropriate document listing:

- Cover Letter, dated 1/1/2018
- Informed Consent, tracked, dated 1/1/2018
- Informed Consent, clean, dated 1/1/2018
- Protocol, tracked, version 2, dated 1/1/2018
- Protocol, clean, version 2, dated 1/1/2018

Note: To facilitate IRB review, please ensure that the listing is **in a format that may be copied and pasted by the IRB**.

4. Tracked versions of all documents for which the IRB stipulated revisions. **It is strongly preferred that documents be tracked using the Tracked Changes feature on the Review tab in MS Word.** Strike through formatting should not be used. Highlighted text is okay, but not preferred.
5. Clean versions of all updated documents
6. If documents were requested via email from the IRB staff in advance of the IRB meeting because they were not provided in HSERA, these documents should be uploaded into HSERA so that the study file is complete.

If any stipulations are not clearly addressed, the submission may be returned to the study team for completion.