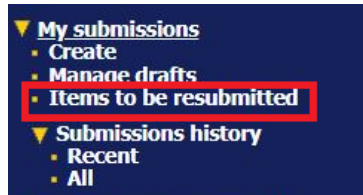




## Responding to Initial Exempt / Expedited IRB Review

### How to Respond to IRB Stipulations

The submission will be returned to you in HSERA with emailed stipulations (exempt or expedited review) within approximately 10 business days. 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.
- Alternating colors are not required but are often helpful. For example:  
*1. Stipulation as phrased by the IRB*  
*Response:*

B. If the response includes additional modifications that were not requested by the IRB, the cover letter should include a detailed summary of the changes. If new documents are being submitted that were not requested or reviewed previously, then this should be clarified in the cover letter.

3. 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.
4. Clean versions of all updated documents

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