Guidance For Responding To Conditional Re-Approval

Responding to Conditional Re-approval:

For Electronic Studies documented in HSERA: The continuing review submission will not be returned to you. Please download and complete a modification form (available on the IRB website). Then create and submit a modification via HSERA with all required documents attached.

For Paper Studies: Please download and complete a modification form (available on the IRB website). Then submit copies of all required documents to the IRB office via inter-office mail.

In addition to the modification form, your response submission should include one copy of the following documents:

- A stipulation response cover letter
- Tracked versions of all documents for which the IRB stipulated revisions demonstrating the requested changes
- Clean versions of all updated documents
- In some cases other documentation may be specifically requested to appropriately respond to a stipulation (sponsor communication, medical monitor or DSMB report, etc....)

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

1. In the response cover letter please directly state, “This is a response to stipulations raised by the IRB on [Date] for a continuing review submission [Confirmation code if applicable].”

2. The response cover letter should include individual responses to all stipulations raised. The IRB stipulations should appear as written in the conditional re-approval letter. A narrative response after each stipulation should be provided with references to locations of related changes or requested info.

3. If any directive stipulation from the IRB will not be followed, please state that clearly in your response and provide rationale. If any stipulations are not clearly addressed, the submission may be returned to the study team for completion.

4. The response cover letter should clearly demonstrate the IRB’s stipulations and the study teams 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

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

6. If you intend to include new changes to the HS-ERA Application (e.g. addition or removal of study personnel) or new documents (e.g. a new questionnaire) with the response to stipulations your cover letter should clearly state that additional changes are included that do not pertain to the stipulations.

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