

## Tufts Health Sciences IRB

### Tip sheet: Responding to IRB comments

Follow these tips when responding to IRB comments & stipulations to ensure your study is reviewed and approved as quickly as possible:

1. Respond to IRB comments as soon as possible. We always review submissions as quickly as possible, but the sooner you respond, the sooner your study will be reviewed!
  - a. Please note that if you do not respond to IRB comments within 6 months, the study could be closed-out by the IRB, and the study would need to be reviewed as a new study.
2. Always reference the IRB # (*if the IRB has assigned one*) and the type of submission.
3. Responses should be on Division or Department letterhead, signed by the Principal Investigator (original signature). (*If the IRB specifically states that you can respond by e-mail, the PI should e-mail the response to the IRB.*)
4. Be sure to respond to each numbered comment made by the IRB.
5. If the IRB provides notated documents with tracked changes & comments, please:
  - a. Accept changes in the documents (*or provide your rationale for not making the changes*).
  - b. Address each revision and comment in the documents.
  - c. **DO NOT** remove the IRB comments from the notated documents when you track your changes. Instead, leave all IRB comments in the tracked version of the revised documents you submit with your response. You can add your own comments in response to the IRB comments by typing additional information within the comment box *or* by inserting another comment into the document, but IRB comments should not be removed in your tracked version.
  - d. Always track any further changes you make to the documents so the IRB Reviewers can see all additions/revisions you make.
  - e. Provide a tracked version (*that highlights the changes made*) and a clean / updated version (*for approval/validation*) of each revised document.
6. Include an updated version date on all revised documents to ensure proper version control.
7. Deliver the original paper copy of your response (*as well as an **electronic** copy of the documents*) to the IRB office on Tupper 1 (15 Kneeland Street, 1<sup>st</sup> Floor) *or* mail your response to the IRB, Box 817.
8. When hand delivering items to the IRB, if you do not have access to the Tupper building, call the IRB office main line at 6-7512 so we can let you in.
9. **Always feel free to call the IRB office ext. 6-7512 with any questions. You are always welcome to set up an in person meeting and/or speak with an IRB Analyst over the phone anytime you have questions or need assistance with your response!**