ORARC Tip Sheet: COMMUNICATING WITH YOUR IRB REVIEW SPECIALIST

Purpose:
This tip sheet provides researchers with a quick overview of finding the Review Specialist assigned to their project and contacting them via ESTR. This Tip Sheet is written for those familiar with the ESTR. If you are less familiar the ESTR system/terminology, please visit their Job Aids Site for a more detailed overview.

Background:
When a study is in review, questions or concerns may arise, and investigators may need to contact their IRB Review Specialist. Adding comments to ESTR can be a great way to link the question directly to the submission. However, for various reasons, comments are often added in ESTR and never seen by the Review Specialist. All IRB staff are happy to accept various modes of communication; the content below identifies the most efficient communication method when corresponding with your IRB Review Specialist.

Content:

- **Finding your IRB Review Specialist**
  - If you are unsure of who serves as your IRB Review Specialist, consult the Department Assignments List. The Harvard Longwood Campus (HLC) IRB assigns one IRB Review Specialist to each HSPH/HMS/HSDM department. Email address and phone numbers can be found on the ORARC Staff Contact Information webpage.
  - If you are new to Harvard, a first time submitter, or have not submitted to the IRB for some time, verify who your IRB Review Specialist is via the links above, as department assignments may change over time.
  - When IRB Review Specialists are out of the office for significant periods (or time-sensitive requests), temporary department coverage is typically put in place. This means from time to time, your submissions may be assigned to another member of the IRB team for the timeliest review.

- **Communicating with your IRB Review Specialist in ESTR via Comments**
  Once your application is submitted in ESTR, the IRB’s preference is to keep all correspondence within the ESTR record.
  - When submitting a Comment in ESTR, the prompt indicates that the comment is visible to anyone with access to the submission. Although visible, submitting a comment will not automatically notify the IRB or your IRB Review Specialist. Before submitting a Comment, you must check the IRB Coordinator box in prompt 3 to send a notice to your IRB Review Specialist. See the screen grab below:
• Verifying the IRB Review Specialist assigned to the submission
  o Navigate to the main study workspace and/or Follow-On Submission page
  o At the top of the page, the PI, Primary Contact, and IRB Coordinator are listed. The assigned IRB Coordinator is the person who will be sent an email notification.
  o If the IRB Coordinator differs between the main study workspace and the Follow-On submission:
    ▪ Leave your comment on the Follow-On submission page, following the instructions above,
    ▪ Or reach out to the Review Specialist via email/phone.

Principal investigator: Leslie Howes
Submission type: Initial Study
Primary contact: Leslie Howes
PI proxies:

IRB office: HMS
IRB coordinator:
Regulatory authority: Pre-2018 Requirements

o Note: If you have not received a response to your comment in 3-5 business days, please follow up with an email/phone call.