ORARC Tip Sheet:
PROVIDING IRB GUIDANCE TO YOUR STUDENTS:
A TIP SHEET FOR FACULTY ADVISORS

Purpose:

This Tip Sheet describes the role and responsibilities of faculty members supervising students conducting human research. Unless a student's project qualifies as "Not Human Subjects Research" (NHSR) or "Exempt" from IRB review, the student must name a faculty member as Principal Investigator (PI) on IRB applications (including reliance requests). See the IRB's PI Eligibility policy here. As PI, that faculty member is ultimately responsible for conduct of the study. To review the specific responsibilities of serving as PI, click here.

Guidance:

What should I be asking my student mentees to do?

When you supervise a student conducting human subjects research, discuss the following:

- **Have you prepared a Harvard IRB application?** Remember: Even projects that may be Exempt must be submitted to the IRB. The IRB, not the student or advisor, will make the decision about whether IRB review is required. Self-determination is only appropriate when the project does not meet the regulatory definition of Human Subjects Research. Additionally, researchers can use the IRB Decision Tool to determine if their activities are research, if their research involves human subjects, and/or if they need to submit an IRB application.
- **Have you completed your CITI training?**
  - Harvard requires that all investigators conducting human subjects research have current CITI Human Subjects Protection training. The IRB will accept either the Biomedical or Social & Behavioral Research module. The IRB will accept equivalent CITI training from another institution as long as it is current and not expired.
  - More information and a link to CITI's website can be found on the ORARC website here.
- **What institutions or personnel outside of Harvard are involved in the project? Have they obtained IRB approval from their home institution?** External collaborators generally must either obtain approval from their home IRB or request that their home institution rely on Harvard for IRB review and approval. Per Harvard's policy, a reliance agreement can only be executed for non-exempt studies; NHSR and Exempt studies are not eligible. Consult with your department-assigned IRB Review Specialist for more information.
- **Do you understand that before any changes to an approved study are implemented in the field, you need to have the IRB(s) approve the changes?** A Modification is required to revise or update an approved study. Even minor changes, such as edits to recruitment scripts or questionnaires, require IRB review and approval prior to use in the field.
- **Are you working with HMS MD students?** If the project will involve medical education research with HMS MD students and/or faculty as participants (data and/or interaction), the PI will need to have the project reviewed by Program in Medical Education (PME) within the Office of Education Scholarship (formerly known as The Academy) prior to submitting to the IRB for approval. Medical education research could include research related to curriculum change efforts, studies that provide evidence for specific academic approaches that are not already demonstrated to be effective in existing literature, research that will contribute to theoretical, or conceptual models of teaching and learning.

- If the project will recruit HMS students as participants, the PI will need to have the project reviewed by The Academy prior to submitting to the IRB for approval.
- **For international research, have you secured local ethical review for your project?** Approval from an in-country ethical review board is required for international research. The Research Protocol should identify the local ethics oversight body that will review the project. This review may be secured after Harvard approval is granted, but no research may begin in-country until local approval has been obtained. See the link below to the OHRP International Compilation for in-country regulations/policies.

How should I be helping my student mentees?

- Prepare the Research Protocol and study documents:
  - Make sure you understand what the study procedures are and who is responsible for what activities (especially if collaborators are involved). If you were to be given the protocol and asked to perform the intervention, would you be able to do so with the information provided?
  - Make sure all documents are consistent. Is what is written in the Research Protocol consistent with the consent form, recruitment script, study tools, etc.? Do they align with how the study will be conducted?
  - Suggest that the student have a friend, relative, or classmate read their consent form. Is it written in lay language? Can an objective reviewer understand the study?
- Review/discuss any clarifications from the IRB with them. Has the student made the changes as requested? Have they only partially addressed the IRB's questions/concerns? Only full and complete responses should be submitted back to the IRB for subsequent review.

Provide Mentees with Resources:

- Familiarize students with the IRB's website and resources:
  - Investigator Manual: Outlines policies, procedures, and definitions.
  - Student Guidance: A student-specific guide on the IRB, how studies are reviewed, and requirements for each level of review.
  - OHRP International Compilation: Outlines international regulatory requirements.
  - ESTR Submission Support: Provides links for training, support, definitions, and account information for the IRB's e-submission system, ESTR.
- Request submission assistance. If your student needs more in-depth help with their IRB application, and/or their ESTR application, request submission assistance from the Quality Improvement Program (QIP).
- Writing, Language and Translations: See "ORARC Tip Sheet - Writing, Language and Translations" for more information.

How does my student submit an IRB application?

The IRB must review and approve all research prior to the initiation of any study activities. To create a new IRB application online using ESTR, follow these instructions on the ESTR Support website.
TIP: Students that are not listed as the PI can open, create and modify any submission. However, the listed PI must hit the submit button at the initial submission. The button will not be visible to any other member of the study team.

Who can we contact for more help?

Contact your department-assigned IRB Review Specialist with any questions.

Additionally, it may not be required by the IRB as part of a study's approval but you may find it useful to meet with the Quality Improvement Program (QIP) to take advantage of their extensive research support services (e.g. submission assistance, study staff orientation, study management tools, regulatory binder orientation, etc).