IRB Amendments

Institutional review boards (IRBs) play a vital role in protecting the welfare and rights of human research subjects. Every research proposal with human subjects requires IRB review and approval. If a student researcher will have direct contact with participants and or access to identifiable data then they must be listed on the IRB submission. Students cannot apply for IRB approval directly, and obtaining this approval is the responsibility of the mentor as a faculty member. However, every individual working on a given research project, including medical students, is responsible for understanding the protections researchers must guarantee to human subjects and the ethical issues that underlie these protections.

Every GW medical student working on research involving human subjects or human specimens must complete the Collaborative Institutional Training Initiative (CITI) course. This online course that takes about 4-6 hours and is free for students and faculty. Dr. Chretien oversees CITI training for all first year medical students, and Dr. Leitenberg sends instructions in approximately January. Documentation of CITI training is valid for multiple institutions including Children's. Students must have completed the required Human Subjects Research Training requirements before they can be approved for a protocol.

Students should work with the mentor to understand which category of review the research proposal falls under (i.e., Exempt Verification, Expedited Review, or Full Review). In establishing a time frame for the clinical research project, be sure to provide sufficient time for the faculty mentor to complete the IRB application and approval process in relation to the student start date. For example, GW fellowships such as the WT Gill and Health Services fellowship require an approved IRB by June 1 for any funds distribution.

Specific Instructions to add a medical student to an approved IRB
Medical students may perform research with investigators who obtained approval from one of three IRBs. Mentors should follow these instructions to add the student's name and documentation of CITI and lack of conflict of interest.

GW IRB. If the study has already received IRB approval, then adding the medical student as study personnel is done through the study modification request form in **iRIS**. When the modification request form is accessed, there an option for personnel changes. Follow the prompts to provide the necessary information and submit for review. For more information, please contact Sheila Garrity, AVP Research Integrity
srgarrity@gwu.edu 202-994-6255

Western IRB. Industry-sponsored, industry-designed clinical trials at GW use the Western IRB; Any student wishing to participate on an industry sponsored trial will need to complete additional sponsor mandated study specific training before being added to the study Delegation Log. Students should contact Holly Liu, Associate Director, MFA Research Regulatory & Compliance & Operations at hliu@mfa.gwu.edu to learn more about additional steps required for these trials.

Children's IRB. Children's uses a web-based platform called IRBEAR.. Personnel amendments are handled by the PI/study team through IRBEAR and are quickly approved. The contact person is Kay Ayers at 301-565-8447 or OPHS@ childrensnational.org.