Summer Student Research Team Members

Below is the procedure that should be followed for requesting IRB oversight for summer students, if there are any missing documents or the application is not completed correctly, you can expect a delay in the approval time.

ONLY students who will be engaged in human subjects research should be added to study teams. Students participating in animal research, handling only de-identified data or specimens or observing subjects visits only should NOT be added to the research team. These directions apply to ALL summer students, regardless of the funding source or program in which they are participating.

1) Students must complete Human Subjects Research training (CITI) before they can begin the process of being added to any study team. CITI can be accessed here. http://hrpo.wustl.edu/education/human-subjects-education/. If the student is able to complete CITI training at their home institution, it can be done there.

2) Once CITI training is complete, students must request a limited access ID in myIRB. Instruct student to go to https://hrpo.wustl.edu/ and click on myIRB then click on Request Limited Access. The student must fill out the requested information and attach their CITI and CV. Once the limited access ID is approved, they will receive an email stating that study teams can now add them as a study team member.

3) When you are ready to add the student to a study team, complete the highlighted sections of the IIA Summer Student Research Program Template Agreement that is attached to this procedure and available on the HRPO website. If the study does not have any funding and/ or do not have a grant number please type “NA” in those areas.

4) Obtain appropriate signatures on the agreement:
   a. The student (or student’s parental signature for those under 18) AND
   b. The principal investigator’s signature (delegates or sub-investigators will NOT be accepted)

5) Submit a modification in myIRB.
   a. The student should be added as a research team member.
   b. Provide a thorough explanation of the student’s specific activities on the study in the Role area. Please be sure to include what information and identifiers they will have access to, what procedures they will be conducting, and where all activities will occur (WU or elsewhere).
   c. Attach the fully completed and signed Agreement in the Miscellaneous section of the attachments page.

5) A separate agreement must be submitted for each study the student is being added to. We will NOT accept agreements that have multiple studies listed in section 1 of the agreement.

REQUIREMENTS FOR SUBMISSION:

• Make the addition of your summer student(s) to the study team the ONLY modifications to your protocol. Do not include any other changes on the request to add summer student(s).

• Do not submit the modification in combination with a continuing review.

• Make sure the student’s CV/ resume that is provided in the limited access request is current and lists the school or university they are currently attending.

• If they are a student at a university that has an IRB, they should answer Yes to the question “Are you an employee or student of an Organization that has an IRB?” and complete the information about their university’s IRB. They may need to contact their IRB in order to obtain this information. Please advise them that we are not requesting an agreement from their institution at this time, only collecting information to assist us if an agreement is needed.
Points to Remember

- This procedure does not apply to WUSTL students. They can be added to the study team in the regular manner.
- This procedure does not apply to SLU students. SLU student should be submitted in the usual manner without a signed agreement attached.
- Do not insert images of signatures on to agreements. Print the document and have parties physically sign (wet ink signature) and scan the document for submission to HRPO. Other research team members cannot sign on behalf of PI.
- HRPO staff will collect Martha Jones signature on the agreement. Please submit the document with just the PI and student (and parent if applicable) signatures.
- Students cannot be added as research team members to repository studies in order to conduct a project that uses the data from a repository. If HRPO determines that the students described role is unique research that requires a new approval you will be required to submit a new project.
- Summer student agreements will NOT be accepted before April 15 or after July 31. Any student added before or after that time will need to complete the normal agreement process.
This Agreement ("Agreement") is by and between The Washington University (WU), (Principal Investigator or PI), and (Student).

1. WU IRB shall provide IRB review for the following Research Project:
   - myIRB Number:
   - Research Project Contact Person:
   - Name of Research Project:
   - Source of Funding:
   - Sponsoring Agency:
   - Grant Number:
   - WU PI:
   - Department:
   - WU OHRP Federalwide Assurance ("FWA") Number: FWA00002284
   - WU IRB Registration Numbers: IRB00005594, IRB00009237

2. Student shall rely upon WU IRB review for the Research Project.

3. Student shall successfully complete patient privacy training applicable to the Health Insurance Portability and Accountability Act (HIPAA), CITI Human Subjects Training, and shall review relevant WU policies and procedures applicable to individuals engaged in human subject research.

4. Student understands and accepts the responsibility to comply with the standards and requirements stipulated in the HIPAA and CITI training and to protect the rights and welfare of human subjects involved in the Research Project.

5. Student will abide by all determinations of the WU IRB and will accept the final authority and decisions of the WU IRB, including any directives to terminate participation in the Research Project.

6. Student acknowledges that activities related to the Research Project are to be carried out under the direct supervision of the PI. Student shall follow all directions of the PI, who is responsible for managing the Research Project and obtaining prior IRB review and approval for any changes in the Research Project.

7. Student shall report immediately to the PI any problems involving risks to the subjects or others in the Research Project. The PI shall be responsible for immediately reporting such problems to the WU IRB.

8. Student shall comply with all aspects of the Research Project and study procedures and will only participate in study activities as documented and approved by the WU IRB.

9. Student is not permitted to participate in the Research Project until this Agreement has been signed by all Parties.

10. Student accepts responsibility for safeguarding the rights and welfare of each research subject or subject’s data, and that the subject’s rights and welfare must take precedence over the goals and requirements of the Research Project.
Summer Student Research Team Members

WASHINGTON UNIVERSITY

By: __________________________
Martha F. Jones, MA CIP
Executive Director
Human Research Protection Office
Date: __________________________

STUDENT
Signature: _______________________
Printed Name: ___________________
Date: __________________________

PARENT/LEGAL GUARDIAN (if Student is under 18 years of age)
Signature: _______________________
Printed Name: ___________________
Date: __________________________

PRINCIPAL INVESTIGATOR
Signature: _______________________
Printed Name: ___________________
Date: __________________________