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 or handling only de-identified data or specimens 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 be added to any study team. CITI can be accessed here. [http://hrpo.wustl.edu/education/human-subjects-education/](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) When you have determined you will need to add a student to a study team, complete the highlighted sections of the IIA Summer Student Research Program Template Agreement that is attached to this procedure. If you do not have any funding and/ or do not have a grant number please type “NA” in those areas.

3) 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

4) Submit a modification in myIRB.
   a. The student should be added in the NON-WUSTL portion of section II for the application.
   b. A complete and thorough explanation of the student’s specific activities on the study must be included in the Role area of section II. Please be sure to include what information and identifiers they will have access to, what procedures they will be conducting, where all activities will occur (WU or elsewhere) and any specific training and oversight they will have when conducting research activities.
   c. Attach each document in the Miscellaneous section of the attachments page. Attach each document separately and **DO NOT** submit as one combined PDF attachment.
      i. The fully completed and signed Agreement
      ii. The student’s up-to-date CV or resume
      iii. Documentation of the student’s CITI training

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 is current and lists the school or university they are currently attending.

- Describe in detail the activities in which the student will participate. We would not typically expect summer students to be responsible for recruiting or consenting subject for participation. However, we encourage students observing the recruitment and consent process for educational experience. If it is required that they do either of these activities please expect that this will cause a delay in the approval of the modification as additional review time will be required. You will be asked to provide a justification for why they must do these activities and a description of the specific training and oversight they will have to qualify them for this role in the study.
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Points to Remember

- This procedure does not apply to WUSTL students. They can be added to the study team in the WUSTL team member section.
- 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.
- 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 after July 31. Any student added 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.
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: __________________________