**Students in Research**

**Students as Subjects**
- Targeted for enrollment:
  1. Permission from the dean (BUMC campus)
  2. Student may not work for investigators or the study or be a student of the investigators

**Students as Investigators**
- Students who go to work for research projects at other institutions (e.g. summer work)

**Classroom experience**
- Purpose - students to learn the research process
  - Not physically or psychologically stressful, invasive
  - No more than minimal risk
  - Not accessing research or clinical databases /medical records containing identifiable data
  - Not designed to contribute to generalizable knowledge (no plans for publication)
  - IRB review not required

**Are they acting as an employee or agent* of BU/BUMC?**
- If yes and if they are engaged in the research then BU/BUMC is engaged. Therefore BU/BUMC must
  - a. review the research
  - b. enter IAA with the other institution

  **Most likely in this case the student is “working” as part of the other institution’s study staff so BU/BUMC IRB review is not required**

  *a BU/BUMC student is not necessarily acting as an agent of BU/BUMC

**Student Research (thesis or dissertation or original idea)**
- This must be submitted as a separate IRB protocol
  - May be linked to a parent protocol
  - Member of faculty/advisor must be the PI and student is co-investigator
  - Will often be a sub-study of another researcher’s study
  - Study description must clearly state
    - a. it is a student project
    - b. who is the mentor
    - c. if it is a sub-study of another study
    - d. BU CRC and BUMC may agree to do one IRB review

**Students who work on other investigators’ research projects as members of the study staff or co-investigators (includes student-trainees not doing original research for thesis or dissertation)**
- Usual process apply as with other non-student investigators

  *These students can be added to a protocol using the amendment process*
Points of Consideration

1. Since class work assignments and class projects are usually not intended to and are not likely to lead to generalizable results the BUMC IRB does not routinely need to review these projects as they would not be considered to meet the definition of human subjects research. Research practica (course-related projects), the object of which is to provide research experience to students (not to contribute to generalizable knowledge) do NOT require IRB review if they
   a. do NOT involve physically or psychologically invasive, intrusive or stressful procedures; and
   b. do NOT involve research on special populations including pregnant women, neonates, fetuses, prisoners, children, mentally disabled, economically or educationally disadvantaged or others who might be judged to be vulnerable; and
   c. do not involve accessing research repositories containing individually identifiable data or clinical databases/medical records
   d. in the judgment of the instructor do NOT have the potential for placing the subjects at more than minimal risk.

2. Instructors are responsible for reviewing student “research” projects to ensure they meet the criteria above. If an instructor determines that a research project is assigned for the purpose of producing generalizable knowledge, may involve greater than minimal risk, is using protected health information from a clinical database or medical records, involves a vulnerable population or could be physically or psychologically invasive or stressful then the project must be submitted to the BUMC IRB for a determination.

3. If there is a reasonable expectation on the part of the student or instructor that a project will be published or funded (regardless of the source), then IRB approval must be obtained.

4. Student initiated research (including master’s thesis or doctoral dissertation) must be submitted as an independent project, not as an amendment to an already approved protocol. The student’s advisor (mentor) must be listed as the PI of the project. The student is listed as a co-investigator. The project description clearly explains the student’s role in the research. The PI/mentor’s role carries the following responsibilities:
   a. supervision of the student’s research
   b. assisting the study in designing the research and preparing the IRB application (while the IRB can offer assistance, the IRB cannot take the place of the faculty member for training and mentoring the student)
   c. protecting the human subjects in the research

5. In some cases the student may be on one BU campus and the student’s advisor may be on the other. A "BUMC CRC Single IRB Review Request Form" may be completed and submitted to the Director of either the CRC IRB or the BUMC IRB. In most instances review by only one BU IRB will be required. The determination as to which IRB will review the research will be made by the IRB Directors based on where most of the research activities are taking place and where the most risk will occur.

6. If a student or trainee has a BU stipend, but is essentially taking a placement elsewhere under supervision at another institution and his BU mentor is not involved in the human subjects research, then BU may not be engaged in the research and BU/BUMC IRB approval may not be required. The BU/BUMC IRBs make determinations regarding engagement in research.
a. if the BU/BUMC faculty/mentor is supervising the research activities at the other institution then he/she and the BU student may be “engaged in research”, in such cases BU/BUMC IRB review would be required (as well as IRB review by the other institution)

b. If there is a question as to whether the student, engaged in research at the other institution, is acting as an employee or agent of BU/BUMC then the BU/BUMC IRB should be consulted.

7. When determining where BU students are engaged in research as an “employee or agent” of that campus the determination will be made based on the “engagement criteria” posted on the OHRP Guidance on Engagement in Research

   http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

   a. if the student research is receiving a direct award (funding) for the research project then the institution receiving the funding is engaged in research

   b. if a student from institution X is participating as a member of the study staff at institution Y then institution X is NOT necessarily ENGAGED in research (just because the student is a student of Institution X) - he needs only to be listed as an investigator on the Institution Y protocol

   c. if a student from institution X, as part if his thesis or dissertation is conducting “original research” then institution X (from which he will obtain his degree) is engaged in research and Institution X’s IRB must review the project or delegate review to Institution Y