ROSALIND FRANKLIN UNIVERSITY of MEDICINE AND SCIENCE

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Guidance for Students Interested in Conducting Research

Medical/graduate school provides a wealth of wonderful opportunities and participating in a research project is one of them. Some types of research (such as those involving human subjects or vertebrate animals) require approval and oversight from a federally mandated compliance committee. In the case of human subject research, approval from the Institutional Review Board (IRB) is needed; in the case of live vertebrate animal work, approval from the Institutional Animal Care and Use Committee (IACUC) is required. We have created this guidance document to facilitate students' engagement in research.

STEP 1: Find a mentor. Ideally you should identify an RFUMS faculty mentor who is currently conducting, or has previously conducted, research in the area you are interested in studying. Even if your project does not require IRB or IACUC oversight, faculty mentorship is necessary to the conduct of ethical and sound research. For research requiring IRB or IACUC oversight the faculty member must hold a full time appointment at RFUMS. Otherwise, prior authorization from the Executive VP for Research must be obtained.

STEP 2: Identify a project. Work with your faculty mentor to identify a project you will be able to complete given the competing demands of medical school and access to the necessary resources. For research projects with human subjects requiring IRB oversight, be advised that you may need to wait 1-2 months before obtaining approval to start your project. Some of this depends on how quickly and thoroughly you and your mentor respond to IRB reviewer suggestions. There are also online training modules that will need to be completed. For research projects involving live vertebrate animals, allow at least one month to work with the IACUC. Please note that the student's faculty mentor is responsible for communicating with the IRB and submissions, reviews and approvals are tracked via the **principal investigator's name** (the faculty mentor), not the student's name.

Not all research projects that involve people require IRB oversight. Projects that require IRB oversight would be those that meet the Federal definitions of "research" and "human subject", which may be summarized as: A ***systematic investigation***, including research development, testing and evaluation, designed to develop or contribute to ***generalizable knowledge*** that involves a ***living individual*** about whom an investigator conducting research obtains information or biospecimens through ***intervention or interaction*** with the individual, and uses, studies, or analyzes the information or biospecimens or obtains, uses, studies, analyzes, or generates identifiable ***private information or identifiable biospecimens***.

Not Human Subject (NHS) Research

Here are some suggestions for projects that can be conducted without IRB approval/oversight because they do not meet the federal definition of "research with human subjects". Note that the intent to publish is not a factor in determining whether something is NHS research.

- If you have access to existing data that has been collected for non-research purposes and the data does not include any identifiable information (e.g., patient name, medical record number, address, telephone number, treatment date, IP address etc.), then your project probably does not require IRB oversight. Be advised that the research cannot be FDA-regulated, cannot involve human stem cell research and you cannot have access to identifiers or keys to link coded data (even temporarily).
- Research with live human tissue, i.e., surgical tissue that has been resected for clinical purposes and will otherwise be discarded is not considered human subjects if, and only if, an agreement exists between both parties that the individual providing the specimen will never provide the you the recipient with information that would allow identification of living donor.
- Analyzing "coded data" collected from a study being done at a different institution. The RFUMS PI and the other institution PI have entered into an agreement that prohibits the RFUMS PI from receiving the key to the code that would identify participants, and there is a written agreement between the RFUMS researcher and the collaborator that the key or access to the identifying information will never be shared.
- Research with extra vials of identifiable or coded human biological specimens from Pathology or Laboratory Medicine. The provider of the samples must remove the identifiable information prior to turning the samples over to the researcher.
- Aggregate data that has been de-identified from its source and is provided to the PI, i.e. many national datasets can be downloaded and they do not contain any identifiers (e.g., BRFSS data).

Quality Assessment / Quality Improvement / Process Evaluation QA/QI/PE projects are ***typically not*** considered human subjects research because the goal of the project is to study and/or improve a program, clinic, course rather than contribute to *generalizable knowledge*. It should be noted that QA/QI/PE projects can often seem like the type of human subjects research that the IRB reviews because they may include activities such as conducting surveys, reviewing identifiable data, drawing conclusions about problems, and suggesting methods for improvement. The key, however, is determining whether the project is designed to be *generalizable* to the extent of meeting the federal definition of research. Typically, QA/QI projects are focused on improving the performance of an institutional practice in comparison with an established standard or goal. Because they are focused on local practice their scope is typically limited to the specific institution. The results of a QA/QI/PE project are not *intended* to apply to anyone beyond the scope of the project, and conclusions are drawn only in relation to the particular practice/s at the institution. Even if the results of the project are shared outside the institution (i.e. published or presented at a meeting), this would only be for the purposes of sharing a successful improvement in practice at the institution, allowing other institutions to interpret the results and draw their own conclusions. The key is that the institution conducting the QA/QI/PE project is not drawing broad conclusions and is not using their participants as a representative sample. Here are some examples:

- Surveys whose primary purpose is to gauge/assess the opinions and perceptions of internal and external "customers" (e.g., trainees, staff, patients, referring physicians, students and others) for the purpose of improving the delivery of health care at a particular institution or center (or improving teaching or processes in the case of educational or other research).
- Activities to implement or improve adherence to established/accepted standards (such as clinical practice guidelines) for the purpose of improving care or the delivery of education or some other quality improvement metric.

For non-human subjects research (including QA/QI/PE studies), a formal "NHS Research Determination" can be obtained from the IRB. IF there is *any* doubt about whether your planned project needs IRB review and oversight, it is always advisable to contact the IRB for a formal determination prior to beginning. A NHS determination will NOT be given after a project has been completed (and some journals may require a formal letter from the IRB).

Here are several basic links / resources to guide you in deciding whether or not your project meets the federal definition of research with human subjects

- Does my project require an application to the IRB?
- Does my existing data project require an application to the IRB?
- Is my project considered QA/QI/PE?

If your study requires IRB oversight, the **RFUMS IRB website** contains the current application forms as well as guidance information on a variety of topics. If you have questions that you are not able to solve from the website, please contact the IRB Chair or administrator at IRB@rosalindfranklin.edu.

What about animal research overseen by the IACUC?

- If your study will involve Live Vertebrate Animals, your project will always require IACUC approval.
- If you take custody of a dead animal or animal parts, you do not require an IACUC protocol.
- The rules concerning who can serve as the PI are the same as for IRB projects (e.g. a full time RFUMS faculty member on site must serve as PI).
- A considerable amount of both online training, in lab training and specialty procedure training (surgery, anesthesia, etc.) as well as enrollment in the occupational health and safety program for animal researchers, and a tour of the vivarium that goes over rules and regulations before security clearance is issued will be required prior to beginning your study.
- The **RFUMS IACUC website** contains additional resources about training, regulations, protocol forms and more. You may also address questions to the IACUC Chair or the IACUC administrator at IACUC@rosalindfranklin.edu.