Types of Research – Types of IRB Applications

1. You have a population of interest (e.g., women who have been diagnosed with breast cancer) that you would like to contact for future studies

   IRB Application type:

   Contact Registry (http://irb.ufl.edu/wp-content/uploads/Banks.pdf)

   ICF see http://irb.ufl.edu/irb01/forms/forms-2-2.html, go to Informed Consent forms with HIPAA -> go to 'Contact Registry only ICF'

   Alternative: Use Consent2Share (note – not available in most of Jacksonville…yet)

   http://irb.ufl.edu/wp-content/uploads/Consent2Share-Study-Subject-Recruitment.pdf

2. You want to collect and store patient clinical data and/or tissues (including serum, plasma, saliva, biopsies) for future research use.

   IRB Application type:

   Data / Tissue Bank (http://irb.ufl.edu/wp-content/uploads/Banks.pdf)

   ICF see http://irb.ufl.edu/irb01/forms/forms-2-2.html, go to Informed Consent forms with HIPAA -> go to 'Tissue/Data Bank ICF (banks conducted at UF/Shands)

   Please note! Contact Registry and Tissue/Data Bank IRBs are not the studies themselves. You must write separate IRBs for studies that use a contact registry to recruit patients, or that use samples/data from the bank for analysis.

3. **You are writing a Case Report** (http://irb.ufl.edu/wp-content/uploads/Case-Reports.pdf)

   If 3 or less patients, then UF IRB approval is not required. If more than 3 patients, then it constitutes research and IRB approval is required. As an aside, some journals require patient permission for case reports.

4. **You are writing a clinical review or a review of a research topic.**
   Typically, not an IRB matter, as long as the review is of published articles and no new data analysis or protected health information is involved.

5. **You are doing a systematic review and/or meta-analysis**. See answer for #4 if it's a systematic review ONLY. If also doing a meta-analysis an IRB application may be required (would likely be an exempt or non-human subjects research application) *depending* on the source(s) of the data you are synthesizing.

6. **You are conducting an observational study of a new resident educational technique**.

   What is exempt research?

   Exempt = human subjects research that is exempt from IRB review (http://irb.ufl.edu/wp-content/uploads/Exempt-Submissions.pdf and https://www.research.uci.edu/compliance/human-research-protections/docs/categories-of-exempt-human-subjects-research.pdf).

7. You want to measure the response to magnesium infusions in patients with a severe migraine, who would be getting magnesium anyway as their standard of care.

   What is expedited research?
   Expedited = Human Subjects Research that involves no more than minimal risk to human subjects. What is minimal risk? The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (http://irb.ufl.edu/wp-content/uploads/Expedited-Submissions.pdf).

   Common FAQ: Does expedited mean I don't need to obtained informed consent?

   Not necessarily. Your study may fit the requirements for waiver of informed consent, or it may require informed consent.

8. I want to look at the Thousand Genomes Project, do some data analysis, and write a paper.
   What is non-human research?

   http://irb.ufl.edu/wp-content/uploads/Non-Human-Research.pdf

   Research that does not involve human subjects. Examples could include data obtained from another source (not directly from the patient or UF) that is totally anonymous (e.g., WHO Global Repository Datasets) or that is coded so that you, the researcher, could NEVER have access to any identifiable data/tissue.

   Do I have to submit non-human research to the IRB?

   Yes, it is UF policy that the IRB will make the determination if your medical research it meets the definition of non-human research.

9. Catheter-associated UTIs are bad! We want to decrease the incidence of CAUTIs on our unit. We implemented an educational tool from Vizient as a training tool for nurses. We want to measure the incidence of CAUTIs before and after we started the training tool.

   Is this QI or is this research?

   http://irb.ufl.edu/wp-content/uploads/Quality-vs-Research.pdf

   Unfortunately, there is no regulatory definition of QI. This example above is QI. It is a "systematic, data-guided activity designed to bring about immediate or nearly immediate improvements in health care delivery."

   Do I submit my QI project to the IRB?

   No, you submit it to QIPR (https://qipr.ese.ufhealth.org/approver/)

   What if I still don't know if my work is QI or Research?

   Fill out the QA vs Research form located in http://irb.ufl.edu/wp-content/uploads/Quality-vs-Research.pdf and send to the IRB Chair Dr. Iafrate (iafrate@ufl.edu)

10. I have a colleague at another university with the same research interests and we want to do a study together.

    Is your colleague at another University or unaffiliated with an institution that has a Federal Wide Assurance (FWA)?

    http://irb.ufl.edu/wp-content/uploads/Guideline-Unaffiliated-Investigators.pdf

    In general, most faculty work with investigators at another institution with an IRB. The unaffiliated investigator guideline therefore does NOT apply to them because that institution likely has an FWA.

    You can of course still collaborate and do studies with other institutions, but the IRB structure, data transfer/use agreements, etc., vary based on the type of study and the type of funding.

    In that case, consulting with the IRB is advised!

11. **I still have questions, what do I do?**
    You can visit the IRB website (http://irb.ufl.edu/irb01.html), email IRB-01 (https://uf.tfaforms.net/356), or locally email Dr. Wajeeh Bajwa (Wajeeh.Bajwa@jax.ufl.edu).

*This document is a guide and does not cover every situation/study. When in doubt, consult the IRB!