Best reference starting point for student newbies

- http://www.ohsu.edu/xd/research/about/integrity/irb/upload/IW-Preparing-an-IRB-Submission-FINAL.pdf

- PI on IRB protocol has to be paid OHSU faculty member
- Students cannot be PI on IRB protocols, even if they are PI on grant from which protocol arises

Core documents needed for IRB submission

- PPQ (Proposed Project Questionnaire)
- Lay Language Protocol Summary
- Protocol
- Consent and (HIPAA) Authorization Form
  (or waiver of authorization)

Other items

- **Full Grant** – required if federally funded (e.g., NIH)
- **Data Safety Monitoring Plan** – can be described within the protocol or uploaded as a separate document
- **Drug/Device Information** – as applicable, include Investigator's Brochures, Package Inserts, Manufacturer's Product Information, FDA Communications (e.g., regarding IND/IDE, exemptions)
- **Clinical Billing Schedule** – if clinical procedures will be performed
- **Questionnaires, surveys, focus groups** - include all study instruments used for interactions with subjects. For focus groups, provide an outline with as much detail as possible about anticipated topics/dialogue
- **Recruitment materials** - if advertising for subjects, submit flyers, web ads, newspaper ads, flyers, and/or recruitment letters
- **Screening scripts**

Lay Language Summary

- Used by the IRB to get a quick rundown of the study, and by non-scientist members of the IRB
- Should provide a clear overview of the research in straightforward, non-technical language
- May serve as the protocol itself for very simple studies

NOT! Lay Language Summary

Lay Language Summary

“There is a paucity of literature describing graft versus host disease (GVHD)-associated serositis and pericarditis, rare but severe complications associated with allogeneic hematopoietic cell transplantation (HCT)”

Protocol

- Everything flows from this document – do it first!
  - What, why, how, who
  - statistical considerations and human subject protections
  - Literature cited
- OCTRI has a template on web

Protocol

- **What** are you going to do?– study title, specific aims
- **Why** are you doing it? – hypothesis, background and significance, preliminary studies
- **How** are you going to do it? – study design, methods, procedures
- **Who** will be involved? – subject population and study personnel

Protocol

- Human subjects considerations / protections
  - Risks, benefits, protections from risks, risk benefit discussion
  - Rationale for inclusion of vulnerable populations
- Statistical considerations
  - Study endpoints, covariates / confounders, randomization procedures, sample size calculation
- Literature cited

Consent / authorization

- Informed consent process central to human subjects research
  - Shows subjects permission to be in study
  - Key elements well covered in templates available on IRB Forms page
- HIPAA privacy rule requires that human subjects also give their *authorization* to use and disclose their protected health information
- Both consent and authorization can be altered in certain circumstances

Alterations to usual consent / authorization process

- Minimal risk research may allow use of short form, waiver or alteration of documentation of consent; waiver of some elements of consent; total waiver of consent
- Authorization may be waived or modified in certain circumstances

Issues that require special care in submission

- Will you be screening subjects prior to consent / authorization?
- Will you be collecting data / samples without written consent?
- Does the study involve banking of data and/or samples?
- Does the study involve genetic analysis?
- How/where are data and samples stored and coded/identified, and when are they destroyed?
- What is required for study participation and what is "optional" (e.g., additional sub-studies)? Has this been explained clearly throughout?
- Are there any inconsistencies *within* any given document and/or *among* documents, including the IRQ?

If in doubt, ASK!

We’re here to help!