

## Preparing an IRB Submission

**Would you like your eIRB submission to move through the IRB review process as efficiently as possible? If so, consider the following four steps as a guide to creating a clear & consistent submission:**

### 1. GATHER TOGETHER ALL THE REQUIRED DOCUMENTS

#### All studies must have:

- **PPQ** (Proposed Project Questionnaire), fully signed (including Department Chair & Dean)  
[www.ohsu.edu/research/rda/forms.shtml#ap](http://www.ohsu.edu/research/rda/forms.shtml#ap)
- **Lay Language Protocol Summary** (Note: In some cases, such as a retrospective chart review only, the Lay Language Protocol Summary may serve as the protocol, and may be longer than 1 page.)  
[www.ohsu.edu/xd/about/services/integrity/policies/research.cfm#irb](http://www.ohsu.edu/xd/about/services/integrity/policies/research.cfm#irb) (IRB Forms-Human Subjects)

#### Most studies have:

- **Protocol**
  - Be sure it describes the study purpose/aims, procedures, data collection, statistical analysis, sample size, measures to protect subjects' safety, etc.
- **Consent and (HIPAA) Authorization Form(s)**
  - When crafting these forms, consider whether the study
    - includes additional ("optional") activities,
    - includes banking and/or genetics,
    - includes vulnerable populations (e.g., children, decisionally impaired, etc.)
  - Templates for most situations are available :
    - Consents: [www.ohsu.edu/xd/about/services/integrity/policies/research.cfm#hsf](http://www.ohsu.edu/xd/about/services/integrity/policies/research.cfm#hsf) (IRB Sample Forms –Human Subjects)
    - HIPAA Authorization Forms: [www.ohsu.edu/xd/about/services/integrity/policies/ips.cfm#research\\_forms](http://www.ohsu.edu/xd/about/services/integrity/policies/ips.cfm#research_forms) (Research Forms)

#### Additional documents that may be required:

- **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** - for example, if screening for eligibility by phone

### 2. COMPLETE THE IRQ

#### As you go through the Initial Review Questionnaire (IRQ) in the eIRB, consider the following:

- The way you answer questions on one page will determine which pages populate as you move through the IRQ. Thus, it is important to consider each question carefully.
- Pay attention to the Help Text that sits in the right hand margin.
- Pay attention to links, which lead you to templates for further documents you may require (e.g., Data and Safety Monitoring Plan (DSMP), Clinical Billing Schedule, Ionizing Radiation in Humans).

### 3. CONSIDER THE IRB's FAQs

Consider the following frequently asked questions to increase your chances of a clear & consistent submission:

- **Will you be screening for subjects prior to written consent/authorization?**
  - Describe if/how medical records, clinic schedules etc. might be used
  - If using Protected Health Information before written authorization can be obtained, you will need to submit either a HIPAA Activities Prep to Research Form or a Waiver of Authorization Form (WOA)
    - [www.ohsu.edu/xd/about/services/integrity/policies/research.cfm#irb](http://www.ohsu.edu/xd/about/services/integrity/policies/research.cfm#irb) (Section 6: Privacy & Confidentiality)
    - [www.ohsu.edu/xd/about/services/integrity/policies/upload/WOA\\_v-04-2009.doc](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/WOA_v-04-2009.doc) (IRB Forms - Human Subjects)
- **Do you wish to collect data and/or samples without individuals' written consent?** (*Examples include retrospective chart review or blood/tissue samples analysis.*)
  - Make very clear how "identifiable" is the source (person's identity) of the information you receive or collect. This will help determine the level of IRB review required. Ways to do this include:
    - Submit your data collection form
    - Ensure that all study documents and IRQ are consistent
- **Does the study involve banking of data and/or samples?**
  - If so, do all the study documents consistently and accurately reflect this?
  - Consider in particular the consent and authorization forms
- **Does the study involve genetic analysis?**
  - If so, do all the study documents consistently and accurately reflect this?
  - Consider in particular the consent and authorization forms & be sure to include required genetic template language
- **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?**  
Common inconsistencies and errors include (but are not limited to):
  - Study purpose
  - Sample size and age range
  - Study procedures
    - Number or length of study visits/procedures/focus groups/phone calls/blood draws
    - Total length of time a subject will participate in the study
    - Characterization of the study groups, when there is more than one
    - What is basic to study participation and what is additional/optional (e.g., sub-studies)
    - Inconsistencies between text and tables in the consent form

### 4. USE TOOLS & RESOURCES AVAILABLE TO YOU

In addition to links cited above and the help text in the IRQ, **please feel free to call the OHSU Research Integrity Office if you have questions along the way.** We are happy to help!

503 494-7887, option 1 or [irbinbox@ohsu.edu](mailto:irbinbox@ohsu.edu)