Initial Submission Guide

OREGON **HEALTH&SCIENCE** UNIVERSITY

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

1. GATHER TOGETHER ALL THE REQUIRED DOCUMENTS

You can find many of these documents and further guidance on the IRB Policies and Forms website.

All studies must have:

Brief Project Description – provides the IRB with a non-technical snapshot of your study.

Protocol – be sure it describes the study purpose/aims, procedures, recruitment plan, data collection, statistical analysis, sample size, measures to protect subjects' safety (including security and confidentiality of data), etc. Templates are posted on the IRB Policies and Forms website.

Most studies have:

Consent and HIPAA Authorization Form(s) or Information Sheet

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 also available on the IRB Policies and Forms website. The Consent and Authorization Form INSTRUCTIONS document on the website details which template to use when, and how to customize the form to fit your study.

Additional documents that may be required:

Local Context Supplement – required for multi-site studies where you do not have the ability to edit the protocol.

Complete Grant – required if federally funded (e.g., NIH) or foundation funded.

Proposed Project Questionnaire (PPQ) – for unfunded studies, must be uploaded with all required signatures. For funded studies where the PPQ is completed electronically, enter the the PPQ number in the IRQ.

Data Safety Monitoring Plan (DSMP) – can be described within the protocol or uploaded as a separate document. A template is available on the IRB Policies and Forms website.

Drug/Device Information – as applicable, include Investigator's Brochures, Package Inserts, Manufacturer's Product Information, FDA Communications (e.g., regarding IND/IDE, exemptions).

Questionnaires, surveys, focus group scripts, etc. - all instruments used for interactions with subjects. For focus groups or semi-structured interviews, provide an outline of anticipated topics/dialogue.

Recruitment materials - if advertising for subjects, submit final versions of flyers, web ads, newspaper ads, flyers, recruitment letters, and/or phone screening scripts.

Other HIPAA Forms – if you will be using or disclosing PHI but not obtaining authorization, you may need a Prep to Research, Decedents Representation, or Waiver of Authorization form. Sharing PHI outside OHSU without authorization may require a Data Use Agreement or Business Associate Agreement. See the IRB's HIPAA and Research website for further guidance on what applies to your study.

Repository Protocol/Forms – if your study stores data or specimens in a repository for future research activities, you may need a Repository Protocol, Submittal/Sharing Agreements, and/or a Tracking Sheet.

Collaborative Agreements – an Individual Investigator Agreement (IIA) or IRB Authorization Agreement (IAA) may be needed if you are collaborating with a non-OHSU investigator or another institution and one institution or investigator is relying on another institution's IRB for review.

Example document lists for common types of studies:

Clinical Trial – industry sponsored

- Brief Project Description
- Consent and Authorization Form
- Cover Memo to IRB
- DSMP
- IND Letter
- Investigator's Brochure
- Local Context Supplement
- Protocol
- Questionnaires
- Recruitment – Facebook
- Recruitment – Brochure
- Recruitment – Flyer
- Prep to Research

Chart Review – unfunded

- Brief Project Description
- List of Data Variables
- PPQ – signed
- Protocol
- Waiver of Authorization

Survey Study w/ Repository – funded

- Brief Project Description
- Complete Grant
- Consent and Authorization Form
- Protocol
- Protocol – Repository
- Repository Sharing Agreement
- Repository Tracking Sheet
- Recruitment - Flyer
- Survey for Patients
- Survey for Providers

Curriculum Evaluation Study – unfunded

- Brief Project Description
- Information Sheet
- Links to Curriculum and Tests
- PPQ – signed
- Protocol
- Recruitment Email
- Survey

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, so 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 may lead you to more information or templates for further documents you may require.

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 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 Prep to Research Form or a Waiver of Authorization Form (WOA).

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 listing the variables to be collected
- Ensure that all study documents and IRQ are consistent

In addition, provide justification for:
- Why it would be impracticable to conduct the research if written consent were obtained, and
- Why not obtaining consent will not adversely impact subjects' rights or welfare.

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. If you are doing anonymous or coded

genetic research with existing samples or data and will not obtain subjects' informed consent to do so, include a plan for checking genetic opt-out status with the OHSU Privacy Office.

How/where are data and samples stored and coded/identified, and when are they destroyed?
See the "Protocol Checklist – Security and Confidentiality" for guidance on what security and confidentiality protections the IRB expects to see.

What is required for study participation and what is "optional" (e.g., additional sub-studies)? Has this been explained clearly throughout, including in the consent and authorization form?

Does the protocol include all activities proposed in the grant? If not (e.g. because the grant funds multiple protocols), include a submission cover memo with a guide for the IRB to map the activities described in the grant to the protocol. If other activities included in the grant involve or will involve human subjects research, provide the IRB approval status of those protocols or confirm your plan to obtain IRB approval before beginning those activities.

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 the tools cited above, the materials on the Policies and Forms website, 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 irb@ohsu.edu