Step-by-Step
Initial Study Submission Guide
Contents
Home Page .................................................................................................................................................... 3
Basic Information ........................................................................................................................................ 4
Funding Sources ....................................................................................................................................... 7
Study Team Members ........................................................................................................................... 9
Study Scope .......................................................................................................................................... 12
External Sites ........................................................................................................................................ 15
Drugs ..................................................................................................................................................... 16
Devices ................................................................................................................................................. 18
Recruitment, Consent, and Authorization .............................................................................................. 20
Study Details ......................................................................................................................................... 23
Ancillary Reviews and Notifications ....................................................................................................... 25
Study Participation Opportunities .......................................................................................................... 27
Supporting Documents .......................................................................................................................... 29
Submitting Your Study ............................................................................................................................. 30
The Review Process ............................................................................................................................... 31
Clarification Requests ............................................................................................................................... 32
Responding to Clarification Requests ...................................................................................................... 33
Uploading New Documents – Quick Guide ............................................................................................... 37
Uploading Revised Documents – Quick Guide ........................................................................................... 38
1. Click the “Create New Study” button.
1. **Title of study**  
   • The study title must match the protocol document title. Be careful to avoid spelling errors.

2. **Short title**  
   • The short title identifies the study throughout the eIRB system, including your inbox and the IRB’s list of submissions to review.  
   • Use the short title provided by the study sponsor or another unique name if one is not provided. Keep it shorter than 50 characters.

3. **Brief description**  
   • The brief description is a quick, lay-language reference for IRB staff and reviewers.  
   • In three to five sentences, summarize the following:  
     o Central question the research is intended to answer.  
     o Primary objectives  
     o Methods used  
   • For example: “This is a [drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study] that will examine…”

4. **Principal Investigator**  
   • Click the “Select” button to access the “Select Person” dialogue box.  
   • Type the Principal Investigator’s last name and click “Go.”  
   • Select the correct name from the list and click “OK.”

   ![Select Person Dialogue Box](image)

   • For OHSU PI eligibility requirements, see:  
     [http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HRP-040-POLICY-Principal-Investigator-Eligibility-ohsu.pdf](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/HRP-040-POLICY-Principal-Investigator-Eligibility-ohsu.pdf).

   • For VA PI eligibility requirements, see:  
5. Does the investigator have a financial interest related to this research?
   • Click “Yes” if the PI has a significant financial interest in the sponsoring agency or the manufacturer/licensee of the investigational products being studied.
   • For the OHSU conflict of interest policy, see: http://www.ohsu.edu/xd/research/about/integrity/coi/.
   • For the OHSU General Guidelines for Conflict of Interest Management, see: http://www.ohsu.edu/xd/research/about/integrity/coi/upload/CoIR-Management-General-Guidelines-3.pdf
   • For the VA conflict of interest policy, see: http://www.portland.va.gov/research/documents/hrpp/coi-policy.pdf.

6. Which IRB are you submitting to?
   • Click “OHSU or Joint OHSU/VA.”
   • Do not click the “VA Only” option. The VA has opted not to use eIRB for VA-only studies at this time.

7. Are you requesting a waiver of IRB oversight?
   • Click “Yes” if you are requesting permission for OHSU to rely on another IRB for oversight of this study.
   • Typically, OHSU will not cede IRB oversight if OHSU subjects will be recruited for enrollment at OHSU or if OHSU will receive funding for the research.
   • Research conducted at VAPORHCS must be reviewed by the VAPORHCS IRB or the OHSU/VAPORHCS combined IRB.

8. Attach the protocol.
   • For industry-sponsored or multi-site research, attach the sponsor’s protocol and a local context supplement. The local context supplement describes any variations to the protocol being performed at OHSU.
   • For all other research or research where a sponsor’s protocol is not provided, attach a protocol using the appropriate OHSU template.
   • For projects applying for a determination of non-human subjects research or non-engagement in research, attach a request for determination form.

9. Naming documents
   • The IRB requires you to name documents using the naming conventions detailed in this document. Failure to follow these guidelines will result in delays to your review.
10. Uploading documents

- Click “Add.”

- Click “Browse” to find the document you wish to upload.

- Name the document as you or your sponsor needs it to appear on the IRB approval memo or using OHSU’s naming conventions. Add a version number if needed.

- Click “OK and Add Another” to upload additional documents.

- Click “OK” to finish uploading documents.

Once all basic information and relevant documentation have been provided, click “Continue” to move to the next form.
Funding Sources

The main purpose of this section is to help the IRB identify all studies associated with particular grants. To assist with review, identify all external funding sources, such as industry sponsors and government agencies. If funding comes from a specific internal funding program, list it here.

1. This project is:

- Mark the option that best applies to this study.

- “Unfunded” means your study is not funded by an external funding source, including departmental general funds or program development accounts.

- Unfunded studies require that you upload a Proposed Project Questionnaire (PPQ) with your submission. It must be signed and dated by the study PI and Department Chair.

- If your study is unfunded with externally provided drugs, equipment, or supplies, list the provider of the donated items as the funding source.

2. Identify each organization supplying funding for the study.
- Click “Add” to add all sources of support. Include any current or pending funding sources.

- If your study is or will be funded by a subcontract, list the funder of the subcontract to OHSU and the original funding source as two separate entries.

○ Funding Organization
1. In the “Add Funding Source” dialogue box, choose “Select” to search for your funding source using the % sign in front of your search criteria. For example, enter “%NIH” if searching for NIH funding.

2. Searching for specific sources may not yield the result you are looking for if the source has been abbreviated in Oracle. For example, searching for “Diabetes” will not yield “National Institute of Diabetes and Digestive and Kidney Disease. Try searching “NIH” or “DHHS” instead.

3. If you cannot locate your funding source in the list, contact awards@ohsu.edu or 503-494-1884 for assistance. It may take up to two days for new funding sources to be added. You will be notified when the requested funding source is available.

4. Once you select the correct funding source, click “OK.”

   a. **Sponsor’s Funding ID**
      i. The Funding ID is assigned by an external sponsor. Please enter if applicable.

   b. **PPQ #**
      i. Enter the PPQ number assigned to your study in InfoEd.

      ii. Enter “N/A” if your study is industry-sponsored or unfunded.

      iii. Unfunded studies are required to upload a paper PPQ on the Supporting Documents page of the eIRB.

   c. **Attach Files**
      i. Upload relevant funding source documents, including full grant applications, using the “Uploading New Documents” instructions on page 38 of this guide.

5. Back in the Funding Source window, click “OK and Add Another” to add additional funding sources following the steps above.

Once all funding sources have been identified and all IDs, PPQ #s, and required files have been uploaded, click “Continue” to move on to the next form.
Study Team Members

Add information about each person engaged in the research. See federal guidance regarding engagement in research for more information. Only personnel listed on this page will have IRB approval to be engaged in the research.

1. Identify each additional person involved in the design, conduct, or reporting of the research.
   - To be available for selection, individuals must be registered for the eIRB system.
   - If the study is being reviewed and approved by a non-OHSU collaborator’s IRB, do not add the individual as a study team member.
   - For VA study staff, please list all personnel who will work onsite at the VAPORHCS, need access to CPRS patient records, directly interact with VAPORHCS subjects, and/or see identifiable data for VAPORHCS subjects.
   - Click “Add” to open the Add Study Team Member window.

   o Study Team Member
     1. Add information about each person involved in the design, conduct, or reporting of the research. You do not need to add the PI here.

     2. Do not add the study’s primary contact person for IRB communications here unless the person is also engaged in research.

     3. The person who creates the study in eIRB is assigned as the primary contact by default and can be changed later. See Changing the Primary Contact for more information.

     4. Click “Select” to open the search window.

     5. If you have difficulty finding the person in the list, try typing the beginning of the first or last name.

     6. Contact the IRB for assistance if the person you are looking for has already registered for eIRB access and is not listed in the system.
Role in Research
1. At least one role must be assigned for each individual.

2. If the study is being reviewed and approved by a non-OHSU collaborator’s IRB, do not add them as a study team member.

3. Non-OHSU collaborators can indicate their externally managed training, conflict of interest (COI) disclosure, or lack of training/COI disclosure by using the last four checkboxes.

- Is the team member involved in the consent process?
  1. Mark “Yes” or “No” as applicable.

- Does the team member have a financial interest related to this research?
  1. Mark “Yes” for individuals who have a significant financial interest in the sponsoring agency or manufacturer/licensee of the investigational product under study.
  2. Mark “No” for individuals who have only administrative/financial responsibilities for this study and who have no involvement with subjects or study data.
  3. See page 5 of this guide for a refresher on OHSU and the VA’s conflict of interest policies.

- Back in the Add Study Team Member window, click “OK and Add Another” to add additional team members following the steps above.

- Once all team members have been added, click “Continue.”
2. **External Team Member Information**
   - Upload any external collaborator training certificates or related documents using the “Uploading New Documents” instructions on page 38 of this guide.

   - For collaborative agreements that may be required for external team members, see: 
     [http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Collaborations-Non-OHSU-Researcher-Decision-Tree-Quick-Guide.pdf](http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Collaborations-Non-OHSU-Researcher-Decision-Tree-Quick-Guide.pdf); and 

3. **Start/Stop Dates**
   - This section records the date staff members are added and removed. No changes can be made by the study team.

   Once all Study Team Members and relevant information have been added, click “Continue” to move on to the next form.
Study Scope

1. **Are there external sites where the investigator will conduct or oversee the research?**
   - Mark “Yes” or “No” as appropriate.
   - An external site includes any non-OHSU affiliated site where the OHSU PI will be responsible for the conduct of the research. This does not include industry multi-site studies with sites other than OHSU.

2. **Does the study do any of the following:**
   - Mark “Yes” if one or more options apply to your study.
   - Mark “No” if none of the options apply to your study.
   - “Specify the use of” means that the protocol requires one or more subjects to use the drug, biologic, dietary supplement, or food as part of study participation, regardless of whether its use is considered standard of care or whether it is FDA-approved for that use.
     - Example 1: The protocol indicates that subjects in group one will take 650mg or aspirin in response to a headache. The use of aspirin is specified.
     - Example 2: The protocol indicates that subjects in group one may take 650mg or aspirin in response to a headache. The use of aspirin is not specified.

3. **Does the study do any of the following:**
   - Mark “Yes” if one or both options apply to your study.
   - Mark “No” if neither option applies to your study.
   - A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including a component part or accessory that is:
     - Intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in humans or other animals, OR
Intended to affect the structure or any function of the body in humans or other animals and that does not achieve any of its primary intended purposes though chemical action within or on the body of human or other animals, AND

Not depended on being metabolized for the achievement of any of its primary intended purposes.

- “In vitro diagnostics” include reagents, instruments, and systems intended for the use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequela.

- Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

- The FDA defines in vitro diagnostic products as devices and may also classify them as biological products.

4. Does the study specify the use of a food, medical food, or dietary supplement that is NOT intended to diagnose, cure, treat or mitigate any disease or condition?

- Mark “Yes” or “No” as appropriate.

- The IRB requests information on items used in the study even if they are not being used to diagnose, cure, treated, or mitigate any disease or condition.

- Example: Mark “Yes” if your study requires subjects to take vitamin D even if it is not being tested as a treatment for a disease or condition.

- If you mark “Yes,” upload information about the item using the “Add” button.

1. Select the food/medical food/supplement.
   a. Click “Select” to open the “Drug Selection” dialogue box.

   b. Type the item name you are looking for and either:

   i. Use the down arrow key to highlight your selection and press “Enter.”

   ii. Use the “Select” button to choose your item from the list and click “OK.”

   c. If you cannot find the item in the search window, enter the name and brand name manually.

2. Attach files related to this food/medical food/supplement.
   a. Upload any relevant documents using the “Uploading New Documents” instructions on page 38 of this guide.
5. Is the sole purpose of this study to establish a VA only repository?
   • Mark “Yes” or “No” as appropriate.

6. Is the study funded by a training grant?
   • Mark “Yes” or “No” as appropriate.
   • Examples of training grants are: NIH K23, KL2, etc.

Once all food/medical food/supplements and relevant supporting documentation has been provided, click “Continue” to move on to the next form.
1. Identify each external site where the investigator will conduct or oversee the research.

- Click “Add” to access the “Add External Site” dialogue box.
  
  o Enter the name of the external site.
  
  o Enter the name of the site contact.
  
  o Provide the site contact’s preferred phone number.
  
  o Provide the site contact’s preferred email address.
  
  o Indicate if the external site’s IRB will review the research.
  
  o Indicate if the external site will rely on OHSU’s IRB to oversee the research.

- Click “OK and Add Another” to add additional sites.

- Click “OK” when all external sites have been added.

Once all external sites have been added and relevant information provided, click “Continue” to move on to the next form.
Drugs

This page will become active if you marked “Yes” on question #2 of the Study Scope page.

1. List all drugs, biologics, foods, and dietary supplements to be used in this study.
   - Click “Add” to access the “Add Drug Information” dialogue box.
     - Click inside the “select the drug” text box and type the name of the study drug.
     - Use the down arrow key to highlight your selection from the drop down list.
     - Click “Enter.”

1. If the drug does not appear, click “Select” to open the drug search dialogue box.

2. Search using the generic name of the drug (e.g., “acetaminophen, not Tylenol”)

3. Select the correct drug using the radio button.

4. Click “OK.”

   - If the drug does not appear in the list, enter the name and brand name manually.

   - Click “Add” to attach files related to the study drug, including investigator brochures, package inserts, prescribing information and product labeling.

2. Will the study be conducted under any IND numbers?
   - Mark “Yes” or “No” as appropriate.

   - If the study is conducted under an IND, mark “Yes” and provide the following information in the dialogue box:
     - IND number
     - IND holder (e.g., Sponsor, Investigator, or Other)
     - Name of IND holder if you select “Other”
- Upload any files related to the IND, such as the IND letter from the FDA, using the “Uploading New Documents” instructions on page 38 of this guide.

Once all drugs and relevant documentation has been added, click “Continue” to move on to the next form.
This page will become active if you marked “Yes” on question #3 of the Study Scope page.

1. Select each device the study will use as an HUD or evaluate for safety or effectiveness.
   - Click “Add” to access the “Devices” dialogue box.
     o Click inside the “select the device” text box and type the name of the study device.
     o Use the down arrow key to highlight your selection from the drop down list.
     o Click “Enter.”
   1. If the device does not appear, click “Select” to open the device search dialogue box.
   2. Search using the name of the device.
   3. Select the correct drug using the radio button.
   4. Click “OK.”

   o If the device does not appear in the list, enter the name and brand name manually.

   • Indicate whether the device qualifies as a humanitarian use device (HUD). Click here for guidance on HUDs.
   • Click “Add” to attach files related to the study device, including instructions for use, device manuals, etc.
   • Click “OK and Add Another” to add additional documents.
   • Click “OK” when you are finished.
2. **Device exemptions applicable to this study:**
   - Click the “?” icon for help text guidance to choose which of these categories apply to your study.

3. **If applicable, identify each IDE and HDE holder.**
   - Click “Add” to access the dialogue box.
   - Enter the following information:
     - IDE or HDE number
     - IDE or HDE holder (e.g., Sponsor, Investigator, or Other)
     - Name of IDE or HDE holder, if you select “Other”
   - **FDA Classification**
     - The FDA classification is determined by the FDA and is typically indicated on the FDA letter documenting the IDE number. Click on the “?” icon for help text guidance.
   - Upload any FDA documentation regarding the device exemption or classification using the “Uploading New Documents” instructions on page 38 of this guide.

Once all study devices and relevant documentation have been added, click “Continue” to move on to the next form.
Recruitment, Consent, and Authorization

Refer to the OHSU and VA policies and forms pages for templates and guidance. Please use the templates provided whenever possible.

1. **OHSU Study Participants Opportunities**
   - Check this box if you would like a recruitment listing on the OHSU Study Participants Opportunities webpage.
     - If you check this box, you must complete the Study Participants Opportunities smatform as part of your eIRB study submission.

2. **Researchmatch.org**
   - Check this box if you would like to use researchmatch.org to recruit for this study.
     - If you check this box, you must upload a copy of the recruitment email text you plan to use under “Section 3: Recruitment Materials.”

3. **Recruitment Materials**
   - All material to be seen or heard by subjects must be included in your submission. Provide the following, as applicable to your study:
     - Flyers
     - Brochures
     - Letters
     - Radio and TV scripts
     - Social Media
     - Websites
     - Posters
     - Telephone scripts for recruitment and screening
   - Ensure that any materials you plan to use, especially radio and TV scripts, are approved by the IRB before production.
   - Refer to the following templates and instructional documents:
     - Telephone Script - Recruitment and Screening
     - OHSU Research Advertising Templates
     - VA Advertisement Content Requirements
     - VA Recruiting Potential Research Subjects - Executive Summary
     - VA Phone Script Template
     - VA Recruitment Letter Template
   - Upload recruitment materials using the “Uploading New Documents” instructions on page 38 of this guide.
4. **Consent Forms**
   - Consent forms must be submitted on OHSU and/or VA templates, as appropriate.
     - Refer to the [IRB Policy and Forms Website](#) for current OHSU templates.
     - Refer to the [VA Website](#) for current VA templates.
   - If obtaining signed consent from subjects, use the appropriate Consent and Authorization template for your research.
   - If you are requesting a waiver of documentation of consent, use one or more of the following templates:
     - Information Sheet
     - Email text
     - Telephone consent
   - Upload all consent materials using the “Uploading New Documents” instructions on page 38 of this guide.

5. **HIPAA Documents**
   - Include Waiver of Authorization (WoA), Prep to Research, Decedents, and/or Data Use Agreements (DUA) as applicable to your study.
     - Refer to the following OHSU templates and instructional documents:
       1. Waiver or Alteration of HIPAA Authorization
       2. HIPAA - Prep to Research Form
       3. Decedents Representation
       4. HIPAA - Data Use Agreement
     - Refer to the following VA templates and instructional documents:
       1. VA HIPAA Authorization
       2. VA IRB Policies and Forms
       3. VA Decedents Research
       4. VA Data Use Agreement
     - Note that the IRB does not sign Data Use Agreements (DUAs).
       1. DUAs, along with the study title, PI, grant/funding information, and PPQ should be sent to contract-triage@ohsu.edu.
       2. The contracting office that handled the contract, if any, is responsible for signing the DUA.
3. If there is no contract for the study, Deb Golden-Eppelein, Associate Vice President for Research, is responsible for signing the DUA.

- Upload all HIPAA documents using the “Uploading New Documents” instructions on page 38 of this guide.

6. If VA subjects are involved, will any identifiable information be accessed or utilized in any way prior to informed consent when identifying potential subjects?
   - Click “Yes” or “No” as appropriate.
   - If yes, complete an Application for a Waiver of Authorization and Informed Consent Process for Screening/Recruitment Purposes and upload it to "Other HIPAA Documents."

7. Will any identifiable health information be accessed or utilized in any way prior to informed consent when identifying potential subjects?
   - Click “Yes” or “No” as appropriate.
   - If yes, complete a Prep to Research Form or Waiver of Authorization form and upload it to HIPAA Documents.

Once all recruitment, consent, and HIPAA Documents have been added, click “Continue” to move on to the next form.
Study Details

1. Clinical Trial
   - Check this box if your research study is one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

2. OHSU Signed Consent
   - Check this box if subjects will be consented by OHSU personnel with an OHSU consent form.
   - Do not check this box if consent is being obtained with an Information Sheet and/or if documentation of consent is being waived.

3. Billable Services
   - Consider all procedures that subjects will undergo as part of the study and will incur a charge in EPIC.

   □ Billable Services: Subjects in the study will receive potentially billable clinical services, procedures, tests, exams, or items as part of the study. (This includes all studies where subjects will be scheduled for study visits in the Clinical and Translational Research Center):
     - If checked, will ALL clinical services be billed to either the subject or subject's insurance?  
       ○ Yes  ○ No  Clear
     - If no, will ALL clinical services be billed to the research account and/or performed at no charge?
       ○ Yes  ○ No  Clear

   - Consider all procedures that subjects will undergo as part of the study and will incur a charge in EPIC.

<table>
<thead>
<tr>
<th>Billing Option #1</th>
<th>Billing Option #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>All study procedures are standard of care (SOC)</td>
<td>Select YES</td>
</tr>
<tr>
<td>All study procedures are research related</td>
<td>Select NO</td>
</tr>
<tr>
<td>The study requires a mix of SOC and research procedures</td>
<td>Select NO</td>
</tr>
</tbody>
</table>

4. Minimum Age/Maximum Age
   - Indicate the minimum and maximum age of subjects that will be considered for enrollment.

5. Decisionally Impaired
   - Check this box if the study will enroll adult subjects with decisional impairment.

   - If applicable, download and prepare the DI supplement.
• See the Decisionally Impaired Adults Help Sheet for additional information.

6. International Site
• Check this box if the PI will oversee study activities at any site outside of the United States.

7. Native Americans
• Check this box if the study plans to specifically target Native Americans as subjects.
• Do not check this box if the study may enroll Native Americans only incidentally.

8. Grade School
• Check this box if the study will be conducted in grade schools (Kindergarten – 12th grade).

9. Select Study Topics
• Indicate the general topics the research covers.
  o Type the topics in the text field to access pre-populated options to select from, or
  o Click “Add” to display the picklist search box.

10. Repository
• Check this box if data will be stored for future unspecified research by someone other than an industry sponsor.

• Choose one of three types of repositories:
  o Repository operated outside OHSU by non-OHSU personnel (not industry sponsors).
  
  o Repository at OHSU that is defined in a protocol other than the one presently being submitted. If this option is chosen, enter the eIRB# of the protocol where the repository is defined.
  
  o Repository at OHSU that is defined in the protocol presently being submitted. If this option is chosen, check the appropriate boxes to indicate what is being stored for future use (e.g., data, specimens, other).

11. Does this study have a certificate of confidentiality (CoC)?
• Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other Department of Health and Human Services (DHHS) agencies on behalf of the Department of Justice in order to protect the confidentiality of sensitive information obtained from research subjects.

Once all study detail items have been addressed and relevant information provided, click “Continue” to move on to the next form.
Ancillary Reviews and Notifications

Use this page to indicate any study activities that require review by one of the OHSU ancillary review committees.

1. **Institutional Conflict of Interest**
   - Check this box if the study involves any of these companies in which OHSU has significant financial interest.
   - “Involvement” may include financial support, drugs and/or devices used in the study, and/or use of the company as a centralized laboratory or repository.
   - If checked, indicate which company applies in the text box provided.

2. **VAPORHCS (Veterans Administration)**
   - Check this box if the study involves the VA in any way, including staff, resources, or VA facilities.

3. **Cancer**
   - Check this box if the study has any involvement with cancer patients or if the aim of the study examines a key cancer prevention intervention (e.g., smoking cessation.)
   - Check the box immediately below “cancer” if the study looks at cancer care in adolescents or young adults between the ages of 15 and 39.

4. **OHSU Radiation**
   - Check this box if OHSU subjects will be exposed to radiation for research-only purposes (e.g., not standard of care).
   - If checked, complete and upload a Use of Ionizing Radiation in Humans Form.

5. **VA Radiation**
   - Check this box if VA subjects will be exposed to radiation for research-only purposes (e.g., not standard of care).
   - If checked, complete and upload a VA IRQ Appendix F form.
   - Direct questions regarding VA radiation to Shannon Voss at Shannon.Voss@va.gov.

6. **OCTRI (Oregon Clinical & Translational Research Institute)**
   - Check the first box if OCTRI resources will be used in any capacity.
• Check the second box if OCTRI CTRC resources, such as inpatient rooms, clinic rooms, nursing, bionutrition, and/or study coordinators) and/or Core Lab resources will be used for the study.

• Check the third box if the study will use the OCTRI Research Data Warehouse.

7. Biological Agents
• Check this box if the study uses a drug or agent that consists of recombinant DNA, synthetic nucleic acids, non-recombinant infectious agents, or biomedical toxins (e.g. botox).

• More information is available here.

8. Stem Cells
• If the study uses any of the below types of stem cells, check the appropriate selection and complete the Stem Cell Supplemental Questionnaire indicated.

<table>
<thead>
<tr>
<th>Adult Stem Cells</th>
<th>Undifferentiated cells found in adults</th>
<th>No questionnaire needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryonic Stem Cells</td>
<td>Cells obtained from the inner mass cells of a human embryo</td>
<td>Fill out stem cell questionnaire</td>
</tr>
<tr>
<td>Human Induced Pluripotent Stem Cells</td>
<td>Cells obtained from adults and manipulated to differentiate into a variety of cell types</td>
<td>Fill out stem cell questionnaire</td>
</tr>
<tr>
<td>Other</td>
<td>If your cells doesn’t fit into any of the other categories, describe here.</td>
<td>Fill out stem cell questionnaire</td>
</tr>
</tbody>
</table>

9. Emergency Department
• Check this box if any research activities will take place in the emergency department.

10. Recruitment/Visits in the Center for Women’s Health/OBGYN areas (inpatient or outpatient)
• Check this box if your study will take place or recruit subjects from the Center for Women’s Health OBGYN areas.

• Send a brief project description to whru@ohsu.edu and include details about recruitment methods.

Once information provided has been provided, click “Continue” to move on to the next form.
Study Participation Opportunities

Use this page to provide a lay description of the study that will be posted on OHSU’s Study Participant Opportunities website. To activate this page in the eIRB, the OHSU Study Participant Opportunities box must be check on the Recruitment, Consent, and Authorization page.

1. Study purpose
   • Briefly describe the purpose of the study in lay language.

2. Condition(s) studied (Keywords):
   • List the health conditions being studied or any keywords that you would like to have searchable on the website.

3. Eligibility criteria
   • List the criterial required by subjects in order to qualify for participation in lay language. Do not copy this from the protocol.

4. Do you want to recruit healthy volunteers?
   • Mark “Yes” or “No” as applicable.

5. Percent chance of receiving placebo if placebo controlled
   • If the study is placebo controlled, enter the percent chance that a subject could receive the placebo instead of active drug.
     • If the study is not placebo controlled, enter “N/A”

6. Duration of participation (including any follow-up time)
   • State the average duration of subject’s participation including any follow-up time.

7. Recruitment contact information
   • Provide the appropriate contact information as applicable. An email address should be provided at minimum; preferably include email, phone, and contact name.

8. Study sponsor
   • Provide the name of the study sponsor funding the project, if any.

9. End date of recruitment
   • Enter the date you wish the listing on the OHSU Study Participants Opportunities website to expire.
     • Your study listing will no longer appear on the website after this date. If you wish to change the end of recruitment date after the study has been approved, you must submit a modification.
10. Will compensation be provided?
   • Mark “Yes” or “No” as applicable.
   • If compensation will be provided, specify the amount per visit, total compensation available, and any plans to prorate payment for subjects who do not complete the entire study.

11. Subjects under 18 are included
   • Check this box if subjects under 18 will be recruited to enroll in the study.
1. **Supporting documents may include any of the following:**
   - Questionnaires
   - Surveys
   - Focus group or interview questions
   - Subject ID cards
   - Diaries
   - Dosing instructions
   - Translation certificates
   - Data Safety Monitoring Plan (if applicable, DSMB, DSMC charter, etc.)
   - Memo to IRB
   - Individual Investigator Agreements (IIA)
   - IRB Authorization Agreements (IAAs)

2. **Upload all supporting documents using the “Uploading New Documents” instructions on page 38 of this guide.**
Submitting Your Study

1. When you click “Finish,” the system will return you to the main study screen. You will see this banner at the top of the page:

   ![This project has not been submitted yet.](image)

   The Principal Investigator must submit the project before the review can proceed.

2. The banner indicates that the study has not been submitted yet. This means that the IRB cannot see your study and no action will be taken on it until it has been submitted.

3. Studies that are required to use eCRIS must create their study in eCRIS by clicking the “Create or Update eCRIS Study” action in the eIRB. Note that you will receive an error message if you try to submit the study in eIRB before creating the study in eCRIS.

   ![Create Or Update eCRIS Study](image)

4. Use the “Assign Primary Contact” action to indicate the study staff member that will be primarily responsible for communicating with the IRB. For expedient IRB review, it is crucial that the person assigned as the primary contact be responsive to requests from the IRB.

5. **If you are the study coordinator**, use the “Notify PI” action to send an automated message to the PI that the study is ready for submission.

   ![Notify PI](image)

6. **If you are the PI**, use the “Submit” action to submit the study to the IRB for review.

   ![Submit](image)
1. **Pre-submission** is when the study team is preparing the study submission by uploading essential documents and answering the questions in the eIRB.

2. **Scientific Review Committee (SRC) Review:** Studies that are not otherwise externally peer reviewed, including unfunded studies and some career development grants, are reviewed by the SRC.

3. **Cancer (CRRC) Review:** Studies that enroll cancer patients or investigate matters related to cancer prevention require a separate review by the CRRS. See the [Knight Cancer Institute Bridge Page](#) for submission instructions and templates.

4. **Pre-Review:** The study is being assessed by the assigned IRB coordinator and/or assigned to a full board meeting. Studies are assigned to a full board based on the availability of appropriate board member expertise.

5. **IRB Review:** The study is in active review by one of the following:
   - **Full Board:** Typically, a study spends about a week in this status before the study team is notified of the board’s determination.
   - **IRB Chair:** Expedited, exempt, and waived projects will sometimes require review by the IRB chair. Depending on availability, this can take up to two weeks.
   - **IRB Coordinator:** Minimal risk studies that qualify for expedited review are able to be reviewed by IRB coordinators.

6. **Post-Review:** The study has been reviewed and the determination letter and other associated materials are being prepared.

7. **Review Complete:** The study has been reviewed and approved.
1. The study reviewer may send your project back for clarification at any phase in the review process.

2. The PI and primary study contact will receive an email notification from the eIRB system that the IRB has requested clarification.

   - **Expedited/Exempt Studies:** Studies that qualify for in-office review will typically be reviewed entirely by the IRB coordinator. The study will have to address all concerns raised by the IRB coordinator prior to receiving approval.

   - **Full Board Studies:** The IRB Coordinator will communicate with the study team to obtain all necessary documents for the board to conduct their review. After the board has reviewed the study, the IRB coordinator will most likely return the study with a “Conditional Approval Memo” detailing required changes.
Responding to Clarification Requests:
Expeditied, Exempt, and Waived Studies and Requests for Determination

1. The above referenced project types are reviewed in the IRB office by a designated reviewer (e.g., an IRB coordinator or IRB chair).

2. During the pre-review phase of the process, the designated reviewer may send the project back for corrections or clarifications.

3. Look for the “Clarification Requested” entry on the “History” tab on the main study page of your project in the eIRB. The required clarifications will be detailed under this entry in the history tab.

4. If changes to documents are required apply the changes to the documents already uploaded in the eIRB. Click the “Documents” tab, and click the draft document you wish to revise.
5. Once the document is open, turn on track changes by navigating to the “Review” tab in the Word document and clicking the “Track Changes” button.

   a. Added text will be indicated with underline. Deleted text will be indicated with a strikethrough.

   b. Do NOT accept changes made by the IRB even if you agree with them.

   c. Do NOT reject changes made by the IRB even if you disagree with them. Instead, provide a comment in the document justifying why you feel the change is not needed.

6. Save the revised tracked document to your desktop.

7. Open the study questionnaire using the “Edit Study” action.

8. Navigate to the smart form where the previous version of the document in question is uploaded using the ”Jump To” menu at the top and bottom of each smart form.

9. Use the “Update” function to stack your revised document on top of the previous version.

   a. **CORRECT** – using the “update” function ensure that only the most recent version of the protocol displays

   b. **INCORRECT** – using the “Add” function uploads an entirely new document making it difficult for the IRB to determine which the most recent version is.
10. Upload to “Supporting Documents” a memo to the IRB addressing all required changes.

11. Once all required changes have been addressed in the eIRB, resubmit the study.
   a. **Study staff** – Use the “Notify PI” action to alert the PI that the project is ready to be resubmitted to the IRB.
   b. **PI** – Use the “Submit Response” action to resubmit the project to the IRB.
Responding to Clarification Requests
Full Board Projects

1. The above referenced project types are reviewed by a convened full IRB.

2. After the IRB meets to discuss the project, the board may have additional requirements above and beyond what was requested by the IRB coordinator.

3. The modification required for full board projects are detailed in a memo titled “Correspondence for eIRB Project #” that can be found in the eIRB in two places:
   
a. Top right hand side of the main study page

   ![Study Example](image1.png)

   b. Project History Log

   ![History Log Example](image2.png)

4. If changes to documents are required apply the changes to the documents already uploaded in the eIRB. Follow the instructions in the previous section to edit documents and resubmit.
Uploading New Documents – Quick Guide

- Click “Add.”

- Click “Browse” to find the document you wish to upload.

- Name the document as you or your sponsor needs it to appear on the IRB approval memo or using OHSU’s naming conventions. Add a version number if needed.

- Click “OK and Add Another” to upload additional documents.

- Click “OK” to finish uploading documents.
Uploading Revised Documents – Quick Guide

1. Open the study questionnaire using the “Edit Study” action.

2. Navigate to the smart form where the previous version of the document in question is uploaded using the “Jump To” menu at the top and bottom of each smart form.

3. Use the “Update” function to stack your revised document on top of the previous version.
   a. **CORRECT** – using the “update” function ensure that only the most recent version of the protocol displays
   b. **INCORRECT** – using the “Add” function uploads an entirely new document making it difficult for the IRB to determine which the most recent version is.

4. Upload to “Supporting Documents” a memo to the IRB addressing all required changes.

5. Once all required changes have been addressed in the eIRB, resubmit the study.
   a. **Study staff** – Use the “Notify PI” action to alert the PI that the project is ready to be resubmitted to the IRB.
   b. **PI** – Use the “Submit Response” action to resubmit the project to the IRB.