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 and 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 submissions must have:

- **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 as well as within the study questionnaire (Initial Review Questionnaire or IRQ).

**OR**

- **One of the following forms** (available on the IRB Policies and Forms website as well as within the IRQ):
  - **Request for Determination Form** – use if (1) you are not sure if your project requires IRB oversight; (2) you would like a formal determination from the IRB as to whether the project requires IRB oversight; or (3) you are conducting research with samples or data that are not individually identifiable to the research team, but the project involves genetic research or has health information and very limited HIPAA identifiers (e.g., date of service but no name/MRN). If you have a protocol, you may upload it in addition to this form.
  - **Future Human Subjects Form** – use if you need certification of IRB review in order to release your grant funds, but you are not ready to submit a full study because further protocol development activities must take place before the research will involve human subjects.

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 (an assent form may also be required for children or decisionally impaired adults).

  Templates for most situations are also available on the IRB Policies and Forms website under Consent and HIPAA Forms and Templates. The Consent and Authorization Form INSTRUCTIONS document in the same section details which template to use when, and how to customize the forms to fit your study.

  If you would like the IRB to consider a waiver or alteration of informed consent and/or HIPAA authorization (for instance, because you will not be interacting with subjects), see the Consent – Waiver or Alterations Help Sheet on the IRB Policies and Forms website for guidance. Describe your request in your protocol and/or local context supplement and include a waiver of authorization (if the study has health information).

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, for example, to provide the IRB with your recruitment plan, how data security/privacy will be handled, etc.

- **Complete Grant** – required for federally funded (e.g., NIH) or foundation funded studies as well as for Future Human Subjects submissions.

- **Proposed Project Questionnaire (PPQ)** – for unfunded studies, must be uploaded with all required signatures. For funded studies where the PPQ is completed electronically via InfoEd, enter the PPQ number in the IRQ. For
industry sponsored studies that also involve an eCRIS submission, a separate PPQ is not needed, so indicate "N/A" in the PPQ number field in the IRQ.

Data Safety Monitoring Plan (DSMP) – required for all studies that are greater than minimal risk, as well as multi-site studies where OHSU is performing coordinating center activities regardless of risk level. A template is available on the IRB Policies and Forms website. This information can be described within the protocol instead of in a separate document as long as all points in the DSMP template are addressed.

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, 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 the subject’s 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 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 and would like just one IRB to review the study, and have the other institution or investigator rely on that IRB review.

Example document lists for common types of studies:

<table>
<thead>
<tr>
<th>Clinical Trial – industry sponsored</th>
<th>Chart Review – unfunded</th>
<th>Survey Study w/ Repository – funded</th>
<th>Curriculum Evaluation Study – unfunded</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consent and Authorization Form</td>
<td>• List of Data Variables</td>
<td>• Complete Grant</td>
<td>• Information Sheet</td>
</tr>
<tr>
<td>• Cover Memo to IRB</td>
<td>• PPQ – fully signed</td>
<td>• Consent and Authorization Form</td>
<td>• Links to Curriculum and Tests</td>
</tr>
<tr>
<td>• DSMP</td>
<td>• Protocol</td>
<td>• Protocol</td>
<td>• PPQ – fully signed</td>
</tr>
<tr>
<td>• IND Letter</td>
<td>• Waiver of Authorization</td>
<td>• Protocol – Repository</td>
<td>• Protocol</td>
</tr>
<tr>
<td>• Investigator’s Brochure</td>
<td></td>
<td>• Repository Sharing Agreement</td>
<td>• Recruitment Email</td>
</tr>
<tr>
<td>• Local Context Supplement</td>
<td></td>
<td>• Repository Tracking Sheet</td>
<td>• Survey</td>
</tr>
<tr>
<td>• Protocol</td>
<td></td>
<td>• Recruitment - Flyer</td>
<td></td>
</tr>
<tr>
<td>• Questionnaires</td>
<td></td>
<td>• Survey for Patients</td>
<td></td>
</tr>
<tr>
<td>• Recruitment – Facebook</td>
<td></td>
<td>• Survey for Providers</td>
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<tr>
<td>• Recruitment – Brochure</td>
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<td>• Recruitment – Flyer</td>
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<tr>
<td>• Prep to Research</td>
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</table>

2. UNDERSTAND THE REQUIREMENTS FOR STUDY STAFF
Consider the following guidance to better determine who to list as study staff in your eIRB submission and what will be required in order to be compliant with regulations.

Eligibility criteria to be listed as the Principal Investigator:

Principal Investigator Eligibility (Policy No. 04-00-005.100)

The Principal Investigator (PI) is responsible for ensuring compliance with the financial, administrative and programmatic aspects of the project; for conducting the research in an ethical manner; and for compliance with all applicable laws, policies, guidelines and regulatory requirements regardless of the source or existence of any sponsorship. PIs must maintain current knowledge of all requirements, policies and procedures related to the management and conduct of the research, including funding agency requirements. See Integrity’s Roles and Responsibilities in Research website or the HHS Investigator Responsibilities FAQs for more information.

PIs must also meet the criteria for Principal Investigator Eligibility. Those eligible to be listed as the PI on IRB, IACUC, or IBC protocols are:

- OHSU Faculty
- Affiliated (Emeritus, adjunct) faculty, or other OHSU employees, on a case by case basis, with written Department Chair/Institute Director permission

Post-Doctoral Research Fellows and students are not eligible to act as the PI of IRB, IACUC, or IBC protocols. A mentor or another individual that meets the requirements for PI eligibility must be named the PI instead. For further details and possible exceptions, please see Policy No. 04-00-005.100.

Listing study staff in your eIRB submission:

Engagement in Research

Any individual that is determined to be “engaged” in research must be listed as study staff in your eIRB submission. Engaged individuals can include administrative staff, physicians, nurses, students, volunteers, and others. An individual is generally considered to be engaged if they are performing any of the following:

- Obtaining data about subjects through interaction or intervention for research purposes including: invasive or noninvasive procedures (drawing blood, cheek swabs, counseling or psychotherapy, administering drugs or other treatments, other measurement procedures), or manipulation of the environment (controlling environmental stimuli, presenting sensory stimuli, orchestrating events or social interactions).
- Obtaining identifiable private information about the subjects for research purposes.
- Obtaining informed consent of subjects in research.
- Studying, interpreting, or analyzing identifiable private information or data for research purposes.

Exceptions to Engagement

There are some exceptions for individuals that might normally be considered engaged in research. These individuals would not need to be listed in your eIRB submission as study staff. The most common exception is for individuals who perform procedures for the study as a ‘commercial service’. Examples include: Hospital or outpatient clinic staff who perform routine, standard imaging procedures (x-rays, CT/MRI scans, Echocardiograms) in the same fashion that they would be done for clinical purposes; Hospital or outpatient laboratory staff who perform routine, standard blood draw and run standard clinical laboratory tests on them. The service must not be the study intervention that is being tested in the protocol. Additional exceptions exist for emergency coverage.

No exceptions are made for individuals that enroll subjects or obtain consent. For more information on engagement and exception criteria, please see the HRPP worksheet HRP-422 Engagement or the HSS guidance for Engagement of Institutions in Human Subjects Research (2008).

If you believe you may have individuals involved in your research that may qualify as exceptions, please contact the IRB for assistance in determining if such individuals need to be added to your study.

Requirements for all study staff:

Required Research Training

Research training requirements vary depending on the study, as listed below. Completion of training is required for grant set-up or IRB, IACUC, or IBC protocol approval. All courses are available in Compass. You may be redirected to the CITI website to take the modules once you have launched the course in...
Compass. For more information on what training applies to you and other training you may need, please see Integrity’s training websites on O2 and the public website.

For non-OHSU study staff, documentation of completed training courses at their own institution must be provided. If non-OHSU study staff do not receive training for necessary courses at their institution, please see the Research Compliance Education website to learn how external researchers may take training through Compass.

Required trainings:

- **Responsible Conduct of Research (RCR)** – In compliance with federal regulation and OHSU institutional policy, all investigators, research staff, and other relevant personnel (those reasonably involved in the design and/or conduct of human, animal, applied and/or basic science research) must complete CITI's Responsible Conduct of Research (RCR) education.

- **Human Subjects in Research (HSR)** – This training is required of any research staff conducting research with humans.

- **Good Clinical Practices (GCP)** – This training is required of any research staff involved in conducting a clinical trial funded by the NIH or a funder that requires GCP training.
  - **CITI GCP** – This course is required of any research staff on a clinical trial of an FDA regulated product (drug or device) and meets the requirement for GCP training on other clinical trials as well.
  - **GCP for Social and Behavioral Research** – For low-risk, social or behavior interventions that are clinical trials funded by the NIH, this course is offered as an alternative course to the FDA products-focused CITI GCP course. If you are involved in any studies that use FDA regulated products, you must take the CITI GCP course listed above. Please contact the IRB if you have questions about whether your study qualifies for this alternative course.

**Conflict of Interest in Research Disclosure**

Completing a Conflict of Interest in Research (CoIR) Disclosure form is required of all researchers. In order to comply with research regulations, you will need to update your disclosure annually. You can complete your CoIR disclosure form in the eCoI system. For more information on Conflict of Interest, please see Integrity’s Disclosure Requirements website.

Non-OHSU study staff may be covered by their own institution’s CoI policy, which must be compliant with the federal regulation 45 CFR Part 94. In this case, they are generally not required to submit a CoIR form in OHSU’s eCoI system. However, if they are not covered by their institution’s CoI policy, or from an institution that does not have a policy compliant with 45 CFR Part 94, they must complete OHSU’s CoIR disclosure form. Please see the Research Compliance Education website for instructions on how various types of non-OHSU researchers should complete the CoIR form.

Note: There may be additional requirements, such as safety trainings, credentialing/staff privileges, depending on the individual’s role on the study.

### 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 subjects will be contacted for information by telephone, provide a telephone script (template available on the IRB Polices and Forms website). 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 complete and consistent.

In addition, provide justification for:

- Why it would be impracticable to conduct the research if written consent was required to be 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. If you are managing the repository here at OHSU, you likely also need a repository protocol, and possibly a tracking sheet and submittal/sharing agreements (see the Repositories Help Sheet and Repository Forms and Templates on the IRB Policies and Forms website for details).

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? Is the form clear about how the subjects give permission for only certain parts of the study, such as including optional lines to initial?

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. Complete the IRQ

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

The way you answer questions on each 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 displays when you click on the blue question mark icon next to a question.

Pay attention to links, which may lead you to more information or templates for further documents you may require.

For more detailed guidance in filling out the IRQ, the Initial Submission Guide (Step-by-Step Guide 5.3.2017) provides information and instructions for every question in the IRQ. This guide is located on the IRB Policies and Forms website under IRB Help Sheets and Quick Guides.