A Faculty Mentor's Guide to the IRB

Those who mentor research trainees often face the challenges of limited time, limited resources, and limited support while they try to provide the support and guidance their trainees need. WVU Office of Human Research Protections (OHRP) would like to help with one aspect of this process, so we've compiled the following information and resources to help you guide your students and trainees through the Institutional Review Board (IRB) process at WVU.

Roles and Responsibilities

The roles and responsibilities of each person in the student/advisor/IRB relationship can vary from institution to institution. There are also some common misconceptions about the roles of IRBs and their support staff regarding student researchers, so let's clarify those items first.

Advisor/Mentor

The advisor's role is to guide student researchers in how to develop and conduct research. This includes:

- direct supervision and oversight of research conduct
- ensuring that adequate facilities and resources are available
- providing or sourcing ongoing training
- mentoring through the publication process
- guidance in other research-related activities, such as regulatory reviews

At WVU, students and residents may not serve as principal investigators (PIs) on IRB protocols. Learn more about who is eligible to be a PI in WVU General Policy 100 [PDF]. The student's faculty advisor or mentor serves as the PI on the IRB protocol and is held to all the usual responsibilities of a PI described in SOP 003, Investigator and Key Personnel Responsibilities, Qualifications, and Training.

Student/Trainee

The student is expected to:

- define the research question
- develop the study plan with their advisor
- conduct the research under the supervision of their advisor
- adhere to training requirements and other responsibilities of study personnel, as described in SOP 003 – Investigator and Personnel Responsibilities

Students should be encouraged to develop study materials and IRB submissions with their advisor's input and guidance. As study personnel, students can work on and submit IRB

protocols, but the advisor must give the final approval as the PI and is ultimately responsible for all materials and study conduct.

OHRP Staff and Reviewers

WVU OHRP staff and IRB reviewers are responsible for evaluating protocol submissions to ensure the research plan meets the requirements of applicable regulations, policies, and ethical principles. Their primary obligation is to protect human subjects from potential harm. While staff and reviewers may provide feedback on protocol submissions and direct students to relevant resources, their role does not extend to general guidance and support for student researchers.

IRB reviewers may comment on a study's design if there are concerns related to the protection of human subjects, but reviewers do not provide a comprehensive scientific review. That should be completed at the department level prior to submission.

Navigating the IRB

Plan for Success

Advance planning can make the entire process easier and less stressful for the advisor, student, OHRP staff, and IRB reviewers. The following considerations for each phase are largely focused on the IRB process and not exhaustive, but they do provide a useful starting point. It's important to remember that there are institutional requirements beyond the scope of the IRB such as the data protection process, funding considerations, departmental scientific review, and more. The planning process is an ideal time to impress upon your students that IRB approval is limited in scope and is not the only requirement they need to account for. IRB approval is also not blanket approval from the institution to conduct a study, especially regarding access to information, physical spaces, or potential subjects.

Before the study begins:

- Determine whether the project is research with human subjects. The resources on OHRP's Not Human Subjects Research page can help you through this.
- Ensure that there are adequate resources, facilities, time, and personnel to conduct the research.
- Complete all required training courses and ensure that all study personnel complete their training. More information on IRB-required training is available on the training page.
- Get familiar with the resources. Review the information on OHRP's Get Started and Guidance A to Z pages so you know where to go when your students have questions.
- Complete the research data protection process. This is required for all human subject research, and is managed by Research Data, Technology, and Services. Data is categorized as low, medium, or high risk through this process. These risk assessments

relate to data and storage requirements rather than the IRB risk assessment. For example, a study with high-risk data could still be considered minimal risk for IRB review.

- Is a data use agreement required? To determine your next steps, see the data agreements page from Research Data, Technology, and Services.
- Work with your department to complete any required scientific reviews.
- Plan for storage of data and research records after the end of the study.
- Plan for the end of the study, including when to request closure of the IRB protocol.
- If the project is human subjects research, submit for and obtain IRB review. Review the relevant pages for not human subject research and protocol types for more information.

During the study:

- Conduct the study as described in the protocol after obtaining IRB and other relevant approvals.
- Provide oversight and ongoing training for the student researcher and other study personnel.
- For expedited or full review studies, submit amendments as needed to update study procedures or personnel.
- WVU+kc does not allow amendments for flex and exempt studies. Track minor amendments in the study records. Contact IRB@mail.wvu.edu regarding significant changes to the study as those may affect whether the study still qualifies for the original review type. A new submission may be required for significant changes.
- Maintain accurate study records. Download and save all IRB materials at the time of approval, including the IRB approval letter. Do not rely on the electronic IRB submission system for study records.

After the study ends:

- Close the IRB protocol.
- Maintain the study data and records as planned.
- Complete any remaining authorship and publishing activities.
- Continue to provide oversight and guidance to the student as needed.

Does the project need IRB review? If so, what type?

Figuring out what needs to be reviewed by the IRB and what kind of protocol to submit can be challenging. Some projects might not meet the threshold to be reviewed at all, some will fit into lower-level review tiers, and some may even require review by the full board. The following information will help you and your students determine where their proposed research fits.

When making this assessment, review the materials carefully and select the lowest level of review that the study qualifies for. IRB review is generally managed with a risk-based

approach, with lower-risk activities needing less oversight, and the majority of student projects will fit into NHSR, Flex, Exempt, or Expedited review. While it's possible for student research to need full board review, it is uncommon.

Not Human Subjects Research (NHSR)

Per federal regulations, IRBs only review and oversee activities that meet the definitions of both "research" and "human subjects." These definitions are laid out in regulations set forth by the Department of Health and Human Services. Research is considered by this agency to be a systematic investigation which is designed to develop or contribute to generalizable knowledge. Human subjects are defined as living individuals who researchers will interact or intervene with for research purposes, or identifiable biological specimens or identifiable private information which will be used for research purposes.

"Research" and "not research" determinations can be confusing, as there are some scholarly activities that do not meet this specific, narrow definition but may be considered research in their respective fields of study. It's important to remember that these definitions only serve to assess whether activities need IRB review. A "not research" determination in this context is not an assessment of the value or validity of the activities in any context.

Flex

The WVU flex category is used for research that is not federally funded and not otherwise subject to federal regulations. This category allows us to simplify review for some low-risk studies. To qualify for this process, a study needs to meet the criteria outlined in our Flex Protocol Type Guide [PDF].

Exempt

Certain types of minimal risk research are exempt from some of the federal regulations. The regulations outline several strictly defined categories which qualify for this exemption, and all the research activities must fit into one or more of these. The categories do have some limitations, including limits on certain subject populations and when identifiable information can be retained/used. Federal regulations don't specify who should determine what qualifies for exemption, so each institution sets its own policies for who makes these determinations. At WVU, those determinations are made by an IRB reviewer.

Exempt review submissions are accepted on a rolling basis and reviewed by one person unless additional expertise is needed. For more information on exemption categories review our exempt research page.

Expedited

For research which doesn't fit into exempt categories, the next step up is to explore expedited review. Although it sounds like a rush order, the term "expedited" is a bit of a misnomer. It doesn't necessarily mean that this review type is fast; what it really means is that the process has less administrative burden and a bit less oversight than a full review. Like exempt studies

these are accepted on a rolling basis, not tied to a meeting date, and are generally reviewed by one person.

To qualify for expedited review, all the activities in the study need to fit into one or more predefined categories. The categories for expedited research are less restrictive than those for exempt, but the research must still be minimal risk AND meet the category requirements to qualify. For details on categories, visit our expedited review page.

Full

The full, or convened board, review type is for studies which pose more risk to participants or just don't fit into exempt or expedited categories. The process for full review is more involved than the other types. These reviews do not take place on a rolling basis; each submission is placed on a meeting agenda, then reviewed and voted on by the committee during the meeting.

Full review submissions also require, at a minimum, annual continuing reviews to remain active. If the PI does not submit the annual review with enough time for review and approval, the protocol approval will expire and study activities must be paused while it is resubmitted for a new approval. For more information on full review studies, review our full review procedures.

Developing Materials

Informed Consent Forms

WVU OHRP has developed several consent and assent form templates which are designed to help investigators comply with federal regulations, state law, and institutional policies. The requirements for consent forms vary depending on the type of research and how the consent process will be conducted. It's important to select the correct template for the study and then tailor that form to meet the needs of the study population.

Some key tips and strategies for advising students on consent forms include:

- Remind them to pay close attention to the directions in the template and tailor the form as needed.
- Remind them that this document is aimed toward the study participants and the language should reflect that. The audience should dictate how descriptions of the study are written. For students who struggle to simplify language, ask them to pretend they're explaining the study to a friend or relative who isn't familiar with their work.
- Remind them that formatting matters! Fonts should be consistent throughout and easy to read, and any template instructions should be removed.
- Encourage them to work with a friend for proofreading and feedback on readability, preferably someone who is not involved in their field or topic.
- Direct them to the consent development guidance page for resources on readability.

Participant-facing materials

Much like consent forms, participant-facing study materials (including advertisements, questionnaires, and instructions) should be written to meet the study participants' needs. The language, formatting, and formality of these materials can vary depending on the specific study population involved.

The primary goal of these materials is to communicate information in a way that is easy to understand. Students sometimes focus on writing to impress rather than to communicate effectively with their audience, so consider taking this opportunity to remind your students that the audience drives the writing style and vocabulary.

OHRP has published guidelines for recruitment and advertising materials, which you can share with students who need help putting those items together.

Submission

One of the first steps, the data protection process is required for all human subject research conducted at WVU and is administered by Research Data, Technology, and Services. The certificate you receive at the end of this process must be included with the IRB submission, and it must be attached correctly. There is a hard stop in the system for this attachment; if the certificate is not correctly uploaded using the Data Protection Certificate document type you cannot proceed with the submission.

In addition to the data protection certificate, each submission must be complete and contain sufficient detail for the IRB to review it and make their determinations. It's important to think in terms of specific actions rather than theory or general plans, and it's common for students to miss out on those details. Aside from paying close attention to the questions in the IRB submission, one helpful strategy is to encourage students to think of the IRB protocol like a story: describe the who, what, when, where, and how. **Who** is conducting research and **who** will participate? **What** will they each do and **how** will they do it? **What** resources are needed and available? **When** and **where** will each step occur, from recruitment through analysis?

WVU OHRP has also put together a protocol prep checklist [PDF] to help guide researchers through the submission process. This is also available from the Get Started page, and it's a helpful tool to point out for students or anyone else new to the WVU IRB.

If the study involves HIPAA-regulated protected health information, the study will require either a HIPAA authorization from subjects or a waiver of the requirement for a HIPAA authorization. If the waiver applies, that will be flagged for you during the data protection process and the approved waiver must be attached to the IRB application. If the waiver does not apply, a HIPAA authorization can be included in the study consent form or as a standalone document. OHRP's HIPAA guidance [PDF] has more detailed information.

Review

The first step of the review process is pre-review. This is when staff in OHRP examine the protocol to verify that it has all the necessary information and components, meets major regulatory and ethical requirements, and is generally ready for review. At this stage, staff will likely provide notes about items that need to be completed or should be adjusted. If you aren't sure why you're being asked to make a change or there's a reason it wouldn't work for your study, please contact our office for clarification. A quick conversation can often clear up frustrating misunderstandings for researchers and OHRP staff.

Once the pre-review is complete and the protocol is ready for review, it's forwarded on to the appropriate IRB reviewer or reviewers. At this point, the IRB will review the materials, make their determination, and possibly request additional information or changes. Students may be alarmed when they get a request to adjust some aspect of the protocol; explaining early that this is a normal part of the review process can help alleviate that anxiety. Review can also be a collaborative process – students and advisors shouldn't be afraid to contact our office if they are confused, have questions about what's being asked of them, or would like to talk through solutions when a requested revision presents a problem for the research plan.

Once the revision process is done and the IRB has determined that the study meets the criteria for approval, that approval will be processed, and an approval letter will be generated. It's a common misconception that this is a blanket approval from the institution to conduct the study. In fact, this review process is quite limited in scope; the IRB's role is to ensure that protections are in place for human subjects. The IRB doesn't have any sway over access to facilities, study populations, data held by various departments and units, equipment, and other resources which may be necessary for a given study. Researchers need to seek permission and approval for those items independently of IRB review.

Ongoing Oversight

Once the IRB approves a study, the process isn't over! Ongoing oversight takes several forms. This can include annual IRB reviews to maintain approval, quality reviews, reporting new information to the IRB, submitting amendments to the IRB, or submitting a closure request. These all give the IRB a chance to check or review specific aspects of the ongoing study, and for the study team to provide updates and change information as needed.

Amendments

For expedited or full review studies, amendments must be submitted and approved before implementing changes to the study. Minor and major amendments may be reviewed differently, depending on the review type. For information on submitting an amendment, review the Researcher's Guide to Amendments and Renewals [PDF].

WVU+kc does not allow amendments for flex and exempt studies. For those protocol types, record minor changes in the study records. Contact IRB@mail.wvu.edu regarding significant

changes to the study as those may affect whether the study still qualifies for the original review type. A new submission may be required for significant changes.

Continuing Reviews

For Full Review and some Expedited Review protocols, researchers must submit an annual continuation review to keep the IRB approval active. Other expedited studies are approved for a five-year period. Details on submitting a renewal are available in the Researcher Guide for Amendments and Renewals [PDF].

It's common for student projects to not need to be renewed – often they are either too short in duration or the review type doesn't require it. If that's the case for your students, it's still a good idea to discuss this process with them so they know its role in the IRB review cycle.

Guiding Students

Manage Expectations

IRB Review Timing

IRB review and approval take time. Protocols must be pre-reviewed by OHRP staff, possibly revised, reviewed by the IRB, potentially revised again, and will be approved only once the IRB has ensured that the submission meets all applicable requirements. Depending on workload and study team response times, this process could take several weeks to complete. When building out a timeline for the research project, guide your students to include ample time for IRB review and any other administrative processes that need to be completed before the study can begin.

Students often wait too late to submit their projects and end up in a time crunch when IRB review takes longer than they anticipated. Avoid a stressful experience for everyone and encourage students to budget at least three weeks for flex, exempt, or expedited review. While it's uncommon for a student project to require full review, researchers should budget at least six weeks for that process. Remind students that these times are estimates and not guarantees. Review times can be highly variable depending on details of the study, completeness of initial submission, responsiveness of study team, and reviewer availability.

Research Timeline

The overall research timeline also needs to be realistic and achievable for the student's circumstances. Research trainees seldom have the experience and insight to know when they're getting in too deep, so part of your role as an advisor is to help them put together a research plan that they can accomplish with the available time and resources. To help you both, consider asking your student the following questions:

- How much experience do you have doing human subjects research?
- What is your deadline for the project you plan to do?

- How much time do you have in your calendar to devote to this project?
- How many other people and institutions will be involved in your project?
- Are there areas you can simplify?
- Can you team up with another student on this project?
- How will this project fit into your future career goals?
    - What field do you want to have a career in?
    - Why is this field interesting to you?
    - Why is this project interesting to you?
    - Does the project address issues that have not yet been addressed?

Consider Complexity

Students who are just entering into the world of research and scholarship bring a wealth of enthusiasm and passion to their work. They hope to do something meaningful and impact the world around them. While this enthusiasm should be encouraged, mentors should also remind students that there are practical considerations and limitations when planning a study.

This guide has already touched on the importance of planning a study within the constraints of available time and resources, but there are some additional points to discuss with students as they engage in this process.

Risk-based approach

Among IRB professionals, you'll often hear the phrase "risk-based approach". This is an approach to human research in which the risks surrounding a study drive how it is handled and overseen. WVU OHRP applies this by ensuring that studies are reviewed through the least burdensome method they qualify for and seeing that higher-risk studies get the ongoing oversight they need.

Advisors and students can apply this philosophy when developing a research plan as well. Consider the goal of the study, what practices are essential to meeting that goal, the characteristics of the study population, and what risks the study will pose to the participants. Do the research procedures incur risks that are greater than what those people would experience in everyday life? If so, is there a way to mitigate those risks? What is the least risky and least burdensome way to effectively answer the research question?

While this approach won't eliminate the risks or administrative burdens of conducting research, it can help reduce them and streamline some of the processes. Unnecessary study procedures may create complications during administrative processes such as IRB review while also creating extra burden for the study participants. It's important to critically assess the study procedures with this in mind.

Layers of requirements

In addition to this risk-based approach, students should be aware that there are many layers of regulations and requirements that can apply to different types of research. To those who aren't familiar with the different types of requirements involved, it can seem like everything is up to the IRB's discretion. In reality, there are a variety of regulations, laws, and policies which govern research conduct. These include the IRB review regulations from DHHS, FDA regulations, various federal agencies, state laws, international laws, and local institutional policies. Which of those applies to a given study will depend on who is participating in the study, what the study is about, what the study procedures are, and where it is conducted.

Some scenarios that can add layers of requirements and administrative complexity include:

- International research, involving laws and regulations of another country
- Collaborative work involving people outside WVU
- Studies involving children, prisoners, or pregnant people
- Studies involving people who have cognitive impairments
- Studies conducted at off-site locations
- Clinical research

These scenarios can add time to the review process and may have additional requirements to protect the people involved in the study. This doesn't mean that students can't conduct research with these groups or complicating factors. It *does* mean advisors and students should carefully consider whether a research plan with complicating factors is achievable with the time and resources available. It all comes back to ensuring that the proposed research is feasible for that student at that time.

Provide Oversight

Even with students who exhibit confidence and self-reliance, it's important to remember that they are still research trainees who need guidance and oversight. Many advisors struggle with finding a balance between empowering their students to problem-solve and learn on their own while providing adequate guidance. The following suggestions may be old news for experienced advisors, but please read through for some helpful tips if you're new to mentoring.

One common strategy is to set aside dedicated time to meet with individual students on a regular basis. This provides a space for the advisor to provide necessary ongoing guidance and get regular updates on progress, and for the student to ask questions and get help on any areas they struggle with. Ongoing communications like this also provide an opportunity to identify and correct any misconceptions or misunderstandings on the part of the student.

Protecting time to work directly with an advisee can also aid in developing the mentor/mentee relationship, building a rapport so that students feel comfortable asking questions and asking for help. Similarly, building trust with students creates an environment where advisors can

admit their gaps in expertise. There can be a lot of pressure on educators and advisors to always have the right answers, making it harder to say, "I don't know the answer to that." However, this phrase can be an important tool in any educator's arsenal, leading to the exploration of information and ideas. Don't be afraid to say "Let's find the answer together" or to help students engage with additional mentors with other areas of expertise.

Finally, remember that as the listed PI the advisor has ultimate responsibility for the student's research. That includes ensuring that all study personnel are capable and qualified, and overseeing the study to ensure that it is being conducted correctly. Routine check-ins and guidance help to fulfill that responsibility as well as benefiting the student.

Know When to Ask for Help

Faculty advisors can face a lot of pressure from multiple directions, with finite time and resources. They're often expected to have all of the answers at their fingertips for a variety of complex issues, but the fact is that it's just not possible for advisors to know absolutely everything their students may need help with. When you come up against an IRB quandary, or you just aren't quite sure of the answer, reach out to OHRP staff.

OHRP staff are IRB experts – it's their job to know about the federal regulations and institutional policy governing human research. Our staff work with a variety of issues day in and day out and are available to help you and your students.

If you accidentally give your students the wrong answer to one of their IRB-related questions, it can lead to complications for the student, you, OHRP staff, and IRB reviewers. This is an area where the common adage "it's better to ask for forgiveness than permission" does not apply. It's far better to reach out and ask for help from OHRP staff than to face complications of conducting research that doesn't comply with federal regulations or WVU policies. We're always here to help!

Where to Go with Questions

Website Resources

Get Started

Our Get Started page is a quick start guide to the IRB. This will take you through the basic steps and most important points of the process.

Learning Center

The Learning Center is focused on helping students and new (or new-to-WVU) researchers. The guides and videos provide an overview of what most new researchers will need. The student quick start guidance on this page will be especially helpful.

Guidance A-Z

The guidance listing is a comprehensive library of guidance and policies from OHRP, information from federal agencies, and other resources to help with specific and in-depth questions. It's organized alphabetically with anchor links to each section so it's easy to navigate. You can also use the page search function in your browser to quickly find specific topics.

Frequently Asked Questions

Find a selection of common questions and their answers on our FAQ page.

WVU+kc

For help with WVU+kc, first visit the IRB Protocol Module section of the IT services training page. You may need to log in using your WVU credentials. You can find helpful instructions for most of the tasks you'll need to perform in the system. The training page also has sections for other modules in the system, such as Proposal Development and Conflict of Interest.

Contact Us

Even the most seasoned researchers can't be expected to know everything about the IRB process or the regulations that govern the IRB and their work. The great thing is that you don't have to! WVU OHRP staff are available to help you and your students sort through confusing items in the submission process, regulatory questions, and other hurdles you may face. You can always reach our office at IRB@mail.wvu.edu for help.