Guide for Students
Conducting Human Participant Research

The Basics

Most people see conducting ethical research as easy – and a fair amount of it is easy. The concepts of respect for people, consent, and voluntary participation are already well known. The less intuitive part is the various laws, policies and procedures that regulate research. That is where the Research Compliance Office steps in.

In order to conduct human subjects research as a Western student you need to submit an application to the Research Compliance Office, which is located in the Office of Research and Sponsored Programs. Our office is responsible for coordinating the application review process and monitoring ongoing research. Approval must be received before starting **any** research activity. That includes recruiting people.

> Important!
> Do not recruit or collect data before IRB approval

A Research Compliance Officer reviews your submitted application to determine the type of research and risk level. If your research is higher risk, it will be sent to the Institutional Review Board (IRB), which is a committee of individuals who provide review, approval, and oversight of higher risk research involving humans. Application reviews take into account federal, state, and local laws as well as university policies and procedures.

The IRB's main goal is to safeguard the rights and welfare of human research participants. We also exist as a safeguard for you. We learn the laws and regulations, so that you don't have to, and help apply those regulations to your research.

Is it the IRB's job to make your life difficult?

No, definitely not. Otherwise, our job titles could be much more exciting.

We understand that this process can seem overwhelming and possibly irritating. It gets easier, and hopefully less irritating, and our office is here to help.

A few things are guaranteed though:

❖ Yes, the application will take time and attention. A well thought-through application will move quickly through the IRB review process. A half-hearted attempt at an application will take a while to get to approval.
❖ Yes, you'll have to plan ahead. To be fair, we review applications in the order received. We can't rush applications because they are submitted late. Carve out time for the review process and you will be set to go.
❖ Yes, the IRB will focus on the details. That's just the nature of the job, but bear with us.

Start the process early, meet with your faculty advisor, review this guide, decide whether to meet with a Research Compliance Officer for extra help, and call our office when in doubt. You'll be conducting your research in no time.

Do you need to submit an application?

Only activities that are defined as "research" with "human subjects" need to be reviewed by the IRB. The federal definitions of these terms are very specific.

Find out if your activity needs review by either:

1

> **Completing our** online survey tool

2

> **Using the definition of "human subjects research":**
>
> Go through these questions. If the answer is "Yes" to both questions, then the activity is considered human subjects research and requires submitting an application.
>
> 1. Is your project research?
>
>   Research is a **systematic investigation** – including research development, testing, and evaluation – designed to develop or contribute to **generalizable knowledge**.
>
>   - **"Generalizable knowledge"** is using the data beyond the subject group being studied. That includes publishing, presenting, posting on CEDAR, etc. This includes pilot research, which is generalizing to the eventual study.
>
> 2. Does your project involve human subjects?
>
>   A human subject is **a living individual about whom** an investigator conducting research either (1) obtains data through **intervention or interaction** with the individual OR (2) obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**.
>
>   - "**Living individual**" is what is sounds like – your subjects are alive
>   - "**About whom**" means the data is about someone, not just about facts
>   - "**Intervention**" includes both:
>   - Gathering data from someone
>   - Manipulating someone's environment for research
>   - "**Interaction**" includes communication or contact, whether in-person, online, or on paper
>   - "**Identifiable**" means the person's identity could be found out in some way
>   - "**Private information**" is any non-public information or behavior
>   - **"Biospecimens"** is biological samples
>
>   If you are still not sure whether to submit an application, email compliance@wwu.edu or call a Research Compliance Officer for help.

What types of projects DO NOT need to be submitted?

Projects that do not meet the regulatory definition of human subjects research do not need IRB review. These include:

- Class activities/research methods classes where the focus is solely to learn about research (see the section about class projects below)
- Case studies
- Some quality improvement/quality assurance/program evaluation activities
- Journalism/documentary activities that are NOT for the purpose of drawing generalizations
- Oral history that is NOT for the purpose of drawing generalizations

Class Projects

You may be learning about research methods or asked to collect data as part of a class. As long as there is no intent to generalize the results of this data beyond the class, these activities do not require review by the IRB.

If you would like to use this data beyond the classroom or generalize from the results, you can choose to submit an application to the IRB for review. The IRB **cannot give retroactive approval**, so if there is any chance that you want to publish or present your data then we would recommend submitting an application.

We cannot give

retroactive approvals!

Student Responsibilities in Research

A Principal Investigator (PI) is the person on a research study application who is primarily responsible for the ethical conduct of the research. There is one PI per application. If you are working with other students on the research, you have to decide who will take on this responsibility.

As a student, you can be the PI as long as you have a Faculty Advisor working with you. We encourage students to be PIs, while at the same time emphasizing that there are expectations for this role.

Expectations for a Student PI

Under the mentorship of your faculty advisor, you must:

- Ensure that your research team completes training in the protection of human subjects in research, maintain documentation of trainings, and make sure training remains up to date.
- Submit an accurate and complete application to the IRB.
- Obtain IRB approval before beginning any research activity (including recruitment and screening).
- Conduct the research according to the approved application.
- Understand whether your application requires renewal each year (some applications do, some don't).
- Manage research data carefully and according to the data security protections listed on the application.

- Consult with your faculty advisor about problems.
- Report any unanticipated problems or deviations from the protocol to the IRB as soon as possible.
- Close your application when you have completed all interaction or intervention with human participants or their identifiable data.

If you are not comfortable with fulfilling any of these responsibilities, then talk with your Faculty Advisor. If you are not sure what any of these responsibilities mean, talk to a Research Compliance Officer.

Expectations for a Faculty Advisor

The Faculty Advisor shares responsibility with you for the ethical conduct of human subjects research.

Faculty advisors are expected to:

- Help students determine whether their activity requires IRB review.
- Ensure that students understand the principles of conducting research with humans and the importance of compliance.
- Ensure that the consent form is well written.
- Guide students through the IRB application process.
- Read the IRB application prior to submission and provide feedback.
- Support students in the conduct of research after a project has been approved.

How much should a student PI and faculty advisor collaborate?

We expect that you and your faculty advisor will actively work together on the research project. What that looks like will depend on the parties involved and the risk level of the research. You may need less support, especially if you have conducted research in the past.

The Research Compliance Officer reviewing your application will direct questions and emails towards you, as the PI. Please involve your faculty advisor in the conversation as appropriate or needed.

Get To Know Your Research Category

There are different categories of research. Knowing your category is important for both the application process and afterwards.

You can find your category in a few ways. Start from the top of this list and work your way down if you need more help or clarification:

1. Complete our online research guidance survey.
2. Talk to a research compliance officer.
3. Read a summary of the categories in our procedures manual.

The categories are Exempt, Expedited, and Full Board. Throughout this guide we will elaborate on what is required for your category.

Required Training

You and your faculty advisor need to complete an online training program in the protection of human subjects in research. Western pays for any affiliated employee or student to use the training program (known as "CITI"). The name of the training is the **CITI Social & Behavioral Research – Basic/Refresher course**. Information about the training is available through our website.

If you have other people working on your research project who will interact or intervene with human subjects or have access to their identifiable data then they will also need to complete this training.

Certifications are valid for 5 years.

Some people may already have a certificate. The NIH used to offer a similar certification program. These previously obtained certificates are still valid until expiration (also 5 years).

As the PI, you are responsible for:

- Maintaining a list of all research personnel, past and present
- Maintaining documentation of trainings
- Tracking the expiration dates for certifications for all research personnel and making sure they are up to date

If all of your research personnel completed trainings through CITI, it will be easier to track. CITI stores documentation of trainings online and sends automatic email reminders when certificates are about to expire. If you or any of your personnel have trainings through NIH, you have to do that work manually. You need to maintain PDFs of the NIH training certificates as well as track their expirations and remind personnel to complete the training again.

Training certifications are not submitted with your application or in any future modifications. A Research Compliance Officer may randomly check in to make sure that records are kept correctly. Be sure that you are always in compliance, just in case!

Applying

In order to receive approval for research you need to submit an application.

The IRB requires a certain amount of time to review submitted protocols, so plan ahead. The amount of time that IRB review takes will depend on your research category and your preparation. Estimates are available on the compliance website (www.wwu.edu/compliance) or through our online guidance tool. Keep in mind that these estimates rely on how well put together the application is, the workload of our office, and how responsive you are to questions. In general, allow our office 3 business days after your "received date" before checking in on the status of your application. Applications are received (even electronically) Monday through Friday 8:00 am – 5:00 pm. If you email your application after 5:00 PM, your application is marked as received on the following day.

> Tip: Our busiest times are mid fall quarter, mid winter quarter, and mid to late spring quarter.
>
> If you have a choice, submit your application when our office is slower.

Almost every person who submits an application wants it reviewed right away. There are likely other applications ahead of you though, and applications are reviewed in the order they are received. If you submit late, we cannot rush the process for you.

To apply you must complete and submit an application form along with your study materials.

Study Materials

Your research type and procedures will determine the materials to submit along with your application. We recommend gathering these materials before diving into the application.

The attachments required for all applications include:

Document	Additional Information
☐ Study instruments	Any materials involved in data collection or study participation: • questionnaires, online surveys, interview questions or guides, data collection forms • screenshots of phone applications, virtual reality software, etc.
☐ Recruitment documents	Any information that will be provided to individuals to help them decide if they would like to participate: • Verbal announcements, scripts • Letters, emails, fliers, social media posts • Research database postings (SONA, MTurk, etc)
☐ Consent form(s) or script(s)	All studies should have a consent process and form or script, unless otherwise waived by the IRB.

The documents to attach if applicable for your research include:

Document	Additional Information
☐ Supplements as Needed	If you are working with minors or other populations with special considerations there are additional forms that need to be completed and attached. The application will direct you towards any applicable supplements.
☐ Assent form	Assent forms may be used for minors over 7 years old participating in research.
☐ Debriefing Statement	If your study involves deception or incomplete disclosure, a debriefing statement should be attached unless otherwise justified.
☐ K-12 Clearance Letter(s)	If your research involves schools (K-12) a clearance letter will be required from an administrator at the site who has authority to give permission on behalf of the school to approve the conduct of research.
☐ Registrar's Office Clearance	If you are accessing student education records without consent, permission must be obtained from the Registrar's Office and submitted with your application.

☐ Field Training Program	If are requesting an alternative to the approved human subjects protections trainings, submit an attachment with a description of the program and justification for its use.

Please title your attachments

This helps us reference forms. For example, if you are attaching a questionnaire called the "Positive and Negative Affect Schedule Questionnaire (PANAS)", make that the title of the document.

Consent Forms

Informed consent is one of the most important parts of the research process. To help you put together your consent form we have both a consent checklist and consent templates available. To access these resources go to our Human Subjects Forms webpage and scroll to the bottom of the page.

Work with your Faculty Advisor to ensure that the consent form is complete. You can also ask our office to look at your draft consent form for comments.

Application Form

The application form is available for download from our website (www.wwu.edu/compliance).

The first few pages are instructions. Please read them. It's easy to tell which researchers didn't read all the instructions. One day we'll sneak a secret reading test question in there, so be prepared for that day.

Give Yourself Some Leeway

This form is an agreement between you and the Research Compliance Office. Whatever you write in your application is what we'll expect you to do after approval. That means that you have control over our office's expectations. One of the best pieces of advice that we can give is to write some flexibility into your application, where possible. Also, it should go without saying, only write in your application what you plan to do.

Some of the best areas to incorporate flexibility are your research location, your recruitment methods, the length of your study, the number of research participants, and your retention of identifiers.

Here are three examples of describing recruitment methods:

A. Participants will be recruited through an announcement in Professor <whoever>'s class.
B. Participants will be recruited through announcements in WWU classrooms where the professor has agreed to allow the announcement.
C. Participants will be recruited through announcements in WWU classrooms (where the professor has agreed to the announcement), fliers posted around Bellingham, and social media posts.

All of the three examples are valid ways to describe your recruitment method(s). Option A is the most limiting. If you get approved for Option A, the IRB expects that you will only give an announcement in that one classroom. If you ever wanted to recruit elsewhere, you would need to submit a modification. Option B is pretty good – it incorporates more flexibility because it allows you to recruit in multiple classrooms. Option C gives the researcher multiple options. Notice that you don't need to be overly specific about where fliers are posted. You also don't need to be overly specific about what you mean by social media.

If you include multiple recruitment options, and you end up not doing one component, that is okay. It's only bad if you skip an important step like consent or do something beyond what you are approved for.

Times When You Need to Be Specific

You need to be detailed when describing:

- Your recruitment when you are working with populations that require special clearance, like when conducting research in K-12 schools or with indigenous populations
- the study tasks that participants will be asked to complete
- how long the study takes for participants to complete
- your incentives (if any are provided)

How much writing in the application this involves depends on the study. Here are a few examples of study procedure descriptions:

A. Participants will log in to complete an online Qualtrics survey. The survey will ask about whether subjects prefer puppies, kittens, or ponies. The survey will take 5 minutes.
B. Participants will be asked to complete a paper survey and an interview. The paper survey asks about the subject's preferences between tacos versus enchiladas and will take an estimated 5 minutes. In the paper survey, participants can opt into completing the additional interview, which will be scheduled at a convenient time in a private location. The interview will be audio recorded and asks more in depth questions about their food preferences. The interview will be around 30 minutes.
C. Participants will asked to complete a paper survey about their physical fitness (~20 minutes). Then they will be asked to complete a series of physical exercises (~45 minutes) in this sequence:
   a. 5 minute warm-up jog at the participant's own pace
   b. 10 jumping jacks
   c. 20 lunges
   d. 20 lateral lunges where the participant starts with knees slightly bent, steps a leg out of the side, lowers into a lunge, and extends back up
   e. 20 sit-ups/crunches
   f. 5 minute cool-down with stretching

   Exercises will be supervised by the researcher at all times. Participants are allowed to take breaks as needed.

All of these three examples are decent ways of describing your study procedures, depending on their complexity. Option A is for a very simple online survey. We understand the concept of the online survey and don't need much more information. Note though, that if you specify an online survey, after

approval if you wanted a paper survey you would need to submit a modification. Option B shows a slightly longer description because the study involves two parts. The text shows how the two parts connect and describes how the interview will be held. Note that you don't need to tell us specific locations for interviews, unless there's something specifically necessary about the room. All we need to know is that the interview location is private. Option C is a longer description because there are more procedures involved. Note that it's acceptable to give a general time estimate for the exercises. You can choose to list the items rather than put them in a paragraph. Also, general terms that most people know like "jumping jacks" are just listed, but when "lateral lunge" was used, a longer description was provided to give context for the movement.

In all of examples used, the IRB will expect you to follow the protocol that you outlined. If the researchers in Option B decided to just interview people first and then give the paper survey, that would be deviating from the protocol. In that case the researcher would have to submit a Problem Report form to our office, where the deviation was described.

Participants opting out of a procedure is not the same thing as a protocol deviation. For example, in Option C, if a participant chose not to do jumping jacks, then that's within their rights.

Signatures

The application approval signatures page is important to show that your faculty advisor and department chair are on board with your research.

There are two options for obtaining signatures:

- o Get an ink signature.
  The person signs the form and either the original can be submitted or scanned to send as a PDF.
- o Get a valid electronic signature.
  There are programs like DocuSign and Adobe Signatures that allow someone to digitally sign PDF documents. This signed PDF can be submitted to our office.

Faculty advisors and department chairs are busy people. Try to make this process easier for them. If getting ink signatures, consider printing out the page for them. They will need to view the application as well, which can also be printed or sent electronically. If you are relying on them to print the application signatures page, make it clear that they only need to print, sign, and scan that one page.

Form Troubleshooting:

The formatting looks weird OR the checkboxes are not working

It's difficult to make a form type that works for every operating system and software version. We are working towards solutions, but in the mean-time we need to make the current format work. These operating systems/software versions might give you some difficulty:

- Word Online
- Google Docs
- Older versions of Word for Mac
- Word for PC versions older than 2003

The text has a grey shaded background

This happens because we are using protected Word form. The grey shading is to show where the form fields are. You can turn this off. There is a link in the application form instructions that will show you how to do this.

How Your Application Is Reviewed

Applications are reviewed in the order they are received. When you submit your application, give us at least 3 days to respond.

Step 1. You Will Receive an Initial Screening Email

A Research Compliance Officer screens your application. We look to see that the application is complete and clear and confirm the appropriate review category (exempt, expedited, or full board).

If we need to clarify an ambiguous answer, request a revision, or request a missing attachment, the Research Compliance Officer will send a screening email. The email will have instructions on how to respond.

Step 2. Working on Revisions or Clarifications

To keep the process moving, respond as soon as possible to screening emails. When we give an estimate of how long it takes for an application to be approved, it all depends on how prompt you are in responding.

Special note: In our emails we try to be brief and clear, with as many pleases and thank-yous as possible without going overboard. If we seem terse because of the brevity, that's not the intent.

Call or email our office if any of the screening questions are confusing. It is not worth struggling through something, when we can happily clarify or help you through it.

If we do not receive a response, or any indication that you are still interested in pursuing this process, within 60 days then we will close your application. Tell us if you are having trouble responding and we can extend this time and give you some help.

Step 3. Final Review and Determination or Approval

The next step for your application depends on your review category:

Exempt

The Research Compliance Officer who conducted the screening will process an exempt determination for your research. You will be sent an email with notice of the exemption, which is when you know you can begin your research.

Expedited

Your application will be sent to another reviewer for a second review. If the second reviewer has additional questions or revisions, the screening process above repeats. Once the application is ready, you will be sent an email with your notice of approval, which is when you know you can begin your research.

If you're wondering why you have to go through multiple rounds of revisions, it has to do with time management. The preliminary review and revisions are there to get your application into the best shape possible for the next person. Hopefully, the application is so complete that the next person has no additional questions.

Full Board

Your application will be sent electronically to the IRB members for review. All comments, clarification questions, and revisions of the committee members will be compiled into an email and sent by the Research Compliance Officer. Once responses and revisions are received, an IRB meeting will be convened where the committee discusses and votes on your application.

If you're wondering why you have to go through multiple rounds of revisions, it has to do with time management. We have to balance the number of revisions with the available time of the IRB. The preliminary review and revisions are there to get your application into the best shape possible for the IRB.

Once the application is ready, you will be sent an email with your notice of approval, which is when you know you can begin your research.

After Approval – Running Your Study

Once you receive your approval or exemption determination, you can begin your research! These are things you need to keep in mind about your open application:

Know Your Protocol Number

Your protocol number or IRB application number is how we reference your research going forward. For example "5555EX19". Our numbering system has changed over time, so you may have a different looking number. Always use the full number (including all numbers and letters) to reference your application. Otherwise your application may be confused with a different protocol.

Know Your Research Category

Take note of the research category that you were given (Exempt, Expedited, or Full Board). This designation will determine what types of things you need to do (or not do) after approval.

You Can Request Changes to Your Research

	Full Board & Expedited Applications	Exempt Applications
Things that Require approval BEFORE changing	**All changes require approval.** Assume that if the IRB approved it originally, that we will need to re-approve it when changed. This includes: • The subject population • The maximum number of approved subjects • The recruitment plan or materials • Study instruments • The Lead Investigator • Any investigator working with human subjects or their identifiable data	**Some changes require approval.** Any modifications that will change the risk level or fundamentally change the research require approval. • The subject population • Recruitment methods • Compensation amounts or methods • Consent forms and consent procedures • Changes in study materials that deviate from the approved scope • Changes in procedures or tasks • Anything that may change the project's eligibility for your exemption category
Things that DO NOT Require Approval Before Changing	NA – All changes require approval	• Edits in spelling, punctuation, and grammar on your study materials (not including consent forms) • Minor wording changes to your study materials (not including consent forms) that do not change the overall content and resulting comprehension • Adding or editing questions in questionnaires that are not outside of the scope of the questions are currently approved to ask

To request a change, you need to submit a Modification Form.

Your Research May Expire

	Full Board	Expedited	Exempt
DOES expire	X		
Does NOT expire		X*	X**

If your research expires, your initial approval memo will have an approval period listed (For example: 10/9/2018 – 6/1/2019). We are working to make these approval periods coincide with the approach of the end of the academic year. In order to extend your application, submit a Status Report.

Status reports should be submitted 6 weeks in advance of your study expiration date to allow enough time for the IRB committee to meet and review the paperwork.

Please do not let your application expire! If your application expires, you have to stop all human subjects activity, including analysis of identifiable data. If you have already stopped human subjects activity, please close your application.

*Even though expedited applications do not expire, they do need to be closed when activity with human subjects is complete.

**Our office retains records for 6 years. After that time, we will no longer have your application on file and you will not be able to modify it. If you need to make changes to an exempt application after this time, you will need to submit a new application.

Close Your Application When Ready

	Full Board	Expedited	Exempt
NEED to close	X	X	
Does NOT need closure			X

When you have completed all activity with human subjects and analysis of identifiable data, please close your application. We need to know which full board and expedited applications are still open.

To close your application, submit a [Status Report.](#)

Report Problems

Problems happen in research. When they do, you need to report them to our office. Adverse events can include:

- A risk of or actual breach of confidentiality
- An adverse event occurring during a study task
- An injury occurring as result of your research
- Discovering you used unapproved materials
- Any issue of non-compliance

To report a problem, submit a Problem Report.

Keep Documentation

The University has specific requirements around holding on to research records. Your research record includes your application approval/determination packet, correspondence with the IRB (which we include in your approval packets), any form approvals (modifications, study closures, problem reports, etc.), and signed consent forms.

The current retention period for research records is 6 years after the completion of the research.