Obtaining IRB Approval

Submitting Human Subjects Research Protocols
Institutional Review Board

A committee mandated to make sure that all research being done under the auspices of an institution adheres to ethical guidelines for the treatment of human subjects.
What is a human subject?

• A living individual about whom an investigator obtains private information or data through intervention or interaction
• A participant in a research study
The Belmont Report

Prompted in part by unethical treatment of human subjects during the Tuskegee Syphilis Study (1932-72).

Core principles for human subjects research:

- Respect for persons and their autonomy
- Beneficence
- Justice
Belmont Report Recommendations

Applications to IRBs must include:

1. Informed consent
   a. Information about what the study is and why it is being done
   b. Explained in simple language
   c. Consent must be voluntary

2. A careful assessment of risks and benefits

3. An explanation of how subjects are selected
Winona State IRB
Human Subjects Research Policy

1. Complete the WSU IRB education program (Human Subjects Education Module in D2L)

2. Complete the protocol form

3. Complete other documents (consent form, survey instrument, subject recruitment messages, etc.)

4. Submit the package for IRB review through IRBNet
Types of Review

Exempt
- Does not disrupt or manipulate subject’s normal life or involve intrusive procedures
- 1 IRB member reviews, 5 business days

Expedited
- Minimal risk; does not involve deception, at-risk populations, or sensitive topics
- 1 IRB member reviews, 5 business days

Full IRB review
- More than minimal risk; intentional deception, at-risk populations
- Full IRB reviews, 10-14 business days
What kind of a study is mine?

**Exempt from full review** if research involves (1):
- Educational practices in educational settings unlikely to adversely impact subjects’ opportunities to learn
- Tests, surveys, interviews, observation when data is anonymous or does not place subjects at risk
- Interventions with adults where data is verbal, written, or recorded and it is anonymous or does not place subjects at risk
- Research using existing data if it is publicly available and subjects cannot be identified
What kind of a study is mine?

Exempt from full review if research involves (2):
- Evaluation of public benefit or service programs
- Taste and food quality evaluation, consumer acceptance studies
- Storage or maintenance of secondary research for which broad consent is required
- Secondary research using identifiable information if broad consent or informed consent is documented
What kind of a study is mine?

**Expedited review** if research involves:

- Minimal risk
- Does not involve intentional deception
- Does not involve vulnerable populations or sensitive topics
- Includes appropriate informed consent procedures

*Minimal risk = the probability and magnitude of anticipated harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*
What kind of a study is mine?

**Full committee review** if research involves:

- Invasive procedures
- Procedures that could cause harm
- At-risk or vulnerable populations (children, the elderly, prisoners, cognitively impaired, disadvantaged)
- Intentional deception about its purpose
- External funding (from a source other than Winona State)
To submit your study to the Winona State IRB, use the website called IRBNet

- Easy to register
- Provides automatic notifications to you, the IRB administrator, and your reviewer
- Forms, examples, user guides, and checklists are available in the **Forms & Templates** library
Go to irbnet.org

Click New User Registration
Complete the registration form
Accept the terms of agreement
Search for Winona or scroll through list below

Highlight and click Continue

Add Affiliation

Specify the organization with which you are affiliated. If you are affiliated with more than one organization, you may add additional affiliations after you complete the registration process by logging in to IRBNet and accessing your User Profile.

Search for an organization: Winona

Organization types to display: Research Institutions

Your Organization:

If you do not see your organization listed you may add a new organization.

Continue Cancel
Starting a new project

Go to irbnet.org, enter your user name and password and click Login.
Click Create New Project
Give the project a name and fill in the name of the Principal Investigator.

Click Continue.

You do not have to fill out other fields.
Click Share to share the project with the faculty advisor and the other members of your research team.
Share Project

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with Full, Write or Read access.

- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).

- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted Full access.

[Click Share]
Highlight Winona State and click Select Organization.
Type in the last name and click search click full access and click save

Repeat this for each person on your team and the instructor
Click Designer and when the window opens, click the down arrows.
Highlight Protocol Request form and click Download
## PROTOCOL REQUEST FORM FOR WSU IRB APPROVAL

### I. BACKGROUND INFORMATION

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Click Add New Document

Uploading a Document
Using the down arrows, select the document type and click choose file, then select Attach.
Complete and upload the following documents:

- Protocol
- Consent form
- Letter of support (only needed if the research is for an agency or organization outside of the University)
- Questionnaire or interview guide
- Training/certification – (a screenshot of your and your team’s IRB test results)
Don’t forget to sign your project – everyone, on your team and your faculty sponsor must sign.

NOTE: you must take and pass (80%) the Human Subjects Module before you sign!
Select your position on the team and click Sign

Signing your project
Once everything is done, submit the project.
Click the Winona State IRB and click Continue
Red flags that hold up approval

• Not completing Human Subjects Education Module
• Incomplete protocol – fill out every field
• Vague description of research
• Vague description of subjects and how they are recruited
• Unclear plan for ensuring confidentiality
• Missing or vague consent form
• Missing survey, interview instrument
• Missing signatures – PI and faculty advisor
• Not “Submitting” the package in IRBNet
That’s it. Congratulations!

You will receive an email with your approval or instructions about any modifications that you need to have your study approved.

If you need to make modifications, read the “Modifications Required” letter carefully.

Forgot to include something in your package? Notify the IRB Administrator (“Send Project Email”) and it will be unlocked and you can easily make modifications.