IRB Information for Researchers

What Research Must Be Reviewed by Westfield State University's IRB?

Any research project that uses members of the WSU community as participants, or a project being conducted off campus by a member of the WSU community must go through the WSU IRB. This includes case studies of one or a very small number of participants, and it includes qualitative research methods, such as interviews. IRB approval must be secured before the project starts and informed consent and debriefing must be part of the process. Data collected prior to obtaining IRB approval may not be shared in any way, such as in a manuscript, poster, paper, presentation, publication, blog, listserve, or digital common.

What does it mean for a project to be exempt or expedited?

There are three types of reviews: exempt, expedited, and full. The researcher indicates on the application which review they believe is most appropriate, but the IRB chair might reassign.

Exempt – This research involves very minimal or no risk (e.g., surveys or interviews about topics that are not controversial nor stressful). Projects are not Exempt if they include any degree of deception, involve more than very minimal risk to participants, involve sensitive information, or vulnerable populations. All researchers must ensure privacy of participants and minimize risks to participants. Informed consent and debriefing is still needed with exempt research. The IRB Chair determines if research qualifies as exempt.

Expedited – A proposal that does not fulfill all criteria for Exempt may undergo an Expedited review if it involves minimal risk and meets other standards, such as not including deception, nor vulnerable populations. "Expedited" does not refer to how much time it will take to complete the review. A subset of the IRB that includes the Chair and at least one other board member will review this proposal.

Full Review – A proposal that does not qualify for exempt or expedited requires a full review. These studies typically involve more than minimal deception, sensitive topics, or vulnerable populations (e.g., children, prisoners, terminally ill, cognitively impaired, veterans). A majority of the IRB members will review and vote on the proposal.

Why should you get IRB approval before you begin your research project?

Because it is federal law. The purpose of the IRB is to assure the rights of research participants, but this is also good for researchers. Most researchers believe their study has no possibility of unethical practices. Nonetheless, every study can benefit from a thoughtful review by individuals trained to identify potential risks.

Who can submit an application for review by Westfield State University's IRB?

The primary investigator (PI) is responsible for submitting the IRB application. Faculty and staff can serve as a primary investigator (PI). Students can act as PI as long as they have a faculty/staff member as a sponsor. Researchers from off campus must have a WSU faculty/staff member serve as a sponsor. Sponsors are expected to have reviewed applications prior to submission, and should be copied on communications with the IRB. IRB approval does not imply consent to access members of the WSU community; it only means the research protocol was reviewed to determine if risks to subjects are minimal or reasonable in relation to anticipated benefits.

What if it is "just" an Honors Project, Class Project or internal department project?

If the results of the project will be presented, published, or shared "publicly" in any way (e.g., presented for Honors Presentations, at CURCA, presented at a conference, posted in a blog, published someplace, included in a digital commons, or shared in any other way), then that project must get IRB approval. If the project is being done for the purpose of learning how to do research and the results of the project will not be shared beyond the classroom/department, that project does not need IRB approval and the professor will assume the responsibility for reviewing the project for appropriate ethical procedures.

What if the procedures are benign and will not cause any harm to participants? Or what if it only involves interviews, or only involves a small number of participants?

All research with human participants must be reviewed by an IRB, even if it seems to the researchers as if the procedures are perfectly safe. This is federal law, it is not unique to WSU.

What if the project is looking at data already collected for some other reason or by some other set of researchers?

If there is any way to identify participants in the data set, then IRB review is required. If the researcher extracts the data and removes identifying information, then IRB review is required. If data are already deidentified and decoded (by someone outside of the study) and if there is no way a reasonably knowledgeable person could discover identities of participants based on variables such as gender, age, location, etc. then no review is necessary (the exception to this is if the source of the data requires IRB review).

What if the Project was approved by another Institution's IRB?

Projects with approval from other institutions (exempt, expedited or full), still need to go through the WSU IRB by filling out the IRB form. However, attaching evidence of approval from another institution to the application will make the IRB review process quicker.

What if the Project was approved by WSU's IRB last year and is continuing?

IRB approvals are good for 12 months. Renewing an IRB approval involves completing the application form again, and submitting supporting materials to WSU's IRB; however, in their email communication researchers should provide the IRB proposal number provided in the email from the IRB chair that indicated approval. (Proposal numbers include the academic year, followed by a number, e.g 20/21-999.) This number insures the renewal process is quicker than a regular review. Failing to provide this number will result in the proposal undergoing a regular review.

Where and how do I apply for WSU's IRB approval?

The link for the WSU IRB Application can be found on Westfield State's website and in mywestfield under governance.
http://www.westfield.ma.edu/committees/institutional-review-board-for-human-subjects-research-irb
The email to submit the application to is irb@westfield.ma.edu. Only digital materials will be accepted. Most researchers complete the application electronically and email it to the IRB address. You could also print, complete and send a scanned copy.

What should I include with the IRB application form?

The IRB application form asks for a description of procedures, and wording of informed consent. The application is thorough, but there are attachments the researchers should include when this information is not in the form, such as a copy of the informed consent, copies of questionnaires/measures, and wording of interviews. A thorough description/exact wording of debriefing is also expected. A reference for these materials is not enough.

What red flags might slow down the review?

Exempt projects are reviewed the fastest (see earlier for what an exempt project is). Anything else requires the materials to be reviewed by more members of the committee and that will take longer than an exempt review.

Deception, Invasive Procedures, Risky Procedures, Sensitive Subjects: If your project includes deception, more than very minimal risk to participants, or is studying sensitive information, you should have a good rationale for these actions, and you should have an *appropriate way to debrief* participants. Sensitive subjects raise risks that need to be managed, such as emotional distress, social consequences of disclosing information, or unforeseen health consequences.

Population Studied: A project with a vulnerable population will get more intense review. There are many definitions of vulnerable populations, but groups considered vulnerable could be children, adults with diminished capacity, individuals who are ill or dependent on a clinician for care, individuals who are incarcerated or in residential care, and federal law requires review of projects with veterans. Also included are individuals who might not understand the informed consent, such as language minorities.

Voluntary Participation: Researchers should be thoughtful about how they invite participants to participate, and what happens if the participant declines. Researchers should ask themselves if participation is truly "voluntary." "Using" people, such as students can be a concern. Students often feel like they cannot decline participation when a teacher or professor asks them to do something, without it negatively affecting their grade or their relationship with the teacher/professor. Those who are in residential care or incarcerated, can also feel pressure to participate. There are ways to do research with these populations, but the IRB application should evidence that the researchers thought about and attended to concerns such as these.

Recordings and Biological Data: If video or audio recordings will be made, or biological data collected, there should be a good rationale for this, as well as a thorough description of how these data will be stored and kept secure.

Privacy: All researchers must ensure privacy of participants, and describe how data will be stored in a secure manner. All projects should consider confidentiality or anonymity (these are not the same thing and it is expected that the researcher knows the difference), but especially those collecting more sensitive or private information such as biological samples, or video recordings.

How to Apply for IRB Review

1. If the Principal Investigator is not a WSU Faculty or Staff Member (for example, if the researcher is a student, or not affiliated with Westfield State University), the researcher must include a WSU Advisor/Sponsor on the application (indicate this on the application in the box for WSU Faculty Advisor). The Advisor/Sponsor should be copied on email communications with the IRB.
2. Prepare Informed Consent Documents or if verbal consent will be obtained, provide the procedures for obtaining such consent and the exact wording of how informed consent will be obtained.
    1. All Research projects involving human participants requires informed consent.
    2. If the research includes participants who are from vulnerable populations (eg., children, incarcerated, terminally ill patients, veterans, or cognitively impaired persons) be sure to describe how extra protections will be provided in the informed consent process.
    3. "Informed Consent" must state:
        1. briefly and simply, what **the research is about**.
        2. **what participants will be asked** to do and for how long.
        3. any **risks and benefits**, and if there is no direct benefit, the participant should understand what the study hopes to discover and why.
        4. How the researcher will **protect participants' identity** (including where data will be stored, who will have access to it, and if identifying information will be stored). Researchers should understand the difference between anonymous and confidential!
        5. **participation is voluntary**, and participants may skip questions or withdraw from the study at any point **without penalty**.

6. Full names, addresses, telephone numbers and e-mail addresses of **persons to contact** if participants have questions or concerns about the study (i.e., researchers and advisor/sponsor).
7. Participants cannot be asked to waive (or appear to waive) any of their legal rights.

3. Prepare a detailed description of the procedures that will be used, including where data will be collected, how it will be collected, and how long it will take for each participant.
4. Prepare all questionnaires, and/or interview questions. If questions will be asked about demographic variables those should also be included. Work "in Progress" or "Draft" is not acceptable. Materials should be in their completed form.
5. Debriefing after the participant's involvement is done is always necessary, and a thorough description is required in the application. Sometimes, in instances of exempt research, debriefing can be done by reminding the participant what the study was about, how to contact the researchers, and how to access the summarized results, but if there is any risk of psychological or physical harm (including stress, confusion, anxiety), or if deception was used, debriefing must occur after the study and include concrete steps toward remedying the harm.
6. Complete the WSU IRB Application, and submit the application, including informed consent, procedures, and measures and a description of debriefing to irb@westfield.ma.edu
7. Be patient. The proposal will first be reviewed by the IRB Chair for completeness. Researchers are sometimes asked for supporting materials or clarification. The chair then determines the type of review (although the application also asks for the Researcher's opinion about type of review). The IRB strives to return all reviews within 30 days, but cannot make any guarantees. If nothing is heard from the IRB within 21 days, it is appropriate to email the IRB to check on the status of the review.
8. If there are any changes, a document describing the changes should be emailed to irb@westfield.ma.edu and usually those changes can be added as an addendum to the application.
9. If the project is approved and data collected, be sure to submit an end of the year summary when the project is done.
10. IRB approval is only good for one year. Researchers can apply to renew a proposal, however, a new IRB application form must be completed (be sure to include in the email communication the original IRB number provided in the approval email).

Who is on the WSU IRB?

An Institutional Review Board is federally required and does not fall within campus governance, although most members of the WSU IRB are full-time faculty. IRBs must have at least 5 members of varying backgrounds, and the training and professional experience to provide appropriate scientific and ethical review. An IRB must have at least one member whose primary concerns are nonscientific. At WSU IRB members are appointed by the president. There is no support staff for the IRB, and members are volunteers.