

Institutional Review Board - Human Subjects Research Quick Start Guide for Researchers

The Federal Government requires Wor-Wic Community College (WWCC) to document compliance to federal guidelines for human subject's protection when conducting research. WWCC assures federal regulators that we comply with all relevant regulations. The WWCC Institutional Review Board serves as the institution's safeguard regarding human subjects research (HSR) and its primary function is to meet the following three goals: first and foremost; the protection of human subjects, second; the encouragement of research, and third; absolute compliance with state and federal requirements.

This document describes the WWCC IRB review and approval process. The federal regulations are dense and somewhat confusing, but the WWCC process has been designed to be as efficient as possible. For a complete description of the process and your responsibilities, please refer to the IRB Handbook, available at our [IRB website](#).

Step 1: Determine if the work you are doing constitutes human subjects research (HSR).

To help determine if your work is HSR, ask yourself two questions; is it human, and is it research? This may seem simple on the surface, however, if you have any questions; contact your institution's IRB representative.

Definition of Human Subjects. As defined by US code 45 CFR 46102(d), a human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information through any means. Intervention means any physical procedures undertaken with the subject or any manipulation of the subject or the subject's environment for research purposes. To summarize, if you are gathering data from or about living people, it is probably HSR. Some clear cases which are not "human" are gathering data about people who are deceased, or gathering secondary data.

Example: Faculty members are planning to use census data from the late 1800s to examine the relationship between median income and susceptibility to disease in the Gilded Age. While the data that will be gathered contains identifiable private information, the faculty members can assume these individuals are all deceased; therefore, they do not need to seek review of their protocol.

Definition of Research. As defined by US code 45 CFR 46102(f), research is gathering information or data in a systematic way to draw generalizable conclusions, or otherwise develop or add to a body of knowledge. One way to determine if the project adds to a body of knowledge is if it will be shared publicly, such as in a conference presentation or other publication. However, publication does not, by itself, constitute research.

Example: Professor Smith is planning to solicit student feedback on her PowerPoint slides as part of her Faculty Evaluation Plan. She does not plan to publish her findings or otherwise share the student feedback; she is just assessing the effectiveness of her own pedagogy. While her students are clearly human subjects defined above, she is not engaged in “research” and would not need to seek IRB approval.

Step 2: Become trained in the ethical guidelines and federal regulations.

If your work is HSR, you will need to seek IRB review prior to gathering any data. You must know what the ethical guidelines are for HSR in order to avoid any inadvertent violations of the federal guidelines. Prior to IRB review, researcher(s) must have documentation of up-to-date (not older than 2-years) HSR training. WWCC utilizes The Collaborative Institutional Training Initiative (CITI) training program to provide on-line training. Employees or students can access the program at <https://about.citiprogram.org>. Once finished, you will email your certificate of completion along with your HSR application.

Step 3: Complete an Application for Human Subjects Research.

Download the WWCC HSR application form located at our [IRB website](#). Fill out the form completely, and attach all documentation that will be given to subjects, such as informed consent, survey instruments, or enrollment instructions. If submitting an application as part of a grant project, attach the grant application. If you have any questions about this process, contact your institution’s IRB representative or IRB coordinator.

Step 4: Obtain Institutional Approval.

Before initiating any type of research or contacting your study participants, you must obtain institutional approval. Typically, WWCC Vice President for Academic Affairs grants institutional approval as soon as the IRB approves the project/study and submits a recommendation. For estimated processing times, please refer to the schedule located at our [IRB website](#).

Step 5: Maintain records and annually renew authorization if needed.

Once you receive an email notification that your project is approved, you may proceed to collect data. Exempt, expedited, and full board studies are typically approved for one year. If your project extends beyond the one year timeframe, you must seek annual renewal for the duration of your project. Complete the annual renewal form available at our [IRB website](#).

If you need to make any changes to a proposal that has already been approved, you must notify the IRB using the Modification Form also available on the site.

If in the course of your study, a negative incident occurs to a subject, you must notify the WWCC IRB using the Negative Incident Report form available at our [IRB website](#).

The IRB is required by law to notify the Federal Office of Human Protection (OHRP) of the incident and what course of action was taken. Please note this process must be followed regardless of the perceived seriousness of the incident, or whether or not you agree with the subject that something negative has occurred. If the subject reports an incident, you must follow up with it.

You are required to keep all records (signed informed consent forms, returned surveys, developed datasets) for three years for exempt or expedited studies, and seven years for studies requiring a full board review. These records will protect you and WWCC from liability risks associated with your study.

Step 8: Submit a Close-Out Form if needed.

Once you are finished with your project, you will need to submit a close-out form to the IRB. Visit our [IRB website](#) and complete the closure form. This notifies the IRB that its oversight responsibilities are over. Exempt studies do not require submission of this form.