Human Subjects Research
Quick Start Guide for Researchers

The Federal Government requires the Maricopa County Community College District (MCCCD) to document compliance with federal guidelines for the protection of human subjects in research. MCCCD assures federal regulators that we will comply with all relevant regulations. The MCCCD Governing Board administrative regulation regarding human subjects research (HSR) is designed to meet three primary goals: first and foremost, to protect human subjects; second, to encourage research; and third, to comply with state and federal requirements.

This document describes the MCCCD IRB review and approval process. The federal regulations are dense and somewhat confusing, but the MCCCD 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.

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

To help determine if your work qualifies as human subjects research, you can ask yourself these two simple questions: Is it research, and does it involve humans? While the questions may be simple, the answers may have nuances that require expert opinion. For assistance, please refer to your college IRB representative.

Definition of Human Subjects. As defined by US code 45 CFR 46.102(e), a human subject is a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual or obtains 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 46.102(l), research is gathering information 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 as defined above, she is not engaged in "research" and would not need to seek IRB approval.

Step 2: Obtain site authorization

Before completing your IRB application, you must obtain site authorization. Typically, institutional approval is granted by the Vice President of Academic Affairs (or their designee) at each college.

Step 3: Complete required HSR training

If your work is HSR, you will need to seek IRB review prior to gathering any information. 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, researchers must have documentation of up-to-date (not older than 3-years) HSR training. MCCCD utilizes CITI Program

for online training. Researchers may access the program at CITI Program. (The Organization Affiliation is Maricopa County Community College District and the training course is the one for Social-Behavioral-Educational Researchers. It has both required and elective modules.) The training requires registration but it is provided at no cost to those affiliated with Maricopa Community Colleges. Once finished, you will upload your certificate of completion into eProtocol, the MCCCD online IRB application system.

Step 4: Obtain eProtocol login info

Contact the IRB Coordinator at (480) 731–8701, or at irb_office@domail.maricopa.edu to request an eProtocol login ID. The Principal Investigator (PI), and the Co-PI, if any, must request a login ID from the IRB Coordinator.

Step 5: Submit the IRB application

Complete the application in eProtocol, which is available via the MCCCD IRB webpage or at (https://mcccd.keyusa.net/). Fill out the form completely, and attach all relevant documents such as the informed consent form, survey instruments, and 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 college IRB representative or IRB Coordinator.

Step 6: Maintain records and annually renew authorization if needed

Once you have received an email notification that your project is approved, you may begin to recruit for the study. Full board and expedited protocols are typically approved for one year. If your project extends beyond one year, you must seek annual renewal for the duration of your project. Complete the annual renewal form via eProtocol.

If you need to make any changes to a study that has already been approved, you must notify the IRB using the Modification Form available through eProtocol prior to making any such changes.

If in the course of your study, a negative incident occurs to a subject, you must notify the District IRB using the Adverse Incident Reporting form available online at Adverse Incident Report Form.

The IRB is required by law to notify the Office for Human Research Protections (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 (e.g., 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 MCCCD from liability risks associated with your study.

Step 7: Close the IRB application

Once you are finished with your project, you will need to submit a close-out form to the IRB. Go to the MCCCD IRB webpage for the close-out form. This notifies the IRB that its oversight responsibilities are over. Exempt studies do not require submission of this form.