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

The Federal Government requires the Maricopa County Community College District (MCCCD) to document compliance to federal guidelines for human subject's protection when conducting 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 efficient as possible. For a complete description of the process and your responsibilities, please refer to the IRB Handbook, available at www.maricopa.edu/irb.

Step 1: Determine if the work you are doing is 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 college 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: Obtain Institutional Approval

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

Step 3: 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. MCCCD utilizes the National Institute of Health (NIH) training program to provide on-line training. Employees or students can access the program at http://phrp.nihtraining.com. Once finished, you will upload your certificate of completion into eProtocol, the MCCCD online IRB application system.

Step 4: Request eProtocol Login ID

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

Step 5: Complete an Application for Human Subjects Research via eProtocol.

eProtocol is available via the MCCCD IRB webpage (www.maricopa.edu/irb) or at (https://mcccd.keyusa.net/). 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 college IRB representative or IRB coordinator.

Step 6: 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. 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 on-line at http://www.maricopa.edu/irb.
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 MCCCD 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. Go to http://www.maricopa.edu/irb for closure form. This notifies the IRB that its oversight responsibilities are over. Exempt studies do not require submission of this form.