

## HSR Quick Start Guide for Researchers

The federal government requires the Maricopa Community Colleges to document compliance to human subjects protections when conducting research. Maricopa has assured the federal regulators that we will comply with all relevant regulations and with the principles set forth in the Belmont Report on human Subjects research. The administrative regulation governing human subjects is designed to meet three primary goals: **first and foremost, to protect human subjects**, but also to encourage research, and comply with state and federal requirements.

It is currently unknown how many studies involving students or student data are presently being conducted in the Maricopa system. It is expected that most of the research being done is either not human subjects research as defined by the federal regulations and can be properly viewed as not covered by federal guidelines, or research that is covered but which is viewed as exempt from the regulations by the federal guidelines. Presently we have no way to substantiate this claim if challenged. The new administrative regulation enables us to make this claim legitimately and thereby shield researchers and the District from undue regulatory burden or liability risk.

This document describes the process for reviewing human subjects research that will be undertaken using Maricopa employees or students to ensure that the subjects are protected and all relevant guidelines are followed. The regulations are dense and somewhat confusing, but the process at Maricopa has been designed to be as unobtrusive and fast as possible. By taking the following steps you can easily get the approval you need to gather data for your research or grant. This document is meant to be an aid in navigating the process. For a full description of the process and your responsibilities, please refer to the Researcher Guide, available at [www.maricopa.edu/irb](http://www.maricopa.edu/irb).

### **Step 1: Determine if the work you are doing is human subjects research.**

If your work is human subjects research, then you must comply with the rest of the process outlined below. To decide if it is, ask yourself two questions; is it human, and is it research?

**Definition of Human.** As defined by US code 45 CFR 46102(d), a human subject is a living individual about whom an investigator (whether a Maricopa professional or a student) 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. In plain English, if you're gathering data from or about live people, it is probably human subjects research. Some clear cases which are not "human" are gathering data about people who are dead and gathering secondary data.

Example 1: 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 that these individuals are all deceased, and they therefore 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 is going to be published or shared publicly, such as a conference presentation. Publicity does not by itself constitute research though.

Example 2: Professor Smith is planning to solicit student feedback on her PowerPoint slides as part of her Faculty Evaluation Plan (FEP). 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 review of her FEP. If her FEP showed that her students felt her lecture slides were constructed in a way that aided their learning, and she wanted to write up an article about her slides for her discipline’s educational journal, she would need to treat her FEP as a pilot study and seek review prior to gathering any student feedback she planned to include in her write-up.

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

If your work is human subjects research, then you will need to seek review of your protocol prior to gathering any data. It is important to know what the ethical guidelines are for human subjects research in order to avoid any inadvertent violations of the federal guidelines. While most post-graduate programs include instruction on the ethical treatment of human subjects, it is important to refresh that training as well as update your knowledge of recent developments in the guidelines. It is also necessary that Maricopa be able to document that those who engage in research are trained in the guidelines. Accordingly, Maricopa has contracted with the University of Miami’s Collaborative IRB Training Initiative Program (CITI Program) to provide on-line training. All Maricopans (professionals or students) can access the program at no charge to them to receive the required training. To begin, log on to [www.citiprogram.org](http://www.citiprogram.org) and register as a Maricopa Community Colleges affiliate. There are four different training modules to choose from, listed below in increasing complexity. The modules can be completed piecemeal, and each unit within the module has a short exam which must be passed before moving to the next unit.

### **CITI Training Modules**

- 1. Social and Behavioral Research Investigators (Principal Investigators, Co PIs, Project Directors, Researchers)** – This module is the standard module most Maricopans who conduct human subjects research should take. It covers the basics on ethical guidelines, informed consent, assessing risk, and conflict of interest. Estimated time for completion: 4-6 hours.
- 2. Undergraduate Training** – This module is for undergraduates to take to learn about the ethical treatment of human subjects. Instructors are encouraged to make completion of this module a course requirement for those students who will be

designing or conducting research during their course of instruction. Estimated time for completion: 1 hour.

3. **IRB Members** – This module is for members of the District Institutional Review Board (IRB) and College Research Review Committee (CRRC). It includes all of the basic units from the modules above, and some additional details. Estimated time for completion: 7-10 hours.
4. **Educational Processes Only** – This module is for those who only plan to do pedagogical research for classroom use or program or institutional assessment studies. These are considered “exempt” under the guidelines and do not require more detailed training in risk assessment and informed consent. Administrators should take this module as well to gain quick familiarity with the review process. Estimated time for completion: 2 hours.

**This Module only works for a limited category – if you have Exempt proposals.** Only the IRB can make the determination as to whether a proposal is Exempt or not.

### **Step 3: Complete an Application for Human Subjects Research.**

The application provides the information the review committee needs to determine whether the protocol is exempt and what level of risk is posed to subjects. The more complete the application, the faster the response will be from the committee. The applications are available on-line at [www.maricopa.edu/irb](http://www.maricopa.edu/irb). When completing the application, provide all the information asked for on the form itself, but feel free to attach other documentation or notes of explanation you think will expedite the process. Be sure to include copies of anything that will be given the subjects, such as informed consent forms, survey instruments, or enrollment instructions. If this is a grant project, attach the grant application.

### **Step 4: Submit Application Form.**

Once your application is complete, you will need to submit it for review to the CRRC at your college. Each college has its own protocol for submission, but generally you will need to obtain institutional approval prior to submitting your document. (This is typically the Vice President of Academic Affairs (or designee) at your college.

**See the “Application Process” on the web.** [www.maricopa.edu/irb](http://www.maricopa.edu/irb) Select the application process that most closely matches the research or project you are planning.

In some cases, you will send your application directly to the District IRB, specifically, if any of the following criteria apply to your protocol:

- The project is funded from an external source, i.e.: federal, state, or local agency.
- The project involves investigators or subjects from more than one college.
- The project involves more than minimal risk to the subjects and therefore requires full board IRB review.
- The project is a request from an external entity to use Maricopa subjects.

- The project involves vulnerable populations and may pose more than minimal risk.

In other cases, you will send your application directly to the College Research Review Committee (CRRC) at your college. In some cases, the CRRC will forward your protocol to the District IRB rather than review it at the college.

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

Once you receive word (via email or letter) that your project has been approved by the CRRC or IRB, then you can proceed to gather and analyze data. If the project was not deemed exempt, then you will need to seek annual renewal for the duration of your project. There is a simple renewal form for this available on-line at [www.maricopa.edu/irb](http://www.maricopa.edu/irb). You will report some summary figures on how many subjects you have enrolled in your study, any changes in investigators, and, most importantly, any changes to the study design for which you would like to gain approval.

It is important to note that if you want to make any changes to a study that has already been approved by the IRB, you need to notify the IRB using the Study Modification Form also available on-line prior to making any such changes.

If in the course of a study something negative happens to a subject then you must notify the District IRB using the Adverse Incident Reporting form available on-line at [www.maricopa.edu/irb](http://www.maricopa.edu/irb). The IRB is then required by law to notify the Federal Office of Human Protection (OHRP) of the incident and what course of action was taken. Please note that 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, then you must follow up with it.

You should keep all records surrounding the use of human subjects (signed informed consent forms, returned surveys, developed datasets) for three years for exempt or expedited studies, and seven years for studies that required full board review. These records will protect you and Maricopa from liability risks associated with your study.

### **Step 6: Submit a Close-Out Form if needed.**

Once you are finished gathering and analyzing data, you will need to submit a close-out form to the IRB. This notifies the IRB that its oversight responsibilities are over. Exempt studies do not require submission of this form.