MCCCD Institutional Review Board: An Overview

**What is an IRB?**

Committee established by institution to administer and monitor adherence to OHRP guidelines. Minimum composition requirements are spelled out in federal guidelines. Maricopa IRB is composed of representatives from each campus, the district, outside community, and sometimes, special subject area experts.

**Definition of Human Subjects Research**

*Research* involving *living individuals* or collecting *identifiable private information* about living individuals to develop or contribute to *generalizable knowledge*.

**Why do we need an IRB?**

* Protection of Human Subjects in Research
* Ensure Ethical Practice of Research
* Comply with Federal Law
* Basic HHS Policy for Protection of Human Research Subjects

**What types of projects require IRB review?**

* Research involving students/staff from Maricopa
* Dissertations
* Some graduate study projects
* All grant proposals
* Consortium protocols (e.g. Maricopa and NAU)
* Faculty/staff research
* Research/grants conducted by outside agencies (League for Innovation)

**Maricopa’s Two-Level Process**

1. Maricopa IRB—campus/district representatives and others (as mentioned above).
2. College Research Review Committee (CRRC)—appointed by VPAA, one member is college representative to full IRB. Basically, the CRRC is a sub-committee of the IRB.

**IRB Reviews and Determinations**

Three types of reviews of research projects

1. Exempt—minimal risk, minimal impact on participants §46.101(b). There are 6 categories and most of our research can be considered exempt.
2. Expedited—there are 9 categories of research in this type, most of which involve collecting medical specimens. Categories 6 and 7 usually pertain to Maricopa projects.
	1. (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
	2. (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)(b) (2) and (b) (3). This listing refers only to research that is not exempt.)
3. Full board review—more than minimal risk, potential for harm to participants. This includes, but is not limited to collection of sensitive information, invasive medical procedures, and research on special populations. There have been only few full board projects at Maricopa.

Type of review is *suggested* by Principal Investigator (PI) but ultimately *determined* by IRB or CRRC. It is not permissible for a PI to *declare* their research to be exempt and bypass review.

**Training Certificate for IRB Members and PIs**

NIH – National Institutes of Health training - http://phrp.nihtraining.com/users/login.php

* Free to the person taking the training
* Certificate must be within two years of date of completion
* CITI certificate is accepted as well

**What Goes Where**

*CRRC* –Expedited or exempt research conducted only by students from that campus will be reviewed by the CRRC. This speeds up the process and makes it easier for PIs to get quick advice. Some campuses also require students in research methods classes to undergo IRB review.

*IRB (District)*

* All protocols that require full-board review
* All research conducted by non-students (including internal and external PIs)
* All research involving the DO or the entire district (all students and/or employees)
* All grant proposals
* Consortium protocols (e.g. Maricopa and NAU)
* Requests from district personnel

**eProtocol**

 Online IRB management software in use at MCCCD. Provides for electronic submission and review of protocols. Allows for consistent record keeping, and provides central location for all files related to each submission. Has advantages and disadvantages and a “learning curve” especially for reviewers. Makes submissions and revisions more manageable, and keeps a good record of activities.

**IRB Application Process**

1. Determining if research is about human subjects;
2. Completing training for human subjects research;
3. Obtaining institutional approval via email;
4. Obtaining eProtocol login info from IRB Coordinator; and
5. Completing the application via eProtocol.

**Institutional Approval**

Institutional approval is to be granted by the VPAA of the college that is site of the study, or by the Associate VCAA if the study involves the DO or more than five colleges in the district. The VPAA or Associate VCAA may want to consult the department that would be involved in the study to see if it is able and available to participate. Additionally, they may want to ask the PI to provide answers to the following questions to help them decide whether to grant institutional approval.

1. What is the purpose of the research?
2. What methodology will the researcher employ?
3. Who are the intended participants of the study?
4. What is the research design of the study?
5. What data will be collected as part of the study? Be specific.
6. How will the college or MCCCD benefit from the research?
7. How will the results of the study be used or published?
8. What is the researcher’s relationship to this college or MCCCD?
9. What resources (e.g., personnel, departments, technologies) of the college or MCCCD will be used for this study?

**Institutional Approval Granted: Response to PI (*from HSR Application*)**

I approve of this project, subject to MCCCD IRB review for risks to human subjects. I reserve the college or district right not to participate in the project, or to withdraw participation from the project at any time. Note the following:

1. This approval does not commit the college or district to provide resources or data collection for the investigators;
2. IRB approval does not commit the college or district to participate in the project or to provide resources or data collection for the investigators; and
3. If the IRB disapproves the study, the investigators cannot conduct the study, but they may revise and resubmit their proposal to the IRB.

**Resources**

MCLI - https://mcli.maricopa.edu

MCCCD IRB - http://www.maricopa.edu/irb/

NIH - http://phrp.nihtraining.com/users/login.php

US Department of Health and Human Services – Office for Human Research Protections - http://www.hhs.gov/ohrp/

Lutfi Hussein, MCCCD IRB Chair – Lutfi.Hussein@mesacc.edu

Lori Thorpe, MCCCD IRB Coordinator - Lori.Thorpe@domail.maricopa.edu