

# IRB Member Handbook

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## **IRB Member Handbook**

The federal government recently began requiring the Maricopa 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: protect human subjects, 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. This document is designed to help you administer this process in order to help your colleagues and your institution engage in their desired research projects. This handbook is to be considered a facilitating tool, not as a substitute for the Standard Operating Procedures (SOP) of the IRB. You should have a copy of the SOP and refer to it when questions arise.

### **Getting Started**

Now that you have been asked to be a member of the District Institutional Review Board (IRB) or College Research Review Committee (CRRC), you will need to get the necessary training to be able to perform that task. In addition to reading the SOP, you should become familiar with the federal regulations and ethical guidelines covering the use of human subjects in research. To do this, you will need to complete the on-line training module offered by the University of Miami's Collaborative IRB Training Initiative Program (CITI Program). 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**

**Educational Processes Only** – This module is for those who only plan to do pedagogical research 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.

**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.

**Social and Behavioral Research Investigators** – 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 – 3.5 hours.

**IRB Members** – This module is for members of the District Institutional Review Board (IRB) or College Research Review Committee (CRRC). It includes all of the basic units from the modules above, and additional details that reviewer should be aware of. Estimated time for completion – 7 hours.

Once you have completed training, inform the chair of the CRRC you are serving on or, if you are the chair, the IRB coordinator. An additional reference that would be very useful is the IRB FAQ on the National Science Foundation (NSF) website ([www.nsf.gov/bfa/dias/policy/hsfaqs.jsp](http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp)). Also, you will need to re-certify your training every two years. The CITI site offers a refresher module that will not take more than a half hour.

If you are serving on a CRRC, see your chair about when the meetings are scheduled and be sure to arrange your schedule so that you can be a contributing member. If you are the chair, then you will also be serving as a member of the District IRB and will need to attend those monthly meetings as well. CRRC Co-chairs serve as alternates to the IRB when the chair is unable to attend. If both are attending a meeting, the chair is the one with voting privileges. Additionally, both the chair and co-chair you will need to forward their Curriculum Vitae (CV) to the District IRB coordinator. These will then be forwarded to the Federal Office of Human Research Protection (OHRP), the body that regulates IRBs, as part of the Federal Wide Assurance (FWA) document that certifies Maricopa’s compliance to the regulations.

## Entering a Protocol into the System

Most likely, the IRB or CRRC coordinator will be accepting applications for review from investigators. It is important to know the process though as you will need to ensure that it is being followed correctly. Also, you may get requests from colleagues to help them go through the process. Aside from making sure the application is complete, there are two things that if done will avoid most potential problems or delays in the review process. The first is to make sure that the principle investigator (PI) has undergone the CITI training. The second is to make sure that the application has received institutional support prior to being submitted to the committee for review. Each college will have its own procedure for this. At some, a department head signature is sufficient, at others, the VPAA must sign off on all research. Ask your committee chair what the process is at your institution. This is important because IRB approval should not be construed as institutional approval. All your committee does is ensure that the proposed research complies with federal and ethical guidelines.

Once a complete application has obtained the necessary institutional signatures and has been submitted to the committee coordinator, it is assigned a number and added to the agenda of the next meeting. Each protocol receives its own identifying number according to the following protocol: Institutional Code, Year, and four digit identifying number. The institutional codes are:

Chandler Gilbert	CG
District Office	DO
Estrella Mountain	EM
Gateway	GW
Glendale	GC
Mesa	MC
Paradise Valley	PV
Phoenix	PC
Rio Salado	RS
Scottsdale	SC
South Mountain	SM

For example, the first protocol submitted to Mesa College's CRRC in 2008 would be MC-2008-0001. This number will remain with the protocol as a tracking number, even if it is referred to the District IRB.

One other factor to consider is whether the protocol should be reviewed by a CRRC or the District committee. Most of the research done in the district will be reviewed by a CRRC. If any of the following criteria apply to the protocol in question, then you will need to send it to the District IRB for review with its identifying number:

- The project is funded from an external source, ie: 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.

## **Running a Review Committee Meeting**

Like most effective meetings, the CRRC or IRB meeting will run most effectively if there is an agenda that has been published prior to the meeting. This enables all participants to prepare for the meeting. The agenda and meeting notes should be kept for the committee records. Should a question arise about a protocol, these records will be your protection from liability risk.

The meetings are to be open to the public, though spectators can be asked to leave if confidential proprietary information is being discussed. PIs are welcome to attend the meeting where their protocol is being discussed to make themselves available for questioning or to clarify any details in their application. The federal regulations are clear though that the PI cannot be in the room when the protocol is discussed by the committee.

Each protocol being considered should have its own IRB Decision Summary Form. This form is filled out by the chair and provides a record of the discussion and reasoning behind the committee's determination. The PI's name and institution, and the protocol's name and identifying number should be entered on the form.

Unless the meeting is a full board meeting of the IRB, one efficient way to conduct the meeting is to immediately break into subcommittees or discussion groups and divide the protocols on the agenda among the groups for detailed discussion. Once sufficient time for discussion has elapsed, the chair can then reconvene the committee and hear reports from each group on the protocols they considered. The committee can then make decisions on each application quickly. An alternate method would be to make the protocols available to the committee prior to the meeting in a secure location. The committee could then discuss each protocol in turn.

There is an important difference between the research review committee and most other college or district committees. The CRRCs exist as panels of the District IRB. The federal regulations allow the IRB chair or a designee to approve exempt or expedited studies. The chair of the CRRC is the person designated by the IRB chair to do that at each college, or the co or vice-chair if the chair is absent. No other person has the authority to make that determination. This means that although the Chair should take into consideration the discussion of the committee that occurs on a given protocol, and should of course treat all members of the committee with respect, the chair is free to make a determination that would not be in agreement with the rest of the committee. The primary responsibility of the committee chair is to protect human subjects, and the chair is not therefore bound to a majority vote of the committee. This is not true of a full board

meeting of the IRB when considering research that cannot qualify for expedited review. In this case, the research can only be approved by a majority vote of the committee.

### **Is it Human Subjects Research?**

The first thing for the committee to determine is whether or not the protocol in question falls under the coverage of the federal regulations governing human subjects research. 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: Professor Knowsalot is planning on using 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 good professor can assume that these individuals are all deceased, and she therefore does not need to seek review of her 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 Knowsalot 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.

## Is it Exempt?

If the protocol is human subjects research, then the next step is to decide if it is one of the types of research that the regulations allow to be exempted from additional oversight. Most of the research conducted at Maricopa should fall within this category. Only the CRRC or IRB has the authority to determine these exemptions. If a protocol is declared exempt then no additional reporting is required and the researcher can begin collecting and analyzing data, as long as they don't modify their research design.

Federal human subjects protection regulations (45 CFR 46.101(b)) define the following six types of human subjects research as exempt:

1. Research conducted in established or commonly accepted educational settings and practices, involving normal educational practices, such as  
(a) research on regular and special education instructional strategies, or  
(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods;  
45CFR46.101(b)(1) may apply
2. Educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews and observation of public behavior, unless  
(a) information obtained is recorded in such a manner that human subjects can be identified directly or indirectly and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;  
45CFR46.101(b)(2,3) may apply
3. Surveys, interviews, and observation of public behavior when maintenance of confidentiality is federally mandated, or when subjects are appointed public officials or candidates for public office;  
45CFR46.101(b)(2,3) may apply
4. Existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or indirectly; 45CFR46.101(b)(4) may apply
5. Evaluation of public benefit or service programs; 45CFR46.101 (b)(5) may apply
6. Non-risk taste, food quality, and consumer acceptance studies.  
45CFR46.101(b)(6) may apply

On the IRB Decision Summary Form, enter the criteria number under which the protocol was determined to be exempt, along with a summary statement of why.

## Can it be Expedited?

If the protocol does not qualify as exempt, it should be considered for expedited review. The main consideration is whether the protocol poses minimal risk to subjects. Anything that poses more than minimal risk must be considered under full board review.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

1. Definition of Minimal Risk: "the probability and magnitude of [physical or psychological] harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily [normally] encountered in daily life or during the performance of routine physical or psychological examinations or tests [of healthy children]."\* 45CFR46.102
2. Examples of minimal risk include; subject experiences no pain or physical danger, no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life, the project neither induces nor attempts to induce long-term significant change in the subject's behaviors or attitudes towards self or others, the data would not embarrass or socially disadvantage the subject if confidentiality were broken, and if PI conceals information about the specific purpose of the project, there is not reason to believe the subject would choose not to participate if s/he had known that information initially.

\* What is ambiguous in this definition is whether for patients involved in research the minimal risk definition pertains to the probability and magnitude of harm normally encountered in the daily life of patients with the respective disease or condition (i.e., a relative standard) or the daily life of a member of the general public (i.e., an absolute standard). The OHRP has specified that IRBs should be conservatively applying the absolute standard for the definition of "minimal risk."

### Expedited Review Criteria

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an IND application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an IDE application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110

pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
  - (a) hair and nail clippings in a non-disfiguring manner;
  - (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - (c) permanent teeth if routine patient care indicates a need for extraction;
  - (d) excreta and external secretions (including sweat);
  - (e) un-cannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
  - (f) placenta removed at delivery;
  - (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
  - (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
  - (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - (b) weighing or testing sensory acuity;
  - (c) magnetic resonance imaging;
  - (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
  - (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the

individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
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(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

\* The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

On the IRB Decision Summary Form, enter the criteria number under which the protocol was determined to be expedited review, along with a summary statement of why.

### **Can Informed Consent be waived?**

Some studies that are not exempt may be able to waive the normal requirement of informed consent. This should only be considered for minimal risk protocols and only when the PI demonstrates that seeking and/or documenting consent would be impractical or would prevent the data desired from being collected, such as a protocol which requires deception. The committee should take into consideration these needs, along with the level of risk present, when determining if consent can be waived. The chair should record on the IRB Decision Summary Form the rationale for granting a request to waive consent.

### **Full Board Review**

Protocols that pose more than minimal risk to subjects require full board review. The federal requirements are very specific, so the committee will need to be extra careful to document their discussion and rationale in such a case.

Prior to beginning a full board review meeting, all members of the committee should have reviewed the protocols being considered so the meeting time can be spent in deliberations. At the beginning of the meeting, roll should be taken and recorded. A full

Board IRB meeting must have a minimum of 5 members present, and there must be a scientist, a non-scientist, and an unaffiliated person in attendance. If at any time in the meeting these criteria are not met (such as if someone leaves the room for a phone call or excuses themselves for a conflict of interest), the discussion must stop and not restart until the federally mandated quorum is present.

It is customary to allow PIs to attend the beginning of the meeting to make themselves available to answer any questions the committee members may have about the protocol. The PI cannot be present once discussion begins on the protocol, though she can remain outside the room in case any further questions come up in the discussion. The committee can also invite persons with special expertise to address the committee if it is considering a protocol which is outside the experience of the committee members.

The committee discusses the protocol to ensure that the ethical and regulatory requirements have been met, paying special attention to the level of risk to the subjects. The presence of risk does not require that the committee reject a protocol. If the risk is balanced by the potential benefit to the subject or society, and the PI has demonstrated competence to professionally handle such risk, and the subjects are fully informed of the risk potential, then an IRB could approve the protocol. Just remember that the IRB's loyalty is to the research subject, not the PI or institution. The essential elements of the discussion, including any dissenting opinions, should be captured in the notes of the meeting.

Once the committee has discussed the protocol to the chair's satisfaction, the chair calls for a vote and the committee votes on whether or not to approve the protocol. The chair records the vote tally in the notes of the meeting, and fills out the IRB Decision Summary Form.

## **Rejections and Appeals**

There will be times when the committee determines that a protocol does not meet the ethical or regulatory guidelines for the protection of human subjects. The regulations allow the IRB chair or a designee to approve exempt or expedited studies, which is what the CRRCs do. They do not, however, allow a chair or designee to reject a protocol. This means that any protocol that is rejected by a CRRC is automatically sent to the District IRB for full board review, as only the full board can vote to reject a protocol. This measure is in place to protect PIs from arbitrary rejections. If a CRRC has enough concerns with a study design that they are not comfortable giving a conditional acceptance, then the PI should be given an opportunity to modify the research design to address the committee's concerns. If the PI is not willing to either withdraw the protocol or resubmit a modified application, then the CRRC places the protocol on the District IRB agenda, with the original tracking number intact. If the District IRB is discussing a protocol that was thought to be exempt or expedited, but then determines that it should be rejected, it cannot vote to reject that protocol unless there is sufficient quorum to hold a full board review.

If a PI is unwilling to accept the determination of a CRRC or IRB, there is an appeal process. If the decision of a CRRC is being contested, then the PI can request that the chair place the protocol on the District IRB agenda. If the decision of the IRB is being contested, then the PI can request that the chair notify the IRB coordinator. The coordinator can then set up an appeal board composed of 3 to 5 Maricopa employees who are knowledgeable in the human subjects protection process who will then review the disputed protocol. The appeal board then gives a report to the full board District IRB. The IRB then votes on whether or not to accept the appeal board's recommendation. This vote is final, with no further appeal.

The regulations are clear that if an IRB rejects a protocol, the institution or its officials cannot override the IRB and grant approval. This is why institutional approval is sought prior to IRB review.

## **Protocol Modifications**

There will be times when the PI may want or need to make a change in their protocol. These are categorized into minor and major changes. Minor changes include such things as adding or changing a co-PI, altering the title of the study, or adding a demographic variable requested by a funding agency. For minor changes the PI should notify the IRB coordinator, who adds an addendum to the protocol's file. Major changes would include altering the informed consent document, significantly increasing the scope or scale of the subject pool, or adding questions of a personal nature to a survey. For such changes, the PI will need to fill out a Study Modification Form and the same committee that approved the protocol would then review and approve the modification.

## **Incident Reporting**

If in the course of a study something negative happens to a subject then the PI 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 the PI agrees with the subject that something negative has occurred. If the subject reports an incident, then you must follow up with it. It is always a good idea for informed consent forms to have contact information for the IRB coordinator so subjects can report incidents to someone other than the PI.

## **Annual Renewal and Close out**

If a protocol is not deemed exempt by the IRB, then the PI will need to seek annual renewal for the duration of your project. There is a simple form available on-line at [www.maricopa.edu/irb](http://www.maricopa.edu/irb). The PI will report some summary figures on how many subjects were enrolled in the study, any changes in investigators, and, most importantly, any changes to the study design that the PI would like to gain approval for (this would be any changes not previously accepted using the Study Modification Form). The committee

reviews the annual renewal request to ensure that the protocol is being administered in the way it was proposed, then, if approved, files the renewal form with the original protocol application. To be clear, studies that are exempt do not require annual renewal.

Once the PI is finished gathering and analyzing data, he or she will need to submit a close-out form to the CRRC or IRB that granted authorization initially. This notifies that IRB that its oversight responsibilities are over. Exempt studies do not require submission of this form. This form is also filed with the original protocol application.

## **Record Keeping**

The CRRC and IRB are responsible to maintain records of their meetings and of the protocols they review. The PI is responsible to maintain records of their data, signed consent forms, and data analysis. All files should be secure as they contain private information. The CRRC should prepare a summary report to give the IRB at each meeting. This report will contain the Protocol title and number, the PI name and institution, the date the protocol was discussed, and the status decided by the CRRC, whether exempt or expedited. If the protocol was expedited, the criteria number should be included as well as whether informed consent was waived. The IRB will then keep this report in its meeting minutes.

CRRC and IRB records regarding protocols should be kept for at least seven years, and indefinitely where possible. The CRRC chair should meet with the Vice president of Academic Affairs to make a secure, permanent location available for these records. Should the federal OHRP audit the IRB, or should litigation arise over a protocol, these records will need to be available on demand.