Maricopa County Community College District

Institutional Review Board Handbook

Standard Operating Procedures

Prepared by the Research Policy Group

2025 Update

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ACKNOWLEDGEMENTS

The Maricopa County Community College District (MCCCD) Research Policy Committee acknowledges and thanks Sinclair Community College for permission to use their Institutional Review Board Charter and Operating Procedures as the model for developing Maricopa's Institutional Review Board Standard Operating Procedures Manual. Permission was obtained from the Director of the Grants Development Office at Sinclair Community College.

The MCCCD Research Policy Committee acknowledges and thanks Arizona State University for the use of their operating procedures and materials and the cooperation of their office that handles human participant research reviews (the Office for Research and Sponsored Projects Administration (ORSPA)).

The Research Policy Committee acknowledges and thanks the MCCCD Faculty Executive Council for their support of the development of human participant research policy and process at MCCCD.

The Research Policy Committee has worked diligently to develop a Human Participant Research Policy, an Institutional Review Board, standard operating procedures, and supporting documents and forms. This work was made possible by dedicated members, including faculty, administration, and staff. The Committee thanks the members for their dedication, commitment and hard work; the Committee Chair who served as Facilitator; and also the Executive Vice Chancellor/Provost for support of policy development.

The current handbook was updated by an IRB task force in 2017 to reflect the changes made to the federal regulations; and it was further updated in 2025 to reflect the changes made to internal procedures.

INTRODUCTION

The Maricopa County Community College District (MCCCD) encourages and supports the scholarly endeavors of its faculty, staff, and students. Pursuit of scholarly work and research will often involve human participation for data collection and analysis.

MCCCD's Institutional Review Board (IRB) reviews research proposals involving human participants to ensure that the rights and welfare of research participants are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human participants only volunteer to participate in research after being provided with legally effective informed consent; and that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit human participation or begin data collection until they have obtained clearance by the MCCCD IRB.

While some research projects involving human participation are considered "exempt" from IRB approval requirements, they must still go through a review process. The types of research generally "exempt" from IRB approval requirements include normal educational practices such as work undertaken as a part of a course, educational tests when the participants are not identified, and surveys or interviews in which the participants volunteer and are not personally identified. They all need to be reviewed and only the IRB can determine "exempt" status.

The MCCCD IRB has the responsibility to oversee procedures for carrying out the District's commitment to protect human participants in research. The role of the IRB is to review proposed research projects that involve human participation and to ensure that the proposed research complies with the guidelines set forth by the Office for Human Research Protections (OHRP), within the U.S. Department of Health & Human Services (HHS).

The MCCCD IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the MCCCD IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

INSTITUTIONAL AUTHORITY

These Standard Operating Procedures establish and empower the Maricopa County Community College District (MCCCD) human research protection committee. MCCCD has one committee, representing all ten colleges and the District Office, registered with the federal Office for Human Research Protections (OHRP), within the U.S. Department of Health & Human Services (HHS), as Institutional Review Board (IRB00005745). This committee is hereinafter referred to as “the IRB.”

PURPOSE OF THE IRB

The primary purpose of the IRB is to protect the rights and welfare of human research participants. This applies to research involving MCCCD employees and students as participants or researchers (e.g., through interaction or intervention with participants; or obtaining identifiable private information about MCCCD employees or students).

BASIC PRINCIPLES

I. The basic principles that govern the IRB in assuring that the rights and welfare of human research participants are protected are contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report") by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, published in the Federal Register on April 18, 1979. The three principles are Beneficence, Justice, and Respect for Persons. (For more information, visit this link: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.)

II. The following principles guide IRB review of all research, including student projects, involving human participants at MCCCD:

   A. Participants' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

   B. Risks to participants must be reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

   C. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research participant.

   D. Adequate provisions should be made for recruiting a participant population that is representative of the population base, for example, in terms of gender and race/ethnicity, unless scientifically justified otherwise.

   E. Research involving human participants must be supervised by qualified persons, including qualified clinicians for all study-related health care decisions and faculty members for undergraduate research projects.

   F. Research involving human participants must be voluntary and the right to withdraw at any time must be provided. Information provided to gain participant consent must be adequate, appropriate, and presented in lay language appropriate to the participant population.

   G. Any research project that involves human participants must be reviewed by the IRB and it must be approved prior to its initiation or initiating any major changes to it. Additionally, research may be subject to periodic review.

AUTHORITY OF THE IRB

I. MCCCD holds a Federalwide Assurance (FWA) through OHRP. As part of this Assurance, MCCCD agrees to consider all human participant research as being subject to federal regulations, regardless of the source of funding, if one or more of the following apply:

   A. The research is sponsored by MCCCD (unless the research is conducted at another institution with which MCCCD has an IRB Authorization Agreement as specified in MCCCD's FWA);

   B. The research is conducted by or under the direction of any employee or agent of MCCCD (unless the research is conducted at another institution with which MCCCD has an IRB Authorization Agreement as specified in MCCCD's FWA);

   C. The research is conducted by or under the direction of any employee or agent of MCCCD using any property or facility of MCCCD;

   D. The research involves the use of MCCCD's information systems, personnel, or facilities to identify or contact research participants; or

   E. The research is part of any grant application.

   F. A human participant and human participant research are defined thus (according to 45 CFR 46.102 (e) and (l) of HHS):

      1. A human participant is a living individual about whom an investigator (whether professional or student) conducting research who (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect that will not be made public (e.g., a medical record). Identifiable private information is private information for which the identity of a participant is or may readily be ascertained by the investigator or associated with the information. An identifiable biospecimen is a biospecimen for which the identity of the participant is or may readily be ascertained by the investigator or associated with the biospecimen.

2. Human participant research is any research involving a human participant as defined above. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The definition of research excludes the following activities: (1) scholarly and journalistic activities (e.g., biography, literary criticism, and oral history), (2) public health surveillance activities, (3) collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes, and (4) authorized operational activities in support of intelligence or national defense missions.

G. All human participant research as defined in the section above is covered by this policy except:

1. Assessment done in the context of a class for the purpose of evaluating student performance, for the purpose of improving teaching or augmenting class content as long as the rights and welfare of individuals are not violated.

2. Research and reporting done in the context of responding to required Federal or State submissions or accrediting bodies as long as the rights and privacy of individuals are not violated.

3. Research that involves no intervention nor interaction as defined above, and where private information is de-identified.

II. The IRB reviews all projects involving human participants in accordance with these Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

III. The IRB provides continuing advice and counsel to personnel engaged in human participant research.

IV. In some instances, students may be involved in research activities. The student's faculty supervisor is responsible for ensuring that IRB processes are followed.

V. The IRB has approval authority of human participant projects, and can approve, modify, or disapprove studies based upon consideration of any issue it deems relevant to human participant protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the college or MCCCD as appropriate. However, the college or MCCCD may not approve the research if it has not been approved by the IRB.

VI. The IRB has authority to require progress reports from the principal investigator (PI) and oversee the conduct of the study.

VII. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when such actions are deemed to be in the best interest of the participants in that study.

VIII. The IRB has authority to observe the informed consent process as practiced by any investigator or authorized person in any approved project.

IX. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement) regardless of the location of the records if they are needed to investigate an adverse incident. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of ongoing research.

FUNCTIONAL RELATIONSHIPS OF THE IRB

I. The IRB functions administratively through the Division of Academic and Student Affairs within MCCCD. This structure provides for administrative coordination for the IRB with the various academic and administrative units at MCCCD.

II. The IRB advises and makes recommendations to the Executive Vice Chancellor/Provost (Provost, for short), to policy and administrative bodies, and to any member of the MCCCD community on all matters related to human subjects research.

MEMBERSHIP OF THE IRB

I. The IRB is composed of a representative from each of the colleges, the District Office (DO), and an individual who is not affiliated with MCCCD (i.e., unaffiliated member). Alternates and non-voting members may also be selected, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are designated to alternate. The representatives from the colleges are selected by their respective Vice President of Academic Affairs (VPAA), and the representative from the DO and unaffiliated members are selected by the Provost.

II. The IRB is composed of members with varying backgrounds and expertise in special areas to provide fair and adequate review of the research. Committee members should possess not only specific competencies sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of MCCCD regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be called upon to review proposals that may require specialized expertise.

III. The IRB must be composed of both men and women and must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas (such as a lawyer, clergy member, or ethicist). It must also include at least one member who is not otherwise affiliated with MCCCD, either directly or through immediate family. The diversity of IRB members — including race/ethnicity, gender, cultural background — and their awareness of community attitudes, as well as their qualifications and expertise, shall collectively promote the protection of the rights and welfare of research participants. The appointment of IRB members must be reported to OHRP, including each member’s name, earned degrees, position or occupation, and representative capacity.

IV. No person shall be excluded from serving on the IRB on the basis of race, color, national origin, sex, disability, or age.

MANAGEMENT OF THE IRB

I. The Provost appoints a voting (not alternate) member of the IRB to serve as IRB chair with these responsibilities:

   A. Report to the Provost as immediate supervisor and offer updates on the IRB Office.

   B. Provide guidance to the district leadership regarding IRB policy and processes.

   C. Provide guidance to IRB and CRRC members regarding protocols and federal regulations.

   D. Provide guidance to Investigators regarding submission of protocols or IRB processes.

   E. Conduct all IRB meetings. Generate the meeting agenda and finalize the minutes with the Coordinator.

   F. Develop IRB forms and documents, and update them as needed.

   G. Serve on IRB panels. Serve as Primary Reviewer (and Panel Manager) on protocols involving the district or multiple colleges. Serve on panels of other colleges as needed. Serve on panels during the summer as needed.

   H. Work closely with the Coordinator to keep IRB business functioning efficiently and properly.

   I. Remain updated on federal, state, and local regulations for research involving human participation (e.g., by participating in relevant research workshops and conferences).

   J. Serve a three-year term (to end in May)--it is renewable (upon Provost's approval).

II. The IRB selects one of the members (either a voting or alternate member) to serve as vice chair, who supports the IRB chair in their duties, presides over all convened IRB meetings, and has authority to sign all IRB action items, in the absence of the IRB chair.

III. The Provost, in consultation with the IRB and relevant departments in the DO, selects the IRB coordinator whose responsibilities focus on management of IRB processes and procedures, which include, but are not limited to, the following:

   A. Updating federal registrations;

   B. Assisting with developing, recommending, and implementing policies and procedures to enhance efficiency of operations;

   C. Coordinating fiscal needs of the office;

   D. Preparing meeting agendas and minutes;

E. Assisting investigators in submitting applications;

F. Prescreening proposals and applications;

G. Educating MCCCD employees on IRB business;

H. Communicating IRB determinations to investigators and relevant parties;

I. Keeping apprised of current developments in human participants research;

J. Working with vendors to implement system updates and revisions;

K. Designing and maintaining content of the IRB web pages; and

L. Working with the Chair to orient new members.

IV. The IRB Office shall maintain files, track the workflow, and respond to inquiries in a timely fashion.

V. The VPAA of each college must appoint one of its faculty or staff members to represent that college on the IRB, becoming an IRB member, with voting rights. Once appointed as such, the IRB member, by default, becomes chair of their College Research Review Committee (CRRC) (see the College Research Review Committee section). The Provost will appoint the DO IRB member and unaffiliated members.

VI. Initial formal training is required of all IRB members at the time of their initial appointment, and thereafter as required by the IRB. IRB members must ensure their certificates remain valid. The IRB Office will maintain a log of continuing education completion dates. Continuing education of IRB members will also be supported through information resources on the IRB webpage.

VII. Liability coverage for IRB members and CRRC members is provided through MCCCD's liability insurance coverage.

VIII. Consultants or individuals with expertise in certain areas may be recruited when deemed appropriate by the IRB chair and the Provost.

PROCEDURES FOR REVIEWING APPLICATIONS

SUBMITTING THE APPLICATION ONLINE

A. All investigators and research personnel conducting human participant research in MCCCD must complete requisite training. MCCCD accepts training certificates offered by the Collaborative Institutional Training Initiative (CITI Program) as well as other similar, nationally recognized, programs.

B. When applying to the IRB for approval, the PI must complete the site authorization form and submit it to the member of the college serving as a site for the study. If the study involves more than two sites, the PI must submit the form to the IRB chair.

C. The IRB will not consider any application without written documentation of site authorization, or documentation of human participant research training for all investigators and research personnel.

D. The application and supporting documentation must be submitted through the online application system. The PI must obtain the login information for that system from the IRB Office.

E. The PI must complete and submit a close-out form for non-Exempt research, once all research activities are concluded.

F. The initial review of an application may take up to two weeks so PIs must plan accordingly. The approval process may take longer, depending on the extent of the revisions, if required by the IRB. Full Board reviews may take up to three weeks for the initial review to be completed.

G. The MCCCD IRB may conduct an administrative review of Exempt studies that have already been approved by another IRB. For this purpose, the PI must submit the original application packet in addition to any other materials required by the MCCCD IRB.

TYPES OF APPLICATIONS

A human participant research project may be categorized by the Institutional Review Board (IRB) as Exempt, Expedited, or requiring Full Board review, depending on the level of risk involved. **Exempt** research involves minimal risk and fits specific categories defined by federal regulations, thereby being exempt from certain regulatory requirements but still requiring IRB review. **Expedited** review applies to research posing no more than minimal risk and fitting specific categories, allowing for a streamlined review process. **Full Board** review is necessary for research involving more than minimal risk or not qualifying for Exempt or Expedited review. While the Principal Investigator (PI) may initially suggest the appropriate review category, the IRB makes the final determination.

EXEMPTED

Under the Common Rule, certain categories of human subjects research are designated as **exempt** from specific regulatory requirements due to their minimal risk to participants. While these studies are still considered research involving human subjects, they are not subject to ongoing Institutional Review Board (IRB) oversight. However, it's important to note that investigators must submit these studies to the IRB for an exemption determination before commencing the research. For more information, visit this link: https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)

Exemptions include:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
> (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
> (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by

§46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting

arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

> (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
> (ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

> (i) If wholesome foods without additives are consumed, or
> (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

EXPEDITED

Under federal regulations, certain types of research qualify for an expedited review (for more information, visit this link: https://www.ecfr.gov/current/title-45/section-46.110

These are activities that (1) present no more than minimal risk to human subjects, and (2)

involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the 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 list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug 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 investigational device exemption 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, nonpregnant 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) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase 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 (not involving general anesthesia or sedation) 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 federal regulations for the protection of human subjects. 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 federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

FULL BOARD

Human participant research projects that involve more than minimal risk must go to Full Board review. The PI should allow at least three weeks for projects for Full Board review.

In the application form, the PI assures the IRB that he/she will follow the principles, procedures, and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the PI (1) should present all information that will aid in evaluating the proposal for compliance with this policy, and (2) must be available to discuss the

project and/or consent forms at the discretion of the IRB.

EXCLUSIONS

The Common Rule, codified at 45 CFR 46, delineates specific categories of activities that are either not considered research or do not involve human subjects, thereby excluding them from its regulatory oversight. Understanding these distinctions is crucial for determining whether Institutional Review Board (IRB) review is necessary.

1. Non-Research Activities (Not "Generalizable Knowledge")

Certain endeavors are explicitly excluded from the definition of research under the Common Rule because they do not aim to develop or contribute to generalizable knowledge. These include:

- Journalism, Oral History, Biography, Literary Criticism, Legal Research, and Historical Scholarship: These fields focus on specific individuals without intending to generalize findings. For example, a journalist conducting interviews for a news article is not engaged in research as defined by the Common Rule.
- Public Health Surveillance Activities: Activities conducted by a public health authority to monitor and investigate public health issues, such as a Centers for Disease Control and Prevention (CDC) investigation into disease outbreaks, are not considered research.
- Criminal Justice or National Security Activities: Data collection and analysis by law enforcement or national security agencies for authorized purposes, like a law enforcement agency gathering information on criminal behavior, fall outside the scope of research.

2. Research Not Involving "Human Subjects"

A study may be excluded from the Common Rule if it does not involve human subjects, defined as living individuals from whom data is obtained through intervention or interaction, or from whom identifiable private information is collected. Exclusions include:

- Studies Using Anonymous or Non-Identifiable Data: Research utilizing de-identified medical records or publicly available datasets, such as census data, where individuals cannot be identified, is not considered human subjects research.

3. Secondary Research on Non-Identifiable Data

Research involving the analysis of existing data, documents, records, or specimens that are publicly available or recorded in a manner that subjects cannot be identified is not subject to the Common Rule. Examples include:

- Use of Publicly Available Datasets: Analyzing data from sources like the U.S. Census or stock market trends, where the information is accessible to the public and individuals are not identifiable.

It's important for investigators to consult their institution's IRB or equivalent authority to determine whether their specific activities fall under these exclusions, as interpretations can

vary. Engaging with the IRB ensures compliance with ethical standards and regulatory requirements.

ACTIONS OF THE IRB

The IRB may take one of the following actions in regard to the proposed project: (1) Approved without Stipulation, (2) Contingent, (3) Not Approved. A project is Contingent when the IRB requests modifications to the study to secure approval. Communication between the IRB and the PI, including notification of determination, will be conducted through the online application system.

APPROVED WITHOUT STIPULATION

Approval of the project will be based on the following:

1) The extent to which the project makes explicit in design and procedures the protection of participants' rights.

2) Sufficient justification that the potential benefits to the participant or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any deception, should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative.

3) Assurances of acceptable debriefing, if appropriate. It is the responsibility of the PI to give each participant an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each person, but if such information could adversely affect subsequent data collection in the same study according to the judgment of the IRB, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: In those cases in which it is unavoidable to mislead the participants and/or in which it is possible that the experimental treatment may result in emotional stress for individuals, it is mandatory that they receive a full debriefing immediately following their participation.

4) The adequacy of facilities and other resources necessary for completion of the study and protection of participants' rights.

5) Anticipated benefits, if any.

6) The personal risk to the participant in relation to expected benefits.

7) The adequacy of procedures for securing informed consent from the participant.

8) The adequacy of measures for minimizing risk and the protection of the health, safety, comfort, and legal rights of the participant.

9) The adequacy of measures for protecting the privacy of participants and maintaining confidentiality of data.

NOT APPROVED

An application is not approved if it fails to meet requisite approval criteria or if it seems to violate scientific or ethical standards. In that case, the PI may revise and resubmit the

application for another review. “Not Approved” may be issued only in the case of a Full Board review.

CONTINUING REVIEW

The IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, but not less than once per year. Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances: (1) the research is eligible for expedited review, (2) the research is in accordance with limited review, (3) the research has progressed to the point that it involves at least one of the following: (a) data analysis, including analysis of identifiable private information or identifiable biospecimens, or (b) accessing follow-up clinical data from procedures that research participants would undergo as part of clinical care. The IRB shall have authority to observe or have a third party observe the consent process and the research. The PI will be informed of the continuing review through the online application system. When a continuing review request is submitted, the reviewer shall consider the following: changes to the research, project deviations and violations since the last scheduled review, adverse event reports, reports of unanticipated problems involving risks to participants and, if available, data safety monitoring reports, and PI's compliance.

PROCEDURES PERTAINING TO BOTH INITIAL AND CONTINUING REVIEW

I. The IRB shall have authority to determine which studies need verification from sources other than the PI, and that no material changes have occurred since previous IRB review, particularly: (1) complex projects involving unusual levels or types of risk to participants; (2) projects conducted by a PI that previously failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB;

   (3) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources; and (4) projects where the PI changes the purpose or use for which participants were informed for providing the data.

II. PIs shall be informed at the time of project approval (both initial and continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to participants.

III. PIs shall be informed at the time of project approval (both initial and continuing) that any serious or ongoing problems are to be reported promptly to the IRB.

IV. Serious or continuing noncompliance by a PI, or any suspension or termination of activities, is to be reported promptly to the IRB chair or designee so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

ADVERSE EVENT REPORTING GUIDANCE

I. The OHRP recognizes that any adverse event in research is a potentially important occurrence because it may reflect additional risks to participants. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this

review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.113).

II. The PI must promptly notify the IRB chair and IRB coordinator of any adverse events in the research protocol (within 48 hours).

III. Per federal regulations, all adverse events will be reported to the Provost and the OHRP.

CLOSE OUT OF STUDY FORM

I. The PI shall submit a close-out form for non-exempt research when data collection and analysis are completed within the scope of the IRB approved protocol.

II. If the PI intends to deviate from the original purpose stated on the application and approved by the IRB, the PI must submit an amendment or a new application to the IRB.

OPERATIONS OF THE IRB

MEETINGS

I. IRB meetings are scheduled as required.

II. IRB members are notified of the place and time of meeting as soon as the schedule is developed. The agenda is sent to the IRB a week before the scheduled meeting.

REVIEWS

I. The IRB coordinator assigns the IRB member (CRRC chair) of the research study site (i.e., college or DO) as primary reviewer, and, if needed, other members of the same CRRC as secondary reviewers. The primary reviewer is responsible for issuing the IRB decision to the PI and carrying out any communication with the PI and IRB coordinator pertaining to this application. If the proposed study is to be conducted at more than one site, then the IRB Chair or their designee will review the application. If external reviewers are assigned, they must be subject to the same policies of conflict of interest and confidentiality that apply to IRB members.

VOTING REQUIREMENTS FOR FULL BOARD REVIEWS

I. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through formal notice, shall be a majority of voting members (including at least one unaffiliated member) with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

II. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting, in person or via telephone or video conferencing (as pursuant to OHRP guidelines).

III. PIs, including those who may also be IRB members, may offer information and answer questions about their projects at a convened meeting.

IV. No members of the IRB shall be involved in either the initial or continuing review of an activity in which they have a professional responsibility, except to provide information requested by the IRB. They may not be present during voting, and will not vote on any activity in which they have a conflicting interest (even if this means being unable to continue the meeting because of quorum requirements).

V. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

VI. During convened meetings of the IRB, materials submitted for review, discussions of projects, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the IRB chair moves the meeting to executive session, any visitors will be asked to leave the room until after the executive session has ended.

VII. Prior to service, all IRB members must sign the Confidentiality & Nondisclosure Agreement.

ONLINE COMMUNICATION

Once the application is submitted through the online system (after the PI has received the login information from the IRB coordinator), the IRB will use this system to communicate with and notify the PI of its decisions, conditions, and requirements.

APPEALS

The PI may appeal the decision of the IRB when a project has been disapproved and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the appeal will go back to the IRB. The IRB chair will convene an ad hoc committee to review the appeal and make a recommendation to the IRB. Then the IRB will make a final determination. The IRB is the final determiner by law. Final disapproval of the IRB cannot be overridden by any institutional official.

AMENDMENTS TO THE PROJECT

If a project is to be modified, then the PI must submit all necessary documentation in the online application system as described below.

MINOR MODIFICATION/CHANGE

A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Minor changes must be submitted within five business days of implementing the change. Examples of minor changes to a research study include, but are not limited to, the following:

- Addition or deletion of study team members;

- Addition of procedures that do not significantly increase risk to participants, considering the original purpose and study design of the approved study;
- Removal of research procedures that would thereby reduce the risk to participants;
- Addition of non-sensitive questions to unvalidated survey or interview procedures; and
- Addition of or revisions to recruitment materials or strategies.

SIGNIFICANT MODIFICATION/CHANGE

A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. The PI must seek and receive approval from the IRB prior to implementing the changes to the study. Examples of significant changes to a study may include, but are not limited to, the following:

- Addition of a new and/or separate group of participants (e.g., control group, additional cohort, vulnerable population);
- Addition of research procedures that involve greater than minimal risk to participants;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for participants or damage their financial standing, employability, insurability, or reputation;
- Removal of follow-up visits that appear necessary for monitoring participants' safety and welfare; and
- Change in the purpose of the original project or study or use of the data, from that initially provided to participants and to the IRB.

LEVEL OF REVIEW FOR AMENDMENTS

Amendments will be examined by the original reviewer to determine whether they qualify as minor or significant modifications. If an amendment is determined to increase the level of risk beyond minimal risk, the amendment will be referred to the full IRB. The PI must await the decision of the IRB before implementing significant modifications to the study.

SPONSOR AGENCY MODIFICATIONS

Modifications can be made only to IRB approved studies. A sponsor agency may modify the research project before the study has received final approval from the IRB.

If this occurs, the PI must immediately notify the IRB and await receipt of the IRB approval before making changes to the research project. Sponsor agency generated modifications (or addenda) require review and approval by the IRB. The PI must provide all sponsor documentation and summarize how the changes affect the approved project, including the recruitment, enrollment, and treatment of research participants.

GRIEVANCES

Grievances shall be submitted to the IRB Office. All grievances shall be reviewed by the IRB chair. If the grievance is by a research participant, the grievance will go to the IRB. If the grievance is by a PI, the grievance will go to the Provost.

COOPERATIVE ACTIVITIES

Cooperative activities relating to human participant research are those which involve MCCCD and another institution. Normally, research involving MCCCD students and employees as participants must be reviewed and approved by the MCCCD IRB. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1) Both institutions have Federalwide Assurances (FWAs) approved by OHRP;

2) Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and

3) The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRB(s). The IRB coordinator will verify (via the OHRP website) that the other institutions have approved FWA's.

ADMINISTRATIVE REVIEWS

If a study has already been approved by another IRB, then the MCCCD IRB may conduct an administrative review. To start the process, the PI must first obtain site authorization from the college that will serve as a site for the study. To do so, the PI must complete the site authorization form and email it to the IRB Office. If site authorization is granted, then the PI must attach all of the following documents in eProtocol, the online application system:

1. Original IRB application

2. Official IRB approval letter or email

3. Completed Site Authorization Form

4. Site authorization approval email
5. Consent/assent form
6. Recruitment materials (e.g., email messages, fliers)
7. Instruments to be administered to the participants (e.g., questionnaires, interview questions)

Note: The PI must provide any additional documents or information requested by the reviewers.

RECORD REQUIREMENTS

The IRB prepares and maintains adequate documentation of IRB activities, including the following:

I. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by the PI

II. Detailed minutes of IRB meetings, showing:

   A. Members present (any consultants/guests/others shown separately)

   B. Results of discussions on debated issues and record of IRB decisions

   C. Record of voting (showing votes for and against, as well as abstentions)

III. Records of continuing review activities, updated consent documents, and summaries of ongoing project activities

IV. Copies of all correspondence between the IRB and the PI

V. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to participants

VI. Reports of adverse events and documentation that the IRB reviewed such reports

VII. General project information provided to participants (e.g., informed consent, fact sheets, brochures)

These documents and records shall be retained for at least three years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health & Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner. In addition, the IRB maintains a permanent record of the list of current IRB members and written procedures for the IRB. The IRB can provide, upon request, an annual report to MCCCD Leadership.

INFORMATION REQUIRED FROM THE PI

I. Professional qualifications to do the research (including a description of necessary support services and facilities);

II. Appropriate authorization from the sites involved in the study;

III. Appropriate certification of training in human participant research

IV. Complete study project which includes/addresses:

A. Abstract Describing Project and Purpose: Briefly describe (1) the project or study and its purpose, and (2) what research participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used, design, and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests or other instruments are to be used, include a brief description and a copy of the instruments. (Special note to Grant Project Directors: In the case of educational or training grants, data collected about the participants served, assessment testing, pre- and post-testing and other aspects of project evaluation plans are critical.)

B. Methodology: Specify who the research participants will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant. Describe procedures to which individuals will be subjected. Use additional pages if necessary.

C. Voluntary Participation: Specify the steps that will be taken to ensure that each individual's participation is voluntary. State what, if any, incentives will be offered for their participation.

D. Confidentiality of Data and Privacy Protection: Describe the methods to be used to safeguard the privacy of research participants and ensure the confidentiality of data obtained, including plans for publication, disposition and destruction of data, including that of computer, print, videotape and audio materials.

E. Informed Consent/Assent: Attach a copy of all consent/assent forms to be signed by the participants and/or any statements to be read to or provided to the participants.

F. Risks to Participants: (1) Describe any potential risks to participating individuals–be it physical, psychological, social, legal, etc.; (2) include all known and anticipated risks to the participants such as side effects, risks of placebo(inert) treatments, etc.; and (3) list emergency backup procedures that are in place such as medical or counseling interventions to mitigate any risk.

G. Benefits: (1) Describe the benefits and/or any compensation that the participating individuals can expect, and (2) describe the gains in knowledge that may result from the project or research study.

PRINCIPLES OF INFORMED CONSENT

I. When an activity does not involve therapy, diagnosis, or management, and a professional-participant relationship exists (e.g., participation in a research project), the participant is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be kept on file with the investigator as indicated below, and a copy of the consent form must be given to the person signing the form, whether print or electronic.

II. The informed consent of research participants will be obtained by methods that are adequate and appropriate. Consent must be obtained from the participants themselves except when the participants are not legally capable of giving informed consent because of age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parent(s) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other participants not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative. The representative must be authorized either by a power of attorney or a court order.

III. "Informed consent" means ensuring that research participants and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at this link: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.25

MCCCD requires that all researchers use the approved informed consent template found on the IRB webpage. Other templates may be used provided all requisite elements are included. The IRB may approve the use of digital consent forms that include the participant's electronic signature. In such cases, a copy of the signed digital form, including the elements of the informed consent document, must be provided to the participant via email.

IV. The IRB shall determine whether the consent is adequate in light of the risks to the participant and the circumstances of the research. The IRB shall also determine whether the information to be given to the participant or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, the possible benefits, and the attendant hazards. Where debriefing procedures are considered a necessary part of the research plan, the IRB will ensure that plans for such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the participant population).

V. For research involving more than minimal risk to participants or if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments

required or any personal compensation for injuries received as a result of participation in the research.

VI. Some research may not impose on the rights and welfare of research participants so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all participants in some cases when it finds either:

A. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or

B. That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB shall require the PI to provide research participants with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the project.

The IRB may also choose to approve a consent procedure which does not include or which alters some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

A. The research involves no more than minimal risk to the participants;

B. The waiver or alteration will not adversely affect the rights and welfare of the participants;

C. The research could not practicably be carried out without the waiver or alteration; and

D. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

VII. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the participants during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the participants, and then setting the limits for such procedures.

VIII. The IRB may approve a research proposal in which the PI will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without informed consent if (1) the investigator will obtain information through oral or written communication with the prospective participant, or (2) the investigator will obtain identifiable private information or identifiable

biospecimens by accessing records or stored identifiable biospecimens.

SPECIAL POPULATIONS

The law provides additional protections for research participants who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

CHILDREN

The following considerations only apply to studies that intentionally target minors. The exemptions listed in 45 CFR 46.101(b)1 through (b)(6) apply to research involving children except for 45 CFR 46.101(b)(2) for research involving surveys, interview procedures, or observations of public behavior. Activities listed under 45 CFR 46.101(b)(2) do not apply to research covered by subpart D, except research involving observation of public behavior when the investigators do not participate in the activities being observed. Studies involving children require parental or guardian consent and participation assent.

PRISONERS

The IRB will adhere to Subpart C of 45 CFR 46. The IRB will apply the prisoner specific definition of minimal risk as stated in 45 CFR 46.303(d) and will follow the requirements for IRB membership outlined in 45 CFR 46.107. Investigators using prisoners as human participants should provide specific detail and rationale in the human participant research application. Investigators are also required to take extra measures to ensure appropriate informed consent since prisoners may be influenced by their incarceration to participate in research. If at some point a participant in a study becomes incarcerated, it is the responsibility of the PI to notify the IRB. The protocol will then be re-reviewed according to Subpart C. Subpart C of 45 CFR 46 provides four research categories that the IRB may approve for research involving prisoners. The IRB will review the proposed research to ensure one of the four categories is applicable. For more information, visit this link: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html

PREGNANT WOMEN, NEONATES, AND FETUSES

The IRB reviews all guidelines as set forth in Subpart B of 45 CFR 46 and approves only the studies that it had determined to fulfill all necessary regulatory requirements. Investigators should describe the rationale and details for the inclusion of pregnant women, fetuses, or neonates in the research. Investigators should ensure that the informed consent form adequately addresses the risks to pregnant women, fetus, or neonate. The IRB ensures that there is adequate expertise, scientific and scholarly, to review the research and reserves the right to request expert consultation as needed.

NATIVE AMERICANS

All studies that take place on tribal land will be reviewed by an IRB member familiar with the participant population and receive approval by the Tribal Council. Researchers must document Tribal Council approval or appropriate approval as part of the application process. All research conducted on Tribal Land involving Native Americans must be reviewed by the Full Board IRB except those studies that meet the federal definition as exempt.

STUDENT PARTICIPANT POOLS

Participant student pools are undergraduate students enrolled in particular departmental courses that require students to participate in one or more research projects. The IRB provides guidance and oversight of departmental student pools and reviews all such research. Participation in student pool research must be completely voluntary. Departments may provide students with incentives (usually extra credit) to participate in student pools.

OTHER POPULATION GROUPS

Research involving population groups such as the mentally and physically infirm, and others in conditions of dependency, helplessness, or deprivation, may require additional precautions and procedures to assure their protection. Participants may be paid to encourage their participation. Where participants are drawn from particularly vulnerable groups, however, compensation may under certain circumstances cast doubt upon the voluntary nature of their consent. In such circumstances, the IRB may either limit or disapprove compensation.

STUDENT ENGAGED RESEARCH

I. Undergraduate research is to be encouraged. Learning the human participant research process is an important part of a college education. It is recommended, however, that MCCCD students not engage in research that poses more than minimal risk to participants, as they are unlikely to have received sufficient training or experience at MCCCD to safely conduct such research. Faculty members can encourage course research activities such that students become familiar with developing research proposals that can fall into the exempt or expedited categories.

II. Procedures

    A. Classroom projects are considered research if they involve systematic collection of data and if their objective or design is to develop or contribute to

generalizable knowledge. This applies to human participant research projects that students intend to publish or present in a public forum. Prior to conducting their study, students must seek approval from the College Research Review Committee (CRRC) at the research site.

B. Student classroom projects that meet the definition of human participant research (see above) are to be reviewed by the CRRC at the institution where the study will be conducted. They may be reviewed by the IRB only if they involve more than minimal risk. Each CRRC determines its own processes and procedures for reviewing student-led projects. The CRRC must keep the IRB Office updated on student applications.

III. Responsibility of Faculty as Course Instructors

A. Faculty are responsible for overseeing their student's conduct of a research project. They have the primary responsibility for ensuring that research participants are treated ethically in research.

B. Faculty will inform students of the ethical principles for the protection of research participants in research and provide them with training in this area.

C. Supervising faculty are responsible for student research and thus must serve as the PI and the student can be identified as the Co-PI.

IV. Theses and Dissertations: Research for honor's theses, master's theses, dissertations, and independent research studies is not considered classroom research. As such, these proposals must go through the IRB.

CONFLICT OF INTEREST GUIDELINES

I. Investigators will be asked in the application form whether they have a vested interest in any commercial enterprise associated with any aspect of the project and, if yes, to identify and fully explain the safeguards taken to prevent PI bias in participant recruitment and/or the consent process.

II. Investigators and IRB members who are MCCCD employees and who apply for federal grants and contracts are subject to the MCCCD Conflict of Interest Policy.

III. The Grants Office will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human participation.

IV. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

A. Is an investigator or co-investigator on the project;

B. Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest (for the definition of "significant financial interest," see the MCCCD Conflict of Interest Policy, https://district.maricopa.edu/legal/business-law-contracts/applying-arizonas-con

flict-interest-laws;

C. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or

D. Has identified himself or herself for any other reason as having a conflicting interest.

V. It is the responsibility of all IRB members to identify and avoid any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If IRB members feel that they may have a conflict of interest, they must notify the IRB chair immediately so the matter may be reassigned to another reviewer. If the IRB chair or another IRB member should perceive a conflict of interest, they have a responsibility to bring this matter to the attention of the IRB.

VI. Typically, in a Full Board review, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation and actions (including vote). In general, IRB members who have a real or perceived conflict of interest may remain in the meeting at the discretion of the IRB chair during the discussion of the matter in order to provide answers to questions, clarifications, etc. However, said members must exit the meeting for deliberations and actions/votes regarding the matter.

VII. Minutes of IRB meetings will reflect the absence of members (by name) when they exit the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

CONFIDENTIALITY GUIDELINES

I. Research proposals and grant applications often include confidential, sensitive or competitive data and information. Examples include identifiable private information which is outside the scope of what is considered “directory information” provided on MCCCD students and employees, financial information about students or programs, and innovative programmatic activities.

II. IRB members will keep such data and information confidential and refrain from discussing them outside of the IRB meeting. This information will remain confined to the IRB meeting (unless federal, state or MCCCD regulations should require its release through a formal request or funding requirement).

RESEARCH REVIEW COMMITTEES

FUNCTION AND COMPOSITION

I. There are eleven Research Review Committees, one at each college and one at the District Office. The Research Review Committee may be referred to as the College Research Review Committee (CRRC).

II. The CRRC serves as a panel of the IRB and operates under its direction. The CRRC provides timely reviews of research protocols that will be conducted at the college site. The CRRC, however, is not the IRB, nor does it have the authority and legal standing of the IRB.

III. The CRRC will adhere to the guidelines established for the IRB, including membership, training, procedures and review of protocols.

IV. The CRRC chair is a voting member of the IRB.

V. The VPAA at each college will determine the composition, tenure, and administrative location of the CRRC at their site.

A. Each college has the opportunity to establish a CRRC. The CRRC may include representatives from instruction, research and administration.

B. The VPAA of each college appoints the individual to serve as the CRRC chair. Members of the CRRC can select one of them to serve as alternate chair. In the absence of the Chair, the alternate chair will fulfill the duties of the Chair on the CRRC and the IRB if designated by the Chair to do so.

C. The CRRC chair shall attend IRB meetings. If the CRRC chair is not able to attend an IRB meeting, the CRRC chair shall designate the alternate chair to attend in his/her stead, if possible; otherwise, a CRRC member may be designated by the CRRC Chair to attend the meeting.

D. The CRRC chair shall be the primary reviewer of all applications involving his/her college. The alternate chair shall be a secondary reviewer (as shall other CRRC members, if there is a need for that). If the CRRC chair is not able to serve as primary reviewer, then he/she shall designate the alternate chair to do so. Only the CRRC chair or the alternate chair can sign off on an application--other CRRC members may not do so.

E. The CRRC chair shall provide annual updates to the IRB coordinator on CRRC membership (with names and current training certificates).

F. The CRRC chair shall serve a term of at least three years. CRRC chairs who find themselves unable to attend IRB meetings or review applications must inform the IRB chair and their VPAA so that a replacement can be selected. Additionally, IRB members may be removed from the IRB before their term is completed for non-participation (unless there is reasonable justification). In either event, the IRB chair will communicate with the college VPAA to find a replacement.

G. The alternate chair and other CRRC members are encouraged to attend and participate in IRB meetings.

SAME IRB PROCEDURES APPLY TO CRRC

Unless specifically noted otherwise, the CRRC shall follow the same procedures as outlined above in all aspects (as in this document, MCCCD IRB Handbook).

I. The CRRC chair shall review each application submitted to their college/site, and they may discuss their evaluation with their CRRC members, to ensure consistency of determinations. Consistency will be critical across all CRRCs, as each CRRC chair serves as a member of the IRB. The CRRC chair may designate their Alternate to review an application if the former is not available or has conflict of interest.

II. All CRRCs shall require the same information as that required by the IRB (e.g., application form to conduct human participant research, record of determination).

III. If in a very rare and unusual circumstance where both the CRRC chair and alternate chair are absent, the VPAA can forward the request to the IRB chair or the IRB Office administrator for assistance.

TYPES OF PROTOCOLS REVIEWED BY THE CRRC

I. The CRRC shall review exempt and minimal risk applications submitted by students at that college. Student applications must be submitted directly to the CRRC. The procedures to be followed are determined by the individual CRRC.

II. The CRRC shall review exempt and minimal risk applications submitted by students from other colleges in MCCCD intending to conduct research at that college. Student applications must be submitted directly to the CRRC of the college serving as site of the study. The procedures to be followed are determined by the individual CRRC.

APPENDIX

ACRONYMS

- CRRC: Research Review Committee at each college and at the District Office. The Committee may be referred to as the College Research Review Committee (CRRC), since 10 of the 11 Research Review Committees are located at the colleges and one is located at the District Office. The Committee may also be referred to as the RRC.
- DO: District Office (Administrative Office of the Maricopa County Community College District)
- FDA: Federal Drug Administration
- FWA: Federalwide Assurance
- HHS: (U.S. Department of) Health & Human Services
- HIPAA: Health Insurance Portability and Accountability Act
- IRB: Institutional Review Board
- IRB Handbook: Handbook of Standard Operating Procedures for the IRB
- MCCCD: Maricopa County Community College District
- OHRP: Office for Human Research Protections (within the U.S. Department of Health & Human Services)
- PI: Principal Investigator
- “Provost”: Executive Vice Chancellor/Provost
- “The IRB”: (Maricopa County Community College District) Institutional Review Board
- VPAA: Vice President of Academic Affairs

GLOSSARY

- ADVERSE EVENT. An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.
- ASSENT. Explicit agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.
- AUTONOMY. Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.
- BELMONT REPORT. A statement of basic ethical principles governing research involving human participants issued by the National Commission for the Protection of Human Subjects.
- BENEFICENCE. An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
- COMMON RULE. The Common Rule, formally known as the Federal Policy for the Protection of Human Subjects, is a set of ethical guidelines and regulations established in 1991 to ensure the protection of individuals participating in research studies conducted or supported by U.S. federal agencies. It outlines the basic provisions for Institutional Review Boards (IRBs), informed consent, and Assurances of Compliance. The Common Rule was revised in 2017, with the updated regulations—referred to as the 2018 Requirements—becoming effective on January 21, 2019.
- CONFIDENTIALITY. Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.
- DEBRIEFING. Giving participants previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)
- EXPEDITED REVIEW. Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.
- FEDERALWIDE ASSURANCE (FWA). Agreement that fulfills the requirements of 45 CFR part 46 approved by the Secretary of Health and Human Services. MCCCD has an approved FWA on file with HHS – Assurance Number FWA00006192. A copy of the assurance is available upon request from the Office of the Executive Vice Chancellor/Provost.

- FULL BOARD REVIEW. Research that is reviewed at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
- GRANT. Financial support provided for a project or research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.
- GUARDIAN. An individual who is authorized under applicable state or local law to give permission on behalf of a child to participate in research.
- HUMAN SUBJECTS. Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as living individuals about whom an investigator conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (Also referred to as RESEARCH PARTICIPANTS in this document.)
- INFORMED CONSENT. A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.
- INSTITUTIONAL REVIEW BOARD. A specially constituted review body established or designated by an entity to protect the rights and welfare of human participants recruited to participate in biomedical or behavioral research.
- INTERACTION. Communication or interpersonal contact between investigator and participant.
- INTERVENTION. Physical procedures by which information or biospecimens are gathered and/or manipulations of the participant or the participant’s environment.
- JUSTICE. An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; it is often expressed in terms of treating persons of similar circumstances or characteristics similarly.
- LEGALLY AUTHORIZED REPRESENTATIVE. A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human participant research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research.
- MINIMAL RISK. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves,

than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

- MONITORING. The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and participant protections.
- OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP). The office within the U.S. Department of Health & Human Services, responsible for implementing HHS regulations (45 CFR Part 46) governing research involving human participants.
- PRINCIPAL INVESTIGATOR. The person primarily responsible for a research study or project.
- PRIVACY. Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- PRIVATE INFORMATION. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.
- PROTOCOL. The formal design or plan of an experiment or research activity: specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective participants and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.
- RESEARCH. A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.
- RESEARCH PARTICIPANTS. See HUMAN SUBJECTS.
- RESPECT FOR PERSONS. An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.
- RETROSPECTIVE STUDIES. Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.
- RISK. The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk". (See also: Minimal Risk.)
- VOLUNTARY. Free of coercion, duress, or undue inducement. Used in the research context to refer to a person’s decision to participate (or to continue to participate) in a

research activity.