

INSTITUTIONAL REVIEW BOARD
FOR HUMAN RESEARCH
PARTICIPANT PROTECTION

POLICY AND PROCEDURES

ARIZONA WESTERN COLLEGE
OFFICE OF INSTITUTIONAL EFFECTIVENESS, RESEARCH, AND GRANTS

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I. INSTITUTIONAL RESPONSIBILITIES

A. Arizona Western College hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services, National Institutes of Health regulation 45 CFR 46, Protection of Human Subjects. It is the policy of Arizona Western College that all human participant research and research-related activities involving human participants conducted within or under the auspices of the College, by any faculty, student, or employee, whether or not supported by an external funding agency, be subject to the review and approval of the Institutional Review Board for Human Research Participant Protection (IRB). Federal funds for which this Assurance applies may not be expended for research involving human participants until the requirements of this Assurance have been satisfied. The involvement of human participants in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the participant and/or the participant's legal representative (see 46.111, 46.116 and 46.117 and Part VI, Part VII and Part VIII of this policy).

B. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

C. The President or his appointee shall appoint members to serve on the IRB. Membership shall meet the criteria established in 46.107 and as outlined in Part V of this policy.

II. OFFICE OF INSTITUTIONAL EFFECTIVENESS, RESEARCH, AND GRANTS RESPONSIBILITIES

A. The Office of Institutional Effectiveness, Research, and Grants (hereinafter "The Office of Research") will provide investigators copies of regulation 45 CFR 46, Protection of Human Subjects, and the institution's IRB policy and procedures.

B. The Office of Research will coordinate the review process of all proposals involving the use of human research participants, unless found exempt under 46.101 and Part VI.B. of this policy, including disseminating the proposals to the board for review, notifying the investigator of any changes required by the board in order to secure approval, and informing the investigators and funding agency of the board's final decision. Efforts will be made to relay IRB decisions and feedback to investigators within 10 working days, but longer review periods may be necessary for certain submissions.

C. The Office of Research and the IRB Chair will review projects to determine if they qualify for exemption under 46.101 and Part VI.B. of this policy. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator (within 5 working days) and reported to the full IRB at the next scheduled meeting. All nonexempt research will be forwarded to the IRB either for expedited review or full board review. All members of the IRB will be kept informed of research proposals that have been found to be exempt from IRB review.

D. The Office of Research and the IRB Chair will review projects to determine if they qualify for expedited review under 46.110 and Part VI.C. of this policy. If a project qualifies for expedited review, the Chair or designee and one or more board members will review the project and promptly

(within 10 working days) notify the Office of Research, in writing, of their decision to approve or require modification in order to secure approval. These reviewers may not disapprove the research; disapproval requires a vote of the full board. Expedited review of research activities will not be permitted where full board review is required. All members of the IRB will be kept informed of research proposals that have been approved under the expedited review procedure.

E. Any proposal that is not exempt from IRB review or does not qualify for expedited review will be sent to the IRB for full board review.

F. The Office of Research will supply administrative support for the IRB in accordance with 46.115 including setting up meetings, recording minutes of meetings, maintaining a current file of all correspondence between the IRB and the investigators, all proposals reviewed, progress reports, any reports of injury, records of continuing review, maintaining a list of IRB members and qualifications, etc. All records will be maintained for a minimum of three years after completion of the research. All IRB records shall be accessible for inspection by authorized representatives of any Department or Agency.

G. The Office of Research will promptly report to the IRB, appropriate institutional officials, the Office of Human Research Protection (OHRP), and any sponsoring agency any injuries to human research participants or other unanticipated problems involving risks to human research participants, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspensions or termination of IRB approval for research.

III. INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES

A. The IRB will review, and have the authority to approve, require modification in order to secure approval, or disapprove all research activities covered by 45 CFR 46 and this institutional policy.

B. The IRB shall require that information given to research participants as part of informed consent is in accordance with 46.116 and Part VII of this policy. The IRB may require that information, in addition to that specifically mentioned in 46.116 and Part VII of this policy, be given to the research participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of research participants.

C. The IRB shall require documentation of informed consent or may waive documentation in accordance with 46.117 and Part VIII of this policy.

D. The IRB will ensure effective input for all initial and continuing reviews of research involving the use of human participants. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

E. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

F. In accordance with 46.113, the IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to research participants. Any suspension or termination of approval shall include a statement of the reason for the IRB's action and shall be reported promptly to the investigator, appropriate College officials, and the Department or Agency head.

G. The IRB chair or designee, in coordination with the Office of Research, will determine whether or not a proposed activity is exempt from IRB review, qualifies for expedited review, or requires full IRB review and approval.

H. The IRB shall meet at least once in both Fall and Spring semesters, or more frequently if required by the IRB on the basis of degree of risks to research participants. A meeting of the IRB may be requested by any member of the IRB during a proposal review or at any time the member is concerned with rights and welfare of human participants being used in research.

IV. INVESTIGATOR RESPONSIBILITIES

A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research participants and for complying with all parts of 45 CFR 46, the AWC IRB Policy and Procedures, and the decisions of the IRB. Research investigators that intend to use human research participants must present evidence to the IRB that they are familiar with ethical issues in the use of humans for research purposes.

B. Research investigators are responsible for notifying the IRB of any projects planned which involve the use of human participants in research. Investigators will complete the IRB Application (available on the IRB Web site at http://www.azwestern.edu/Office_of_the_President/Institutional_Research) in its entirety prior to beginning the proposed research. No research will be carried out until it is approved by the IRB. It is the responsibility of the investigator to notify the IRB of any proposed research project well in advance to allow adequate time for IRB review and approval. Each investigator submitting an application to the IRB must also attach a signed attestation form (also available on the IRB Web site) regarding their formal or informal training in the use of human participants in research.

C. The investigator will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of 46.116 and 46.117 and Part VII of this policy. The written consent form is to be approved by the IRB and signed by the research participant or the research participant's legally authorized representative. A copy shall be given to the person signing the form.

D. The investigator will promptly respond, in writing (within 5 working days), to any concerns expressed by the IRB regarding his/her protocol and will comply with the requirements made by the IRB in order to secure approval of his/her protocol. Any protocol disapproved by the IRB cannot be conducted.

E. The investigator will promptly report any proposed changes in previously approved human participant research activities to the IRB. The proposed changes will not be initiated without IRB

review and approval, except where necessary to eliminate apparent immediate hazards to the research participants.

F. The investigator is responsible for reporting progress of approved research to the Office of Research as prescribed by the IRB, but not less than once per year.

G. The investigator will immediately report to the IRB any injuries or other unanticipated problems involving risks to human research participants.

H. Investigators may be invited to attend the IRB meeting to discuss proposed projects.

V. IRB MEMBERSHIP

A. Charter members of the IRB will be appointed by the President. In subsequent years, the Dean of Institutional Effectiveness, Research, and Grants will recommend candidates through a random selection process from a pool of qualified candidates who expressed interest in serving. Those selected will be appointed by the President. The President of the College will, in accordance with 46.107, appoint no less than five members to the IRB. The board members will select one member to serve as Chair. Appointees will have varied backgrounds so as to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. Consideration shall also be given to the inclusion of one or more individuals who have ethical training.

B. If the IRB regularly reviews research that involves a vulnerable category of research participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these research participants.

C. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one profession.

D. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

E. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

F. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

G. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

VI. CRITERIA FOR IRB APPROVAL OF RESEARCH

A. In order to approve research covered by 45 CFR 46 and this institutional policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to research participants are minimized:

i. by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk, and

ii. whenever appropriate, by using procedures already being performed on the research participants for diagnostic or treatment purposes.

2. Risks to research participants are reasonable in relation to anticipated benefits, if any, to research participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies research participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of research participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective research participant or the research participant's legally authorized representative, in accordance with, and to the extent required by 46.116 and Part VII of this policy.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by 46.117 and Part VIII of this policy.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of research participants.

7. When appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.

8. When some or all of the research participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these research participants.

B. Exempt Research. In accordance with 46.101(b), unless otherwise required by Department or Agency heads, research activities in which the only involvement of human research participants will be in one or more of the following categories are exempt from this policy:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - i. research on regular and special education instructional strategies, or
 - ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:
 - i. information obtained is recorded in such a manner that human research participants can be identified, directly or through identifiers linked to the research participants; and
 - ii. any disclosure of the participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if:
 - i. the human research participants are elected or appointed public officials or candidates for public office; or
 - ii. federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that research participants cannot be identified, directly or through identifiers linked to the research participants.
5. Research, program evaluation, and demonstration projects which are conducted by or subject to the approval of agency heads, and which are designed to study, evaluate, or otherwise examine:
 - i. public benefit service programs;

- ii. procedures for obtaining benefits or services under those programs;
- iii. possible changes in or alternatives to those programs or procedures; or
- iv. possible changes in methods or levels of payment for benefits or services under those programs.

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.

The IRB chair or designee is charged with the responsibility of determining eligibility for exemption. Principal Investigators who believe their research with human research participants is exempt must submit applications which are complete and in sufficient detail to permit an evaluation of the claim to exemption and to justify its finding. All IRB members will be notified by the Office of Research of all projects found to be exempt of IRB review. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after full board review.

C. Expedited Review. In accordance with 46.110, research activities involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the expedited review procedure:

1. Recording of data from research participants 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes such procedures as weighing and testing sensory acuity. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
2. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from research participants 18 years of age or older and who are in good health and not pregnant.
3. Voice recordings made for research purposes such as investigations of speech defects.
4. Moderate exercise by healthy volunteers.
5. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

6. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate participants' behavior and the research will not involve stress to participants.

The IRB may use the expedited review procedure to review either or both of the following:

1. Some or all of the research appearing in C.1-6. above and found by the reviewer to involve no more than minimal risk, and minor changes in previously approved research during the period of one year or less for which approval is authorized.

2. Under an expedited review procedure, the review may be carried out by the IRB chairperson or designee and one or more members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after full board review. All IRB members will be notified by the Office of Research of all projects reviewed under the expedited review process.

D. Full Board Review. Any proposal which does not qualify for exemption or expedited IRB review shall be reviewed by the full IRB at a convened meeting in which a quorum (50% of the membership including at least one member whose primary concerns are in non-scientific areas) is present. Only those members present at the meeting may vote on the proposal. No absentee or proxy votes will be allowed. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

VII. GENERAL REQUIREMENTS FOR INFORMED CONSENT

Except as provided elsewhere in this policy, no investigator may involve a human being as a research participant in research covered by this policy unless the investigator has obtained the legally effective informed consent of the research participant or the research participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective research participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the research participant or the representative shall be in language understandable to the research participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the research participant or the representative is made to waive or appear to waive any of the research participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

A. Except as provided in paragraph C or D of this section, in seeking informed consent the following information shall be provided to each research participant:

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the research participant;

3. a description of any benefits to the participant or to others which may reasonably be expected from the research;
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant;
5. a statement describing the extent, if any, to which confidentiality of records identifying the research participant will be maintained;
6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research and participants' rights, and whom to contact in the event of a research-related injury to the participant; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled, and the research participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.

B. When appropriate, one or more of the following elements of information shall also be provided to each research participant;

1. a statement that the particular treatment or procedure may involve risks to the research participant (or to the embryo or fetus, if the research participant is or may become pregnant) which are currently unforeseeable;
2. anticipated circumstances under which the research participant's participation may be terminated by the investigator without regard to the research participant's consent;
3. any additional costs to the participant that may result from participation in the research;
4. the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the research participant;
5. a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant; and
6. the approximate number of research participants involved in the study.

C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the contents of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

- i. public benefit or service programs;
- ii. procedures for obtaining benefits or services under those programs;
- iii. possible changes in or alternatives to those programs or procedures; or
- iv. possible changes in methods or levels of payment for benefits or services under those programs; and

2. the research could not practicably be carried out without the waiver or alteration.

D. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to the participants;
2. the waiver or alteration will not adversely affect the rights and welfare of the research participants;
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, the research participants will be provided with additional pertinent information after participation.

E. The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

F. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

VIII. DOCUMENTATION OF INFORMED CONSENT

A. Except as provided in paragraph C of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the research participant or the research participant's legally authorized representative. A copy shall be given to the person signing the form.

B. Except as provided in paragraph C of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 46.116 and Part VII of this policy. This form may be read to the research participant or the research participant's legally authorized representative, but in any event, the investigator shall give either the research participant or the representative adequate opportunity to read it before it is signed; or
2. A short written consent document stating that the elements of informed consent required by 46.116 and Part VII of this policy have been presented orally to the research participant or the research participant's legally authorized representative.
3. When this method is used, there shall be a witness of the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the research participant or the representative.

Only the short form itself is to be signed by the research participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the research participant or the representative, in addition to a copy of the short form.

C. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all research participants if it finds either:

1. 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. Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant's wishes will govern; or
2. 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 in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

APPENDIX I
GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS

The ethical principle of respect for persons requires that research participants be given the opportunity to choose what shall and shall not happen to them. Valid informed consent requires: (1) disclosure of study procedures and potential risks to prospective research participants; (2) their comprehension of the information, and (3) their voluntary agreement, free of coercion and undue influence, to research participation.

All written informed consent documents must be complete and clearly written so as to promote informed decision-making by research participants participating in research activities.

REQUIREMENTS FOR INFORMED CONSENT

Unless otherwise waived by the IRB, research investigators should obtain valid informed consent from all research participants (or their legally authorized representatives) who participate in their research studies. Generally, after the investigator has explained the research study to the participant, the participant's informed consent is documented by signing the protocol's written consent document, which the IRB must have previously reviewed and approved. The research participant is given a copy of the signed document. The original signed consent document is filed in a manner which ensures the research participant's confidentiality.

BASIC ELEMENTS FOR WRITTEN INFORMED CONSENT DOCUMENTS

- Unless otherwise authorized by the IRB, research investigators must provide the following information to each research participant in writing:
- a statement that the study involves research;
- an explanation of the purpose of the research and the expected duration of participation;
- a description of the procedures to be followed and identification of any procedures that are experimental;
- a description of any foreseeable risks or discomforts to the research participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them;
- a description of any benefits to the participants or to others that may reasonably be expected from the research;
- a disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the research participant;
- a statement describing to what extent records will be kept confidential, including a description of who may have access to research records;
- for research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if research participants are injured, where further information may be obtained, and whom to contact in the event of a research-related injury;
- an explanation of whom to contact for answers to pertinent questions about the research and the participant's rights; and
- a statement that participation is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the research participant is otherwise entitled.