ARIZONA WESTERN COLLEGE

Institutional Review Board

CRITERIA FOR IRB APPROVAL

The Arizona Western College Institutional Review Board (IRB) reviews research involving human subjects in order to ensure that the rights and welfare of human subjects are protected. Federal law and institutional policy mandates that all social/behavioral research involving human subjects must receive IRB approval prior to the start of the research.

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

1. Risks to research participants are minimized:

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

5. Informed consent will be appropriately documented in accordance with, and to the extent required by 46.117.

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

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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.

Determination of "Research"

45 CFR 46.102(l) Research – a *systematic investigation*, including research development, testing and evaluation, (e.g., surveys and questionnaires, interviews, observations, focus groups, collation of extant information, testing, etc.) *designed to develop or contribute to generalizable knowledge.*

As a general rule, anticipated dissemination of results in conference presentations, publications, thesis and dissertations, or reports available outside the institutional confines of Arizona Western College will indicate that the data collection or analysis constitutes research.

Data collection and analysis intended for institutional consumption by employees of Arizona Western College or public information available in report or raw data form is not regarded as research and is therefore exempt from IRB approval. Examples include program reviews, enrollment reports and institutional data which may be legally disclosed. During collection and analysis of institutional data, if an employee decides to pursue disseminating of findings in one of the forms mentioned in above, he or she must have IRB approval to proceed. Employees are encouraged to communicate with the IRB to clarify responsibilities and verify that activities protect the rights and well-being of human subjects.

A *systematic* approach involves a predetermined system, method or plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A Systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.

Activities *designed to develop or contribute to generalizable knowledge* are those activities designed to draw general conclusion, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

Determination of "Human Subject"

45 CFR 46.102(e): Human Subject – a living individual about who an investigator (whether faculty, student, staff, or external) 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.

Intervention includes both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Identifiable is where the identity of the subject is or may be ascertained by the researcher, or will be associated with the information. The research could involve the use of *coded* data/specimens.

Coded means a living individual's identifiable information such as name or social security number has been replaced by a code, such a number, letter, or combination thereof and there is a key to link the code to the identifiable information of that individual. *Coded data are considered indefinable under the Common Rule.*

Key Research Personnel

Key research personnel include the Principal Investigator (PI), Co-Principal Investigator (Co-PI), Co-Investigator(s) and research personnel who are directly involved in conducting research with the study participants or who are directly involved in using study participants' identifiable private information during the course of the research. Key research personnel also include faculty sponsors/advisors who provide direct oversight to graduate students serving as PI on the IRB application.

As defined by the National Institutes of Health (NIH), key research personnel must be included on the list and have current CITI training (within the past 3 years) before they may conduct any activities related to the human research.

Some individuals may act as "gatekeepers" to data and/or participants but they are not active in the data collection or analysis. For example, an individual manages an email contact list and sends an email for the researcher to advertise a study but does not obtain consent from participants or collect their data. Managing the email list and giving permission to the researcher to contact the potential participants does not make this individual a part of the research team. In most cases, gatekeepers are not part of the research team and therefore are not required to be listed on the protocol or complete CITI training. However, for some studies where the participants are more susceptible to risk, it may be necessary that all individuals involved complete CITI training as part of the measures to protect participant safety.

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Principal Investigator (PI)

Principal Investigators (PIs) 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, AWC's IRB Policy and Procedures, and the decisions of the IRB. PIs 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. Though research responsibility may be delegated to research staff, PIs must maintain oversight and retain ultimate responsibility for the conduct of those to who they delegate responsibility.

The PI will ensure that all research staff, collaborators, or colleagues assisting in the conduct of research study have the appropriate training and credentials to conduct the research; and are appropriately informed of the study procedures, informed consent requirements, the potential adverse events associated with study participation and the steps to be taken to reduce potential risks, adverse event reporting requirements, and data collection and record-keeping criteria.

Faculty members, managers, and administrators could be considered as qualified to serve as the PI on research projects. Exceptions may be made with prior approval of the Vice President for Learning Services for graduate students (thesis or dissertation) to serve as the PI.

Investigators from outside AWC must obtain approval from the IRB even for exempt activities.

All PIs considering research projects involving human subjects are required to complete Research Ethics and Compliance Training through CITI.

Co-Principal Investigator (Co-PI)

A Co-Principal Investigator is recognized by the funding agency as an individual who shares with the PO the responsibility for the conduct of the research project, including meeting the reporting requirements. The PI, however, must maintain oversight and retains ultimate responsibility for the conduct of those to who they delegate responsibility.

Investigators from outside AWC must obtain approval from the IRB even for exempt activities.

All Co-PIs considering research projects involving human subjects are required to complete Research Ethics and Compliance Training through CITI.

Co-Investigator (Co-I)

A Co-Investigator is an individual recognized by the institution and the PI as someone making a significant contribution to a project. The PI relies on the Co-I to assume responsibilities above those of other research personnel. Though research responsibility may be delegated to the Co-I,

the PI must maintain oversight and retain ultimate responsibility for the conduct of those to who they delegate responsibility.

Investigators from outside AWC must obtain approval from the IRB even for exempt activities.

All Co-Is considering research projects involving human subjects are required to complete Research Ethics and Compliance Training through CITI.

Students as Researchers

Class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight. The intent in these cases is to teach methods, not to contribute to generalizable knowledge. Neither the student nor the instructor is required to submit a Human Research application when the purpose of the class is for educational purposes only. Faculty members are encouraged to communicate with the (IRB) to clarify responsibilities and verify that activities protect the rights and well-being of human subjects.

When the primary focus and initial intent of the class activities are designed to collect data that will be used beyond the classroom (i.e., scholarly publication or use for future research), it is the responsibility of the faculty advisor to assist students in determining whether obtaining IRB approval or exemption is required and if so, that this is done prior to the initiation of a human subjects research project. The IRB application is completed under the guidance of the student's faculty advisor. The student's advisor is responsible for guiding the student investigator in the development of the research plan as well as the conduct of the research project. The advisor also assists students in a design to maximize the benefits and minimize the risks involved in the research, and to assure the ethical conduct of the project.

Graduate students should go through their thesis or dissertation committees for review of research prior to submitting a Human Research application. In addition, they are required to have an AWC faculty sponsor in order to submit a Human Research application, which verifies that the faculty sponsor approves of the materials being submitted. Approval of the Vice President for Learning Services is also required.

Responsibilities of the Principal Investigator and Research Staff

Though research responsibility may be delegated to research staff, the PI must maintain oversight and retain ultimate responsibility for the conduct of those to who they delegate responsibility.

The PI is responsible for retaining informed consent documents for a period of three years after the project.

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- Protect the rights and welfare of human subjects who participate in research.
- Understand the ethical standards and regulatory requirements governing research activities with human subjects.
- Personally conduct or supervise the research.
- Ensure that all staff, collaborators, and colleagues assisting in the conduct of the study are informed about the study, regulations governing research, and institutional policies.
- Ensure that all research activities have IRB approval and other approvals required by the institution before human subjects are involved.
- Implement the research activity as it was approved by the IRB.
- Obtain the informed consent of subjects before they are involved in the research and document consent as approved by the IRB.
- Maintain written records of IRB reviews and decisions.
- Obtain and keep documented evidence of informed consent of the subjects (or their legally authorized representatives).
- Obtain IRB approval for any proposed change to the research plan prior to its implementation.
- Comply with the IRB requirements for timely reporting of unanticipated problems involving risks to subjects or others including adverse events, safety reports received from the sponsor, or data safety and monitoring summary reports.
- Make provisions for the secured retention of complete research records and all research materials.
- Ensure the confidentiality and security of all information obtained from and about human subjects.
- Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other organizations.
- Notify the IRB of any relevant new information that may impact the safety/security of subjects' health or privacy.

Research Ethics and Compliance Training

All key personnel, including students, who are involved in the conduct of human subjects research are required to complete CITI's Research Ethics and Compliance training online and to recertify every 3 years. This training is separate from the application process to received IRB approval for your research.

CITI (Collaborative Institutional Training Institute) offers human subjects research training and certification. As part of our federal-wide assurance, we have to verify that any researcher conducting human subjects research at AWC has adequate training for conducting that research. CITI offers a streamlined process that provides certification that is recognized not only at AWC but at a variety of institutions nationwide. If you are doing a multi-site study, plan to do research

at another institution, or have done research at another institution, your CITI training may be transferrable however, additional training modules may be required.

Students as Research Participants

Permission may be granted for conduct of research involving students for such purposes as the pursuit of advanced degrees, classroom research, independent student research, and research for off-campus individuals and agencies. Participation therein is the choice of the individual student. Investigators planning research utilizing students as subjects must secure permission in advance of the project from the Vice President for Learning Services. Minimally, such approval will entail:

1. Assurance that the project does not conflict with examinations or require a major loss of classroom time;
2. Assurance that students know they have the alternative of choosing to participate or not;
3. Explanation of the purpose of the research and disclosure of any possible negative consequence of any procedure to which students might be exposed in the research;
4. Provision for students to have the opportunity to see the results of the research;
5. Evidence that the research method is appropriate for the subject to be studied;
6. Guarantee of confidentiality of student records and responses.

Prior to the initiation of such a project, the researcher shall submit a report of the research covering the points listed above to the Vice President for Learning Services. Written permission may be given with or without college endorsement of the project. In such instances where the Vice President for Learning Services deems appropriate, assistance may be sought from others with related knowledge before permission to proceed is granted or denied.

Types of IRB Review

Collaboration between the US Department of Health and Human Services and 15 other Federal Departments and Agencies resulted in revisions to 45 CFR 46, Subpart A – "Federal Policy for the Protection of Human Subjects", or the Common Rule, on January 18, 2017. This is the first revision since its publication in 1991. The explicit goal of these revisions is to reduce administrative burden and better protect subjects in the modern research context.

Human Subjects research is reviewed by the IRB according to the following three (3) distinctive levels:

Full-Board Review: Research that does not qualify for either "Exempt" or "Expedited" review categories (presents more than minimal risks to subjects) must be reviewed at a fully convened IRB committee meeting.

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Expedited Review: Research can be approved as "Expedited" if it is no more than minimal risk and fits in one of the nine (9) federally designated expedited review categories. These categories involve collection of samples and data in a manner that is not anonymous. Expedited reviews are conducted by the IRB Chair or one or more experienced designated IRB members. Reviewers conducting an expedited review may exercise all of the authority of the IRB except that they may not disapprove a study. When a subcommittee cannot approve the research under expedited review, the study is referred to the full IRB committee for review.

Exempt: Research can be deemed as "Exempt" from IRB review if it is no more than minimal risk and fits one or more of the eight (8) new revised exempt review categories. New categories were added, and two new processes were introduced: limited IRB review and broad consent. The pre-2018 rule had six (6) exempt categories in 46.101(b). The revised rule gave exempt categories an entire section 46.104 and now includes eight (8) categories in 46.104(d) (1-8). Arizona Western College is not implementing broad consent for use of identifiable private information or identifiable biospecimens at this time. As a result, exempt categories 7 and 8 are not applicable and not included in the IRB Human Research application. These categories present the lowest amount of risk to potential subjects. Studies that may qualify for "Exempt" must be submitted to the IRB for review. Exempt reviews are conducted by the IRB Chair or a designated IRB member. They do not require a convened IRB meeting.

Limited IRB Review (for select Exemption Categories): The Final Rule introduced a new concept of limited IRB review as a condition of exemption. Limited IRB review is required for exempt categories 2 and 3. Limited IRB review will occur at the same time the proposed research protocol is reviewed for a determination of exemption.

Types of IRB Submissions

Within each type of IRB review, there may be three types of IRB submission:

- **Initial**: Refers to a study being submitted and reviewed for the first time.
- **Continuing**: Refers to a study being reviewed at the time of continuation, often referred to as a "renewal." Frequency of review is determined based upon level of review.
- **Amendment**: Refers to a change, often referred to as a "modification" to the current approved study. Amendments to currently approved research must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the human subjects. Depending upon the nature of the amendment, the IRB may conduct an Expedited or Full Committee review.

IRB Review and Approval, and Exemption Turnaround Times (approximate)

Several factors take part in IRB review/exemption and turnaround times, including but not limited to: the quality of the IRB Human Research application submission; the complexity and/or novelty of the study; whether or not there are unusual and/or difficult ethical issues to consider;

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and the time it takes for an investigator to respond to the IRB requests for additional information and/or revisions. Reviews during holiday periods will take longer. The IRB review is a deliberative process therefore; it is not possible to provide exact turnaround times. However, Investigators may consider the following as rough guides:

Type of Review	Type of Submission	IRB Review & Approval Turnaround
Exempt	Initial	1 – 2 weeks
Limited Review for select Exempt Categories	Initial	1 – 2 weeks
Expedited	Initial	1 – 2 weeks
	Continuing and/or Amendments	1 – 2 weeks
Full Committee	Initial	2 – 4 weeks
	Continuing and/or Amendments	2 – 4 weeks

Human Research Application Submission

Principal Investigators are required to submit a complete Human Research Application and any supporting documents to the Office of Institutional Effectiveness and Research prior to the start of the research. The IRB chair will review the application for exemption. If research is deemed exempt, the Principle Investigator will receive a formal letter of determination of exemption. Otherwise, the application will be further reviewed for expedited or full board review.

Please attach the following documentation to your completed Human Research Application, as applicable:

- PI/Co-PI CV or Biosketch
- List of Project Personnel
- Copies of Completed CITI Training Certificate for All Project Personnel listed
- Data Safety Monitory Plan
- Recruitment Material(s)
- Informed Consent Documentation
- Data Collection Tools
- Email confirmation from Faculty Advisor (required for all students)
- Email confirmation from Department Head

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Types of IRB Determinations

After review of the Human Research application, the IRB will notify the researcher with one of the following determinations. *Investigator will not begin research activities until he/she has received written notification of IRB approval.*

- **Approved** – application, as submitted, is complete and meets the criteria for approval as defined in 45 CFR 46.111. Date of approval is the date on which the IRB reached approval determination.

- **Approved with Conditions** - application is complete however, there are issues/changes that must be addressed before the study can begin. Once a satisfactory response to these contingencies is received, the review is complete and approval for research to be conducted is granted by the IRB.

- **Deferred** - applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. To secure approval, the convened IRB requires modifications in the research or other action(s) to be taken by the Investigator. Written notification of deferral will be sent to the Investigator listing the concerns that must be addressed for approval to proceed. The Investigator's response is reviewed by the convened IRB and will be approved or deferred until all issues are addressed satisfactorily.

- **Tabled** – the convened IRB may table an application for Human Research for the following reasons:

    - Lack of meeting time to conduct thorough review of the item
    - Loss of quorum
    - Insufficient information to make a determination
    - Other reasons as determined by the Chair

    The Investigator will not initiate any new research activities or implement proposed changes to previously approved research until the application has subsequently been reviewed by the IRB and they have received written notification of IRB approval.

- **Disapproved** – the convened IRB has determined that the application, as submitted, does not meet the criteria for approval as defined in 45 CFR 46.111 and/or the IRB required substantial revisions to the application, informed consent documents(s), or other relevant documents in order to assess the risk to benefit ratio of the research. Written notification of disapproval will be sent to the Investigator listing the reasons for its decision and give the Investigator an opportunity to respond in person or in writing, at the discretion of the IRB. Institutional administrative officials may not override this decision.

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- **Exempt** – the IRB chair or designated IRB member has determined that the human subject research activities meet the criteria for exemption under 45 CFR 46.104. *Exempt human subject research activities do not require ongoing review by the IRB unless a change in the research is planned.*

- **Exempt with Limited IRB Review** – the IRB chair or designated IRB member has determined that the human subject research activities meet the criteria for exemption (categories 2 and 3) but limited IRB review is required. *Exempt human subject research activities do not require ongoing review by the IRB unless a change in the research is planned.*

- **Not Research** – the IRB chair or designated IRB member has determined that the proposed activities do not meet the definition of research under 45 CFR 46.102(i).

- **Not Human Subject Research** - the IRB chair or designated IRB member has determined that the proposed activities do not involve human subjects as defined in 45 CFR 46.102(e)(1).

Research Involving Human Subjects That DOES NOT Require IRB Approval

Some projects will involve human subjects as participants but do not require IRB approval. For example:

- Journalism/Documentary/Artistic Activities: Investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism; writing a stage or screen play, poetry, musical, photo display, etc. based on the collected data.

- Oral History or Case Study**:** The project is limited to oral history activities or investigations into an event. Data collected can come from open-ended or one-on-one interviews, but the interviews only document that specific historical event or the experiences of individuals related to an event, without the intent to draw conclusions or generalize findings. These interviews can be with more than one person.

- Existing Data**:** Gathering or analyzing data that have already been collected by someone else (i.e., educational data, census data). These data are publically available and have no identifiers included (e.g., names, addresses, emails, phone numbers, etc.; any information that could specifically identify a person).

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Informed Consent Process

Obtaining informed consent from human research participants fulfills the ethical requirements of 'respect for person' as noted in the *Belmont Report*. Federal regulations require researchers to obtain legally effective informed consent from the subject or the subject's legally authorized representative. Essentially there are two parts to informed consent: 1) provide information to prospective subjects; and 2) documentation that the process took place and record of the subject's agreement to take part in the study.

Several major changes were made to the general requirements for informed consent in the revised Common Rule. The intent of these changes is to promote prospective human research participants' autonomy. One new standard is that both the consent form and consent process, should provide human research participants with the information needed to make an informed decision about whether to participate. The emphasis is on presenting information that a "reasonable person" would want to have in order to make an informed decision about whether to participate, providing opportunity to discuss, and ensuring subject legally authorized representative comprehension. Additionally, the information must be presented in sufficient detail and organized and presented is a manner that facilitates an understanding of why one might, or might not, want to participate. Consent should be provided in a language that subjects understand. In some cases, oral consent without documentation may be approved by the IRB. The regulation does allow the exchange of consent information to take place face-to-face or by mail, phone, internet/online, fax, or video. Electronic format for consent and signatures is also allowed.

45 CFR 46.116 does not apply to studies that met the criteria for exemption and were deemed exempt by the IRB. However, while research is exempt from federal regulations is it still research with human subjects and therefore, the ethical principles as outlines in the *Belmont Report* still apply. Exempt protocols are still required to obtain informed consent from subjects and should be provided in a language that subject understand. Under the revised Common Rule, some exempt research requires a limited IRB review.

As noted in regulation 46.116(b), nine basic elements must be listed on the informed consent. Depending on nature of research and risks involved, there may be additional required elements, as noted in 46.116(c).

Subjects may not be asked to waive or even appear to waive any of their legal rights. Additionally, they may not be asked to release a researcher, sponsor, or institution from liability for negligence.

The IRB must ensure that appropriate safeguards are in place to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence (vulnerable populations).

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Vulnerable populations include children (under 18 years old), prisoners, individuals with impaired decision-making capacity, pregnant woman, or economically or educationally disadvantage persons. Additional safeguards for three groups are provided in regulations Subpart B, C, and D.

The IRB is allowed, by federal regulation 46.116(f), to authorize researchers to modify the consent process or to provide no information at all. Waiver or alteration of any or all elements of consent can only be authorized if these five criteria are met.

1. Research involves no more than minimal risk to subjects.

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

3. If the research involves using identifiable private information or indefinable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

4. Waiver or alteration will not adversely affect the rights and welfare of the subjects.

5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Additionally, under 46.117(g), the IRB may also approve a research study when the investigator will obtain information or biospecimens for purposes of screening, recruiting, or determining eligibility for the study without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative.

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Documentation of Informed Consent

When documentation of informed consent is required, these are the two allowable methods:

1. The subject or the subject's legally authorized representative signs the consent form, either by hand or electronically, containing all the required elements of consent and any additional information necessary to provide complete disclosure. The person who signed the consent form is given a copy as a reference and reminder of the information conveyed.

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2. Consent is done orally, in language understandable to the subject, and is documented by an impartial witness. This process uses two documents: (1) a short form written consent document stating that the required elements of consent have been presented orally to the subject or the subject's legally authorized representative, and (2) a written, IRB-approved summary of what will be said to the subject or the subject's representative. The subject signs the short form. The witness signs both forms. The person actually obtaining consent signs the summary. Copies of the short form and the summary are given to the subject.

   Note: English-speaking subjects who have low literacy (nonreaders) can "make their mark" on the informed consent document, as long as it is consistent with applicable state or local laws.

Waivers of documentation are not waivers of the consent process itself. The IRB may waive documentation of informed consent per 46.117(c)(1) under three circumstances:

1. The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research, and the consent document is the only record linking the subject with the research. When the requirement for documentation is waived, the IRB may require the researcher to offer the subjects information about the study in writing.

2. Study participation presents minimal risk of harm to the subject and the research involves no procedures requiring consent outside the context of participation in a research study.

3. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Questions about a research activity can be directed to the Office of Institutional Effectiveness and Research at (928) 344-7620 or IERG@azwestern.edu.