# Institutional Review Board
# Policies and Procedures Manual for Faculty, Staff, and Student Researchers

Office of Research and Economic Development
University of Wyoming

Updated 2021

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# Contents

# Section 1: Introduction

## 1.1 Purpose and Scope of Manual

The University of Wyoming (UW) Institutional Review Board (IRB) documents its written procedures according to Federal Protection of Human Subjects Regulations 45 C.F.R 46.

All research projects involving human participants conducted by faculty, staff, and students associated with UW must receive IRB approval prior to initiating the research. For more information about the United States Department of Health and Human Services (HHS) policy for the Protection of Human Subjects see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html . For more information about basic ethical questions in the conduct of research, consult The Belmont Report at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html .

The procedures set forth in this manual are provided so that researchers may better understand the reasons for ethical review of research with human participants, the primary ethical principles that govern such research, and the statutory basis of these principles. This document also contains information that should be sufficient to allow researchers to submit an acceptable research proposal for IRB review. The description of information that must be submitted and helpful templates may be accessed the Research Office webpage.

## 1.2 Federal Wide Assurance

UW has made the following assertions in its Federal Wide Assurance (FWA) for the Protection of Human Subjects:

1. UW assures that all of its activities related to human subject research, *regardless of funding source*, will be guided by the ethical principles in The Belmont Report.

2. UW assures that all of its activities related to federally-conducted or federally-supported human subject research will comply with the Terms of Assurance for Protection of Human Subjects for Institutions within the United States.

3. UW elects to apply 45 C.F.R. 46 and all of its subparts (A, B, C, D, E) to federally-supported human subjects research.
    a. Subpart A—Basic HHS Policy for Protection of Human Research Subjects (The Common Rule)
    b. Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
    c. Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
    d. Subpart D—Additional Protections for Children Involved as Subjects in Research
    e. Subpart E—Registration of Institutional Review Boards

## 1.3 Office for Human Research Protections

The Office for Human Research Protections (OHRP) implements a program of compliance oversight for HHS regulations for the protection of human subjects. OHRP protects those who volunteer to participate in research that is conducted or supported by agencies of HHS.

OHRP evaluates all written substantive allegations or indications of non-compliance with HHS regulations. The relevant institution is notified of the allegation and is asked to investigate the basis for the complaint. The institution then provides a written report of their investigation, along with relevant institutional IRB and research records, to OHRP which determines what, if any, regulatory action needs to be taken.

OHRP provides guidance to IRB members and staff as well as to scientists and research administrators on the complex ethical and regulatory issues relating to human subject protections in biomedical and behavioral research. Additionally, OHRP provides quality improvement consultation and research ethics training to domestic and foreign institutions involved in human subjects research to help ensure that recognized ethical protections are afforded to persons participating in research conducted in countries outside the United States. OHRP prepares policies and guidance documents as well as interpretations thereof on human subject protections and disseminates this information to the research community. In addition, every institution engaged in human subjects research conducted or supported by HHS must obtain an assurance of compliance approved by OHRP.

For more information on OHRP, please visit: http://www.hhs.gov/ohrp/.

## 1.4 Applicable State of Wyoming Laws

Wyoming's child protection laws contain a provision that requires the reporting of child abuse or neglect (W.S. § 14-3-205). The following information outlines what actions or inactions constitute child abuse or neglect, who is required to report, and where the report must be made.

**Child abuse and neglect are defined in the following manner:**

1. **Physical abuse:** deliberate physical injuries or physical injuries resulting from indifference, negligence, or improper supervision. Also included are dangerous acts which could cause a serious risk to a child's physical or mental health, such as severely shaking a child five years of age or younger, choking or gagging a child, electric shock or slapping, or using physical discipline on an infant.

2. **Sexual abuse:** any sexual exploitation of a child (molestation, masturbation, incest, oral-genital contact, sodomy, etc.).

3. **Nutritional deprivation:** underfeeding or failure to feed.

4. **Medical care neglect:** refusal or failure to obtain and maintain treatment services necessary for the child's continued health, including failure to give prescribed medication or withholding medical treatment from a child with serious, acute disease or injury.

5. **Intentional drugging or poisoning.**

6. **Psychological or emotional abuse:** including psychological terrorism (e.g., locking a child in a dark cellar or threats of mutilation, etc.).

7. **Negligent treatment:** failure to provide adequate food, clothing, shelter, education, health care, or supervision.

Under Wyoming law, a child is defined as "any person under the age of eighteen (18)."

**Persons Required to Report**

The law requires *any* person who knows or has reasonable cause to believe or suspect that a child has been abused or neglected, or who observes any child being subjected to conditions that would reasonably result in abuse or neglect, to report. Additionally, the University of Wyoming via University Regulation 4-3 and the *Sexual Misconduct Policies and Procedures Document for Faculty, Staff and Students* identifies all employees as mandatory reporters who are obligated to provide any information regarding sexual misconduct involving one or more students to Equal Opportunity Report and Response and/or the Dean of Students Office.

Privileged communications between doctor and patient and psychologist and patient are not exempt from the reporting requirements. Mandated professional reporters who fail to report suspected cases of abuse or neglect may be referred to the Attorney General or the relevant licensing board for appropriate action.

In addition, if a person reporting abuse or neglect is a member of the staff of a medical or other public or private institution, school, facility, or agency, he or she must notify the person in charge as soon as possible. The person in charge is required to make a report.

**Where to report**

A report of suspected child abuse or neglect must be made immediately by telephone. In the Laramie area, all cases of suspected abuse or neglect can be reported to the Laramie Field Office of the Department of Family Services at (307) 745-7324 (Monday-Friday between 8 a.m. and 5 p.m.). After 5 p.m., all calls to the Laramie Field Office will automatically be referred to the local police department. In other areas of the state, reports may be made to any local county field office or to any local law enforcement agency.

## 1.5 Administration of Research Ethics at the University of Wyoming

The Office of Research and Economic Development (Research Office; ORED) is responsible for the functioning of the IRB. If you have questions about the rules or procedures for ethical review

or the applicability of the information in this manual to your proposal, contact:

**Office of Research and Economic Development**
**Attn: Research Compliance Coordinator**
Dept. 3355, 1000 University Avenue
**Old Main 308**

Laramie, Wyoming 82071
Phone: (307) 766-5322
Fax: (307) 766-2608
e-mail: irb@uwyo.edu
http://www.uwyo.edu/research/

### 1.6 Designation of the Institutional Review Board

UW has one IRB responsible for conducting initial and continuing reviews and providing oversight for all human subjects research activities conducted by faculty, staff, and students regardless of the source of funding. The IRB will conduct initial and continuing reviews of research activities according to Section 6 and Section 7 of this manual. All review procedures will meet or exceed the requirements set forth in the regulations.

### 1.7 The Institutional Review Board

The IRB is composed of a minimum of five regular voting members. The IRB may use, as necessary, consultants to provide expertise in discussing IRBs. The Common Rule and UW's FWA require that the IRB have at least five regular voting members, including the Chair. At least one member on the IRB must have primarily scientific concerns, one must have primarily nonscientific concerns, and one must be unaffiliated with the University (community or lay member).

The IRB membership reflects expertise in both science and non-science fields. Scientific members of the IRB generally will have had experience in research involving human subjects. Nonscientific members will have professional expertise in a nonscientific area, such as law, ethics, or human or patient rights. In addition to faculty members representing different disciplines, the IRB currently has at least one community member. The community member is knowledgeable about the local community and willing to discuss issues and research from that perspective. The community member is chosen from Laramie and its vicinity. Neither he/she nor his/her immediate families may have an affiliation with UW. Candidates for this position include but are not limited to: clergy, lawyers, teachers, medical personnel, and businesspersons.

The Office of Research Integrity & Compliance and the IRB Chair will annually review IRB membership. This review includes an examination of attendance, specialty, expertise, education, affiliation, and diversity. Thus, the membership and composition of the IRB are periodically reviewed and adjusted to meet regulatory and organizational requirements.

The Office of Research Integrity & Compliance submits membership recommendations to the Vice President for Research and Economic Development, who formally appoints IRB members

and the IRB Chair. The Office of Research Integrity & Compliance considers the following factors in the selection process: experience, expertise, and community involvement.

# Section 2: The Institutional Review Board

## 2.1 General IRB Policies

The governing regulations for UW's IRB are 45 C.F.R Part 46 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. UW's Federal Wide Assurance (# 00000186) with OHRP specifies that the institution will follow 45 C.F.R. 46 for all federally-supported human subject research. However, all research at the University of Wyoming will adhere to these guidelines regardless of funding.

## 2.2 Functions and Responsibilities of the IRB

1. Safeguarding the rights and welfare of subjects at risk in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds, is primarily the responsibility of the institution. Therefore, no research activity involving human subjects may be undertaken by any faculty, staff, employee, or student at UW unless the IRB has reviewed and approved the research prior to commencing the research activity.

2. The review will determine whether the subjects will be placed at risk and if risk is involved, that:

    a. Risks to participants are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose participants to risk.

    b. Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

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

    d. Selection of participants is equitable.

    e. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by the regulations.

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

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

    h. When appropriate, there are adequate provisions to protect the privacy of participants.

i. When appropriate, there are adequate provisions to maintain the confidentiality of data.

j. When some or all of the 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 participants.

k. The conduct of the activity will be reviewed at intervals determined by the IRB, but not less than annually.

3. The determination of when a research subject is at risk is a matter of common sense and sound professional judgment and relates to the circumstances of the research activity in question.

    a. The IRB will carefully weigh the relative risks and benefits of the research procedures.

    b. Research activities designed to yield fruitful results for the benefit of individual subjects or society, in general, may incur risks to the subjects provided such risks are outweighed by the benefit to be derived from activities.

    c. The degree of risk involved in any activity should never exceed the humanitarian importance of the problems to be solved by that activity. Likewise, compensation to volunteers should never be such as to constitute an undue inducement to the subject.

    d. There is a wide range of medical, social, and behavioral research projects and activities in which no immediate physical risk to the subject is involved (e.g., those utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, stored data, or existing tissues, body fluids, and other materials obtained from human subjects). However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy.

4. Any activity involving the use of radiation, lasers, biohazards, or otherwise prohibited or restricted material, device, or process must have approval from the appropriate UW office before the IRB can issue approval.

5. Compliance with this policy or the procedures set forth herein will in no way render inapplicable pertinent federal laws, laws of the State of Wyoming, local laws, and/or any UW Regulation which may bear upon the proposed activity.

## 2.3 Confidentiality of the Review Process

During the process of an initial or continuing review of an activity, the material provided to the IRB shall be considered privileged information, and the IRB shall assure the confidentiality of the data contained therein, to the extent allowed by law. All members of the IRB, any staff in attendance at a meeting, and any outside consultants will be required to sign a nondisclosure agreement.

## 2.4 Research Determinations

Determinations about whether an activity represents human subjects research are based on the definition of "research" and "human subjects" as defined by the federal regulations.

The regulatory definition of "research" is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. To generalize is to derive general conclusions from particulars. Generalizable knowledge is the goal of most basic research. Even research about the most narrowly defined topic, such as an individual case study or the study of an isolated community, may be intended to contribute to a body of knowledge (45 C.F.R. 46.102).

A "human subject" is a living individual about whom an investigator (whether professional or student) conducting research:

(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 data are gathered (for example, drawing blood) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the researcher and the subject.

Researchers seeking guidance regarding whether an activity is human subjects research should consult with the UW Office of Research Integrity & Compliance.

## 2.5 Suspension & Termination Policy

Suspension means a temporary withdrawal of approval of some or all research, or a permanent withdrawal of approval of some research activities. A suspended protocol requires continuing review. Termination means a permanent withdrawal of approval of all research activities. A terminated protocol does not require continuing review. The IRB has the authority to suspend or terminate approval of a research protocol that has been determined not to be conducted according to UW's human subjects research policies and procedures, or in cases where there has been unexpected serious harm to participants. See Sections 7.4 and 7.5 for details on the IRB's monitoring program.

While the IRB Chair or the Office of Research & Economic Development has the right to suspend a study that poses an immediate risk to participants, generally, suspensions will be determined by a vote of the full IRB. Suspensions or terminations ordered by the IRB Chair or

ORED must be placed on the next IRB meeting agenda for consideration of continuation or reversal of the suspension. Should a study be suspended or terminated so that interventions or interactions with current participants will stop or change; the IRB will communicate to the principal investigator (PI) that the PI must inform current participants as soon as reasonably possible that the study has been suspended or terminated along with the reasons for such suspension or termination. Before suspending or terminating research, the individual or the IRB ordering the suspension or termination will consider whether the action might adversely affect the rights or welfare of current participants. In such cases, the IRB will require explicit conditions for participant withdrawal. The IRB will consider whether follow-up of participants for safety reasons is necessary and if so, the IRB will require that the PI notify participants and require the PI to continue to report unanticipated problems. Such information must be formally submitted to the IRB for their review and approval.

The report of the IRB's suspension or termination of approval will be written by IRB staff for review and approval by the full IRB. The IRB Chair and Office of Research Integrity & Compliance will sign the written report. Information to be included in the written report include the level of study risk, category of review, a summary of the events, previous non-compliance history for the PI, the co-PI, and the faculty sponsor, how the event was reported to the IRB, steps (if any) that the PI has taken to rectify the situation, reasons for IRB suspension or termination, findings of the IRB, actions taken by the IRB, and future plans. This report will be distributed according to the reporting policy detailed below.

## 2.6 Reporting Policy

The IRB enacts the following reporting policy when one or more of the following occurs:

1. The IRB determines an unanticipated problem involves risks to participants or others;
2. The IRB makes a determination of serious or continuing non-compliance with the federal regulations, UW policies and procedures, or IRB determinations; or
3. The IRB, the IRB Chair, or the Office of Research Integrity & Compliance suspends or terminates a previously approved research protocol.

IRB staff will prepare a report. Reports will be reviewed and approved by the IRB Chair, who will also sign the report.

The report is promptly delivered to the PI and copied to:

1. Vice President for Research and Economic Development
2. Office of Research Integrity & Compliance
3. Dean of PI's College or School
4. Chairman or department head of PI's department
5. IRB Chair
6. Researcher project file
7. Faculty advisor (if applicable)
8. Any federal department that has oversight due to funding, conduct, or assurance, including but not limited to, OHRP, National Institutes of Health (NIH), Food and Drug Administration (FDA), Department of Education, etc.

9. The complainant (when necessary)

Unanticipated problems are appropriately reported to the IRB and are reflected in the monthly IRB minutes. Consequences for non-compliance are outlined in Section 6.9.

## 2.7 Meetings

The IRB generally holds one regularly scheduled meeting per month during the academic year, at a time and place to be pre-determined and posted on the web site.

Full board research protocols (all protocols other than exempt or expedited) will be reviewed only at convened meetings of the IRB at which quorum has been established and includes at least one nonscientific member. To be approved, a protocol must receive a majority of votes of members present at the meeting. If a quorum fails during a meeting due to a lack of a majority of IRB members being present, an absence of a nonscientific member, or a conflicting interest (see Section 3.7), the IRB will not take further actions or votes until the quorum is restored.

Prior to each full board meeting, IRB staff or the IRB pre-reviewer will review the agenda of protocols (full board) and will assign a primary and a secondary reviewer knowledgeable about or experienced in working with the proposed research content area. IRB staff ensures that either the primary or secondary reviewer is present at the meeting, available by teleconference during the convened meeting, or submits their comments prior to the meeting. Should such experience within the IRB membership not be available, relevant consultation will be obtained.

## 2.8 IRB Minutes

Minutes of each IRB are recorded in writing. Minutes are distributed monthly to all IRB members and a vote for approval of those minutes takes place at the next convened meeting.

Minutes include the following:

1. Attendance at the meeting for each action;

2. A list of all full board proposals with the respective information:

    a. Actions taken and decisions made by the IRB
        i. Approved
        ii. Approved with explicit conditions or modifications
        iii. Tabled
        iv. Disapproved
    b. The number of members voting for, against, and abstaining, and the names of IRB members who were absent from the vote;

c. Basis for requiring modifications to the research proposal or consent documents or for disapproving the research proposals;

d. A summary of controversial issues and their resolution;

e. A summary of issues pertinent to the protocol;

f. Minutes will also document, by referencing the IRB protocol file, determinations required by the regulations along with project-specific findings that justify each determination. These determinations include those for waiver or alteration of consent, waiver of consent documentation, research involving children, prisoners, pregnant women, fetuses, and neonates;

g. The minutes will also document, by referencing the IRB protocol file, justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in the informed consent document, and for initial and continuing review, the approval period; and

h. The names of IRB members who absented themselves from the meeting due to conflict of interest.

3. A list of all actions that were taken administratively during the previous month, including proposals approved under the expedited review procedure and proposals approved as exempt.

## 2.9 Approval Timeframes

Expedited and full-board proposals are generally approved for a one-year period but may be shorter. The protocol expiration date for expedited and full board protocols may be extended through approval of the Annual Review Form **prior** to the expiration of the project.

Exempt protocols are approved for a 3-year period and do not require an Annual Review Form. Exempt protocol expiration dates may be extended by completing the Annual Review form **prior** to the expiration of the project.

It is the responsibility of the PI to maintain an active protocol and submit the proper forms **prior** to the expiration of the project.

The expiration date is calculated from the date of review by the convened IRB, Chair, or designated reviewer and the date the protocol was approved or approved with stipulations. Continuing review approval periods are one year from the date of formal re-approval unless otherwise necessitated (see Section 7.4).

Proposals may be submitted for review at any time. Processing of **complete** applications for exempt status and expedited review is estimated to take 10-15 business days. Processing time may increase if the application is incomplete, or the pre-reviewer or staff must seek additional information to complete the determination. Applications for full board review must be

submitted three weeks in advance of the scheduled IRB meeting. Even if proposals are received by the proposal due date, they may be deferred to the next scheduled meeting due to application volume. All attempts are made to limit application deferrals. Proposals received after the due date will be deferred to the next scheduled meeting.

### 2.10 Expiration of Research

PIs desiring to continue research beyond the study approval period must submit an annual review two months prior to expiration (see Section 7). PIs do not need to file an annual review if the PIs are only analyzing non-identifiable information. Upon expiration, all research and research-related activities must immediately cease, including enrollment, recruitment, interventions and interactions on current participants, and data analysis of identifiable information. When a researcher does not provide annual review information to the IRB or the IRB has not approved a protocol by the expiration date, interventions and interactions on current participants may continue ONLY when the IRB finds an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants. If the PI does not request a continuation prior to protocol expiration, the study is inactive, and research cannot continue.

### 2.11 Protocol Files

Protocol files are maintained in the Office of Research Integrity & Compliance for a minimum of three years following project closeout or longer as otherwise required. Each electronic file contains the following:

1. A copy of the complete research proposal or exemption request.
2. Any correspondence with the IRB related to the research protocol.
3. Completed designated reviewer determinations, justifications, and findings of the IRB. For an initial review of expedites, include the specific permissible category. For the initial review of exempt studies, the specific category of exemption is documented.
4. Official notification of IRB action.
5. Any changes made to the original research proposal, as requested by the IRB.
6. Applications for continuing review and all correspondence and records related to that review.
7. Applications to amend a protocol and all correspondence and records related to that review.
8. Reports of unanticipated problems and related IRB review and action.
9. Any IRB action regarding non-compliance and related correspondence.

10. Reports of injuries to participants.

11. Statements of significant new findings provided to participants.

## 2.12 IRB Complaints, Feedback, Concerns, and Issues

All complaints, feedback, concerns, or related issues should be directed to the Office of Research Integrity & Compliance and/or the Office of Research & Economic Development:

**Office of Research and Economic Development**
Dept. 3355, 1000 University Avenue
Old Main Room 308
Laramie, Wyoming 82071
Phone: (307) 766-5322
Fax: (307) 766-2608

Any allegations of non-compliance will be directed to the Office of Research Integrity & Compliance and adjudicated accordingly. The Office of Research Integrity & Compliance can direct the IRB to review the complaint or meet with the involved parties to reach a satisfactory resolution. Complaints will be formally documented, with resolutions noted as formal actions in the protocol files. PIs may bring forward to the Office of Research Integrity & Compliance concerns or recommendations regarding the human research protection program. All complaints and/or allegations of non-compliance are reported to the IRB via the monthly meeting agenda or sooner as necessary. This formal communication informs the Board of how the issue is being managed by the Office of Research Integrity & Compliance and/or researcher to seek a resolution and serves to keep the Board informed of potential escalations in risk that may warrant formal IRB review/involvement (see step 6 below).

Process:

1. Office of Research Integrity & Compliance reviews complaint, feedback, concern, or issue ("event")
2. Office of Research Integrity & Compliance consults with the IRB Chair and the Office of General Counsel as necessary
3. Researcher may be allowed to investigate the event, with input and direction from the Office of Research Integrity & Compliance
4. If necessary, the Office of Research Integrity & Compliance can temporarily suspend the research while the investigation is on-going
5. If the researcher cannot resolve, the Office of Research Integrity & Compliance will investigate
6. If determined there is additional risk due to the event, the Office of Research Integrity & Compliance will direct the IRB to review the event
7. If the IRB agrees there is additional risk or non-compliance, the Office of Research Integrity & Compliance will send a report to the Office of Human Research Protections (OHRP)

# Section 3: General Research Procedures

## 3.1 Extramural Research

The IRB requires all off-campus research to have documented approval on file. For example, extramural sites may include school districts, daycare centers, nursing homes, private clinics, shelters, treatment facilities, churches, or businesses. In the event the extramural site does not have an IRB, the PI should request approval from the institutional entity or official with the necessary authority to approve research. The PI should determine and follow all host sites' policies and procedures for human subjects research and should submit approval letters from these institutions or agencies. The letter should grant the PI permission to use the agency's facilities or resources and should indicate knowledge of the study. If these letters are not available at the time of IRB review, approval will be contingent upon their receipt.

## 3.2 Collaborating

If the PI is collaborating with an individual from another higher education institution, the PI may be able to only submit one IRB to one of the institutions. OHRP permits institutions to enter into joint review arrangements, rely upon the review of another IRB, or make similar arrangements to avoid duplication of efforts. For more information on this, please contact the Office of Research at: (307) 766-5322.

## 3.3 Scientific Review

The IRB is responsible for evaluating the scientific or scholarly validity of the research (using its own expertise) so that the IRB can determine whether the research uses procedures consistent with sound research design, whether the research can answer its proposed question, whether the knowledge obtained will outweigh any risk, and whether the knowledge is generalizable. However, it is not the charge of the IRB to comment upon the value of the research proposal relative to other research proposals.

## 3.4 Confidentiality

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 in ways that are inconsistent with the understanding of the original disclosure without permission. Whenever researchers promise participants that their responses and data will be maintained in confidence, all research project members (researchers, directors, transcribers, students, staff, etc.) are required to prevent accidental and intentional breaches of confidentiality. In most cases, confidentiality can be assured by following fairly simple practices (e.g., substituting codes for identifiers, removing survey cover sheets that contain names and addresses, limiting access to identified data, and/or storing research records in locked cabinets). However, all measures used to assure confidentiality of data must be understood by all research staff before the research is initiated and must be followed once research is initiated. Confidentiality procedures must be described in research proposals that come before the IRB. Researchers should recognize that the assurance of confidentiality includes keeping the identity of participants confidential.

Researchers proposing projects that will address sensitive, stigmatizing, or illegal topics must explicitly outline the steps they will take to assure any information linking participants to the study is maintained in confidence whenever legally possible (for possible exceptions, see Section 1.4). The requirement of signed consent forms is often waived in sensitive studies if the consent document is the only written record linking participants to the project and a breach of confidentiality presents the principal risk of harm anticipated in that research.

If the research proposal includes the use of a **focus group** (or some similar method), confidentiality cannot be guaranteed. The following language should be included in the informed consent form if focus groups are being utilized: "Although measures have been implemented by the researchers to ensure participant confidentiality, the researchers cannot guarantee what the other individuals in the focus group may do following the meeting."

If there is any chance that data or participants' identities might be sought by law enforcement agencies or subpoenaed by a court, a grant of confidentiality should be obtained. Under federal law (Public Health Act § 301(d)), researchers, prior to the initiation of the research project, may request grants of confidentiality to protect against forced data and participant identity disclosures. These grants provide protection for specific research projects where protection is judged necessary to achieve the research objectives.

If you believe your research project may require a grant of confidentiality, please contact the Office of Research Integrity & Compliance.

For more information on Certificates of Confidentiality and their limitations, see: https://grants.nih.gov/policy/humansubjects/coc.htm.

For OHRP guidance on Certificates of Confidentiality, see: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/certificates-of-confidentiality/index.html.

### 3.5 Privacy

Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. When participants voluntarily permit researchers access to themselves, they exercise their right to privacy. Privacy is the right to authorize or decline access. It should not depend upon the participant's ability to exert control over another's access. An incapacitated adult or infant is unable to control access to their privacy but still has a right to privacy. The informed consent process should disclose any risks to privacy and how researchers specifically plan to protect privacy. The IRB reviews proposals to ensure adequate privacy protections and prevent unnecessary invasions of privacy. Privacy is best protected by making sure the research is designed so that participants will be comfortable with the way researchers interact or intervene with them. Researchers must maintain the confidentiality of all private and identifiable information unless disclosure is mandated according to federal, state, or local law.

Researchers are required to follow the privacy protections outlined in the required Collaborative Institutional Training Initiative (CITI) Human Subjects Research course.

### 3.6 Protecting Participants' Health Information

Even in those circumstances where an exemption to the signed consent requirement applies, a signed authorization from the research participant, permitting the use and disclosure of his or her Protected Health Information (PHI), will still be required, UNLESS specifically waived by the IRB (see Section 5.5).

### 3.7 Conflict of Interest

All researchers and IRB members are required to disclose any conflicts of interest according to the conflict of interest/conflict of commitment policy found on the University of Wyoming Office of General Counsel webpage.

Should an IRB member declare involvement in any way in a research protocol under review by the IRB, or state a conflict of interest with the research protocol, then the member is excluded from discussion and voting except to provide information requested by the IRB, must leave the meeting room for discussion and voting, and is not counted towards quorum.

### 3.8 Record Retention Requirements

The IRB collects, prepares, and maintains adequate documentation of the following types of IRB activities. All records will be accessible for inspection and copying by authorized representatives of OHRP, HHS, sponsors, university officials, and internal auditors at reasonable times and in a reasonable manner.

1. **Research Protocol Files:**

   Per 45 C.F.R. 46.115(a) and (b) pertinent information on all submitted research protocol files is kept electronically in the Research Office for three years after study closure (see Section 2.10 for details on information kept in the protocol files). After that time, they may be destroyed. Per 45 C.F.R. 46.115(a)(2), minutes of each IRB meeting are recorded in writing or electronically (see Section 2.7 for details of information recorded in minutes). Minutes are kept for at least seven years after the date of the IRB meeting in the Research Office.

2. **Membership Files and IRB Roster:**

   The IRB roster includes the following information (see 45.CFR.46.107):

   a. Full Name
   b. Earned Degrees (e.g., Ph.D., PharmD, JD, etc.)
   c. Scientific status (scientific or non-scientific)

d. Representative capacity
e. Indications of experience (i.e., board certifications and licenses sufficient to describe each members' chief anticipated contributions to IRB deliberations)
f. Relationship to the organization (employee or non-employee)
g. Affiliation status
h. Position on IRB (Chair; member; voting; non-voting; ex-officio)
i. IRB training documentation

NOTE: Changes in committee membership will be reported to OHRP as required.

3. **Records required of and related to the PI of the study protocol:**

At a minimum, the PI or project director shall maintain, in a designated location, the signed informed consent/assent forms and the written research summary relating to research which is conducted for at least three years after completion of the research. The PI may be required to keep certain records longer depending on whether additional regulations apply. For further information, please see the Researcher Data Retention Requirements available on the Office of Research Integrity & Compliance webpage. The signed informed consent/assent forms and the written research summary must be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

Should a PI or project director depart from UW prior to the completion of the research protocol, the PI is responsible for initiating mutually satisfactory arrangements with their department and the Research Office as to the disposition of signed consent forms. Other than minutes, IRB records not related to a specific research activity (i.e., records that are not relevant to a specific protocol file) will be kept for three years and then destroyed.

## 3.9 Guidelines on Compensation for Research Subjects

The guidelines outlined below are meant to assist researchers in determining a reasonable amount of compensation that can be given to research participants and also place some boundaries on what is and is not "reasonable." The reasonableness of a particular sum of money or other form of payment should be based upon the time involved, the inconvenience to the subject, and reimbursement for expenses incurred while participating. The amount should not be so large as to constitute a form of undue influence or coercion. During the initial review of a research protocol, the IRB is required to review both the amount of compensation proposed and the method and timing of disbursement to assure that neither are coercive or present undue influence. The following are some additional guidelines:

1. Any compensation generally should not be contingent upon the subject completing the study, but should accrue as the study progresses.

2. Compensation given as a "bonus" or incentive for completing the study is acceptable to the IRB, providing that the amount is not coercive. The IRB is responsible for

determining if the incentive amount is so large as to be coercive or represent undue influence.

3. The amount of compensation should be clearly set forth in the research proposal AND the informed consent document.

## 3.10 Guidelines for Research Advertisement Content

The IRB must review and approve all materials that will be used to recruit subjects to a specific research study. Generally, recruitment materials should be limited to information that a potential subject would need to determine if they are eligible and interested in participating. More specifically, the ads *should include information* such as:

1. Name and address of the research facility;

2. Focus of the research;

3. Purpose of the research with reference to the fact that the study is investigational;

4. Summary of criteria for eligibility to participate;

5. Time and other commitments that will be required of the subject;

6. Location of the study; and

7. The office to contact for further information.

**THE ADS SHOULD NOT:**

1. Contain explicit or implicit claims of safety, efficacy, equivalency, or superiority to approved procedures or treatments;

2. Emphasize the amount of reimbursement that subjects will receive. The ads *may* state that reimbursement for time, travel, etc. will be given;

3. Promise a favorable outcome or benefits;

4. Include exculpatory language;

5. Promise "free treatment" when the intent was only to say participants would not be charged for taking part in the investigation; or

6. Include a sign-up sheet.

To avoid multiple requests for IRB review and approval, researchers should specify in their original request all recruitment materials that are anticipated.

### 3.11 Equitable Subject Recruitment

The IRB will only approve studies demonstrating equitable subject recruitment, taking into account the purposes of the research and the setting in which it will be conducted. The IRB evaluates all research applications to verify that researchers have demonstrated equitable selection and recruitment of all research subjects and have made every effort to ensure diversity of subject selection. In particular, the IRB evaluates any special problems that may occur with proposed research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively-impaired individuals, and economically or educationally disadvantaged persons. The IRB ensures that proposed sampling efforts do not favor some classes of participants solely due to ease of availability, compromised positions, or manipulability. IRB reviewers also require researchers to make every effort to include women and members of minority groups, if appropriate to the research purpose.

### 3.12 Best Practice Guidelines for Research Involving Exercise Training/Interventions and/or Exercise Stress Testing

1. The UW Health History Screening Questionnaire (UWHHSQ; posted on the Research Office webpage) will serve as the standard and required document to be utilized for pre-participation risk factor stratification prior to any research involving exercise training/intervention or exercise testing (submaximal or maximal), with or without aerobic/anaerobic fitness measurement in humans. Use of the UWHHSQ is required and intended to be a *guiding document* to facilitate comprehensive risk stratification and health appraisal in subjects prior to research participation, but should not replace expertise/experience of researchers, *exercise professionals*, and clinicians in appraising and stratifying research participants on an individual (case by case) basis. A qualified individual must review the completed UWHHSQ for risk stratification.

2. It is *recommended* that all exercise-related research (testing and training/interventions) of moderate or high-risk subjects include a collaborating medical director (defined as MD, DO, PA, NP, FNP with licensure in the State of Wyoming) who is knowledgeable of the testing protocols, measures, population demographics/characteristics, and qualifications of the research researchers and staff. If a collaborating medical director is utilized, a letter of support indicating his/her participation is required.

3. *Exercise testing* is defined as a physical stimulus applied to a human research participant (subject) eliciting physiological changes *typical* of exercise, for example: increased heart rate and blood pressure, increased blood flow (circulation) to active regions, shunting of blood from inactive regions, accelerated respiration/ventilation which may or may not influence blood gas concentrations, and transient alteration in circulating biomarker, metabolite, or hormone concentrations typical of an exercise stimulus. *Exercise testing* may or may not include the measurement of aerobic fitness (oxygen consumption; $VO_2$) by use of direct or indirect calorimetry or anaerobic fitness and may be at submaximal or maximal intensity levels.

4. A qualified physician (MD or DO) is defined as one who is board certified and licensed to practice within the state of Wyoming (or the relevant jurisdiction if research is conducted outside of WY) and who possesses the knowledge, experience, and capability to supervise exercise tests on the appropriate age group. Inherent within this is the ability and competency to read/interpret electrocardiograms (rhythm strips or multi-lead ECG's) and monitor/assesses signs/symptoms and hemodynamic responses/changes before, during, and after exercise tests. This is commonly, but not always, indicated by privilege(s) to supervise exercise tests in clinical settings, which might include but are not restricted to public/private clinics, hospitals, or rehabilitation facilities. Physicians must provide current documentation stating their experience/qualifications to supervise exercise testing to the IRB (accompanying the IRB research application) and to the PI prior to initiation of the research. The IRB will review the documentation to assess acceptable experience/qualifications to supervise exercise tests. The physician must be able to provide updates regarding qualifications as requested by the IRB or PI.

5. The qualified "***exercise professional***" is defined as an Advanced Cardiac Life Support (ACLS) certified exercise physiologist or health professional or an American College of Sports Medicine certified *Exercise Specialist*® who is also ACLS certified. Human research studies involving exercise may only be conducted under the supervision of a qualified "***exercise professional***". The ***exercise professional*** need not be the Principal Researcher (PI) but must be part of the research/investigative team (e.g., contracted, employee, consultant, hospital/rehabilitation employee for off-site research, clinician, etc.) participating in the exercise-related aspects of the research. Risk stratification and health appraisal are the responsibility of the ***exercise professional*** according to the criteria established within this document but often times may involve the expert judgment of a qualified physician or collaborating medical director. This process of risk stratification is intended to maximize research subject safety.

    a. ***Low-risk stratification:*** Maximal or submaximal exercise testing may be administered or directly supervised by an ***exercise professional*** for low-risk subjects determined by the UWHHSQ without medical (MD or DO) supervision;

    b. ***Moderate risk stratification:*** Submaximal exercise testing may be administered or directly supervised by an ***exercise professional*** for moderate-risk subjects as determined by the UWHHSQ without direct medical (MD or DO) supervision. Written authorization from a subject's healthcare provider for participation in such submaximal exercise testing for moderate risk subjects is *recommended* unless deemed unnecessary by a collaborating medical director or participating qualified physician;

    c. ***Moderate risk stratification:*** Maximal exercise testing may be administered or directly supervised by an ***exercise professional*** for moderate risk subjects as determined by the UWHHSQ only with direct medical (MD or DO) supervision. * Exceptions the UW IRB must approve might include situations in which a collaborating medical director authorizes participation in maximal exercise testing without direct medical (MD or DO) supervision after reviewing a

specific subject's risk/safety ratio;

* Consistent with the recently updated recommendation from the American College of Sports Medicine's, *Guidelines for Exercise Testing and Prescription*, Eighth edition (2009).

d. ***High-risk stratification:*** Maximal or submaximal exercise testing may be administered or directly supervised by an ***exercise professional*** for high-risk subjects as determined by the UWHHSQ only with direct medical (MD or DO) supervision;

*For situations in which research-related exercise testing may occur in clinical environments (e.g., hospital or clinic practice) where exercise testing practices are standard operating procedure and in which the clinical setting has existing procedures/protocols and emergency medical support personnel available for exercise testing, these supervision requirements may be reviewed, modified, and approved by the IRB on a case-by-case situational basis.*

6. ***Low risk stratification*** will be determined by the presence of all of the following:
   a. BP $\leq$ 120/80 mmHg
   b. LDL < 100 mg/dL
   c. HDL > 40 for male subjects and > 50 for female subjects
   d. Fasting Glucose $\leq$ 100 mg/dL

7. HDL greater than 60 mg/dL in male or female subjects will not discount another negative risk factor.

8. ***Moderate and High-risk stratification*** are defined according to the most recent definitions provided by the American College of Sports Medicine's *Guidelines for Exercise Testing and Prescription*. Currently, the most recent definitions are provided in the 10th Edition (2017).

9. During risk stratification, ***exercise professionals***, staff, and collaborating healthcare practitioners must be attentive to the two hallmark differentiation points between the collective *low and moderate risk* stratifications compared to the *high-risk* stratification. The two hallmark differentiation points include: a) low and moderate risk stratification is reserved for "Asymptomatic" subjects; and b) high risk stratification is for subjects with "known cardiovascular, pulmonary or metabolic disease or one or more signs and symptoms…". Along with comprehensive screening via the UWHHSQ, attention to these two points will help ensure subject safety. If doubt about stratification level exists, safety should be the preeminent concern; the more conservative stratification should be used, e.g., moderate versus low, or high versus moderate, and guidance from a qualified healthcare provider (MD, DO, PA, NP, FNP) should be sought. Researchers conducting exercise training/interventions and/or exercise testing are required to be knowledgeable of the most recent edition ($10^{th}$) of the American College of Sports Medicine's *Guidelines for Exercise Testing and Prescription* (2017).

10. Current ACLS certification is required for all ***exercise professionals*** conducting/supervising exercise testing or exercise training/interventions.

11. All investigative (research) staff are required to be certified in CPR (basic life support; BLS) with required recertification (typically every 1-2 years); each investigative unit will conduct mock emergency codes quarterly. CPR certifications are to be submitted with new IRB research applications and any request for continuation beyond the 1-year approval.

12. All exercise testing, with or without aerobic fitness ($VO_2$) measurement, will be monitored with at least a 3-lead electrocardiograph rhythm strip.

13. Emergency procedures will be posted in all areas where exercise testing and/or training will occur. Researchers/units will contact emergency personnel (fire department, EMS) and request a site visit prior to conducting any exercise testing/training research.

14. An automated emergency defibrillator (AED) will be immediately available and present during all exercise testing.

15. Individual [subject] research data collected will be available/provided to research participants upon their request unless doing so would compromise the integrity of the research study. Withholding individual data must be justified by the PI within the IRB research application and approved by the IRB. Communication of a subject's personal health information outside of the research team and university IRB or to a healthcare provider identified by the subject, may only occur following receipt of written and signed authorization from the subject indicating his/her desire to have the information sent to a specified healthcare provider. This authorization must be submitted to and retained by the PI. If necessary, a referral to a healthcare provider or the subject's personal healthcare provider for follow-up care may be made by the PI, qualified physician, or collaborating medical director if evidence warrants that such a referral is in the best interest of the subject.

16. The UW IRB will be provided with written emergency plans/procedures for each laboratory/unit.

17. Exercise training/interventions may be conducted in low, moderate, and high-risk subjects. For high risk subjects, participation in exercise training/interventions must be approved, prior to participation, by one of the following healthcare professionals: 1) the collaborating medical director qualified to assess subject risk/safety; 2) a qualified physician (see definition) able to assess subject risk/safety; or 3) a subject's personal healthcare provider (MD, DO, PA, NP, FNP) able to assess subject risk/safety. If a subject's personal healthcare provider approves participation in exercise training/interventions and the subject is high risk, then written documentation/authorization must be obtained from the subject's healthcare provider and maintained in possession of the research team.

18. Prior to participation in research involving exercise training/interventions by adults (18 years or older), it is *required* that subjects complete the Physical Activity Readiness Questionnaire (PAR-Q) with confirmation of **"NO"** on all seven items of the PAR-Q. A **"YES"** response to any of the seven item(s) *requires* approval for participation in exercise training/interventions according to #17 above.

19. The following risk statements relate to participating in exercise (training or testing at any level submaximal or maximal). The research appropriate risk statements must be included in the IRB research application and communicated to subjects in the risk section of the informed consent. The PI should include the risk statement(s) that are appropriate to the research being conducted. For example, studies including exercise testing but not exercise training should include the risk statement specific to exercise testing and studies including both exercise training and exercise testing should include the risk statements for both. Risk statement **(a)** is required in all applications and informed consents involving exercise.

    a. Required statement: *"Participation in any physical activity or exercise has risk. These risks include but are not limited to, pain, fainting, dizziness, fatigue, nausea, shortness of breath, chest pain or angina, swelling, bruising, muscle/bone/joint soreness, joint damage, bone fracture, ligament/tendon/connective tissue damage, hospitalization, and death."*

    b. Required statement for research involving exercise testing: "It is estimated that the risk of a cardiac event during exercise testing is approximately six (6) events per 10,000 exercise tests."

    c. Required statement for research involving exercise training/interventions: *"The risk of cardiac events is higher in adults than young adults (18-24 years). The risk of sudden cardiac death during vigorous physical activity is estimated at one death per year for every 18,000 people. The risk of cardiac event or death in sedentary individuals is higher than the risk in physically active individuals."*

    d. *Suggested* statement for research involving young (traditionally college-age) individuals involved in exercise training or testing: *"The risk of exercise-related death among high school and college athletes is one per 133,000 men and one per 769,000 women."*

20. Should an unanticipated adverse event occur during any research involving exercise testing or training, the research study will be temporarily discontinued. The PI must notify the IRB of the adverse event within 48 hours of the event and will await review and feedback from the IRB before continuing (restarting) the research study.

# Section 4: Training in the Protection of Human Subjects

## 4.1 NIH Policy on Required Training in Research Ethics

On October 1, 2000, the NIH began requiring education on the protection of human research participants for all researchers submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

Before the NIH can award funds for competing applications or contract proposals involving human subjects, researchers must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel are defined as the PIs, co-PIs, and others, specified within each project as having decision-making power over the investigation. The PI is that individual with signatory power on all documents related to the research project. This person has final authority over the project. The PI accepts responsibility for training all personnel associated with the study in compliance with human subjects regulations 45 C.F.R. Part 46. The PI may delegate responsibility, but must maintain oversight and retain ultimate responsibility for research conduct. The co-PI is that individual who co-signs on documents related to the project or who may be designated as a co-PI in grant-related documents. This person has decision-making power with regard to the conduct of the research. The co-PI reports to the PI, who is ultimately responsible for the conduct of the research. Others with decision-making power may include such persons as project managers, directors, and trainers. These designations are not all-inclusive. Operationally, these individuals have some oversight responsibility for one or more portions of the project. Individuals in this category are determined uniquely for each project by the PI.

For further information on NIH policy, see Required Education in the Protection of Human Research Participants at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html and Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects at http://grants.nih.gov/grants/policy/hs_educ_faq.htm.

## 4.2 UW's Policy for Required Training in Human Subjects Ethics

All human subjects research conducted by UW faculty, staff, students, and faculty advisors are required to complete the Collaborative Institutional Training Initiative (CITI) Human Subjects Research course prior to the approval of the proposal. Effective August 27, 2008, completion of this training is mandatory for all researchers and key personnel and must be completed every two years.

Faculty and staff must complete either the *Biomedical Research Researchers* learner group or the *Social & Behavioral Research Researchers* learner group. Students must complete the *Students conducting no more than minimal risk research* learner group. If student research involves more than minimal risk, the student must complete either the *Biomedical Research Researchers* learner group or the *Social & Behavioral Research Researchers* learner group.

Even though not required, we recommend that students complete either the *Biomedical Research Researchers* learner group or the *Social & Behavioral Research Researchers* learner group even if research is no more than minimal risk.

If you have any questions about the educational training requirements and procedures, please contact the Research Office at (307) 766-5322.

For students conducting human subjects research requiring review by the IRB, the faculty advisor or research supervisor is required to complete the Collaborative Institutional Training Initiative (CITI) Human Subjects Research course or have current (last two years) CITI certification. This requirement for current CITI training certification is required of all faculty/research advisor(s) who supervise/oversee student research that involves human subjects.

### 4.3 Alternative Sources of Information on Human Subjects Ethics

For more information about the violations of human subject protections, the foundations for the mandate of consent, and the ethical treatment of human subjects, see: The Nuremberg Code, The Helsinki Declaration, The Belmont Report, 45 C.F.R. 46, and this manual.

In part, codes of research ethics have been developed to address the historical disregard for human safety and dignity. The Nuremberg Code of 1947 was the first international code of research ethics. Another early code was the Helsinki Declaration, adopted by the World Medical Assembly at its meeting in Helsinki, Finland, in 1964. The first ethical code covering social and behavioral research was a set of 10 ethical principles adopted by the American Psychological Association in 1972. The American Psychological Association's principles were the first to recognize the principle of confidentiality. Most professional organizations have ethical codes, and most require authors of manuscripts submitted to the journals of these organizations to state that they have followed these ethical principles in their research. The IRB encourages researchers to abide by their respective professional codes of conduct.

The U. S. Department of Health, Education, and Welfare issued ethical guidelines in 1971 that were codified into Federal Regulations in 1974. The primary incentive for current government ethical regulation, however, began with the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research under the guidance of the Department of Health, Education, and Welfare in 1974. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. The report of the Commission, called The Belmont Report, was published in 1978. The Belmont Report identified three basic ethical principles:

1. **Respect for persons (autonomy):** This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from all potential research subjects or their legally authorized representatives.

2. **Beneficence:** This principle requires that researchers maximize benefits and minimize harms or risks associated with research. Research-related risks must be reasonable in light of expected benefits.

3. **Justice:** This principle requires the equitable selection, recruitment, and fair treatment of research subjects.

These three principles were the underpinnings of both an early (1980) version of a common federal policy for the protection of human research subjects and the current version of that policy. Sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, the Department of Education, and the Central Intelligence Agency, adopted the regulations. This federal policy, sometimes called the Common Rule, is codified as the Common Federal Policy for the Protection of Human Subjects and was published in the Federal Register in 1991 and re-implemented as the revised Common Rule in 2019. It is referred to as 45 C.F.R. Part 46. The regulations further require that each institution at which federally funded research is conducted adhere to the principles of The Belmont Report and set forth in writing its ethical principles, policies, and procedures.

UW's agreement to abide by The Belmont Report and 45 C.F.R. Part 46 is approved by the federal agency that oversees ethical issues in human research. UW has determined that all research projects involving human subjects, *regardless of funding status*, abide by the same ethical and regulatory standards.

# Section 5: Informed Consent of Research Participants

## 5.1 Informed Consent

Except as described in Section 5.6 and Section 5.7, researchers may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative prior to enrollment of the subject in the research. Researchers are responsible for ensuring that the subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence. The IRB is responsible for evaluating the informed consent process.

The IRB may request to observe the informed consent process to ensure adequate consent when the research involves particularly vulnerable populations. The PI may not involve a human being as a participant in research unless the researcher has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. Information given to potential subjects or their representatives must be in a language that is understandable to the subject or representative. No process of obtaining consent may include exculpatory language through which subjects waive any of their legal rights or releases or appear to release the researcher, sponsor, or institution, or its agents from liability for negligence. The consent process must provide sufficient opportunity to consider whether to participate.

Occasionally, the institutional setting in which the consent is sought will pose the possibility of coercion or undue influence. Conducting research at institutions that provide services to subjects may be perceived as implying that continued service is dependent upon participation in the research. Students in the educational setting may be concerned that refusal to participate will affect their grades. These institutional pressures should be addressed in the research design. The protocol must adequately preserve the right to refuse participation.

There are many other examples of possible sources of undue influence on subjects. It may not be possible to remove all sources of undue influence, but the principal researcher must examine each project to assure the elimination of coercion and minimization of undue influences. The requirement to obtain informed consent should be seen as not only a legal obligation, but also as an ethical obligation. The research design must adequately address how informed consent will be obtained and what information will be given to prospective subjects. The IRB looks at the issues of coercion and undue influence in each proposal and insists on protocols where the circumstances of the consent process minimize the possibility of coercion and undue influence to participate.

For research studies involving non-English speaking participants, the IRB requires the submission of the translated consent as an explicit condition for approval.

## 5.2 Elements of Informed Consent and Assent Forms

Current informed consent documents may be found Office of Research Integrity & Compliance webpage. The sample consent form contains all the required consent elements. **The following are the basic required elements (45 C.F.R. 46.116):**

1. Statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's 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 subject;

3. A description of any benefits to the subject or to persons that 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 subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject 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 an injury occurs and, if so, what they consist of, or where further information may be obtained (**Minimal risk research:** research in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life [of normal subjects] or during the performance of routine physical or psychological examinations or tests. Clinical investigations are usually more than minimal risk.);

7. An explanation of whom to contact about research subjects' rights using the following language: “If you have questions about your rights as a research subject, please contact the University of Wyoming IRB Administrator at 307-766-5322.”

8. An explanation of whom to contact for answers to pertinent questions about the research; **and**

9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

10. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility (broad consent); **or**

(ii) A statement that the subject's information or biospecimens collected as part of the research will not be used or distributed for future research studies, even if identifiers are removed.

Whenever appropriate, one or more of the following elements of information shall also be provided to each subject:

1. If the risks of any research procedure are not well known, for example, because of limited experience in humans, a statement that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable.

2. If the research includes women of childbearing potential or pregnant women, and the effects of any research procedures on embryos and fetuses are not well known, a statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable.

3. If there are anticipated circumstances under which the participant's participation will be terminated by the researcher without regard to the participant's consent, a list of anticipated circumstances under which participation may be terminated by the researcher without the participant's consent.

4. If there are costs to the participant that may result from participation in the research, a list of additional costs associated with study participation.

5. If there are adverse consequences (e.g., physical, social, economic, legal, and/or psychological) of a participant's decision to withdraw from the research, a list of consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation.

6. If significant new findings during the course of the research that may relate to the participant's willingness to continue participation are possible, a statement will be provided to the participant stating such.

7. If the approximate number of participants involved in the study might be relevant to a decision to take part in the research, an approximate number of participants involved in the study.

Informed consent forms should be written in plain language at a reading level appropriate for the age or maturity level of the participants. The informed consent form should be written in second person for clarity and readability (i.e., there is minimal risk to you; you will be required to perform a certain procedure; etc.).

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. 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.

See Section 8.4 for consent and assent requirements for research involving children.

## 5.3 Additional Consent Information for Different Types of Studies

1. **Studies involving blood samples:** The consent form should contain a statement such as, "Blood samples will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood. It is routinely used to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of the needle entry and may result in slight bruising and a feeling of faintness. In this study a trained technician will obtain a 30 ml (about 2 tablespoonfuls) sample of your blood that will be analyzed for…"

2. **Studies involving blood, tissue, or body fluid for possible genetic research:** If the research involves the use of a subject's blood, tissue, or body fluid for current or future genetic research, the researcher should modify the consent form to explain subjects' rights, including:
   a. The fact that the specimens will be maintained without identifiers;
   b. The risk level to the subject if they agree to participate.

3. **Studies that involve physical risk**: UW does not have a plan to provide facilities or insurance to cover research-related injuries. UW student participants will be afforded access to the designated services available to all students through UW's Student Health Services. Other research participants are not covered. If the study involves physical risk, assess the risk and add a statement such as,

   > "The University of Wyoming, the principle researcher, and the research team are not liable for any injury participants might sustain while participating in this study and are not able to offer financial compensation or absorb the costs of medical treatment should the participant sustain such an injury."

   If emergency treatment for research-related injuries is arranged by (for example) having a medical doctor available for emergency treatment, that should be stated, but a disclaimer for extended care should be put into the consent form, such as "You will be charged for continuing medical care and hospitalization for research-related injuries. The university has no plan to provide financial compensation."

4. **Studies that involve a risk to a fetus:** The female participant must be informed of the risk and the methods to be used (such as a pregnancy test) to minimize the risk.

5. **Studies that involve drugs:** The participants must be given a statement of known side effects, warned about possible drug interactions (including interactions with alcohol), and warned about activities that may be dangerous (such as driving with a drug that has a sedative effect).

6. **Studies that involve psychological risk:** The principles that apply to studies that involve psychological risk or mental stress are similar to those that involve physical risk. Participants should be informed of the risk and told that the university has no plan to

provide treatment. They should be given the names and telephone numbers of agencies that may alleviate their mental concerns, such as a crisis hot line, the UW Psychology Clinic, the UW Counseling Center, and the UW Educational Psychology Clinic.

7. **Studies that involve sensitive topics:** Participants should be told that some of the questions are of a personal or sensitive nature and should be given examples of the topics or questions. If questionnaires or interviews may generate reports of child physical or sexual abuse, or abuse/neglect against vulnerable adults, the participant must be informed that the researcher is legally required to report this information to the Wyoming Department of Family Services. The following language is recommended:

   "If the researcher, or anyone involved in the research, knows or has reasonable cause to believe or suspect that a child or vulnerable adult has been abused or neglected or who observes any child or vulnerable adult being subjected to conditions that would reasonably result in abuse or neglect, he or she is required to report to the Department of Family Services."

   If the questionnaire or interview may generate reports that the participant plans to harm him or herself or others, the participant must be told that the researcher is ethically required to report that information to the local police department. Information about the legal obligations to report abuse and threats of harm to oneself or others may be omitted if the responses are anonymous.

8. **Studies that involve deception:** Deception should be employed *only* when there are no viable alternative procedures. Where deception is a necessary part of an experiment, the IRB will generally require that a preliminary consent be obtained, in which the researcher informs the subject of the research. After the experiment, the subject should be informed of the deception and its purpose through a debriefing process explicitly outlined in the research proposal. The IRB recognizes that there are rare instances in which no consent can be obtained or debriefing done. Deception requires that a PI get formal approval of a waiver of informed consent.

9. **Studies that involve audio or video recordings:** The following information must be included in the proposal and the informed consent:

   a. Who will have access to the recordings, where the recordings will be stored, when the recordings will be destroyed (or that they will be kept indefinitely and why), and whether the recordings will be used in other studies or for future research.

   b. If the recordings will be kept indefinitely, the consent should state that subjects have the right to review and delete recordings that will be kept indefinitely or shared outside of the research team.

   c. Include a check-box or signature line for consent to be audio or video recorded (this requirement will be assessed on a case-by-case basis based on the nature of the research proposal).

   d. If the researcher wishes to present the recordings at a convention or to use them for other educational purposes, he or she should get special permission to do so by

adding, after the signature lines on the consent form, the following statement, "We may wish to present some of the tapes from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with the recording of your performance." Additionally, a second signature line should be added with the preface, "I hereby give permission for the video (audio) recording made for this research study to be also used for educational purposes." This procedure makes it possible for a participant to agree to be recorded for research purposes and to maintain the confidentiality of the information on that tape.

10. **Studies that involve monetary or other compensation:** The amount and type of the stipends or other compensations and the requirements to earn them must be clearly specified. If the study extends over a period of time, it is acceptable to reward a participant with a bonus if he or she completes all the interim components of the study.

11. **Studies that involve exercise training/interventions and/or exercise stress testing:** See **Section 3.12** above.

12. **Cover Letters**: Cover letters, rather than consent forms, may be used for some categories of exempt minimal-risk research with adults, such as survey or questionnaire research on non-sensitive topics. The cover letter should state the purpose of the survey, the expected number of respondents, a description of the topic of the survey, the content of the questions on the survey, a description of any reasonably foreseeable risks, a statement about confidentiality or anonymity, and a statement about how the participant may obtain additional information about the study. The cover letter should also state that "Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time." Also, state that "completing and submitting this survey instrument indicates your implied consent."

### 5.4 Authorization to use Personal Health Information (PHI)

Authorization to use Personal Health Information (PHI) must be obtained from the individual through a form separate from the informed consent form described above (medical release form template). Per 45 C.F.R. 164.508, the authorization form must include the following:

1. A description of the information to be used or disclosed that identifies the information in a specific or meaningful fashion.

2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

3. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

4. A description of each purpose of the requested use or disclosure. The statement "at the request of the individual" is a sufficient description of the purpose when an individual

initiates the authorization and does not, or elects not to, provide a statement of the purpose.

5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization. The statement, "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

6. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

The authorization must be written in plain language. If a covered entity seeks authorization from an individual for a use or disclosure of PHI, the covered entity must provide the individual with a copy of the signed authorization.

In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of the following (45 C.F.R. 164.508):

1. The individual's right to revoke the authorization in writing, and either: (A) the exceptions to the right to revoke and a description of how the individual may revoke the authorization; or (B) a reference to the covered entity's notice; and
2. The ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization, by stating either: (A) The covered entity may not condition treatment, payment, enrollment, or eligibility for benefits on whether the individual signs the authorization; or (B) The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization; and

3. The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this subpart.

### 5.5 Waiver of Authorization for Use and Disclosure of PHI

If a researcher seeks a Waiver of HIPAA Authorization 45 CFR 164.512(i)(1)(i)(a) for research purposes, all of the following criteria must be articulated in the IRB proposal:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

    a. An adequate plan to protect the identifiers from improper use and disclosure;

    b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification

for retaining the identifiers or such retention is otherwise required by law; and

c. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

2. The research could not practicably be conducted without the waiver or alteration.

3. The research could not practicably be conducted without access to and use of the PHI.

If all of the criteria are satisfied, the IRB will return the "IRB Waiver of HIPAA Authorization" form to the researcher. The purpose of the form is to:

1. Assist the IRB in making and documenting the determinations required to grant or deny a waiver of HIPAA authorization for research purposes based on federal law.

2. If a waiver is granted, this completed form serves as written permission from the IRB to the researcher to access, use, or disclose PHI without subject authorization.

3. The researcher provides this form to the covered entity maintaining the PHI as documentation that the UW IRB has granted a waiver of HIPAA authorization.

On the form, the IRB will indicate the purpose of waiver of HIPAA authorization:

1. Waiver is granted only for prescreening records containing PHI. When prescreening is complete, the researcher must obtain HIPAA Authorization from eligible subjects for any other access of PHI; and/or

2. Waiver is granted for complete access, use, and creation of records containing PHI, but only as described in the IRB approved application.

### 5.6 Waiver of Documentation of Informed Consent

The IRB can waive the requirement that the consent process includes a signed consent form. Researchers desiring to not have a signed consent form must still provide participants with a consent document or verbal script disclosing all the required elements necessary for informed consent. In such cases, the IRB encourages researchers to use the consent templates and remove the signature section (see template posted on webpage). According to 45 C.F.R. 46.117(c), an IRB may waive the requirement for the researcher to obtain a signed consent form for some or all subjects if it finds:

1. The only record linking the subject and the research would be the consent document; and

2. The principal risk would be potential harm resulting from a breach of confidentiality.

Or,

1. The research presents no more than minimal risk of harm to subjects; or

2. The research involves no procedures for which written consent is normally required outside of the research context; or

3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

The PI must clearly outline the regulatory language and reasons for requesting a waiver of documentation of informed consent in the research proposal.

### 5.7 Waiver of Informed Consent

The IRB may waive the requirements for obtaining informed consent or approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent listed in Section 5.1, provided that **all** of the following four conditions are met:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or amendment will not adversely affect the rights and welfare of the subjects;

3. The research could not **practicably*** be carried out without the waiver or alteration;

And,

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

*It is important to note that the CITI training module, which is required training for all human subject researchers at UW, states with regard to waiver of informed consent that "…impracticable does not mean time-consuming, expensive, or inconvenient. Researchers will have to provide acceptable evidence to their IRBs that securing consent is not feasible (capable of being done or carried out), regardless of cost and time."

The regulatory language and reasons for requesting waiver of informed consent must be clearly outlined by the PI in the research proposal.

# Section 6: Initial IRB Review of a Research Proposal Involving Human Subjects

## 6.1 Requirements for Initial IRB Review

Any faculty member, staff, or student from UW who proposes to engage in any research activity involving the use of human subjects **must submit the following** to the Research Office:

1. A research proposal describing the rationale for the study, research questions to be answered, methods, procedures, data analysis plan, and other required information (see Research Office webpage for UW Research Proposal Form). If a faculty member, staff, or student think his/her proposal may qualify for exempt review, he/she may submit the UW Exemption Request form instead of the full proposal (see research office webpage for the UW Exemption Request Form). The initial reviewer makes the final determination of whether a proposal is exempt, not the researcher. As such, after submitting the UW Exemption Request Form, the researcher may still be required to submit the UW Research Proposal Form.

2. An informed consent form or justification for waiver of informed consent or waiver of documentation of consent (see Sample Consent Form posted on research office webpage);

3. Copies of questionnaires, surveys, or similar instruments, if applicable;

4. Training verification. All human subjects research conducted by UW faculty, researchers, and students are required to complete the Collaborative Institutional Training Initiative (CITI) Human Subjects Research course. Faculty and staff must complete either the *Biomedical Research Researchers* learner group or the *Social & Behavioral Research Researchers* learner group. Students must complete the *Students conducting no more than minimal risk research* learner group. If student research involves more than minimal risk, the student must complete either the *Biomedical Research Researchers* learner group or the *Social & Behavioral Research Researchers* learner group. Even though not required, we recommend that students complete either the *Biomedical Research Researchers* learner group or the *Social & Behavioral Research Researchers* learner group even if research is no more than minimal risk.

5. The certificate of completion is automatically sent to the Research Office upon completion.

6. Site letters, if applicable, for extramural research (see Section 3.0).

7. Additional approval documentation from other IRBs or ethical entities (especially if conducting international research).

8. Recruitment materials (flyers, posters, webpages, email messages, letters, social media posts/advertisements, etc.).

9. If the PI is non-faculty (i.e., student, postdoctoral/visiting scholar, visiting professor, emeritus professor), a signed Research Supervisor Approval Checklist from the faculty advisor, thesis/dissertation committee chair, or other faculty supervisor indicating review and approval of the proposal for submission to the IRB and approval of the project concept and design by the research supervisor and/or graduate committee. The faculty advisor must be current UW faculty. The supervising research or faculty advisor is also required to complete the Collaborative Institutional Training Initiative (CITI) Human Subjects Research course and/or maintain current (see Section 4.1) CITI certification.

### 6.2 Submission Schedule Requirements

The IRB has one regularly scheduled meeting per month during the academic year. See the Research Office website for the list of meeting dates and submission deadlines. Proposals may be submitted for review at any time. However, proposals that require review by the full board must be submitted by email to irb@uwyo.edu by the proposal due date **(six weeks prior to the scheduled meeting)**. Even if proposals are received by the proposal due date, they may be deferred to the next scheduled meeting due to application volume. All attempts are made to limit application deferrals. Proposals received after the due date will be deferred to the next scheduled meeting. Electronic submission of proposals as a single Word file via email is preferred. Supplementary application materials should be contained within the single document as individual appendices (clearly labeled). Following these recommendations will facilitate efficient electronic review and limits the number of applications deferred to later meetings. It is recommended that three months be allowed and planned for completion, review, and approval of projects involving human subjects.

### 6.3 Exempt Research Review Process

Federal regulations identify specific categories of research activities that are exempt from the federal regulations on the protection of human subjects in research. It is important to note that while a project may be exempt from the regulations, the ethical principles of conducting research with humans still apply:

1. All researchers and co-researchers are trained in the ethical principles, relevant federal regulations, and institutional policies governing human subject research;

2. Human subjects will voluntarily consent to participate in the research when appropriate and will provide subjects with pertinent information (e.g., risks and benefits, contact information for researchers and the IRB, etc.);

3. Human subjects will be selected equitably so that the risks and benefits of the research are justly distributed;

4. The IRB will be immediately informed of any unanticipated problems that would increase the risk to the human subjects and cause the category of review to be upgraded to expedited or full board review;

5. The IRB will be immediately informed of any complaints from participants regarding their risks and benefits; and

6. Confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.

The researcher may not make the determination of exempt status. To request exempt status, researchers should submit the UW Exemption Request Form (found on the Research Office webpage) following the above procedures (See Section 6.1). An exempt determination requires that the research activity meets the criteria for exempt status under the federal regulations and involves no greater than a "minimal risk". The pre-reviewer will review the complete proposal and make the determination, consulting with the chair of the IRB or other members of the IRB as appropriate. Upon approval, the IRB staff will then issue a letter of exempt designation to the researcher.

Under federal regulations, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the 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 (45 C.F.R. 46.102(j)).

All administratively approved protocol titles and the respective PIs will be reported in the appropriate agenda and minutes to the IRB at the next meeting.

## 6.4 Criteria for Exempt Status

The researcher may not make the determination of exempt status. To request exempt status, researchers should submit the UW Exemption Request Form (see Section 6.1 and Research Office webpage) following the above procedures.

Categories exempt from IRB review include the following:

> **Category 1: Commonly accepted educational settings involving normal educational practices.** 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.
>
> Vulnerable population applicability:

1. Pregnant women may be included

2. Prisoner population may ***not*** be included if the research targets a prison population, but can be included if part of an overall broader population

3. Children may be eligible for this exemption

**Category 2: Research that only includes interactions involving the use of 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:**

1. Information obtained is recorded in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects' reputation (can only include children when investigators do not participate in activities being observed);

2. 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 (can only include children when investigators do not participate in activities being observed); or

3. 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 that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (NO children in this category).

Vulnerable population applicability:

1. Pregnant women may be included

2. Prisoner population may ***not*** be included if the research targets a prison population, but can be included if part of an overall broader population

3. Research involving children is eligible only when it relates to educational tests or observations in which the investigator does not participate in the activities being observed

**Category 3: Benign Behavioral Interventions (this category <u>may not</u> include children)**. 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:

1. 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; or

2. 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

3. 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 (see <u>Section 6.6</u>) review to make the determination as required by §46.111(a)(7);

   AND one of the following is true:

4. The research does not involve deceiving subjects regarding the nature or purposes of the research; or

5. The research involves deception, but subjects authorize the use of deception through a prospective agreement to participate in research in circumstances in which they are informed that they are unaware of or misled regarding the nature or purposes of the research.

Benign behavioral interventions are brief in duration, harmless, painless, and not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigatory 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.

Vulnerable population applicability:

1. Pregnant women who are adults may be included

2. Prisoner population may ***not*** be included if the research targets a prison population, but can be included if part of an overall broader population

3. Children are ***not*** eligible for this exemption

4. Decision-impaired persons are ***not*** eligible for this exemption

**Category 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:

1. The identifiable private information or identifiable biospecimens are publicly available;

2. 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;

3. 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 (HIPAA), for the purpose 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

4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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.D. 552a, and if applicable the information used in the research was collect subject to the Paperwork Reduction Act of 1995, 44 U.S.C 3501 et seq.

It is important to recognize that this exemption <u>does not</u> cover any primary collections of either information or biospecimens. This exemption only applies to the ***re-use*** of data and specimens that were or will be collected for non-research purposes or research studies other than the proposed study.

Vulnerable population applicability:

1. Data/specimens from pregnant women are eligible

2. Data/specimens from prisoners may be allowed as long as the research was not designed to recruit prisoners and prisoners were only incidental subjects of the research

3. Data/specimens from children are eligible

4. Data/specimens from persons with decisional impairment are eligible

**Category 5: Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs**, including procedures for obtaining benefits or services under those programs, or possible changes in methods or levels of payment for benefits or services under those programs if:

1. The projects are conducted by or supported by a Federal department or agency heads, or otherwise subject to the approval of department or agency heads;

2. There are no statutory requirements for IRB review;

3. The research does not involve significant physical invasions or intrusions upon the privacy of subjects; and

The exemption is invoked with authorization or concurrence by the funding agency. NOTE: ALL of these criteria must be met for this exemption to apply.

**Category 6: Taste and food quality evaluation and consumer acceptance studies**, if:

1. Wholesome foods without additives are consumed; or

2. 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.

   Vulnerable population applicability:

   1. Pregnant women may be included

2. Prisoner population may ***not*** be included if the research targets a prison population, but can be included if part of an overall broader population

3. Children may be eligible for this exemption

4. Decisional-impaired persons may be eligible if inclusion is justified

**Category 7: Storage or maintenance for secondary research for which broad consent is required**.

UW is not allowing for or implementing broad consent at this time.

**Category 8: Secondary research for which broad consent is required**.

UW is not allowing for or implementing broad consent at this time.

### 6.5 Research Populations for Which the Exempt Determinations May Not be Used

**Children.** Research involving children **cannot** be classified as exempt if the research involves:

1. Survey procedures conducted by the researcher;

2. Interview procedures conducted by the researcher; or

3. Observations of public behavior when the researcher participates in the activities being observed.

If the researcher is not directly involved in the survey/interview/observation (i.e., teacher is handling the data collection but is not an investigator on the study), it **may** be classified as an exempt study.

**Prisoners.** The federal regulations on exemptions listed above do not apply to research involving prisoners. Research involving prisoners as subjects is **never** exempt from the regulations.

### 6.6 Limited IRB Review*

The revised federal regulations governing human subjects research, effective January 19, 2018, require a new type of review called “limited IRB review” for certain exempt and expedited protocols.

The new provision for limited IRB review allows certain research to be categorized as exempt, even when the identifiable information might be sensitive or potentially harmful if

disclosed. In order to qualify for an exemption, the study must meet the standards of the limited IRB review.

If the information is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review may allow an exemption determination to be made.

**Limited IRB review is required in the following circumstances:**

1. Exempt category 2 (educational tests, surveys, interview, or observations of public behavior)
   When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

2. Exempt category 3 (benign behavioral interventions)
   When the information is recorded by the investigator in an identifiable manner and disclosure of the subject's responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

**Purpose of Limited IRB Review**
When reviewing the exempt categories 2 and 3, the limited IRB review assures adequate protection for the privacy of subjects and adequate plans to maintain the confidentiality of the data.

**Reviews Related to Privacy and Confidentiality**
In order to assure appropriate protections, the limited IRB review may consider the following topics:

- The nature of the identifiers associated with the data
- The justification for needing identifiers in order to conduct the research
- Characteristics of the study population
- The proposed use of the information
- The overall sensitivity of the data being collected
- Persons or groups who will have access to study data
- The process used to share the data
- The likely retention period for identifiable data
- The security controls in place
    - Physical safeguards for paper records
    - Technical safeguards for electronic records
    - Secure sharing or transfer of data outside the institution, if applicable
- The potential risk for harm that would occur if the security of the data was compromised.

Additional information about adequate protections will be outlined in guidance issued by the

Secretary of HHS.

**Individuals Performing the Limited IRB Review**
Limited IRB review must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. Disapprovals must be made by the convened board. If the limited IRB review does not result in an approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories.

Expedited research must meet all the approval criteria under 45 CFR 46.111, including either informed consent or waiver of consent.
*Adapted from University of Kansas Medical Center

## 6.7 Criteria for Expedited Review

**The researcher may not make the determination of expedited review. Researchers should submit a research proposal following the above procedures (See Section 6.1). Applicability for initial review:**

1. Research activities that:
    a. Present no more than minimal risk to human subjects; and
    b. Involve only procedures listed in one or more of the expedited review categories (listed below) may be reviewed by the IRB through the expedited review procedure authorized by 45 C.F.R. 46.110. The most current guidelines are presented in OHRP Expedited Review Categories (1998).

    The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of the subjects.

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

4. Researchers are reminded that the standard requirements for informed consent (or its waiver, amendment, or exception) apply, regardless of the type of review (expedited or full board) utilized by the IRB.

Per federal regulations, the categories that fall under expedited review may include the following

(for both initial and continuing review). **However, to ensure adequate protection of UW employees and human subjects, *some* of the research proposals that fall under the following categories will go to the full board for review:**

**Category 1:** Clinical studies of drugs and medical devices if:

1. Research on drugs for which an investigational new drug application (21 C.F.R. 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); or

2. Research on medical devices for which (i) an investigational device exemption application (21 C.F.R. 812) is not required; or (ii) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

**Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period, and collection may not occur more frequently than 2 times per week; or

2. 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.

**Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

1. Hair and nail clippings in a non-disfiguring manner;

2. Deciduous teeth at the time of exfoliation, or if routine patient care indicates a need for extraction;

3. Permanent teeth, if routine patient care indicates a need for extraction;

4. Excreta and external secretions (including sweat);

5. Uncannulated saliva collected, either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;

6. Placenta removed at delivery;

7. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

8. Supra- and sub-gingival 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;

9. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

10. Sputum collected after saline mist nebulization.

**Category 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 include:

1. Physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of significant amounts of energy into the subject or an invasion of the subject's privacy;

2. Weighing or testing sensory acuity;

3. Magnetic resonance imaging;

4. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; or

5. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the individual's age, weight, and health.

**Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.

**Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

**Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may be exempt from the HHS

regulations for the protection of human subjects. This listing refers only to research that is not exempt.

**Expedited review process guidelines:**

1. The reviewer may approve the protocol or request modifications in order to secure approval.

2. When requesting modifications, if the reviewer and researcher cannot agree on the proposed modifications, the protocol is sent to a convened IRB for review.

3. If a reviewer believes the protocol should be disapproved, the protocol is sent to the convened IRB for review.

4. In conducting the initial or continuing review, the reviewer must determine that all applicability criteria are met and that all research activities fall into one or more research categories, allowing review by the expedited procedure.

5. In conducting a review of modifications to a previously approved protocol, the reviewer must make sure that the modification is a minor change as defined by policies and procedures.

6. In order to grant approval, the reviewer must determine that the protocol meets all regulatory requirements for approval.

7. When granting initial or continuing approval, the reviewer must document the category allowing review by the expedited procedure.

8. When granting initial review, the reviewer must document any determinations required by the regulations for waiver or alteration of consent, waiver of consent documentation, research involving prisoners, pregnant women, fetuses, neonates, or children, and must document protocol-specific findings that justify those determinations.

**Applicability for Continuing Review**

There are two categories of continuing review that can qualify for expedited review:

1. Research eligible for initial review by an expedited procedure; or

2. Research previously approved by the convened IRB as follows where:

    a. The protocol is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the protocol remains active only for long-term follow-up of participants;

b. Where no participants have been enrolled and no additional risks have been identified; or

c. Where the remaining research activities are limited to data analysis. In addition, each of the above items must meet the following criteria:

    1. The research presents no more than minimal risk to subjects; and

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

**Applicability for Review of Modifications to Previously Approved Research**

A modification to previously approved research falls under expedited review if:

1. The modification to the protocol or consent forms is minor (a modification that does not increase the risk or decrease the potential benefit to participants);

2. The modification does not involve the addition of procedures involving more than minimal risk to participants; and

3. All added procedures fall into categories 1-7 of research that can be reviewed by the expedited procedure.

## 6.8 Full Board Review Process

All submissions for initial review, continuing review, or review of modifications to previously approved research determined by the pre-reviewer to not be eligible for exemption or review by expedited procedures must be reviewed and approved at a fully convened IRB meeting. The IRB adheres to the process outlined below to facilitate the thorough review of each protocol according to 45 C.F.R. Part 46.

IRB staff provides a complete set of documents provided by the researcher to IRB members, each of whom is asked to review the protocols and supporting documentation. Additionally, the pre-reviewer specifically assigns each new protocol to two IRB members for a primary and secondary review. The pre-reviewer makes every effort to identify reviewers based upon expertise, relevance, interest, and possible conflict of interests.

The IRB meets monthly during the academic year to review and discuss each protocol. The protocols undergoing initial review are presented and discussed individually by the IRB, as well as those protocols undergoing continuing review. The primary and/or secondary reviewer presents each new study to the board, raising any additional points for discussion. Researchers

and **faculty advisors** (if the researcher is a student) are strongly encouraged to attend the meeting to clarify any questions or concerns. After discussion, the Board may vote to (1) approve; (2) approve with explicit conditions; (3) table; or (4) disapprove.

A study may be tabled because the IRB did not have sufficient time, expertise, or appropriate personnel present (i.e., absence of prisoner advocate for a study involving prisoners) to vote on the study, or because the IRB needed substantive clarification or modifications regarding the protocol or informed consent documents.

A study may be approved with explicit conditions when the convened IRB is able to stipulate specific revisions that require simple concurrence by the researcher. If the IRB approves a study with explicit conditions, then the IRB member or another member designated by the IRB Chair may approve the revised research protocol under an expedited review procedure to determine whether the researcher has incorporated the specified, explicit conditions into his or her project.

The potential IRB actions are:

1. **Approved:** Accepted and endorsed as written with no conditions.

2. **Approved with explicit conditions or modifications:** Accepted and endorsed with minor changes or simple concurrence of the principal researcher. All explicit conditions requested of the researcher must be completed and documented prior to beginning the research. For these conditions, the IRB Chair or designated reviewer can, upon reviewing the PI's response(s) to stipulations, approve the research on behalf of the IRB. If the proposal has received approval with explicit conditions, a copy of the corrections must be submitted to the Research Office with any changes underlined or in bold.

3. **Tabled:** Generally, a research proposal is tabled if the protocol, consent form, or other materials have deficiencies that prevent accurate determination of risks and benefits. A research proposal is also tabled if the IRB requires significant clarifications, modifications, or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions (the Research Office will send an email to the PI with the requested revisions). If the study was tabled, revisions need to be submitted to the Research Office with any changes highlighted in yellow, underlined, and in bold and will be reviewed at the next convened IRB meeting.

4. **Disapproved:** A research proposal is disapproved if the protocol describes a research activity that is deemed to have risks that outweigh potential benefits or the protocol is significantly deficient in several major areas.

Following the presentation and discussion of protocols receiving either initial or continuing review, a listing of protocols reviewed and administratively approved for continuation, a listing of protocol modifications, a listing of unanticipated problems reported (off-site and at UW), a listing of those protocols approved through expedited review procedures and other information relating to ongoing research activities are reported to the IRB.

## 6.9 Non-Compliance with IRB Policies, Procedures, or Decisions

Human subjects research that deviates from the policies, procedures, state, or federal law is non-compliant and subject to further inquiry by the IRB and the Research Office. All reports and complaints of non-compliance should be directed to the Research Office (via email, phone, mail, or in-person). The Research Office will immediately investigate all allegations of non-compliance. If necessary, IRB staff will send the researchers in question a notice requesting the immediate suspension of all specified research activities while the issue of non-compliance is reviewed, consistent with the federal regulations (45 C.F.R. 46.113). This initial notice will also include a statement detailing the rationale for the IRB's action.

The three categories of non-compliance are general, serious, and continuing. Other definitions include an allegation of non-compliance and a finding of non-compliance:

1. **Non-compliance**: Any deviation from UW IRB policies and procedures, federal regulations, or state law. Failure to follow requirements and determinations of the IRB is also considered non-compliance.

2. **Serious non-compliance**: All non-compliance substantially affecting participants' rights and/or welfare or impacting upon the risks or benefits.

3. **Continuing non-compliance:** A pattern of non-compliance that indicates an inability or unwillingness to comply with the regulations or the requirements of the IRB.

4. **Allegation of non-compliance:** An unproven assertion of non-compliance.

5. **Finding of non-compliance:** Non-compliance that is true in fact. A finding of non-compliance may exist because there is clear evidence, an admission, or an investigation into an allegation that has determined the allegation to be true.

All allegations of non-compliance will be brought to the attention of the Research Office. If the general non-compliance is neither serious nor continuing, and there is a corrective action plan that can be readily implemented to prevent a recurrence, then the matter may be placed in the protocol file, and no further action is needed (for example, failure to sign the application or lost consent forms). Otherwise, the Research Office will refer allegations and findings of non-compliance to undergo an evaluation by the IRB.

The IRB will review the nature of the non-compliance at a convened meeting. When allegations are found not to have a basis in fact, the investigation is closed. For findings of non-compliance, the IRB considers the following recommendations:

1. Modifying the research protocol;

2. Modifying the consent process;

3. Contacting past or current participants with additional information;

4. Re-consenting participants;
5. Modifying the approval period;
6. Retraining of personnel;
7. Other research staff required to take over work temporarily or permanently;
8. Written reprimand;
9. Written warning;
10. Inform supervisor, Department Head, Provost, etc. as appropriate and necessary;
11. Suspension; and/or
12. Termination.

The IRB will also recommend whether the non-compliance was serious or continuing. Deliberations and determinations of the convened IRB will be fully documented in the minutes. All cases of non-compliance which the IRB determines to be serious or continuing non-compliance will be reported according to the Reporting Policy found in Section 2.5.

# Section 7: Continuing a Research Project: Annual Review, Amendments, Monitoring of Existing Protocols, and Data and Safety Plans and Boards

## 7.1 The Annual Review Procedure

Any research activity (including exempt, expedited, and full board) involving the use of human subjects that has received initial review and approval by an IRB is subject to continuing review and approval. Time intervals for such reviews shall be made at the discretion of the IRB. Review of full board and expedited protocols shall occur no less than annually. Annual reviews should be submitted to the Research Office using the Annual Review Form posted on the Research Office webpage.

Expedited and full-board proposals are generally approved for a one-year period but may be shorter. The protocol approval period for expedited and full board protocols may be extended through approval of the Annual Review Form **prior** to the expiration of the project.

Exempt protocols are approved for a 3-year period and do not require an Annual Review Form. Exempt protocol expirations may be extended by completing the Annual Review form **prior** to the expiration of the project.

It is the responsibility of the PI to maintain an active protocol and submit the proper forms **prior** to the expiration of the project.

Unless the proposal was approved as exempt, researchers should submit an annual review when any of the following apply:

1. Research is ongoing;

2. The remaining research activities include human subjects data collection (including the analysis of identifiable information); **or**

3. The research remains active for long-term follow-up of participants despite the protocol being permanently closed to the enrollment of new participants, and all participants have completed all research-related interventions.

PIs do not need to submit an annual review if the PIs have completed data collection and are only analyzing non-identifiable information.

For projects in which any of the above apply, an annual review form must be submitted to the IRB. It is the principal researcher's and the faculty sponsor's responsibility to turn in this form by the end of **11 months** of the project's start date in order for a review to take place for continued data collecting.

The form includes the following information:

1. The number of subjects accrued, including the number of subjects enrolled to date by ethnicity and race (if applicable);

2. A summary of any unanticipated problems and available information regarding adverse events;

3. A summary of any withdrawal of subjects from the research since the last IRB review (how many and why);

4. A summary of any complaints about the research since the last IRB review;

5. A summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last IRB review;

6. Any relevant multi-center trial reports (if applicable);

7. Any other relevant information, especially information about risks associated with the research;

8. A copy of the current informed consent document and any newly proposed consent document; **and**

9. If necessary, a copy of the approved proposal (with any changes highlighted in yellow, underlined, and in bold).

The PI must submit renewal letters from cooperating IRBs as relevant (e.g., site still operational). If the site(s) in question did not have an IRB of record and thus submitted an official letter granting permission for the researcher to conduct the research, then a second letter is not required.

Annual reviews ensure that current informed consent documents are accurate and complete. Reviewers will compare the annual review materials with the prior years' submission materials to verify accuracy and precision.

The IRB may vote to (1) approve; (2) approve with explicit conditions; (3) table; or (4) disapprove the annual review.

Annual reviews for **expedited studies** are reviewed by the pre-reviewer, IRB chair, or IRB designee. No research protocol may continue until final approval for continuation is granted.

Full board annual reviews are subject to agenda deadlines and will be reviewed accordingly. Annual review approval periods are one year from the day of formal re-approval, unless otherwise necessitated (see Section 7.4). Annual reviews submitted prior to their expiration date but not formally reviewed and approved by the expiration date are expired, and all research and research-related activity must cease until formal IRB re-approval. To the extent possible, annual reviews will follow the original time-frame for consistency (for example, if the original IRB proposal was approved from 1/10/11 to 1/9/12, the annual review will be approved from 1/10/12 to 1/9/13 if the PI submitted the annual review within 30 days PRIOR to the original expiration date.

**Annual reviews submitted after the expiration date may require the PI to submit a new full IRB proposal, unless one of the exceptions outlined in Section 2.9 applies (this applies to both expedited and full board annual reviews).**

If the findings of such investigations during the annual review process warrant corrective action, the IRB may suspend or terminate a research project to ensure the quality of research. Annual review materials are stored in the IRB protocol files.

Annual review may stop only when:

1. The research is permanently closed to the enrollment of new participants; **and**
2. All participants have completed all research-related interventions; **and**
3. Collection of private identifiable information has been completed; **and**
4. All private information has been de-identified.

## 7.2 Amendments to Protocols

All amendments, modifications, or changes to protocols (exempt, expedited, and full board) or consent forms must be submitted to the Research Office using the Protocol Update Form (see Research Office webpage). The Protocol Update Form will be reviewed and approved, as appropriate, by the IRB under the same procedure as for initial review, prior to making any changes in study procedures. Requests must describe what modifications are desired, why the changes are required, and if the changes pose any additional risks to the subjects. PIs are required to submit complete and updated research materials and indicate all changes highlighted in yellow, underlined, and in bold.

Minor changes to the protocol or consent forms may be administratively approved according to 45 C.F.R. 46.110(b)(2). The IRB uses the expedited review procedure to review minor changes in previously approved research. Minor changes are defined as changes that involve minimal risk procedures and/or do not increase the risk or decrease the potential benefit to subjects and may include expedited review categories 1-7 (45 C.F.R. 46.110(a)). Typical minor changes include changes in personnel, non-significant changes in sample size, an addition of a questionnaire that does not include sensitive or controversial questions, a change in the compensation schedule, or an addition of a site. Minor amendments submitted to the Research Office will be forwarded to the pre-reviewer, IRB Chair, or designee for review and approval. At the reviewer's discretion, the amendment/update may be reviewed by the full convened IRB.

Changes considered to be more than minor may be reviewed at a convened IRB meeting. When the convened IRB reviews amendments, modifications, or changes, all IRB members will be provided with a copy of all documents submitted by the researcher.

## 7.3 Identification and Reporting of Unanticipated Problems

The IRB requires PIs to promptly report a summary of each unanticipated problem to the IRB through the Research Office using the Unanticipated Problem Report Form (see Research Office

webpage).

UW defines an "unanticipated problem involving risks to participants or others" as an event that (1) was unforeseen; (2) was more likely than not related to the research; and (3) either caused harm to participants or others, or placed them at increased risk of harm.

An unanticipated problem may include, but is not limited to, any of the following:

1. An unforeseen harmful or unfavorable occurrence to participants or others that relates to the research protocol (injuries, side effects, deaths);

2. An unforeseen development that potentially increases the likelihood of harm to participants or others in the future;

3. A problem involving data collection, data storage, privacy, or confidentiality;

4. A participant complaint about IRB approved research procedures;

5. New information about a research study (e.g., a publication in the literature, interim findings, safety information released by the sponsor or regulatory agency, or safety monitoring report) that indicates a possible increase in the risks of the research;

6. Changes in approved research initiated without IRB review and approval to eliminate apparent immediate hazards to the participant; or

7. Incarceration of a subject.

**The process for reporting an <u>unanticipated</u> problem is as follows:**

1. Reporting responsibilities of PI:

    a. Within 48 hours of knowledge of the unanticipated problem, the PI is asked to submit an Unanticipated Problem Report Form to the Research Office.

    b. <u>Expected</u> adverse events (adverse events described in the risks section of the consent form) only have to be reported in the annual review application (not as an unanticipated problem).

2. Reviewing and reporting responsibilities of the IRB:

    a. Unanticipated problems not meeting the definition above involving risks to participants or others: The Research Office and the IRB Chair will confer to determine if the reported unanticipated problem is an event that (1) was unforeseen; (2) was more likely than not related to the research; and (3) caused harm to participants or other, or placed them at an increased risk of harm. For those unanticipated problems failing to meet the criteria, the Research Office will work with the PI towards a satisfactory and reasonable resolution for all parties.

If the event is determined to be an unanticipated problem, it will be referred to the full IRB for review.

b. Unanticipated problems found to meet the definition above are placed on the agenda for the next IRB review.
    i. If, after reviewing the information, the IRB determines that the event was not an unanticipated problem, the issue will be returned to the Research Office to be handled administratively.
    ii. If the IRB determines that the event was an unanticipated problem, the IRB votes to take one of the following actions:
        1. Accept the actions taken by the PI to report and resolve the incident;
        2. Notify current participants when information about the unanticipated problem might affect their willingness to continue to take part in the research;
        3. Alter the continuing review schedule;
        4. Approve with explicit changes;
        5. Suspend some or all research activities;
        6. Approve the study for a shorter period of time (e.g., 6 months versus 12 months); or
        7. Terminate the study for cause.

c. Deliberations and determinations of the IRB will be fully documented in the minutes.

**Additional reporting requirements for unanticipated problems:**

1. If a sponsor funds or supports the study, then the **PI is responsible for notifying the sponsor.**

2. Similarly, if the study is a multi-site project, and the unanticipated problem occurs at a site other than the university, then **the sponsor and the PI** are required to inform researchers of unanticipated problems or reactions that occur at other sites.

### 7.4 Monitoring Program for Existing Protocols

The IRB may require certain on-going protocols to be reviewed more than annually. Any study requiring more than an annual review will be notified in advance. The IRB will require more than an annual review for the following **four** categories:

1. **Routine:** Five percent of the expedited review studies (approximately seven studies) and five percent of the full board studies (approximately three studies) per year may be randomly selected by IRB staff to be reviewed by the IRB's Data Safety and Monitoring Board (DSMB). Exempt reviews are not included in the random sampling.

2. **Greater than minimal risk:** Any studies determined to be greater than minimal risk by the IRB will be reviewed more than annually.

3. **For cause:** This review is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention of the IRB; an Unanticipated Problem Report is submitted; or multiple expected adverse events occur.

4. **Researcher initiated:** A PI may request an on-site review to help keep records and procedures in compliance with federal regulation and institutional policies or to prepare for an external audit by a sponsor or federal agency.

All of these reviews (routine, greater than minimal risk, for cause, and researcher initiated) may be conducted by the IRB or the IRB's Data Safety and Monitoring Board (DSMB), which will be appointed by the Office Research and Economic Development and will report directly to the IRB. The DSMB will consist of individuals knowledgeable in human subjects research, clinical trials, statistics, and other relevant areas of specialty.

The goal of monitoring in these cases is to ensure full IRB understanding of the research protocols and full understanding by the researcher, research group, or department regarding IRB policies and procedures.

If DSMB is used, the DSMB will contact the PI to set up a review:

1. The review process may be conducted on-site, may necessitate access to relevant protocol files and may require the researcher or research coordinator to be present to handle questions as they arise. The DSMB members may ask the researcher(s) to walk them through a mock participation scenario.

2. The process requires the DSMB to ask the researcher(s) the questions outlined in the Annual Review Form (see Research Office webpage) plus any other questions determined necessary, including reviewing where the data are stored, whether the computer and the data files are password protected, whether a locked file cabinet is used, etc. (in accordance with the procedure that was outlined in the original protocol).

3. The materials reviewed may include, but are not limited to, reviewing all regulatory documents related to the study, requesting additional materials for review (e.g., consent forms, summary of procedures, specific subject records, exclusion/inclusion criteria, unanticipated problem reports, intervention records, follow-up procedures, etc.), lab/field review (e.g., observation of study procedures or consent process, review of data management), and attendance at an IRB meeting.

4. The reviewer may also contact and interview random participants to ensure that the study procedures were conducted in accordance with the approved protocol and that participants were adequately informed of what to expect when they initially enrolled in the study.

5. A report for each review (routine, greater than minimal risk, for cause, and researcher initiated) is generated by the DSMB for the IRB. More serious problems may necessitate a report being forwarded to the Vice President for Research and Economic

Development.

## 7.5 Data and Safety Monitoring Plan and Data and Safety Monitoring Board

A data and safety monitoring plan (DSMP) is a process that reviews the integrity, safety, and progress of a research protocol with the purpose of protecting participants during the course of the study and makes decisions regarding continuance, modification, or termination of the study for reasons of efficacy or safety. Some research activities may require a Data and Safety Monitoring Board (DSMB) to review interim analyses of data and cumulative unanticipated problem data to determine if the research activities should continue as originally designed, be changed, or be terminated.

Much of the research conducted at UW pertains to social and behavioral sciences and is generally considered to be not greater than minimal risk. Thus, many research studies may not be required nor need to establish a DSMP.

The UW IRB requires the use of a DSMP in the following cases:

1. If the research project is funded/supported by an agency requiring a DSMP or a DSMB; and/or

2. Studies in which the **risk level is more than minimal** (to be determined by the IRB).

The methods and amount of monitoring required are dictated by the degree of risk involved to the individual subjects and the complexity of the research, but the DSMB will review any of the above cases at least once before annual review occurs. The IRB, not the DSMB, will conduct the annual review (see Section 7).

For more information on the definition of a DSMP, the types of information that it may review, and when it should be reported to and used by an IRB in its continuing review process, see http://grants.nih.gov/grants/guide/notice-files/not98-084.html and 45 CFR 46.111(a)(6).

# Section 8: Procedures for Research with Vulnerable Populations

## 8.1 Inclusion of Pregnant Women, Human Fetuses, and Neonates in Research

The IRB shall follow special procedures with respect to vulnerable populations. The procedures provide additional safeguards in research activities involving pregnant women, human fetuses, and neonates. This section is intended to follow the guidelines set forth in Subpart B of 45 C.F.R.46. Researchers should include in the research proposal the rationale and details for the inclusion of pregnant women, fetuses, or neonates in research activities. Researchers should ensure that the informed consent process adequately addresses the risk to the fetus or neonate and pregnant women.

The IRB approves only those studies the IRB has determined to fulfill all necessary regulatory requirements. When reviewing research, the IRB ensures that there is adequate scientific and scholarly expertise to review the research. The UW IRB reserves the right to request expert consultation as necessary for adequate review.

**Definitions (**Derived from 45 C.F.R. 46.202**)**

1. **Pregnancy:** Encompasses the period of time from implantation until delivery. Delivery means complete separation of the fetus from the woman by expulsion, or extraction, or any other means. A woman shall be assumed to be pregnant if she exhibits any of the presumptive signs of pregnancy, such as missed menses, until the results of pregnancy testing are negative or until delivery.

2. **Fetus:** The product of conception from implantation until delivery.

3. **Neonate:** A newborn.

**Pregnant women or fetuses may be involved in research if all of the following conditions are met (**45 CF.R. 46.204**):**

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal, and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

3. Any risk is the least possible for achieving the objectives of the research;

4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect

of benefit for the woman nor the fetus when the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, the woman's consent is obtained;

5. If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;

6. Each individual providing consent under (4) or (5) above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

7. For children who are pregnant, assent and permission are obtained in accord with Subpart D of 45 C.F.R. 46 for studies involving children;

8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy;

10. Individuals engaged in the research will have no part in determining the viability of a neonate; and

11. If applicable, a data and safety monitoring plan has been established to monitor participants (see Section 7.5).

**Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met (45 C.F.R. 46.205(a)):**

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate;

3. Individuals engaged in the research will have no part in determining the viability of a neonate; and

4. If the neonate is of uncertain viability (45 C.F.R. 46.205(b)), until it has been ascertained whether or not a neonate is viable, the following additional conditions are met:

    a. The IRB determines that the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or the purpose of the research is the development of important biomedical knowledge which cannot be obtained by

other means and there will be no added risk to the neonate resulting from the research; and

b. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with Subpart A of 45 C.F.R. 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. **OR**

5. If the neonate is nonviable after delivery (45 C.F.R. 46.205(c)), all of the following additional conditions are met:

   a. Vital functions of the neonate will not be artificially maintained;

   b. The research will not terminate the heartbeat or respiration of the neonate;

   c. There will be no added risk to the neonate resulting from the research;

   d. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

   e. The legally effective informed consent of both parents of the neonate is obtained, except that the waiver and alteration provisions of Subpart A of 45 C.F.R. 46 do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirement of this paragraph.

According to 45 CF.R. 46.207(b), research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates will be sent to the Secretary of HHS for review. The Secretary will determine the approvability of the research based on the conditions stated in 45 C.F.R. 46.207(b).

## 8.2 Inclusion of Prisoners in Research

Special procedures are in place in the federal regulations that provide additional safeguards for the protection of prisoners involved in research activities. Researchers using prisoners as participants should provide specific detail and rationale in the research proposal. Since their incarceration may influence prisoners to participate in research, and, in order to assure that their decision to participate is not coerced, the IRB will adhere to Subpart C of 45 C.F.R. 46.

In the review of research involving prisoners, the IRB will apply the prisoner specific definition

of minimal risk under 45 C.F.R. 46.303(d): "Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons."

In the review of research involving prisoners, the IRB will follow the requirements for IRB membership outlined in 45 C.F.R. 46.107. If, at some point, while participating in a research project, a participant becomes incarcerated, it is the responsibility of the PI to notify the Research Office. The protocol will then be re-reviewed according to Subpart C of 45 C.F.R. 46 or the participant-prisoner will be withdrawn from research.

The IRB will review the proposed research to ensure one of the following four categories is applicable (45 C.F.R. 46.306):

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary of HHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research; or

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary of HHS has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

The IRB will then proceed to confirm that the following items are applicable (45 C.F.R. 46.305(a)):

1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

3. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal researcher provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

4. The information is presented in language which is understandable to the subject population;

5. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole;

6. Where the IRB finds there may be a need for follow-up examinations or care of participants after the end of their participation, adequate provisions have been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact; and

7. If applicable, a data and safety monitoring plan has been established to monitor participants (see Section 7.5).

### 8.3 Inclusion of Children in Research

Special procedures are in place in the federal regulations that provide additional safeguards for the protection of children involved in research activities. The IRB will adhere to Subpart D of 45 C.F.R. Part 46. The exemptions listed in 45 C.F.R. 46.104(d)(1) through (d)(8) are applicable for research involving children except for 45 C.F.R. 46.104(d)(3) for research involving survey procedures, interview procedures, or interventions with children.

Studies involving children require a parental, guardian, or legally authorized representative consent and participant assent. If any person other than the biological or adoptive parent claims to be the child's guardian (grandparents, foster parents, etc.), the PI must contact the Research Office, and IRB legal counsel will be consulted to determine whether the individual has the legal authority to make health care decisions on behalf of the child and therefore is the guardian as defined in the federal regulations. The IRB formally documents findings in the appropriate minutes.

**Definitions (**As described in 45 C.F.R. 46.402 and elsewhere**):**

1. **Children:** Persons who have not attained the legal age for consent to treatments or procedures involved in research or clinical investigations, under the applicable law of the jurisdiction in which the research or clinical investigations will occur. In Wyoming, a child can petition to be "emancipated" under W.S. § 14-1-202, but must do so by filing a written application and meeting the statutory requirements. Only if a child were

"emancipated" as described above would the state of Wyoming consider the child an "adult."

2. **Assent:** The child's affirmative agreement to participate in research or clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent.

3. **Permission:** The agreement of parent(s) or guardian to the participation of the child in the research or clinical investigation.

4. **Parent:** The child's biological or adoptive parent.

5. **Guardian:** Pursuant to Wyoming's Probate Code, W.S. § 2-1-103(xviii), a "guardian" means the person appointed by the court to have custody of the person of the ward under the provisions of this code.

For studies involving children, the IRB may approve only the categories of research listed below provided all applicable criteria are met:

1. **Research not involving greater than minimal risk (**45 C.F.R. 46.404). If the IRB finds that no greater than minimal risk to children is presented, approval may be given only if adequate provisions are made for soliciting the assent of the children and the permission of at least one parent or guardian. Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.

2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (**45 C.F.R. 46.405**)**. If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, **approval may be given only if the IRB finds that:**

    a. The risk is justified by the anticipated benefit to the subjects;

    b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches;

    c. Adequate provisions are made for soliciting the assent of the children and permission of at least one parent or guardian; and

    d. A data safety monitoring plan has been established to monitor participants (see Section 7.5).

3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's**

**disorder or condition (**45 C.F.R. 46.406**).** If the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, **approval may be given only if IRB finds that:**

a. The risk represents a minor increase over minimal risk;

b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

c. The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition, which is of vital importance for the understanding or amelioration of the subject's disorder or condition;

d. Adequate provisions are made for soliciting the assent of the child and permission of both parents or guardians; and

e. If applicable, a data and safety monitoring plan has been established to monitor participants (see Section 7.5).

4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (**45 C.F.R. 46.407**),** if the IRB does not believe the research meets the requirement of 46.404, 46.405, or 46.406 **approval may be given only if:**

a. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

b. The Secretary of HHS, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either (1) that the research in fact satisfies the conditions of 46.404, 46.405, or 46.406; or (2) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and the research will be conducted in accordance with sound ethical principles and adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians; and

c. If applicable, a data and safety monitoring plan has been established to monitor participants (see Section 7.5).

## 8.4 Requirements for Consent and Assent Involving Children

In accordance with 45 C.F.R. 46.408(a), the IRB must determine that adequate provisions have been made for soliciting the assent of children, when in the judgment of the IRB, the children are

capable of providing assent. The IRB recommends that assent be sought for children ages five and older, but may be appropriate for younger children depending on their aptitude.

The IRB may determine that assent is not a necessary condition for proceeding with the research if:

1. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart);

2. The intervention or procedure involved holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of research; or

3. The research meets the required criteria for waiver of consent stated in 45 C.F.R. 46.116(d) (see Section 5.6).

When assent is required, it must be documented. Assent can be oral or written, depending on the age and aptitude of the child. Assent should be written in terms that the child can understand. The University of Wyoming Institutional Review Board (IRB) has implemented the following policy regarding assent:

1. Verbal assent should be obtained for ages 7-13

2. Written signed consent should be obtained for ages 14-17. The assent form for this age group should be similar to the adult consent form (i.e., the same information required for adults should be provided but at a lower reading level if needed).

3. For children 6 and under, neither written assent nor verbal assent that is scripted is required (unless you want to). This type of assent can be a short, one-sentence question between the researcher and child (e.g., "Would you like to help me with my project?").

In addition to the children's assent, the PI is required to solicit the consent of each child's parents or adoptive parents. If there is any other person who claims to be the child's guardian (grandparents, foster parents, etc.), the PI must contact the Research Office and IRB legal counsel will be consulted to determine whether the individual has the legal authority to make health care decisions on behalf of the child and therefore is the guardian as defined in federal regulations.

Parents must be consented following criteria in 45 C.F.R. 46.116(a) (see Section 5.1) and any additional elements the IRB deems necessary. One parent's signature is sufficient for research

that is minimal risk or greater than minimal risk with the prospect of direct benefit to the participant (see 45 C.F.R. 46.404 and 45 C.F.R. 46.405).

For research conducted under 45 C.F.R. 46.406 and 45 C.F.R. 46.407, consent is required from both parents unless:

1. One parent is deceased, unknown, incompetent, or not reasonably available; or

2. When only one parent has legal responsibility for the care and custody of the child.

Parental consent must be documented according to 45 C.F.R. 46.117.

**Waiver of Parental Informed Consent**

The OHRP has addressed whether parental permission can be "passive" on its website (see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html):

> Terms such as "passive" or "implied" consent are not referenced in the HHS regulations. However, OHRP is aware that these terms are sometimes used by researchers or IRBs to describe a process in which consent or parental permission requirements have been altered or waived, or for which the requirement to document consent or parental permission has been waived.
>
> The term "passive consent" is sometimes used in research with children to describe situations in which the researcher can assume that a parent is permitting a child to participate. For example, researchers collecting survey and behavioral data from children at school provide parents with information regarding the study by mail and ask the parent(s) to return a form if they do not want their child to participate. Sometimes this practice is referred to as an opt out procedure, which is not consistent with the regulatory requirement for seeking and obtaining parental permission.

Even though the regulations do not contemplate passive consent, the IRB may waive the requirement to obtain parental permission. There are essentially two ways in which the IRB may waive this requirement when the research involves children:

1. Under 45 C.F.R. 46.408(c), the IRB may waive informed consent if the IRB finds and documents all of the following factors:

    a. The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children);

    b. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and

    c. The waiver is not inconsistent with federal, state, or local law.

2. Under 45 C.F.R. 46.116(f), the IRB may waive informed consent if the IRB finds and documents all of the following factors (see Section 5.6):

    a. The research involves no more than minimal risk to the subjects;

    b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

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

    d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

It is important to note that the CITI training module, which is a required training for all human subject researchers at UW, states with regard to waiver of informed consent that "impracticable does not mean time consuming, expensive, or inconvenient. Researchers will have to provide acceptable evidence to their IRBs that securing consent is not feasible (capable of being done or carried out), regardless of cost and time".

### 8.5 Inclusion of Adults Who Lack Decision-Making Capacity in Research

Special procedures for IRB review and approval apply to research activities involving potential research subjects who, for a wide variety of reasons, are incapacitated to the extent that their decision-making capabilities are diminished or absent. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems. Conversely, individuals with these problems should not be presumed to be cognitively impaired.

Generally, cognitively impaired potential or actual research subjects may not understand the difference between research and treatment or the dual role of the researcher. Therefore, when appropriate, it is essential that the consent/assent process clearly indicate the differences between individualized treatment (e.g., special education in classroom settings) and research.

PIs should also consider implementing DSMP to review the consent/assent process (see Section 7.4). PIs may want to consider using an independent expert to assess the participant's capacity to consent or assent. PIs need to specify in the research proposal consent, assent, and legally authorized representative procedures.

Participants unable to consent must have the consent of their legally authorized representative. The IRB will evaluate whether participants unable to consent should be required to assent to participation. The IRB will only approve research involving adults that cannot consent provided the following criteria are met:

1. The research question cannot be answered by using adults able to consent;

2. The research is of minimal risk or more than minimal risk with the prospect of direct

benefit to each individual participant;

3. The assent of the adult will be a requirement for participation unless the adult is incapable of providing assent; and

4. When assent is obtained, the PI will document the assent by noting on the consent or assent form that the participant assented to participate in research.

## 8.6 Student Research with Human Subjects

Student research involving human subjects falls into one of two categories: (1) research practica, or (2) directed or independent research projects.

### Research Practica

Research practica are class projects or assignments designed to provide students an opportunity to practice various research methodology such as performing interviews, conducting surveys, observing subjects, holding focus groups, or analyzing data. Research practica are intended to provide students in the class with a learning experience about research. They are not intended to create new knowledge about the participants, to result in generalizable information, or to lead to scholarly publication.

Research practica do not require an IRB proposal unless, due to the vulnerability of subjects or the potential risk to subjects, the project falls into one of the following categories:

1. Studies in which data will be collected from minors, pregnant women, prisoners, or cognitively impaired persons;

2. Studies in which students will be asking about illegal activities, such as underage drinking or illegal drug use, which place the data at risk of subpoena;

3. Studies in which subjects are at risk if confidentiality is breached, such as one that asks about socially stigmatized behaviors and attitudes; or

4. Studies that place subjects at risk due to emotionally charged subject matter.

While an IRB proposal is not required, the faculty or staff member must complete and submit to the IRB the "Classroom Research Information Sheet" on the Research Office webpage. If a class assignment moves from the category of "non-research" into the category of "regulated research" because faculty or students decide to use the data for further research and publication, the faculty member or student must submit a full IRB proposal for approval prior to taking this next step. Any data obtained under research practica may not be used for research purposes.

### Research Projects, Directed or Independent

Any research conducted by undergraduate students, graduate students, or faculty that does not fall under the definition of a research practicum, is considered a research project. A research project that uses human subjects and is intended to contribute to generalizable knowledge must

be reviewed and approved by the IRB. This research includes, but is not limited to, independent undergraduate research projects and honors theses, masters' theses, and doctoral dissertations. A research project may be exempt from IRB review, but it must meet explicit criteria, and the IRB must approve the exemption.

**Responsibility of Faculty**

If research practica involving human subjects will be taking place in the classroom, the faculty member must fill out and submit a one-page informational sheet to the Research Office (see Research Office webpage). Faculty have a responsibility to ensure that research practica are conducted according to the ethical standards of the relevant discipline. Faculty also have a responsibility to determine when an undergraduate or graduate student project does not meet the definition of a practicum and must be reviewed by the IRB.

When student research activities are not practica, faculty are responsible for assisting students in preparing and submitting an IRB proposal and to ensure that students complete the required human subjects research training module at https://www.citiprogram.org/. IRB approval will not be granted without documentation of the required training. Although members of the IRB and staff strive for timely IRB approval, the process can be lengthy, and it is recommended that faculty and students look at the IRB proposal deadline and meeting schedule available at the Research Office webpage.

All student-led research, regardless of whether it is a thesis, dissertation, or independent project, must be accompanied by a letter from a faculty sponsor stating that he or she has read and reviewed the research plan and will provide oversight of the project. The faculty sponsor will be the individual responsible to the IRB should any adverse events occur.

**History of Revisions.**

3/26/2021 – Final approval of new policy