# WOU INSTITUTIONAL REVIEW BOARD (IRB) POLICY FOR THE PROTECTION OF HUMAN PARTICIPANTS

REV. 01/15/18

# POLICY FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

## *I. Purpose*

1. The purpose of the review of research involving human participants (in compliance with Title 45, Part 46 of the Code of Federal Regulations for the Department of Health and Human Services, and effective January 18th, 2018, and the Notice of the Secretary of Health, Education and Welfare dated May 20, 1975) is to insure the protection of the human participants in such research. It is the responsibility of the Institution to insure this protection by providing:
    A. Review and approval of each research project prior to the beginning of that activity by an Institutional Review Board (IRB), which will help to assure that:
        i. The risks of injury to the subject, if present, are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
        ii. The rights and welfare of any such participants will be adequately protected; and
        iii. Informed consent will be obtained by adequate and appropriate methods in accordance with the provision of the regulation.
    B. For the certification of such review and approval.
    C. For a continuing review of all research activities in keeping with the above.

## *II. Definitions for the Purpose of this Policy*

2. Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.
3. Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
4. Department or agency head means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.
5. Federal department or agency refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).
6. Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
    A. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
    B. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
7. Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
8. Interaction includes communication or interpersonal contact between investigator and subject.
9. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been

provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

10. **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
11. An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
12. **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).
13. **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.
14. **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
15. **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
16. **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.
17. **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.
18. **Written, or in writing**, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

## *III. Institutional Review Board (IRB) – Duties/Responsibilities*

19. Responsibilities: The IRB will be responsible for:
    A. Implementing WOU's policy for the protection of human participants in a manner as supportive as possible to research at WOU.
    B. Informing research investigators of WOU's policies and procedures for the protection of human participants.
    C. Reviewing research requests, approving, requiring modifications in, or rejecting requests based on risk of injury to participants.
20. In order to approve research covered by 45 CFR §46, the IRB shall determine that all of the following requirements are satisfied:
    A. Risks to the subject are minimized:
        i. By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
        ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
    B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

C. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
D. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR §46.116.
E. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR §46.117.
F. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
G. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

21. For purposes of conducting the limited IRB review required by 45 CFR §46.104(d)(7), the WOU IRB shall make the following determinations:
    A. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR §46.116(a)(1)-(4), (a)(6), and (d);
    B. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR §46.117; and
    C. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
    D. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
22. The WOU IRB will notify the investigator(s) of action taken on requests and the rationale for any action.
23. The WOU IRB will prepare and maintain adequate documentation of IRB activities, in accordance with, and to the extent required by 45 CFR §46.115, including:
    A. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.
    B. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
    C. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in 45 CFR §46.109(f)(1).
    D. A list of IRB members in the same detail as described in 45 CFR §46.108(a)(2).
    E. Copies of all correspondence between the WOU IRB and the investigators.
    F. Written procedures for the IRB in the same detail as described in 45 CFR §46.108(a)(3) and (4). This includes but is not limited to this IRB Procedures manual.
    G. Statements of significant new findings provided to subjects as required by 45 CFR §46.116(c)(5).
    H. The rationale for an expedited reviewer's determination under 45 CFR §46.110(b)(1)(i) that research appearing on the expedited review list described in 45 CFR §46.110(a) is more than minimal risk.
    I. Documentation specifying the responsibilities that WOU and, as the organization operating this IRB will undertake to ensure compliance with the requirements of this policy, as described in 45 CFR §46.103(e).

J. The records required by this policy shall be retained for at least 5 years, and records relating to research conducted shall be retained for at least 3 years after completion of the research. The institution or the WOU IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

24. The IRB has the responsibility to report to the chief academic officer (CAO) any unanticipated problem identified to the IRB involving injury to participants or others, including adverse psychological or medical complications. (Note - it is the responsibility of the principal investigator to report promptly in writing any proposed changes in the research activity that increases risk of injury and unanticipated problems involving injury to participants or others. It is then the IRB's responsibility to re-evaluate the project for risk of injury).
25. It is appropriate for individual members of the IRB to be supportive to the investigator by interpreting WOU's policy for the protection of human participants and by assisting investigators in the preparation of materials for IRB review.

## *IV. Procedures*

26. General procedures
    A. The WOU IRB chair will distribute promptly to all IRB members copies of all completed requests that do not meet the conditions for exempt or expedited review (i.e., requests that need a full board review). The IRB chair will forward requests that meet criteria for exempt to one IRB committee member for review. Requests that meet criteria for expedited review will be forwarded to two committee members for review. Members will respond promptly to the chair by completing requisite review documentation within established timelines and indicating:
        i. Classification of proposed project as exempt, expedited, or full.
        ii. Approval or disapproval based on the policy for the protection of human participants.
        iii. Deferral based on inadequate information.
        iv. Deferral based on specified conditions that must be met (Note – a deferred project may not be initiated or continued until approved by the IRB).
    B. IRB notifications
        i. The WOU IRB will notify, in writing, the principal investigator of its decisions regarding the research activities it reviews. The IRB will attach to its notification a copy of the record of the IRB's review of the research activity and a summary of reviewer concerns.
        ii. If the research activity is approved, a copy of the IRB's letter of approval will be attached to the notification. The IRB will also identify the date by which the next continuing review must take place.
        iii. If the activity is approved subject to modifications, the IRB will explain the required modifications and the basis for them.
        iv. If the activity is disapproved, the IRB will provide a statement of the reasons for its decision, and will offer the investigator an opportunity to respond in person or in writing.
        v. The IRB will also provide investigators with written instructions directing them to report promptly to the IRB any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Final Common Rule or the WOU IRB's requirements.
        vi. The IRB will promptly notify investigators, appropriate institutional officials in the CAO office, and the IRB office, of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Final Common Rule or the IRB's determinations of which it becomes aware.

vii. If the research is suspended or terminated by the IRB, the IRB shall state the reasons for its action and shall report its action in writing to the investigator, the appropriate institutional officials in the CAO office, and the department or agency head.
viii. The IRB will report promptly to investigators and institutional officials any findings or actions not pertaining exclusively to any one particular research activity, as appropriate.

27. Continuing review
    A. The IRB will conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not more than once per year, except as described in 45 CFR §46.109(f).
    B. The IRB may be called into an interim review session by the IRB chair at the request of any IRB member or any university institutional official to consider any matter concerning the rights or welfare of any subject.
    C. The IRB will use the same criteria to make decisions about continuing reviews as it does for initial reviews. It will make continuing review decisions using the material submitted for the initial review, the records of the IRB's initial review, and any new information relevant to the research activity and the IRB's criteria for approval:
        i. At the request of any member.
        ii. At the request of a principal investigator for a formal hearing following disapproval or suspension by the IRB.
        iii. When any member classifies a project as full.
        iv. For other IRB business including proposed policy changes.
    D. For non-minimal risk research, projects will undergo annual continuing review.
    E. Unless the IRB determines otherwise, a five-year continuing review cycle, rather than an annual continuing review cycle will be used under the following circumstances:
        i. The research is eligible for expedited review in accordance with 45 CFR §46.110;
        ii. The research is reviewed by the IRB in accordance with the limited IRB review described in 45 CFR §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
        iii. The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
            1. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
            2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.
28. Exempt or expedited review
    A. If a research request is clearly exempt or expedited (see Classification of Proposed Research—Section VI.), the chair or designee has the authority to expedite the process by assigning exempt or expedited to the project without the necessity of full committee review. Records of the request and its disposition should be maintained by the IRB regardless of whether the request has received full committee or expedited review.
29. Student-initiated research
    A. The role of the WOU IRB is to ensure that research projects involving human subjects are conducted in accordance with accepted ethical and governmental standards related to the protection of human subjects. Although the IRB requires that a faculty member supervise all student research projects, direct IRB review of student projects is only necessary under the following circumstances:
        i. The student class assignment is intended to collect information that will contribute to generalizable knowledge;
        ii. If there is any chance of publication beyond WOU;
        iii. If a faculty member believes that there is any potential for dissemination of class project activities beyond WOU (for example if there is the potential for students to present research at a local, state or national conference, as a result of research activities conducted within a course);
        iv. The project poses more than minimal risk to participants; or

v. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

B. Student theses, honors projects, and independent study projects are by their nature intended to add to generalizable knowledge and not contained within the formal classroom environment. These projects, if they involve human subjects, are always subject to IRB oversight. All such projects must involve a sponsoring/supervising faculty member who must carefully review, approve and sign the IRB application before forwarding it to the IRB.

C. IRB review is not necessary if student class projects are not systematic data collection efforts involving human subjects that are intended to develop or contribute to generalizable knowledge and thus do not meet the federal regulatory definition of research (see45 CFR §46.102(l), if they involve minimal risk to human participants and do not involve members of vulnerable populations, they do not fall under the jurisdiction of the IRB and DO NOT require IRB application, approval, or oversight. These include Academic Excellence Showcase projects that pose minimal risk, do not involve vulnerable populations, and are not intended for dissemination beyond WOU.

## *V. Investigator Responsibilities*

30. WOU administrative or faculty approval of a research proposal is independent of review by the IRB. However, administrative or faculty approval of an individual research project involving human participants is conditional upon IRB approval, and the involvement of human participants may not begin prior to written IRB approval. Conversely, IRB approval of a research project does not bind the investigator to initiate or complete the project.

31. Responsibilities
    A. The principal investigator is responsible for furnishing the IRB with all information necessary for the IRB to meet its responsibilities with the complete application. Copies or descriptions of proposed tests, questionnaires, and all research materials to be used should also be furnished to the IRB.
    B. If the approved project is modified after IRB action in any way, it must be resubmitted to the IRB. New approval must be given to the researcher before any changes are made in the data collection procedure.
    C. The investigator will promptly inform the IRB by memo of any unexpected detrimental effect on a subject, steps taken to eliminate or reduce this effect, and efforts to assure the effect will not reoccur.
    D. If for any reason an approved research project is not initiated within (1) twelve months from the date of approval for non-minimal risk research or (2) five years from the date of approval for research meeting criteria outlined in IV.27.E. of the previous section, and there is intent to involve human participants, the investigator will resubmit the project for re- approval.
    E. The investigator will submit requests for continuation of approved projects annually for non-minimal risk research and every five years for all other approved projects if the research remains in a phase where human subjects are directly participating.
    F. The investigator will be responsible for collection and retention of all signed informed consents from participants (or from legally authorized representatives, when necessary) for a period of three years following completion of the project (see Informed Consent—Section VII).
    G. Before initiating any research involving human subjects, investigators must submit documentation of successful completion of CITI training.

## *VI. Classification of Proposed Research*

32. For the purposes of protection of human participants, research projects involving human participants fall under these categories:

33. Exempt research
    A. The following is exempt from IRB review unless covered by other subparts of the Code of Federal Regulations (45 CFR §46.104(a) and (b)). This research is reported to the IRB for tracking purposes only.
    B. Research conducted in established or commonly accepted educational settings when it specifically involves normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes (i) most research on regular and special education instructional strategies, and (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
    C. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
        i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
        ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
        iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR §46.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality) .
    D. 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 three criteria is met:
        i. The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects;
        ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
        iii. The information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR §46.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality).
    E. Secondary research use of identifiable private information and identifiable biospecimens for which consent is not required, if at least one of four criteria is met:
        i. The identifiable private information or identifiable biospecimens are publicly available;
        ii. The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects;
        iii. The secondary research activity is regulated under HIPAA; or

iv. The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected.

F. Research and demonstration projects conducted or supported by a federal department or agency.

G. Taste and food quality evaluation and consumer acceptance studies. This exemption applies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe by FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

H. Storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens for which broad consent is required. This requires that an IRB conduct limited IRB review to make the following determinations:

i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR §46.116(a)(1)–(4), and (a)(6), and (d);

ii. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR §46.117; and

iii. If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data.

I. Research involving the use of identifiable private information or identifiable biospecimens for which broad consent is required. This exemption will frequently be paired with Category 7. This exemption would apply to a specific secondary research study, provided that the following criteria are met:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR §46.116(a)(1)–(4), (a)(6), and (d);

ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR §46.117;

iii. An IRB conducts a limited IRB review to make the determination required by 45 CFR §46.111(a)(7), and to make the determination that the research to be conducted is within the scope of the broad consent; and

iv. The investigator does not include returning individual research results to subjects as part of the study plan. However, it is permissible under this exemption to return individual research results when required by law regardless of whether or not such return is described in the study plan.

J. The secondary analysis of existing private identifiable data and identifiable biospecimens, provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 45 CFR §46.111(a)(7), and that the use is within the scope of the broad consent. Category J also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

34. Research qualifying for expedited review

A. Research within this category presents no more than minimal risk of injury to participants as a result of the activity. Informed consent is necessary.

B. Under an expedited review procedure, the review will be carried out by two or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved

only after review in accordance with the nonexpedited procedure set forth in 45 CFR §46.108(b).

C. The IRB will use expedited review procedures to review the following:
    i. Some or all of the research appearing on the list provided in item D. of this section, unless the reviewer determines that the study involves more than minimal risk;
    ii. Minor changes in previously approved research during the period for which approval is authorized; or
    iii. Research for which limited IRB review is a condition of exemption under 45 CFR §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

D. Expedited Review Categories: (According to 45 CFR §46 as published in the Federal Register revised January 15, 2009, and effective July 14, 2009). To qualify for expedited review, all aspects of the study must involve only procedures in one or more of the following seven categories. 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 regardless of age.
    i. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
    ii. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR §46.402(a)).
    iii. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
    iv. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a)

physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

v. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR §46.104. This listing refers only to research that is not exempt.)
vi. Collection of data from voice, video, digital, or image recordings made for research purposes.
vii. 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, 45 CFR §46.104. Please see above description of Exempt Research. This listing refers only to research that is not exempt.)

35. Research requiring full review
    A. Research within this category poses a risk of harming participants or violating their rights. May require special protections for participants. Informed consent is necessary, together with assurance of precautions to minimize the risk and significance of injury. Cannot be approved unless in the IRB's judgment the sum of direct benefits to the subject and the importance of the knowledge to be gained outweigh the risks to the subject. Full review is necessary for all research proposals which are not Exempt or otherwise subject to Expedited Review.
36. Determination of risk
    A. Human subjects research may pose either minimal risk or greater than minimal risk to participants.
    B. 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.
    C. Research that poses greater than minimal risk involves the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity that departs from the application of those established and accepted methods necessary to meet his/her needs or which increase the ordinary risks of daily life.
    D. If a determination is made by the WOU IRB that participants will be placed at risk of injury, the IRB must determine, before approving a research project:
        i. That the risks of injury to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
        ii. That the rights and welfare of the subject will be adequately protected; and
        iii. That informed consent will be obtained as outlined in the next section of this document.
37. Examples of risk
    A. Psychological risk: (May be experienced during the research situation and/or later, as a result of participation in the research.) Including but not limited to: depression, loss of self-esteem, feelings of stress, guilt, anxiety, confusion, embarrassment, invasion of privacy.

B. Social risk: Including, but not limited to, negative effects on standing in group or community, overt hostile reaction by others, reduced opportunity for communication, diminished access to otherwise available roles, lost or endangered membership in groups.
C. Physical risk: Including but not limited to: illness, injury, minor discomfort such as temporary dizziness, headaches or pain associated with venipuncture.
D. Economic risk: Including but not limited to: loss of present or future employment, loss of opportunity for career advancement, loss of eligibility for insurance, cost relating to participation in research (including cost for research-related injuries).
E. Legal risk: Including but not limited to: criminal prosecution, civil lawsuit.

38. Research not requiring IRB review
    A. Research that does not require IRB review includes, but is not limited to, the following:
        i. Any research not involving human subjects
        ii. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
        iii. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
        iv. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
        v. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

## *VII. Informed Consent*

39. Informed consent has been defined as "the knowing consent of an individual or legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion."

40. General requirements for informed consent
    A. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
    B. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
    C. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
    D. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
    E. Except for broad consent obtained in accordance with 45 CFR §46.116(d), informed consent must:
        i. Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in

understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

ii. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

F. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

G. Signed informed consent forms must be retained by the principal investigator for a period of not less than three years following the completion of the investigation.

H. Any proposed or continuing project that poses a potential risk to unborn children of participants must be indicated to the IRB, and the informed consent form must include the following statement: "This project poses a potential risk to unborn children. Pregnant women are asked to not participate."

I. If the IRB determines that there is risk of physical injury, informed consent must include any provisions made for medical treatment or compensation in the event of injury.

J. Before a statement concerning provisions for medical treatment or compensation for physical injury is prepared for informed consent, the investigator should meet with WOU Legal Counsel to establish the level of WOU's responsibility.

41. Basic elements of informed consent

A. Except as provided in paragraph 45. or 46. of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

i. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

ii. A description of any reasonably foreseeable risks or discomforts to the subject;

iii. A description of any benefits to the subject or to others that may reasonably be expected from the research;

iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

v. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

vi. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

vii. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

viii. 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; and

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

1. 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; or

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

42. Additional elements of informed consent.
    A. Except as provided in paragraph 45. of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:
        i. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
        ii. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
        iii. Any additional costs to the subject that may result from participation in the research;
        iv. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
        v. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
        vi. The approximate number of subjects involved in the study;
        vii. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
        viii. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
        ix. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

43. Research with minor participants
    A. The principal investigator is responsible for obtaining informed consent from all participants, parents, guardians, or legally authorized representative if the subject is under age 18.
    B. The informed consent must include the subject's assurance that they are 18 or older; if the research is taking place where the legal age is higher or lower, the researchers must obtain the subject’s assurance that they are of legal age in that local environment. No participants under 18 as of the date of the informed consent may participate without the signed consent on the form of at least one parent or guardian. Informed consent must be re-completed by the subject as soon as they attain 18 years of age, if the subject is still participating in research. (Note: It is the investigator's responsibility to check birth date and to obtain parental, guardian, or legally authorized representative consent if a student under age 18 is to serve as a subject).
    C. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, if in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. 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 if the IRB

determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with 45 CFR §46.116.

D. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by 45 CFR §46.116, that adequate provisions are made for soliciting the permission of each child's parent(s) or guardian(s). If parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted.

E. If the IRB determines that a 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 participants (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

F. Permission by parents, guardians, or legally authorized representatives must be documented in accordance with and to the extent required by 45 CFR §46.117.

G. If the IRB determines that assent is required, it shall also determine whether and how assent must be documented. Assent can be obtained by:

i. Developing a form that includes the following six points and is submitted to the IRB for approval:

ii. A fair explanation of the procedures to be followed and their purposes, including identification of any procedures that are experimental. In the event that the research requires that participants be left uninformed about certain aspects or hypotheses of the research, the researcher must provide the IRB with a rationale for such exclusions or deceptions. In certain cases, the IRB may require researchers to provide the IRB with a written debriefing statement to be given to participants upon completion of the research and provide a rationale for the use of deception or withholding information in the informed consent procedure.

iii. A description of any attendant discomforts and risks reasonably to be expected (Note - since informed consent is premised on the possibility of risk, the form should make reference to risks).

iv. A description of any benefits reasonably to be expected.

v. A disclosure of any appropriate alternative procedures that might be advantageous for the subject (Note - reference to alternative procedures need only be made on the form if such alternatives exist).

vi. An offer to answer any inquiries concerning the procedures.

vii. An instruction that participants are free to withdraw their consent and to discontinue participation in the project or activity at any time without prejudice to the participants.

44. Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

A. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements in paragraphs 41. or 42. of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

i. The information listed in 45 CFR §46.116(b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9);

ii. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

iii. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

iv. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

v. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

vi. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

vii. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

45. General waiver or alteration of consent.

A. Waiver. The WOU IRB may waive the requirement to obtain informed consent for research under paragraphs 41. through 43. of this section, provided the IRB satisfies the requirements of paragraph 45.C. of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph 44. of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

B. Alteration. The WOU IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs 41. and 42. of this section provided the IRB satisfies the requirements of paragraph 45.C. of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph 44. of this section.

C. Requirements for waiver and alteration. In order for the WOU IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

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

ii. The research could not practicably be carried out without the requested waiver or alteration;

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

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

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

D. Screening, recruiting, or determining eligibility.

i. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

46. Posting of clinical trial consent form.
    A. For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.
    B. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
    C. The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.
47. Preemption.
    A. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.
48. Emergency medical care.
    A. 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 (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
49. Documentation of informed consent.
    A. Except as provided in paragraph 45. of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.
    B. Except as provided in paragraph 28 of this section, the informed consent form may be either of the following:
        i. A written informed consent form that meets the requirements of 45 CFR §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
        ii. A short form written informed consent form stating that the elements of informed consent required by 45 CFR §46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by 45 CFR §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.
    C. An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:
        i. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach

of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

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

iii. 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.

D. 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.

## *VIII. Additional Protections for Special Populations of Participants*

50. Fetuses, pregnant women, and human in vitro fertilization

A. General limitations: No research activity may be begun unless:

i. Appropriate studies on animals and non-pregnant individuals have been completed;

ii. Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and in all cases, is the least possible risk for achieving the objectives of the activity;

iii. Individuals engaged in the activity will have no part in (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

iv. No procedural changes that may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

v. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

B. Activities directed toward pregnant women as participants: No pregnant woman may be involved as a subject in an activity unless:

i. The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or

ii. The risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means.

iii. An activity permitted under this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if:

1. His identity or whereabouts cannot reasonably be ascertained;
2. He is not reasonably available; or
3. The pregnancy resulted from rape.

C. Activities directed toward fetuses ex utero, including nonviable fetuses, as participants: Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity unless:

D. There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means; or

E. The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

F. No nonviable fetus may be involved as a subject in an activity unless:

i. Vital functions of the fetus will not be artificially maintained;

ii. Experimental activities that of themselves would terminate the heartbeat or respiration of the fetus will not be employed; and
iii. The purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means.

G. In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other parts of this section.
H. An activity may be conducted only if the mother and father are legally competent and have given their informed consent, except that father's informed consent need not be secured if:
   i. His identity or whereabouts cannot reasonably be ascertained;
   ii. He is not reasonably available; or
   iii. The pregnancy resulted from rape.
I. Activities involving the dead fetus, fetal material, or the placenta: Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities.

51. Incarcerated individuals
   A. Inasmuch as incarcerated individuals may be under constraints because of their incarceration that could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as participants in research, it is the purpose of this section to provide additional safeguards for the protection of incarcerated individuals involved in research.
   B. When research involving incarcerated individuals is reviewed, the CAO of WOU has the option to appoint a temporary at-large member to the IRB who has appropriate background and experience [to represent the prisoner's perspective] to assist the IRB in their review of the particular research project, only one IRB member need satisfy this requirement.
   C. The IRB shall review and approve research only if it finds that:
      i. The research is in a permissible category (see next section);
      ii. 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 institutions, 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 institutions is impaired;
      iii. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
      iv. Procedures for the selection of participants within the institutions are fair to all incarcerated individuals and immune from arbitrary intervention by institutions authorities or incarcerated individuals. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available incarcerated individuals who meet the characteristics needed for that particular research project;
      v. The information is presented in language that is understandable to the subject population;
      vi. 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; and
      vii. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of an individual prisoner's sentence, and for informing participants of this fact.
   D. Permitted research involving incarcerated individuals: Biomedical and behavioral research may involve incarcerated individuals as participants only if the proposed research involves solely the following:
      i. 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 participants;

ii. Study of prisons as institutional structures or of incarcerated individuals as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
iii. Research on conditions particularly affecting incarcerated individuals as a class (for example, vaccine trials and other research on hepatitis that is much more prevalent in institutions than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only (when DHHS funding is sought) after the Secretary of DHHS, DOE or other government agency 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
iv. 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 incarcerated individuals in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the study may proceed only (when DHHS funding is sought) after the Secretary 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.

52. Children
    A. Research not involving greater than minimal risk (exempt and expedited)
        i. The IRB may approve projects in which no greater than minimal risk to children is presented, only if adequate provisions are made for soliciting the assent of the children and the permission of their parents, guardians, or legally authorized representative.
    B. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants (full)
        i. The IRB may approve projects in which more than minimal risk to children is presented by an intervention or procedure than 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, only if:
            1. The risk is justified by the anticipated benefit to the participants;
            2. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches;
            3. Participants rights are adequately protected; and
            4. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
    C. Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the subject's disorder or condition
        i. The IRB may approve projects in which 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 that is not likely to contribute to the well-being of the subject, only if:
            1. The risk represents a minor increase over minimal risk;
            2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
            3. The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition that is of vital importance for the understanding of amelioration of the participants' disorder or condition;
            4. Participants' rights are adequately protected; and
            5. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

D. Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children
    i. The IRB may approve projects in this category only if:
        1. 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; and
        2. When Department of Education or other government agency funding is sought, the Secretary of the Department of Education or other government agency, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
            a. That the research satisfies the conditions of the above categories; or
            b. The following:
                i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
                ii. The research will be conducted in accordance with sound ethical principles;
                iii. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

E. Requirements for permission by parents or guardians and for assent by children
    i. The IRB shall determine that adequate provisions are made for soliciting the assent of the children. Almost all children are capable of assenting. The IRB shall take into account the ages, maturity, psychological state, and communication modalities of the children involved. The judgment may be made for all children to be involved in research under a particular protocol, or, for each child, as the IRB deems appropriate. The IRB committee will encourage research teams to include assent procedures that support all children.
    ii. In addition, the IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants. For research involving greater risk and no prospect of direct benefit to participants, permission is to be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
    iii. If the IRB determines that a 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 participants (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanisms for protecting the children who will participate as participants in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.
    iv. Permission by parents, guardians, or legally authorized representative shall be documented.
    v. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

F. Wards

i. Children who are wards of the state or any other agency, institution, or entity can be included in research only if such research is:
    1. Related to their status as wards; or
    2. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.
    3. If the research is approved, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

## *IX. Action*

53. Project approval
    A. In principle, IRB approval will be initiated or continued for a research project that in IRB committee's judgment meets any of the following conditions:
        i. Presents no risk of injury to participants;
        ii. If risk of injury is involved, this risk is outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained;
        iii. Participants' rights are adequately protected, and informed consent is obtained by adequate and appropriate methods.
    B. IRB approval will be given to proceed for projects that have the approval of the majority of the members with the exception of research classified as full. The chair will have one vote. No members may vote on a project in which they are associated as an investigator or project supervisor.
    C. A project classified as full board review by the majority of the IRB must have the approval of two- thirds of the IRB based on the judgment that the benefits to the subject and others clearly outweigh the risk of injury to the subject, and that every precaution is being taken to minimize risk and significance of injury.
    D. IRB approval does not constitute full institutional authorization for a project to begin or continue, but only the IRB's judgment that appropriate attention is being given to the protection of human participants.
54. Project deferral
    A. The IRB will defer its decision on approval or disapproval of a request based on any of the following:
    B. Inadequate information from the investigator to permit an IRB decision;
    C. Absence of, or unsatisfactory provisions for informed consent if required by the IRB;
    D. Inadequate assurances of precautions to be taken to minimize risk and significance of injury if required by the IRB
55. Project disapproval
    A. In principle, the IRB will disapprove the initiation or continuation of research that in its judgment involves the risk of injury that outweighs the benefit to the subject and the importance of the knowledge to be gained.
    B. Disapproval of a project by the IRB may not be overturned by any other body or person within or outside WOU. A hearing will be granted if requested by the principal investigator, the principal investigator's supervisor, or an officer of WOU in order to present additional information or project modifications which might lead the IRB to reverse its decision.
    C. Disapproval may be based on:
        i. Approval of the project by less than a majority of the IRB on their interpretation of the WOU policy for the protection of human participants;

ii. Classification as a full board review project and lack of approval by two-thirds of the IRB.

56. Project suspension
    A. The IRB may suspend a project, on the vote of the majority of the IRB based on information that:
        i. Unanticipated problems increasing risk of injury to participants have arisen;
        ii. The project has been modified with the potential for adding risk of injury to students;
        iii. The principal investigator has withheld information from the IRB, deliberately or otherwise, which may lead to disapproval of the project;
        iv. Failure to obtain or demonstrate to the IRB that informed consent has been obtained as required; or
        v. Non-compliance by any party with the Federal, state or institution policy.

## *X. Cooperative Research*

57. Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.
58. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
59. The following research is not subject to this provision:
    A. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
    B. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
60. For research not subject to paragraph 55 of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.
61. WOU-initiated research in other institutions
    A. WOU researchers seeking the cooperation of other institutions in WOU-initiated research involving human participants must submit their proposals to the IRB for approval regardless of approval by the other institution. Although compliance of other participating institutions with applicable regulations is the responsibility of those institutions, research sponsored wholly or in part by WOU must comply with WOU's policy.
    B. If the cooperating institution has its own IRB for the protection of human participants, it may wish to conduct its own review. The WOU researcher is urged to submit the proposal first to the IRB since its decision and conditions are binding on WOU personnel (the outside IRB may add conditions or decline the participation of its institution). The decision and any conditions to be added by the outside IRB must be received in writing by WOU's IRB before participants become actively involved in the cooperating institution. The decision of WOU's IRB and the WOU policy for the protection of human participants will be forwarded to the outside IRB upon request.
    C. If the cooperating institution does not have its own IRB for the protection of human participants, the investigator should share with that institution the information presented to WOU's IRB, and the decision reached by the IRB. A letter should be prepared by the appropriate official of that institution, on the institution's letterhead, which indicates that the proposal and the decision of WOU's IRB have been reviewed, and that the official believes the decision conforms to the Department of Education or other government agency guidelines

for the protection of human participants. If that institution adds any conditions for the protection of human participants in that institution, these added conditions should be indicated in the letter. The letter should be addressed to the WOU investigator who, upon receipt, should forward a copy to the chairperson of the WOU IRB. Data collection in that institution may not begin until after this letter has been filed with the WOU IRB.

D. The WOU researcher must retain the original or a copy of all informed consents, if required by WOU or cooperating institutions, and comply with all other aspects of the WOU policy.

62. Third party research at WOU
    A. WOU will entertain inquiries from outside institutions and investigators who wish to conduct research and collect all or some of their data at WOU. Regardless of whether a project has been reviewed and approved by the IRB of another institution, it must also be reviewed and approved by WOU's IRB before data are collected at WOU. If the applicant is affiliated with another institution IRB, that IRB should first review the proposed research, and a copy of its findings and documentation should be forwarded to WOU's IRB, as described in item 58.b.i. of this section. WOU's IRB may not reduce the conditions for approval but may add conditions or disapprove the participation of WOU.
    B. If another university has approved research through its IRB, then WOU should have reciprocity with that acceptance. The following guidelines refer to any data collection involving human subjects that is conducted by WOU faculty/staff or students occurring on-campus. This procedure has been developed to protect the safety of both participants and researcher/s and encompasses data collection on or off the WOU campus.
        i. In the case of a research protocol developed and approved by another institution's IRB, the investigator must submit a copy of the IRB approval letter and the institution's federal-wide assurance number as well as any surveys or interview questions and the consent form used to the WOU IRB.
        ii. Consent forms accompanying data collection at WOU must include contact information for at least one WOU-affiliated investigator. This will likely involve using the same consent form already approved by the other institution's IRB and adding WOU contact information.

## *XI. Institutional Review Board Membership*

63. General requirements of IRB membership
    A. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
    B. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
    C. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.
    D. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.
    E. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
    F. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

G. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
H. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

64. WOU IRB constitution
    A. An IRB of five members or more to review research involving human participants will be appointed by the CAO in consultation with Faculty Senate and the faculty of The Research Institute. Membership will meet the following criteria:
    B. Varying backgrounds - membership on the IRB will be inclusive of training and experience in education and social sciences;
    C. Varying job responsibilities - the following job responsibilities will be represented: research, teaching, administration;
    D. Maturity, experience, and expertise to insure respect for its advice;
    E. Representation to insure acceptability of the IRB's conclusions in terms of:
        i. Acceptability of applications and proposals relative to institutional commitments and regulations;
        ii. Applicable law;
        iii. Standards of professional conduct and practice.
    F. Representation of community - one or more members will be selected from outside WOU.
65. The IRB and its chair will be elected by the IRB committee for a three-year term. The initial IRB will have members appointed for varied lengths of membership in order to begin a staggered pattern of membership. At least one member will be selected from each of the following units of WOU: College of Education, College of Liberal Arts and Sciences, and The Research Institute. One or more members will be appointed from outside WOU. Members may be re-appointed. To assure an active and effective IRB, the IRB Chair will promptly replace, following approval from the IRB, members who resign or otherwise fail to meet their responsibilities.

Note. All policies and statements outlined in this document are subject to amendment.