

The University of Montana

**Institutional Review Board (IRB)  
Policies and Procedures Manual**

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# Chapter 1: Introduction and IRB Overview

## 1. Introduction

### Mission and Purpose

The University of Montana (UM) Institutional Review Board (IRB) ensures the protection of the rights, welfare, and privacy of human research participants. The IRB's purpose is to protect the rights and welfare of humans participating in biomedical and behavioral research conducted at the University of Montana. The IRB reviews and oversees such research to assure that it meets ethical principles and that it complies with federal regulations that pertain to human participant protection at 45 CFR 46 and 21 CFR 50 and 56, and other pertinent regulations and guidance.

This manual outlines the policies and procedures guiding IRB operations in compliance with federal regulations, institutional policies, and ethical principles.

### Authority and Scope

The IRB operates under the authority granted by the University of Montana and adheres to all federal regulations governing the conduct of human subjects research in the United States, such as 45 CFR 46 (the Common Rule) and 21 CFR 56 (FDA). The ethical principles which guide the IRB are consistent with *The Belmont Report*. These principles are defined in the Belmont Report as follows:

- Respect for Persons – Individuals should be treated as autonomous agents and persons with diminished capacity are entitled to protection
- Beneficence – Maximize the benefits and minimize the possible harms
- Justice – The burdens and benefits of research should be justly distributed

The UM IRB recognizes that Montana state and local laws may impose additional requirements and restrictions on human subjects research. To ensure that the applicable requirements are met, the IRB and/or administrative staff will consult with appropriate UM administrators and Legal Counsel when needed. The UM IRB also recognizes that local tribes may impose additional requirements and restrictions on human subjects research that involve their territory, peoples, and cultural and/or intellectual property. To ensure that applicable requirements are met, the IRB may request confirmation or other support of the conduct of the research, including but not limited to tribal IRB approval.

The UM IRB operates under the University's Federalwide Assurance (FWA) (FWA00000078), negotiated with the Office of Human Research Protections (OHRP). This Assurance authorizes the University to conduct human subject research and authorizes the UM IRB to oversee

research. To that end, the IRB is granted the authority to approve, modify, or disapprove studies, as well as to require progress reports, oversee the conduct of ongoing research, and suspend, terminate approval, or place restrictions on active studies in the consideration of human subjects protection.

Research conducted at an institution for which the UM IRB has been appointed as the IRB for that institution also falls under the purview of the University's FWA. This includes Montana Technological University (Butte, MT), University of Montana-Western (Dillon, MT), and Helena College (Helena, MT). Human subjects protocols conducted at these institutions require review by the UM IRB so long as they meet the definition of human subjects research.

All human subjects research conducted under the institution's auspices must be reviewed and approved by the IRB. This includes any biomedical and/or social-behavioral research involving human participants that is conducted by faculty, staff, and/or students of UM regardless of the source of funding and location of the study if:

- The research is conducted by or under the direction of any employee, faculty, staff, student or agent of the University of Montana in connection with his/her/their institutional responsibilities;
- The research is conducted by or under the direction of any employee, faculty, staff, student or agent of the University of Montana using any property or facility of the University of Montana;
- The research involves the use of the University of Montana's nonpublic information to identify or contact human research participants; or,
- The research involves the use or disclosure of protected health information.

The UM IRB also functions as the HIPAA Privacy Board for research for the University of Montana.

The UM-IRB is directly responsible to and shall coordinate its actions and policies with the office of Vice President for Research.

## **2. IRB Composition and Membership**

### **Membership Requirements**

The UM IRB follows the IRB membership requirements as outlined at 45 CFR 46.107 and 21 CFR 56.107. No IRB meeting will be conducted without the necessary quorum, and no Committee decisions will be made lacking the vote of at least one non-scientist and at least one scientist. If a quorum fails for any reason, no further actions are taken until quorum is restored.

**Members, including alternates, are expected to attend as many convened meetings of the IRB as possible, but no less than ½ of the convened meetings during a year.**

IRB membership is comprised of faculty members from a broad range of disciplines and the Committee includes at least one community (unaffiliated) member, at least one member without scientific expertise, and at least one member with scientific expertise. In addition, a representative from UM Office of Research and Creative Scholarship serves as a member of the IRB in an ex-officio (but voting) capacity.

A member is considered “unaffiliated” if neither that person nor a member of their immediate family is employed by the University of Montana or its affiliates. A member is considered “non-scientific” if that person’s primary profession or area of interest is in a primarily non-scientific discipline. Alternate members parallel and complement the expertise of the primary members. Unless otherwise noted, “member” in this document will refer to any potential voting member of the IRB, whether designated as a primary or alternate member.

The University of Montana is in compliance with the statutory requirement that a majority of the members (exclusive of the prisoner representative) have no association with prison(s) involved in research other than their membership on the IRB reviewing prisoner studies [45 CFR 46.304 (a)].

Membership reflects basic federal requirements for expertise and advocacy; additional members are added as necessary or appropriate to ensure protection of subjects of a particular population. The IRB may also call upon outside consultants as necessary for additional expertise on a particular topic. Outside consultants are expected to maintain the confidentiality of the research.

The UM IRB Manager is a full board member.

It is desirable to have UM IRB members represent each programs conducting human subject research.

The IRB office maintains a roster of trained alternates who may vote in place of an absent voting member. The alternate member will have similar expertise as the regular committee member for whom they are serving as a replacement (physician to physician; other scientific to other scientific; and non-scientific to non-scientific). The alternate member will assume all of the responsibilities of the committee member for whom they are serving as a substitute. Alternate members may attend IRB meetings without serving as a substitute for a regular committee member; however, in this capacity, the alternate member may not participate in any of the final approval decisions of the committee. IRB minutes will document if a member present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.

Current and past membership rosters are maintained in the IRB office. Rosters are provided to OHRP per the requirements of 45 CFR 46 Subpart E and 21 CFR 56.106. A current membership roster is also available on the IRB website.

## **Appointment and Terms**

Committee members, including alternates, are appointed by the Institutional Official (IO) to a term of three years. Committee members may be requested to accept reappointment to the IRB for an additional term of three years at the discretion of the Chair. If a member declines full

membership, they may be asked to become an alternate member. Alternates will be asked at the end of their three-year term whether they would like to continue as an alternate.

IRB members serve at will and any IRB member may resign from the IRB by written notification to the IRB Manager and/or IRB Chair. IRB members who are unable to fulfill their membership responsibilities are expected to initiate their resignation with sufficient advanced written notice to allow the IRB to identify and appoint an appropriate replacement member. The Vice President of Research/Institutional Official has the authority to remove an IRB member with good cause.

Upon the occurrence of a vacancy, the Chair will request nominations from the current pool of alternates, preferably for a person with expertise similar to the member vacating their membership. If there are several alternate members with similar expertise to the vacating member and who have served as an alternate for a similar amount of time, the Chair will select an appropriate replacement at the Chair's discretion.

Nominations shall be considered at a regular meeting of the UM IRB and voted upon by members for approval. The nominee selected by UM IRB will then be forwarded to UM Vice President for Research for final approval.

## **Roles and Responsibilities**

The UM Vice President for Research shall appoint a Chair of UM IRB, who shall be a faculty member or staff who functions as a voting member of UM IRB, and a Vice-Chair who also shall be a faculty member or staff member. The Vice-Chair shall conduct UM IRB activities in the absence of the Chair. The Chair shall serve for two years after having served as Vice-Chair for at least one year. The Chair may serve multiple terms. The Vice-Chair may serve for two years, unless they begin service as Chair. Vice-Chair may serve multiple terms.

The Chair shall be responsible for seeing that:

1. Meeting agendas are set,
2. Minutes are kept and maintained,
3. Meeting agendas are created and distributed to UM IRB members prior to meetings,
4. Business is conducted efficiently and effectively,
5. Copies of proposals are kept and maintained, and
6. UM IRB actions are implemented.

The UM IRB Manager will assist with the above duties as delegated by the Chair.

The Chair has the authority to sign all UM IRB action items. At the Chair's discretion, this responsibility may be delegated to the UM IRB Manager for routine, minimal risk, and/or administrative approvals, at both exempt and expedited levels, such as, but not limited to: personnel additions, continuations, minor amendments (i.e., wording changes on recruitment materials and other study instruments if the change does not affect the risk level of the study), etc. The UM IRB manager will co-review new protocols and major protocol amendments that fall under an expedited category of review with the UM IRB Chair or the Chair's designee.

In the case where a PI is in the same department as the IRB Chair, the IRB Vice-Chair will assume leadership regarding the proposal.

To allow for successful completion of UM IRB Chair duties, the Chair shall be compensated an amount designated by the Institutional Official, commensurate with the amount of time the Chair spends on IRB duties.

## **IRB Member Training**

IRB members, both primary and alternate, are given initial training when appointed to the Committee and continuing training over the course of their membership. Primary and alternate members receive the same initial training and identical opportunities for continuing training.

## **IRB Meetings**

The UM IRB shall meet monthly as needed during the academic year, and during the summer if necessary. Meetings shall occur during the third week of each month, depending on board member availability.

Minutes of UM IRB meetings shall be kept by the UM IRB Manager.

The UM IRB members shall receive the meeting agenda prior to meetings.

A quorum shall consist of a simple majority that includes at least one member whose primary concerns are non-scientific. A quorum must be maintained to conduct business as per 45 CFR 46.107.

As needed, the Chair may invite individuals with special expertise to serve as consultants in reviewing a particular proposal. This individual does not vote.

Additionally, with consent of the Chair, UM IRB meetings may be attended by persons who are not members. Such persons would have submitted proposals which require oral explanation and questioning or have research in progress that requires monitoring.

Meetings of the UM IRB shall follow Robert's Rules of Order.

Meetings of UM IRB are subject to Article II of the Montana Constitution.

## **3. IRB Records**

The IRB maintains records of all its proceedings, including minutes of each meeting, all correspondence, and all submitted protocols, amendments, consent forms, continuing reviews, unanticipated problems, and statements of significant new findings provided to subjects, as applicable per protocol, including a copy of the IRB-approved consent form for each protocol currently utilizing a written consent form.

Current and past rosters showing qualifications of members are maintained by the IRB office. Rosters are provided to OHRP per the requirements of 45 CFR 46 Subpart E and 21 CFR 56.106. The current membership roster is available on the IRB website.

The IRB maintains records of its policies and practices in its Policies and Procedures Manual. IRB staff are responsible for writing and implementing the standard operating procedures for the UM IRB. New policies and procedures are written and implemented as needs arise.

Revisions to the Policies and Procedures Manual, unless editorial in nature or made at the request of a regulatory auditing body, require review by the IRB Committee prior to implementation. Revisions to internal IRB office operating procedures do not require approval by the IRB Committee or other entities prior to implementation unless otherwise specifically indicated.

The IRB follows all written procedures for:

1. conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
2. determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review;
3. ensuring prompt reporting to the IRB of changes in research activity; and
4. ensuring that changes in the approved research, during the period for which IRB approval had already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazard to the human subjects.

The IRB also follows all written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the Department of Health and Human Services, and the Food and Drug Administration of:

1. any unanticipated problems involving risks to human subjects or others,
2. any instance of serious or continuing non-compliance with federal regulations or the requirements and determinations of the IRB, or
3. any suspension or termination of IRB approval.

IRB individual protocol records are maintained a minimum of 3 years from the date of IRB expiration or termination of the study. Exceptions may be made on a case-by-case basis, dependent upon contractual obligations. IRB minutes are maintained indefinitely.

Relevant Federal Register notices, sections of the Code of Federal Regulations, and NIH and FDA policies, procedures, and regulations are available to faculty from the IRB office or from the IRB website. Scholarly and interpretive articles that pertain to research involving human subjects are also kept in the IRB office as reference items. Such materials are used by the IRB Chair, staff and the Committee, and are available for reference and educational purposes.

## 4. Conflicts of Interest

The purpose of this policy is to provide guidance on how to assure protection of human subjects in the presence of potential conflicts of interest (COI) with investigators or IRB members. COIs can be financial and/or intellectual.

The IRB must consider whether the specific conflicts of interests (perceived or otherwise) may adversely affect the rights and welfare of subjects. The “reasonable person” test should be used in making this determination. In the absence of an IRB opinion or a financial interest, individuals may self-determine that a conflict of interest exists that may adversely affect the rights and welfare of subjects. This may be in cases where they feel that their decision is being altered by other personal factors such as loyalty to colleagues, business competition with investigators, personal agendas or fear of IRB decisions impacting their non-IRB work.

To the extent permitted by law, all statements, letters, other records and information submitted will be maintained confidentially by the IRB and IRB members. Statements, other records and information, however, may be made available to any federal agency funding research upon written request of the agency, and otherwise as required by law.

### Investigator Conflicts of Interest

An investigator conflict of interest is defined as a set of conditions where an investigator’s judgment concerning the design or conduct of a study, including but not limited to subject welfare and the integrity of the research project, could be biased by personal or financial gain.

Individuals directly involved in the conduct, design or reporting of research involving human subjects should not have more than a minimal personal financial interest in a company that sponsors the research or owns the technology being studied. A conflict of interest arises when a researcher is or may be in a position to put his or her own interest before the best interests of research subjects. To manage such conflicts, the IRB must be informed of potential conflicts of interest. Researchers submitting protocols using human subjects must disclose all interests that may be perceived as a conflict with the best interest of the subject in order for the research to be considered for approval.

It is up to the IRB, not the investigator, to make the final determination as to if an actual, potential or perceived conflict of interest is significant enough (or of the mitigation plan worked in conjunction with the Institutional Official or research sponsor is sufficient enough) to require additional steps to be taken to minimize the potential for bias or harm; however, the IRB would usually support any efforts volunteered by the investigator.

In the event the conflict cannot be eliminated, for the study to be approvable, the IRB must be assured that the potential conflict of interest is managed to the point that any potential effects to human subject protections are minimized. The circumstances of the protocol, the subjects and the nature of the conflict will determine the best management plan for the conflict; some examples include:

1. Disclosing the potential conflict of interest during the Informed Consent process.
2. Having another non-conflicted person perform informed consent interviews or collect data.
3. Establishment of a more sufficient monitoring plan.

## **IRB Member Conflicts of Interest**

An IRB member conflict of interest is defined as “...any situation or relationship that biases or has the potential to bias the conduct or outcome of IRB review” (Institutional Review Board Management and Function 2022, 935). Management of IRB member COIs is outlined in the Common Rule (45 CFR 46.107(d)) and the FDA regulations (21 CFR 56.107(e)).

IRB members are determined to be conflicted when: (1) they have a proprietary interest in the tested product, including, but not limited to, a patent, trademark, copyright or licensing agreement; (2) they are involved in the design, conduct, or reporting of the research; (3) they are in a subordinate role to the investigator (i.e., employee, student, etc.); or (4) they have any other interests that would impair their ability to make fair and impartial judgments about an application.

For a conflicted IRB member whose role is limited only to voting on the study, the risk must be managed via the following without exception:

1. The conflicted member(s) may not serve as the primary reviewer, expedited reviewer, determiner of exempt status or consultant for the given research activity.
2. During convened meetings, the conflicted member(s):
  - a. May provide information germane to the discussions but must leave the meeting room during deliberations and voting; AND
  - b. Are not counted towards a quorum, thus a quorum must be re-validated after they leave in order to vote, AND;
  - c. Documentation of such absence must be in the minutes.

No person may use their authority to unduly influence how individual IRB members vote and that any violation of this policy should be immediately reported to the IRB Manager and/or the UM Institutional Official. Depending on the severity and circumstances, the outcome of such investigations could range from requiring education to disciplinary action.

## **Noncompliance with this Policy**

The IRB (or designee) shall assist the University of Montana in any retrospective review they are required to do for DHHS or other funded studies when notified of any of the following:

1. that an Investigator failed to disclose (or inaccurately disclosed) to the IRB a significant financial interest that is determined by the Institution (or IRB if assigned to do so by Institution) to constitute a financial conflict of interest;
2. that the IRB failed to review or manage such a financial conflict of interest; or

3. that the Investigator failed to comply with a financial conflict of interest management plan.

The IRB shall be involved, as necessary, in the University of Montana drafting of any corrective and preventative action plans.

## **5. Amendments to Policies and Procedures**

The IRB Chair and Manager shall review UM-IRB's policies and procedures at least every 5 years, or sooner if necessary, to monitor potential updates and/or modifications of said policies and procedures.

# Chapter 2: Principal Investigators, Co-Investigators, and Other Research Personnel: Eligibility and Responsibilities

Every research study requires a Principal Investigator (PI). A PI is the individual who has the primary responsibility for ensuring the ethical conduct of the research study and assumes full responsibility for the conduct of the research. Sometimes projects may have more than one PI. Other study team members may include Co-PIs, Faculty Supervisors, and Research Assistants.

The PI is responsible for the overall conduct of the study for each human subject research protocol on which he or she is the named PI. This includes any modifications to the original submission. Investigators may not initiate or change research protocols until they have received IRB approval or exemption and may not continue ongoing programs without satisfying the federally-mandated periodic IRB continuing review requirement to assure that the research remains appropriate for human subjects and that the rights of these subjects remain fully protected.

Correspondence from the IRB is directed to the PI, who is then responsible for sharing any necessary information with study co-investigators or staff.

## 1. PI Eligibility

In accordance with University of Montana policy, individuals who are eligible to serve as PIs on proposals for external funding may also serve as principal investigators on IRB protocols. In general, these are individuals who have faculty or other academic appointments or who are staff members at the University of Montana. The groups listed below, which include students, adjunct faculty, faculty affiliates, and emeritus professors, are unique categories of investigators and may have different requirements than UM faculty and staff.

### Students

Undergraduate students may not serve as the PI on any UM IRB study but may serve as Co-PI when the PI is a faculty supervisor. Graduate students may serve as PI on certain protocols but must also list a faculty supervisor.

## Adjunct Faculty

UM adjunct faculty or researchers wishing to undertake research involving human subjects as part of their duties as an adjunct faculty member or researcher shall be subject to the same rules regarding IRB submission of their research proposal as regular UM faculty. If research continues at the University of Montana beyond the adjunct faculty's employment, then a modification shall be filed to transfer the project responsibilities to a new PI, who must be a current UM employee or student. If the adjunct faculty leaves the University of Montana and wishes to continue the research at another institution, then a Closure report must be filed with the UM IRB office, and notification must be given to the IRB at the new institution and their procedures followed.

## Faculty Affiliates

Faculty Affiliates are not University employees. Affiliates may:

1. Collaborate with full-time faculty, where a full-time faculty member serves as the Principal Investigator (PI) and the faculty affiliate serves as a co-PI. Full-time means full-time, not part-time or adjunct. The affiliate must report any Conflicts of Interest. If the affiliate represents an external business, a separate business contract may need to be established, intellectual property addressed, and liability clauses reviewed by legal counsel.
2. Request IRB review as an external researcher on a fee-based schedule.

## Emeritus Professors

The IRB will conduct a review free of charge for emeritus professors. If the emeritus professor is conducting the research on his/her own as the PI, then he/she must provide evidence of their own liability insurance (that would clearly cover such activity). The university's liability insurance does not extend to this. If the emeritus professor proposes research with student assistants, a full-time faculty member must serve as the PI. The PI is ultimately responsible for all aspects of conducting the research study. The emeritus professor may be designated as a co-PI.

## 2. Co-Investigators and Other Research Personnel

Any investigator engaged in human subjects research (other than the PI) must be designated as a Co-Investigator or Other Research Personnel in the IRB submission. Research personnel should be designated with the original submission or with an amendment if added or removed after original approval. An amendment must be submitted when personnel are added to or removed from the protocol. Only the named and approved research personnel may carry out procedures performed upon research subjects. Accordingly, anyone having direct contact with the subjects or their data (obtaining consent from subjects, recruiting of subjects, administering questionnaires and surveys, conducting clinical interventions, performing data analysis, etc.) must be listed on the protocol. The PI must take direct responsibility for the activities of all research personnel.

## Listing Collaborators Outside of UM

UM researchers often collaborate with external partners on human subjects research projects. These collaborators are required to be listed on your IRB application if they are engaged in human subjects research. If your collaborators are affiliated with an institution that has its own IRB (ex., another university, a hospital, etc.), a reliance agreement may be needed if the protocol is Expedited or above. If your collaborators are not affiliated with an institution that has its own IRB, they will be required to complete an Individual Investigator Agreement.

## 3. Training

As federally mandated and required by the UM IRB, all key study personnel must complete a self-study course in human subject protection.

Key study personnel include the Principal Investigator and any other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved in using study participants' identifiable private information during the research. Key personnel also include faculty supervisors/advisors who provide direct oversight to undergraduate and graduate students, as well as postdoctoral fellows. Members of the research team who have not completed human subject research protection training, or whose training is expired, may not take part in aspects of the research that involve human subjects or their private identifiable data.

The UM IRB uses the Collaborative Institutional Training Initiative (CITI) platform for all human subjects training. Researchers must take a CITI Basic course – either Social/Behavioral-Basic or Biomedical-Basic – in order to fulfill training course requirements. CITI training is valid for three years. Investigators and staff must renew their training certification before it expires by taking either a refresher course or retaking the full course. Certificates must be current throughout the duration of the research conducted under IRB oversight. More information about how to create a CITI account can be found on the IRB website.

### Additional Trainings

Please note that researchers pursuing sponsored (funded) projects may need to complete additional training or other compliance requirements, such as a Responsible Conduct of Research (RCR) course. RCR courses are overseen by the Office of Sponsored Programs and are typically required by them for any sponsored projects. **RCR courses do not fulfill the IRB human subjects protection training course requirement.**

Investigators and staff funded by the National Institutes of Health (NIH) may be required to complete a Good Clinical Practice (GCP) course. GCP training demonstrates that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording, and reporting trials that involve human research participants. **GCP courses do not fulfill the IRB human subjects protection training course requirement.**

UM also has additional CITI modules that researchers may be required to take, depending on the research project, including Conflict of Interest and FERPA modules.

## **Training for Community Research Collaborators**

The UM IRB recognizes that in instances when university researchers are collaborating with community partners who are engaged in research, CITI training may not be the best or most accessible training option. In such cases, the UM IRB has the authority to approve alternative equivalent training options.

## **4. Responsibilities of Principal Investigators**

The Principal Investigator is held responsible for ensuring that their protocols are conducted in accordance with the research plan and with all applicable regulations. Consequently, it is the responsibility of the PI to:

- ensure that all procedures in approved protocols (including the consent process) are performed and/or supervised by the listed investigator or other authorized personnel (not unlisted investigators, students, technicians, etc.);
- request approval from the IRB in the form of an amendment to change the investigator or other personnel;
- provide the IRB with the appropriate information on the research protocol including initial information, notification of subsequent modifications, terminations, and unanticipated problems, and to use the appropriate IRB format and forms for supplying this information;
- ensure that no research will be initiated until IRB approval is received;
- carry out the protocol as approved, initiating modifications only after the IRB has approved the amendment;
- obtain appropriate informed consent from subject(s);
- ensure the timely completion and submission of the continuing review materials;
- maintain confidentiality of all records;
- report in writing to the IRB any unanticipated problems involving risks to subjects or others in accordance with the IRB policy;
- keep appropriate records, including if applicable names and access information for all research subjects;

- be aware of current IRB policies and procedures; and
- complete all necessary training, including HIPAA compliance and human subjects protections training, and ensure that listed personnel have completed human subjects protections training as per UM IRB policy.

The IRB will direct original correspondence to the PIs, with exceptions on a case-by-case basis. It is the responsibility of the investigator to ensure that copies of IRB letters are distributed to appropriate individuals (e.g., grant and contract administrators, department administrators, granting agencies or pharmaceutical sponsors, other sites, etc.).

If the protocol is externally funded, the PI should receive a fully executed agreement before work on the research project can begin.

## **Termination of a Protocol**

Investigators should terminate a protocol when human subjects are no longer being followed or studied. As long as subjects are still being followed at this site, even if the protocol is closed to subject accrual, or if data is still being analyzed, even if not being actively collected, a protocol is considered active and continuing review may be required. If no subjects are being followed and data analysis is complete, the study may be officially terminated. When research has been terminated, the responsible investigator must notify the IRB. This applies to certain Expedited protocols and all protocols that have been reviewed by the fully convened IRB.

When a faculty member leaves the University, they should either terminate their protocol(s) or submit an amendment form for each approved study indicating that the protocol(s) should be transferred to another investigator who will take responsibility for the research. See next section.

If the IRB discovers that an investigator has left the University of Montana but that this PI's studies have not been terminated through the IRB, the IRB staff may contact the PI's former department chair to verify that studies are not currently active. IRB staff will also verify that the study or studies in question are not in the process of being transferred to another investigator through the amendment process. Depending on the department chair's response, the IRB will then administratively terminate any remaining studies listed under the name of the departed PI.

## **Transferring a Protocol to Another Investigator**

When an investigator chooses to transfer their status as PI on an approved protocol to another investigator, the IRB must be notified. The new investigator must be eligible to serve as Principal Investigator. To note this transfer, an amendment should be submitted to the IRB. The new principal investigator should provide adequate documentation to acknowledge that he/she is now responsible for the study. Appropriate changes to consent forms, advertisements, and other relevant study documents must also be submitted to the IRB when transferring a protocol. The amendment should specify whether the original investigator will remain on the study as a co-investigator or other research personnel.

The new PI will be notified if and when the amendment is approved.

## Unanticipated Problem Reporting

Investigators are required to promptly report to the IRB all unanticipated problems involving risks to human subjects or others under Title 21 of the Code of Federal Regulations (21 CFR) part 56 (Institutional Review Boards), part 312 (Investigational New Drug Application), and part 812 (Investigational Device Exemptions) as well as under 45 CFR 46.108(a)(4). Sponsors and investigators should differentiate those unanticipated problems that must be reported to the IRB and those that do not, under this policy. The University of Montana IRB policy is consistent with guidance set forth by OHRP (“Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, presented January 15, 2007) and the FDA (Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs — Improving Human Subject Protection, dated January 2009) when determining what related events require review by the Institutional Review Board.

Unanticipated problems involving risks to subjects or others refer to a problem, event or information item that is not expected, given the nature of the research procedures and the subject population being studied; and which suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known. The IRB considers unanticipated problems, in general, to include any incident, experience, or outcome that meets ALL the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol, investigator’s brochure, drug or device product information, informed consent document, or other research materials; and (b) the characteristics of the subject population being studied, including underlying diseases, behaviors, or traits;
2. related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a risk of unknown harm or addition/increased frequency of harms (including physical, psychological, economic, legal, or social harm) than was previously known or recognized.

Unanticipated problems may be adverse events, protocol deviations, noncompliance or other types of problems, but **MUST** meet all the criteria listed above. It is the expectation of the IRB that all approved protocol procedures are being followed without alteration unless the IRB has been informed of a protocol change or deviation.

When reviewing a particular incident, experience, or outcome reported as an unanticipated problem by the investigator, the IRB may determine that the incident, experience, or outcome does not meet the criteria for an unanticipated problem.

Unanticipated problems occurring in research that is federally funded may or may not require further reporting to appropriate institutional officials, the department or agency head (or designee), and OHRP. The IRB has the authority, under HHS regulations at 45 CFR 46.109 and 21 CFR 56.109, to require, as a condition of continued approval by the IRB, submission of more detailed information by the investigator(s), the sponsor, the coordinating center, or the Data Safety Monitoring Board/Committee about any unanticipated problem occurring in a research protocol.

It is the responsibility of the investigator to ensure that written notification of unanticipated problems and adverse events is submitted to the IRB. The investigator should complete an Incident Report in Cayuse HE and attach any additional information necessary in evaluating the report (such as laboratory or autopsy reports). All other events or adverse events that do not meet reporting criteria can be submitted as a summary at the time of continuing review.

In reviewing the unanticipated problem, to ensure adequate protection of the welfare of subjects, the IRB will consider whether the event impacts the risk/benefit ratio and may need to reconsider approval of the study, require modifications to the study, or revise the continuing review timetable. Furthermore, the IRB may suspend or request further changes to an individual study due to safety concerns.

The IRB retains submitted unanticipated problem reports. Notification of review of these reports is sent to the PI.

All internal and external Unanticipated Problems must be reported to the IRB in a timely manner following the investigator's knowledge of the event. For internal events that are fatal or life-threatening Unanticipated Problems, the PI should notify the IRB Manager by phone immediately and consider voluntarily halting subject enrollment.

For device studies, investigators are required to submit a report of an unanticipated device effect to the sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the event. Unanticipated device effects are defined as "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects" (21 CFR 812.3(s)).

## **Reporting Unanticipated Changes to the Protocol**

The federal regulations require the IRB to review and approve proposed changes to research studies prior to initiation of these changes, except when changes are "necessary to eliminate apparent immediate hazards to the subject" [45 CFR 46.108(a)(3)(iii)/21 CFR 56.108(a)(4)]. Most proposed changes are reviewed through submission of amendments. Any changes that are made to eliminate apparent immediate hazards to a subject should be reported as an Unanticipated Problem to the IRB and an amendment should be submitted as soon as possible to change the protocol to eliminate future hazards of this type, as appropriate.

If such a change is implemented to eliminate immediate hazards to a subject, enrollment of new subjects should be halted until the IRB has had an opportunity to consider such changes. The reviewer may also recommend that the subjects on the study be provided specific information about the change and the cause of the change.

## Reporting Deviations

An IRB is asked to ensure prompt reporting of serious or continuing noncompliance with regulations or noncompliance with the IRB's own requirements/determinations [45 CFR 46.108(a)(4)(i) and 21 CFR 56.108(b)]. Deviations from the approved protocol may fall into this category of noncompliance. A protocol deviation occurs when the study departs from the IRB-approved protocol in any way without the investigator first obtaining IRB approval.

Deviations range in seriousness according to how the changes may impact subject safety, the degree of noncompliance with federal and state regulations, and the degree of foreknowledge of the event. Anticipated changes to a protocol should always be reported prior to the event occurrence unless an immediate change is necessary to protect subject safety. Repeated deviations of the same type may be an indication that an amendment is needed to permanently change study criteria.

A major deviation is one that may impact subject safety or alter the risk/benefit ratio, compromise the integrity of the study data, and/or affect subjects' willingness to participate in the study. Major deviations should be reported as Unanticipated Problems. A description of the effect of the deviation on subject safety and a description of how similar events will be avoided in the future should be provided.

## Reporting Noncompliance

Noncompliance is a failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB that results in harm to subject's rights, safety or welfare, or on the integrity of the data. Non-compliance results from the action or inaction of anyone conducting protocol procedures. See Chapter 10 for more information on noncompliance.

Protocol deviations and noncompliance should be reported to the IRB as soon as possible. An initial report should be made to the IRB Office by email within one (1) week (7 calendar days) of when the investigator became aware of the adverse event. Any adverse event involving serious injury or danger to the subject must be reported immediately. The initial report must be followed by a formal Adverse Event submission in Cayuse Human Ethics within no more than two (2) weeks (fourteen (14) calendar days) of when the investigator became aware of the event. Reports of possible noncompliance should include a complete description of the event and include sufficient detail to allow the IRB to make an assessment.

Whenever possible, reports should be submitted via the investigator. However, if the reporting party deems it necessary and/or wishes to remain anonymous to the investigator, they may contact the IRB office directly. The IRB office will do its best to protect the confidentiality of

informants. Protocol deviations and/or noncompliance incidents may be discovered by IRB office staff as part of continuing review of nonexempt protocols, or audit activity, or an incidental awareness (e.g., due to a news article, errant email or incidental finding of recruitment material).

## **Reporting Conflict of Interest**

If there is a known or potential conflict of interest at the time of IRB submission, investigators are asked to detail the nature of the conflict with the initial submission. Any subsequent change to this status as related to a protocol should also be brought to the attention of the IRB. In addition, any new conflicts of interest which arise from the PI or any co-investigator(s) should be brought to the attention of the IRB as soon as possible. The IRB will coordinate with the Institutional Official or designee as to the appropriate measures or protections to be implemented or that may have already been implemented to manage the conflict of interest.

## **Research Records**

It is required that all research records (including a copy of all materials submitted to the IRB) be maintained by the investigator. The permanent record of research done on each subject consists of signed consent forms together with the names and access information for all subjects, other research data, budget and accounting records, and the subjects' medical records, as applicable.

Records should be kept confidential to the extent required by the protocol and, as applicable, the consent form. Records that are subject to HIPAA must be stored in a HIPAA-compliant manner. If the investigator leaves the University of Montana, the records must be kept at the University in the hands of the designated investigator taking over the study, and the IRB should be notified of the transfer prior to the investigator's departure. The records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, and/or the sponsor at reasonable times and in a reasonable manner.

Record retention requirements will vary depending upon the type of research, sponsor requirements, relationship to intellectual property protection, and federal requirements. It is typical to retain records for three years after the completion of the research (as defined by the last publication related to the study). HIPAA regulations require that authorizations (e.g., the consent form) be kept for at least six years. For FDA-regulated studies, materials must be maintained for two years following the date of marketing application approval for the device or drug for the indication for which it was being investigated.

# Chapter 3: Submission and Review of Research Protocols

The University of Montana requires that all research projects involving human subjects be approved by UM's IRB. Any employee, adjunct faculty member or student who, on behalf of the University of Montana, conducts research using human subjects must receive IRB approval prior to recruitment and/or screening. The type of IRB review and the associated review process (e.g., full board, expedited, exempt, not human subjects research) are determined by the:

- Level of risk to research participants
- Type of research being conducted (e.g., an educational intervention, a survey, an ethnographic observation, etc.)
- Sensitivity of the research questions or complexity of the research design
- Involvement of vulnerable populations as research participants
- Use of identifiable information or identifiable biospecimens
- Applicability of one or more of the criteria for exempt or expedited review

After an application has successfully completed the pre-review process, it will be assigned a review type. In general, an application can be assigned to one of four review categories: Not Human Subjects Research (NHSR) (45 CFR 46.102(1)), Exempt Review (45 CFR 46.104), Expedited Review (45 CFR 46.109; OHRP Expedited Review Categories) and Full Board Review (45 CFR 46.109). In all cases IRB staff and members review protocols to ensure that:

- Risks to the subjects are minimal, and are reasonable in relation to anticipated benefits
- The subject selection is equitable
- Privacy and confidentiality are protected
- Informed consent processes meet federal, state, and UM regulatory requirements

All IRB applications should be submitted through the IRB's online application system Cayuse Human Ethics (HE).

## 1. Deadlines and Review Times

New and continuing applications for review may be submitted at any time. Please allow up to three weeks for Exempt and Expedited review time. This timeline is an estimate; reviews may take longer if they are complex, require significant revisions, or require review by other reviewers or departments, such as Legal Counsel or the Institutional Biosafety Committee. Reviews may also take longer during high volume periods. All applications are processed in the order they are received.

If a proposal must be reviewed by the full committee, the application must be received at least four weeks before the next committee meeting in order to be considered at the next IRB meeting.

If this day falls on a weekend or holiday, applications may be submitted the following business day. Principal Investigators will be informed of the committee's decision by email within a week following the IRB meeting. As revisions are often required, please allow four to eight weeks for final approval to be obtained.

## 2. Determining “Research Involving Human Subjects”

Per 45 CFR 46.102(l), an activity is considered to be “research” if it involves a “systematic investigation designed to develop or contribute to generalizable knowledge.” Activities not systematic, not designed to contribute to general knowledge, or done only for personal use (i.e. not shared with anyone else, including other members of the department) do not meet this definition.

Per 45 CFR 46.102(e), research is considered to involve “human subjects” if it entails obtaining information about living individuals, either through intervention or interaction with the individuals, or if the research involves the use or receipt of individually identifiable information, including biospecimens, originally obtained in a context in which the individuals could reasonably expect privacy.

In order for research to be subject to FDA regulations, it must be a “clinical investigation,” which is defined as “any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit... The terms ‘research,’ ‘clinical research,’ ‘clinical study,’ ‘study,’ and ‘clinical investigation’ are deemed to be synonymous for purposes of this part” (21 CFR 56.102(c)). A “human subject” “means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient” (21 CFR 56.102(e)).

The IRB follows the regulatory definitions when considering whether a project is subject to IRB review as research involving human subjects.

If it is unclear as to whether an activity meets the regulatory definition of human subjects research, the IRB staff can assist in making this determination. If the IRB staff finds that the activity does not constitute human subjects research, the staff will, upon request, issue documentation stating that the activity does not require IRB review or approval. No further review of the project is required, unless aspects of the project change so that it then becomes research involving human subjects. Requests for this type of review should be submitted through the Cayuse Human Ethics platform via a “Human Subjects Research Determination Request”.

Note that federal, state, or local laws or regulations may apply to activities whether or not they meet the definition for research involving human subjects as outlined by 45 CFR 46 and 21 CFR 56.

## Deceased Individuals

Federal human subjects research regulations only apply to living individuals. Work with deceased individuals does not need IRB approval. However, please note that the Health Insurance Portability and Accountability Act (HIPAA) Security and Privacy regulations [45 CFR 160, 164] apply to individuals both living and deceased. Thus, if any protected health information as defined by the HIPAA regulations is collected about deceased individuals, additional protections for subjects may be necessary before beginning a proposed activity (even if the activity does not otherwise qualify as human subjects research) to comply with HIPAA.

## 3. Protocol Submission Process

The University of Montana IRB uses the web-based system Cayuse Human Ethics for managing human subject research studies. Cayuse Human Ethics is an electronic protocol management platform that is cloud-based, user-friendly, and secure. Cayuse Human Ethics should be used to prepare and submit all initial human subjects research studies, as well as make modifications, request renewals, and report incidents. Investigators can find information on using Cayuse Human Ethics on the IRB website.

The IRB website is also regularly updated to include revised or new policies and procedures. When preparing a protocol, it is advisable to consult the IRB website and/or contact the IRB staff for assistance to ensure an acceptable submission. Review of a protocol may be delayed if further information is required.

## Developing the Study Protocol

Project information entered into the IRB application should be thorough and complete. Incomplete or inaccurate information is one of the most common reasons IRB applications get returned to PIs for revisions. Sources should always be cited within the application when relevant.

Information requested by the IRB application includes, but is not limited to:

- The purpose of the research and why human subjects must be involved, including any relevant hypotheses, study design, and study location information.
- Project funding, especially if federal funding sources are involved. A note on subcontracted research: when a UM researcher is engaged in a subcontracted portion of a non-exempt human subjects research study, regardless of whether that portion considered by itself would meet an exemption, the subcontracted researcher must obtain IRB review and approval for that activity.
- Identification of the participants, including inclusion/exclusion criteria, the number of people enrolled, their ages (or an age range), whether minors are involved, and/or whether participants are members of a physically, psychologically, or socially vulnerable

population. You will also be asked to describe how the subject's personal privacy will be protected, and the confidentiality of information maintained

- The informed consent process, including copies of any informed consent forms being used. The IRB highly recommends that researchers use our informed consent templates to customize their own forms.
- Recruitment/selection procedures, including copies of all flyers, advertisements, and other recruitment materials that may be used.
- A precise and explicit description of the activities the subjects will perform, including the instrumentation and procedures to be used and kinds of data or information to be gathered. Provide enough detail so the IRB will be able to evaluate the intrusion from the subject's perspective.
- The benefits of the research, if any, to the human subjects and to scientific knowledge. If the subjects will not benefit from their participation, so state.
- The risks and discomforts to which the subjects will be exposed. Such deleterious effects may be physical, psychological, professional, financial, legal, spiritual, or cultural. Some research involves violations of normal expectations, rather than risks or discomforts; such violations, if any, should be specified. It is highly unusual to state there are no risks or discomforts. Also include a description of how each deleterious effect or violation will be minimized.

Additional application sections will be required if study teams are: conducting international research; conducting research on an Indian reservation and/or specifically recruiting a Native American population; and/or are collaborating with external researchers outside of UM.

Be prepared to attach several files to the submission. These may include informed consent forms, recruitment materials, survey instruments, interview questions, site permission letters, and more. All participant-facing materials require prior IRB review and approval.

## **Ensure All Necessary Reviews, Approvals, and Site Permissions are in Place**

Depending on the particulars of your research study, you may need to secure additional reviews, approvals, or notifications from other units or organizations prior to initiating your research. Studies that involve external funding must have appropriate contracts and agreements in place with the Office for Sponsored Programs.

Please note that any researchers working with human blood, body fluids, genetic material, and/or tissue are required to submit a UM Institutional Biosafety Committee (IBC) application.

It is the Principal Investigator's responsibility prior to conducting research to determine what, if any, permissions are required. Certain UM departments, campus buildings, schools, external organizations, and other sites may require researchers to obtain site permission before conducting research. Some examples include, but are not limited to:

- UM Athletics – researchers are required to obtain permission from the UM Athletics director prior to conducting any research that specifically recruits UM student athletes, as per NCAA regulations.
- Other UM auxiliary sites, such as the University Center, clinics, and the ASUM Daycare Center.
- K-12 schools, preschools, and daycare centers – permission must be given by either a principal or the superintendent.
- Corporate and privately-owned businesses, as well as non-profit agencies such as the YMCA, YWCA, or food banks. Hospitals, clinics, and other healthcare organizations are included as well.
- Public locations where there is an expectation of privacy, such as bathrooms.
- Trailheads on Federal Land (A National Park Service (NPS) research permit is required for all types of research).
- Indian reservations.

Site permission can be submitted to the IRB via the IRB application or, in certain cases, via email.

## **4. IRB Review Process**

### **Application Pre-Review**

When an IRB application is submitted, it is first sent to the UM IRB office staff for pre-review. During this process, the application is reviewed for completeness, thoroughness, and accuracy. IRB staff check to make sure that all questions were answered and that the investigator has provided enough information for the application to move to the next step in the workflow process. IRB staff will also review the application for mistakes, such as spelling and grammatical errors (particularly in the informed consent form and any other participant-facing documents, such as flyers) or missed questions. Applications may be returned to investigators at this stage for revisions before it is sent on to the next step in the review process.

Investigators are encouraged to consult with the UM IRB office on complex protocols prior to submission. Clearing up questions and issues beforehand reduces the chances that an application will be returned to the study team for revisions, thus saving time and effort for all involved.

## Assigning a Review Type

After an application has successfully completed the pre-review process, it will be assigned a review type. In general, an application can be assigned to one of four review categories: Not Human Subjects Research (NHSR), Exempt Review, Expedited Review, and Full Board Review. In all cases, but most especially for Expedited and Full Board reviewed studies, IRB staff and members are reviewing protocols to ensure that:

- Risks to the subjects are minimal and are reasonable in relation to anticipated benefits.
- The subject selection is equitable.
- Privacy and confidentiality are protected.
- Informed consent processes meet federal, state, and UM regulatory requirements.

## 5. IRB Review Categories and Decisions

### Research that is Not Human Subjects Research (NHSR)

Not all research-related activities that involve people, their data, or their biospecimens are covered by the regulations governing human research (see above section). Submission to the IRB is not required for the following activities:

- Case studies
- Class activities (with some exceptions; does not include theses and dissertations)
- Journalism/documentary activities
- Oral history
- Quality assurance and quality improvement activities unless they meet the federal definition of human subjects research
- Research using deidentified data or biospecimens
- Research using publicly available data sets

### Exempt Review

Per UM IRB policy, investigators must submit an IRB application for determination of exemption before research begins. It is important to note that an Exempt determination is different than a Not Human Subjects Research determination. Exempt research still meets the federal definition of “human subjects research” and must fit within one of six very specific [Exempt review categories](#) as defined in 45 CFR 46.

While the use of a formal informed consent form containing all the elements of consent is not required for Exempt research, the UM IRB still requires researchers to provide information, in written form, to potential participants prior to their enrollment in the research. At minimum, this information should include:

- A statement that participants must be 18 years or older to participate;
- An explanation of the research, including the expected time commitment;

- Any potential risks or discomforts related to participation, such as discomfort responding to personal/sensitive questions, privacy concerns, disclosure risks;
- A statement that the research is voluntary and that they may withdraw at any time;
- How privacy and confidentiality will be protected;
- Contact information for the PI and the UM IRB;
- And any other key elements of the study that participants should know before agreeing to take part.

Projects receiving an exempt determination are not subject to the Continuing Review process. Amendments are required only if the changes to the project would alter the exemption criteria or if new study personnel are added to the project. An Exempt determination does not lessen the researcher's ethical obligations to participants as articulated in the Belmont Report or to the codes of conduct for specific disciplines.

Research involving prisoners or certain types of research with children (e.g. surveys, interviews, observations of public behavior where the investigator interacts with the children) does not qualify for exemption.

## Expedited Review

Federal regulations (45 CFR 46.110) authorize the use of an expedited review process for:

- Minimal risk human research that meets one or more of the [OHRP Expedited Review Categories](#).
- Minor changes to research previously approved by the full board.

Applications qualifying for Expedited review are reviewed by the IRB Manager, the IRB Chair, and potentially to one or more experienced IRB members. These reviewers may request additional clarifications or changes from a PI before the application is approved. During an Expedited review process, a submission may be referred to the full board for review instead (for reasons of clarification, expertise, etc.), including in cases of disapproval. Only the full board has the authority to disapprove a study.

Most studies that qualify for the expedited review process do not require annual Continuing Review.

Expedited studies must meet all of the federal requirements for the elements of informed consent ([45 CFR 46.117](#)). These elements may only be waived if the investigator formally applies for such a waiver and the IRB formally grants it. Investigators must have a compelling argument for why a certain element of informed consent, such as a written signature, should be waived.

All signed Informed Consent forms must be retained by the PI for at least 3 years after completion of the research, per federal regulation [45 CFR 46.115(b)]. The forms must be stored in a secure, locked location separate from the de-identified data. If the study involves HIPAA, consent forms must be kept for at least 6 years.

## Full Board/Committee Review

Federal regulations and institutional policy require a review by the IRB Full Board for applications where the research involves more than minimal risk to human subjects, does not meet the criteria for one of the categories of expedited review, and/or has been referred to the committee by an Expedited reviewer or the Chair/Manager. Regardless of risk level, the UM IRB may require full board review when the research involves:

- Vulnerable populations, particularly prisoners.
- Sensitive topics, including illegal behaviors which may require an NIH Certificate of Confidentiality (CoC) to protect subject data from compelled disclosure.
- Research involving genetic/genomic analyses.
- A complex research design requiring the expertise of multiple board members to evaluate

If an application is “committee ready”, meaning that it contains all the information and materials necessary for the full board to conduct its review, the application will be assigned to the next IRB meeting date, except where the agenda is already full or a reviewer with the necessary expertise is not available for that meeting. Investigators may be invited to attend the meeting to answer questions from the board. At the conclusion of the meeting, the board votes and issues a determination for the submission.

Possible decisions that can be made by the fully convened IRB include:

- **Approved:** the application is approved as submitted.
- **Conditional Approval:** the application is approved, contingent on submission of specified changes to the protocol, informed consent document(s) and/or other supporting materials. Final approval status is granted when either the IRB or the IRB Chair (if so authorized by the board) has reviewed and approved all requested changes.
- **Resubmission:** the IRB needs additional information from the investigator before the IRB can make all of the determinations found at 45 CFR 46.111 necessary to approve the study. The principal investigator must submit the requested additional information before the IRB will consider the application for further review.
- **Disapproved:** the protocol does not provide adequate protection to human participants, and it is unlikely that it can be modified to provide such protection. The IRB notifies the principal investigator of the disapproval in writing, including a statement of the reasons for its decision, and provides the opportunity for the investigator to respond to the IRB in person or in writing.

All full board reviewed research is required to be issued an expiration date of no more than one year from the original date of approval. Applications must be renewed every year. Projects that are expired must cease all work immediately until the project is brought back into compliance.

All signed Informed Consent forms must be retained by the PI for at least 3 years after completion of the research, per federal regulation [45 CFR 46.115(b)]. The forms must be stored in a secure, locked location separate from the de-identified data. If the study involves HIPAA, consent forms must be kept for at least 6 years.

If you think that your research may require a full board review, please consult with the UM IRB office. The submission deadline for full-board reviewed proposals is the first business day of each month.

## **6. Appeal of IRB Decisions**

If an investigator wishes to make an appeal of any IRB decision regarding a protocol proposal or a previously approved protocol, the investigator must submit a formal request in writing to the IRB Committee. The appeal must include details as to the exact nature of the investigator's disagreement with the Committee decision and the basis for making a claim to overturn that decision, including supporting evidence. The thorough review of and discussion on every submission to the IRB by the Committee ensures that the Committee feels confident in decisions they have made; consequently, an investigator wishing to make an appeal must present sufficient evidence to persuade the Committee to reconsider their decision. Assessments regarding whether or not to bring a protocol back to the Committee for further review upon the appeal of the investigator will be made by IRB Manager and the Chair, in consultation with Vice-Chair(s), Associate Vice President for Research and/or the Vice-President for Research.

If an appeal is insufficient for review by the full Committee, the investigator will be notified in writing. If the Committee does consider an appeal, the Committee's decision regarding the merits of the appeal will be conveyed in writing to the investigator following the meeting.

External institutions or authorities cannot override IRB decisions; only the IRB Committee itself can overturn its decisions.

## **7. Continuing Review and Study Closure**

### **Continuing Review**

When a study is nearing its expiration date, the PI must submit a renewal request, also known as a continuation, in order to continue with the research. The renewal will need to be approved before the PI can continue with the study. A study renewal may be required for certain studies and under certain circumstances. All Full Board-approved studies are required to be renewed not less than once a year and are issued an expiration date. Most Expedited and Exempt studies are not required to be renewed and are not issued an expiration date unless the IRB decides there is a reason to monitor a study.

All Expedited and Full Board studies approved before January 1st, 2019 will have been issued an expiration date and must be annually renewed or formally closed. All studies approved before

January 1, 2024 that have been issued an expiration date will continue to use the previous paper/email submission system.

Projects for which approval has expired are in non-compliance with federal regulation and UM IRB policy and all work must cease.

Studies submitted through Cayuse HE will automatically receive a 90-, 60-, and 30-day notification prior to their study expiration date. Principal Investigators are responsible for keeping track of their study expiration date.

Principal Investigators who are submitting continuations for studies that were approved prior to the Cayuse HE system will receive a notification from the IRB office at least 30 days prior to the expiration of their approval. This notification is simply a courtesy; PIs are responsible for keeping track of their own study expiration date. To submit a continuation/renewal using this method, download, complete, and submit the Continuation / Closure Report (form RA-109), located on the IRB website.

## Study Closure

If a study was issued an expiration date, then it must be formally closed when at least one of the following situations occurs: the research is completed; when analysis is limited to de-identified data only; or if the project has been abandoned or significantly postponed.

A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project no longer needs to undergo continuing review and may be closed. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary. At that point, the IRB can formally close the IRB file for the project and advise the investigator of that action.

Similarly, simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require continuing review. If a study is in data analysis only AND the PI has destroyed all private information about the subjects, the IRB can be notified and they will close the study.

All signed Informed Consent forms must be retained by the PI for at least 3 years after completion of the research, per federal regulation [45 CFR 46.115(b)]. The forms must be stored in a secure, locked location separate from the de-identified data.

If you need to close your study, you can do so by completing a Study Closure submission. A closure submission within Cayuse HE indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified.

Studies approved prior to January 1, 2024 (and prior to the Cayuse HE system implementation) will need to submit a closure report using our paper-based system. To submit a closure report using this method, download, complete, and submit the Continuation / Closure Report (form RA-109), located on the IRB website.

## **8. Student Research and Courses Involving Students' Investigations Using Human Subjects**

UM students wishing to conduct research involving human subjects for any course, including thesis, dissertation, research methods or independent study courses shall be subject to the same rules regarding IRB submission of their research proposal as UM faculty. Student projects involving human subjects must be supervised by a UM faculty member who has been approved by his/her department to supervise this type of student research. The faculty member cannot be a supervisor in name only but must provide actual supervision.

Independent research projects that include human subjects and employ systematic data collection with the intent of contributing to generalizable knowledge will require IRB review. Theses, dissertations, and honors research projects involving human subjects that are considered research as defined by 45 CFR 46 (i.e., “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”) always require review by the IRB.

Research projects for which the overriding and primary purpose is a learning experience in the methods and procedures of research do not meet the federal definition of research and are therefore generally not subject to (i.e., is excluded from) IRB review/approval. Curriculum projects in which students conduct research involving human subjects need not be reviewed by the IRB if the following conditions are satisfied: the research is minimal risk and does not include any vulnerable populations, as defined by the federal regulations (e.g., children, prisoners, pregnant women, fetuses, or neonates); the project does not involve sensitive topics or confidential information like medical or education records data; participation is voluntary; and the results are never distributed outside the classroom (i.e., published or presented at a conference).

## **9. Subcontracted Research**

When a UM researcher is engaged in a subcontracted portion of a non-exempt (i.e., Expedited or Full Board Review) human subjects research study, regardless of whether that portion considered by itself would meet an exemption, the subcontracted researcher must obtain IRB review and approval for that activity. The researcher may take either of the following actions:

1. Submit an application to the UM IRB for review of the subcontracted portion of the study. The complete, approved application from the parent organization's IRB may be submitted to the UM IRB if it contains sufficient detail of the subcontracted work.

Otherwise, a separate UM application needs to be submitted along with the determination letter from the parent organization's IRB.

2. Contact the UM IRB to inquire whether a reliance agreement can be entered into with the parent organization, in which case the researcher would need to comply with their application and review procedures.

## 10. External Reviews

The University of Montana IRB will conduct reviews of appropriate, external, human subjects research proposals on a fee-based schedule.

When an investigator is not engaged with the University of Montana as an employee or student for the purpose of conducting a research project involving human subjects, that project will be considered external and charged a fee regardless of the for-profit or non-profit nature of the project, investigator, or investigator's company or agency.

The UM IRB will only conduct external reviews of proposals for which it is qualified in terms of adequate experience and subject expertise. Specifically, the IRB reserves the right to accept or decline a request for review on a case-by-case basis. In most cases, the IRB authorizes the IRB Manager to make this decision, but accepting or declining review will in some cases be determined by the board. The UM IRB will review proposals at the Full Board, Expedited, and Exempt levels of review as is appropriate to the complexity and risk level of the proposal.

Fee Schedule upon acceptance:

- \$1,000 initial review
- \$400 amendments
- \$200 continued review
- \$50 closure report

The fees are assessments of costs associated with study reviews conducted by the IRB and are charges for services rendered. The initial review fee also includes access to UM's CITI account for any human subjects training that the investigating team may need. Fees are due and payable upon submission to the IRB for initial, continued, amendment or closure review. Checks are payable to the University of Montana.

Fees are non-negotiable and non-refundable. Because the IRB office commits its resources appropriate to each level of review, fees are due in full from the applicant regardless of subsequent conduct of the study, including disapproval by the IRB or early termination by the investigator or sponsor.

## Intellectual Property and Technology Transfer

Externally reviewed projects are not subject to the University of Montana's intellectual property rights and, therefore, are not subject to its licensing policies. Any intellectual property that

results from externally-conducted research is subsequently owned by the external investigator(s), company, or agency.

# Chapter 4: Post Approval Monitoring

Post Approval Monitoring (PAM), or compliance monitoring, is an internal IRB program that monitors research projects to confirm that research is being conducted in accordance with applicable federal regulations, state laws, and institutional policies, and as outlined in the approved IRB protocol. The purpose of PAM is to ensure that ethical and regulatory requirements are followed by investigators. This program is also designed to improve the quality of research by ensuring congruence between what is described in the research protocol and what is occurring during the actual performance of research activities. PAMs also give researchers an opportunity to ask questions and receive information about regulations and issues regarding the protection of human subjects. The ultimate goal of post approval monitoring at UM is to ensure the well-being of human subjects in research.

During a PAM evaluation, IRB staff will assess research activities, identify areas of concern, provide guidance in implementing corrective actions or best practice recommendations, and prepare a final observations report. The IRB office uses post approval monitoring checklists (which contain important elements from pertinent regulations) to complete evaluations. All PAM checklists are available to study teams and can be found on the IRB website. The IRB will receive reports on the activities and findings of the PAM program at monthly committee meetings.

Receiving notification that a study has been selected for PAM does not imply that wrongdoing has occurred or that it is suspected in the conduct of the study. PAM is not designed to “catch” individuals and IRB staff are not the research police; rather, PAM is meant to verify that research is being conducted as approved and to contribute to an overall culture of compliance and research integrity at UM.

## 1. Protocol Selection

All studies, even those determined to be Exempt status, are subject to PAM. Post Approval Monitoring visits will primarily be randomly selected; however, an emphasis may be placed on monitoring studies that are more than minimal risk or have unusual risks; involve vulnerable populations; involve investigational new drugs or devices; or require more than frequent than annual reviews by the IRB.

A PI may also request a PAM review to help keep records and procedures in compliance with federal regulations and institutional policies, or to help prepare for an external audit by a sponsor or federal agency. We also encourage study teams to regularly complete their own internal PAM reviews any time during the lifecycle of a protocol.

The PI and their research personnel must fully cooperate with all monitoring conducted by the IRB, regulatory agencies, funding agencies, and study sponsors. In addition, the PI must implement the appropriate corrective and preventative actions to resolve any observations and ensure that their research aligns with applicable federal regulations, state laws, and institutional

policies. Failure to complete PAM may result in being reported to Office of Research and Creative Scholarship. If your study is federally funded OHRP/FDA may be notified for noncompliance.

## **2. Types of Monitoring Activities**

### **Self-Assessments**

A Self-Assessment PAM is conducted by the research team, usually the PI. The UM IRB office will send the project PI a self-assessment checklist to be completed within a set period of time (usually 30 days). The investigator self-assessment is meant to monitor adherence to the IRB-approved protocol, including but not limited to the retention of study records and participant files, compliance with investigator training requirements, the recruitment and selection process, the informed consent process, the conduction of the research procedures, and evaluation of other research activities.

### **Consent Document Review**

The IRB office may also request that an investigator complete a Consent Document Review checklist as part of its PAM procedures. During this process, the PI is required to provide information about their consenting process and may be asked to submit all signed consent/assent signature pages for all enrolled participants within a specified period. This type of PAM is more likely to occur with studies that enroll many participants.

### **Consent Process Review/Observation**

During a Consent Process Review, the PI will be asked to complete a checklist during an active consent process with participants. This type of PAM is usually conducted when a project has been issued a waiver of documentation of consent, and/or when there are multiple research team members consenting participants. Consent Process Reviews are a good opportunity for investigators to ensure that consent is being collected and documented (if applicable) properly and according to the approved IRB protocol.

In some cases, IRB staff may request to observe a project's consent process.

### **Investigator Training Audit**

Another PAM procedure that the IRB office uses to ensure compliance is random training audits. Once a month, an active study will be randomly selected and asked to provide current training certificates for all team members listed on the IRB protocol.

## Full Site Assessment

A Full Site Assessment PAM consists of a full audit of all records and processes for a human subjects research project. This includes, but is not limited to:

- Regulatory and IRB documentation
- Protocol adherence, including investigator training records
- Participant recruitment and selection procedures
- Participant enrollment and corresponding records
- Informed consent procedures
- Participant payment
- Document and data retention and storage practices
- Confidentiality and privacy practices and processes
- Clinical trial requirements (if applicable)

Full Site Assessments are generally reserved for complex protocols, protocols that involve vulnerable populations, protocols that are deemed more than minimal risk, and/or protocols that are federally funded; however, the UM IRB may randomly do an on-site assessment for any active protocol.

## For Cause Audits

If a concern or complaint about the conduct of a project is discovered or reported to IRB staff, any member of the IRB, or other administrative official, an audit for cause may be initiated. Audits for cause may occur at any time. The determination of the need for an audit for cause shall be made by the IRB Manager, IRB Chair, and/or the Office of Research and Creative Scholarship. An audit may be project-oriented (focused on a specific project) or research-oriented (focused on all the projects of a particular researcher). The PI of a project that has been selected for an audit for cause shall be notified at least one (1) working day in advance of the audit.

## 3. Preparing for a Monitoring Assessment

When a study is selected for Post Approval Monitoring, a UM IRB staff member will reach out to the Principal Investigator and primary study contact (if applicable) to inform them that their study was selected to undergo a PAM review. For Self-Assessments, Consent Document Reviews, and Consent Process Reviews, the IRB office will ask the PI to review their study records within 30 days of the initial notification and return their findings, in the form of a completed checklist(s), for review. For Training Audits, the PI will have 30 days from receipt of the initial notification to provide current (unexpired) training documentation for all study team members.

For in-person PAM visits, the IRB office will notify the PI and their designee (if applicable) that their study has been selected for post-approval monitoring and schedule an assessment. We will

do our best to accommodate everyone's schedules. Once scheduled, the UM IRB office will provide the PI with a checklist so that the study team can do a self-assessment of the project before the visit. During an in-person assessment, the IRB asks that the following information be made available: access to study files and regulatory documentation; access to participant records; space in which to review study documents; and sufficient time to discuss the project with the PI or a designated team member.

In preparation for addressing PAM questions, it is important for the PI to carefully and objectively review the approved protocol and ensure that all staff are carefully following all activities as described and approved by the IRB. All IRB study procedures must be followed and if any changes are needed to the approved protocol, an amendment must be submitted and approved. The HRPP cannot stress the importance of following the approved protocol. Even small changes from the approved protocol may be of great concern to the IRB, federal regulatory agencies, and internal and external auditors.

The goal of PAM is to help support the research team, and facilitate research by ensuring that the approved IRB protocol and University Policy are being followed. The HRPP can also help researchers by identifying deficiencies so that the research team can put a plan in place for success and correct any deficiencies.

## **4. IRB Actions After a PAM Review**

Upon completion of a PAM activity, the IRB office will prepare a case report that will be sent to the investigator within ten (10) business days via email. The case report will provide study teams with an overview of the findings and any potential follow-up actions that may be needed.

Findings may include:

- No issues found and no action required.
- Recommendations or suggestions for consideration by the PI, such as sharing current best practices.
- Additional education for the principal investigator and/or study staff.
- Items requiring action – a request that an amendment or unanticipated problem be submitted.
- Forwarding to IRB Chair and/or Committee for consideration of non-compliance findings. Please refer to the IRB's Noncompliance policy for what constitutes research noncompliance.

# Chapter 5: Institutional Authorization Agreements/Reliance Agreements

All U.S. institutions engaged in cooperative research conducted or supported by a Common Rule (part 45 CFR 46.114) agency are required to rely upon approval by a single Institutional Review Board (IRB) for the portion of the research conducted in the United States.

A Reliance Agreement (also called an Institutional Authorization Agreement, or IAA) is an agreement signed by two or more institutions engaged in the same human subjects research project. The Agreement permits one or more institutions to cede review to another central, or single, Institutional Review Board (IRB). This means that only one IRB will maintain primary oversight over a single project for several collaborators across institutions.

The National Institutes of Health (NIH) also have their own [Single IRB policy](#). This policy applies to any NIH-funded or -supported non-exempt human subjects research study being conducted cooperatively and/or at more than one U.S. site. Please note that as of January 20, 2020, studies that are not subject to the NIH single IRB policy - such as domestic, multi-site, career development (K), fellowship (F) awards, and Other Transaction (OT) awards – must still use a single IRB as required by the provisions in 45 CFR 46.114(b).

The University of Montana IRB will not enter into reliance agreements for Exempt-level research. In such cases, all collaborating investigators are responsible for applying to their own institution's IRB. Reliance Agreements will be put in place for Expedited and Full Board-reviewed studies.

A Reliance Agreement is needed if your study is Expedited or Full Board-reviewed AND one of the following is true:

- You are a Principal Investigator (PI) on a human subjects research project reviewed at the University of Montana, and you plan to have non-UM colleagues engaged in the project as well or,
- You are a UM researcher and you will be an investigator on a human subjects research project, but the PI is at another institution.

Cooperative research for which more than a single IRB review is required by law, including tribal law, is not subject to the Single IRB provision.

## 1. Current Reliance Agreements

The University of Montana and Montana State University have an Independent Authorization Agreement for all research with human subjects covered by the respective university's Federal Wide Assurance. Notification via a copy of the approval memo to the PI from the IRB is sent to

the non-reviewing IRB. This relieves a PI from having a proposal reviewed by both the UM IRB and Montana State University IRB.

The University of Montana and Salish Kootenai College (SKC) have an Independent Authorization Agreement for all research with human subjects covered by SKC's Federal-wide Assurance. Any research approved by the SKC IRB is generally approved by the UM IRB. Notification via a copy of the approval documents, including a copy of the application and any approval letters, should be submitted to the UM IRB.

If the University of Montana provides IRB review of research concurrently with the collaborative institution's IRB, all the policies and procedures, rules, regulations, and laws described in this document shall apply to University of Montana's review just as they would in non-collaborative research IRB reviews.

## **2. UM IRB Reliance on Another IRB**

Regarding any cooperative research projects that fall within the jurisdiction of the UM IRB, the University of Montana may rely on another appropriately constituted IRB for the review of the research.

The Institutional Official (IO) has the sole authority to make the decision whether or not to rely on another IRB. The IO is authorized to execute IAAs on the University of Montana's behalf and may delegate this authority, provided the delegation of authority is recorded in writing.

In deciding whether or not to rely on another IRB, the UM IRB Manager/Chair shall consider the following criteria:

- Whether other IRB's policies and procedures meet University of Montana standards. If the other IRB is part of an AAHRPP-accredited HRPP, then it will be presumed that the University of Montana standards are being met; however, accredited status does not in itself necessarily suffice as a basis for the IO's decision.
- Where the human subjects research activities would take place.
- Which institution's facilities and personnel would be involved.
- The capacity of the other institution and its IRB to sufficiently to be informed about the University of Montana local research context and applicable laws and regulations.

The IAA must contain the University of Montana's Federal Wide Assurance (FWA) number and, for research subject to federal regulations, the FWA of the other party to the Agreement. The IAA should identify by title, respective PIs, sponsorship and the human subjects research scope of the IAA. The IAA should clearly state which party is relying on the other for IRB review, and how the relying party will be kept informed of the reviewing IRB's actions. Further details should be included in an appropriate template for use by the University of Montana IRB and IO.

When the University of Montana relies on another IRB for review, the UM IRB office shall ensure that a periodic assessment is done of the reviewing IRB's actions to ensure appropriate oversight, including sensitivity to the UM IRB's local research.

Records of the IAAs shall be kept by the UM IRB Office.

### **3. UM IRB Serving as the IRB of Record**

The University of Montana may provide IRB review of human subjects research for another institution pursuant to a signed IAA. In deciding whether or not to provide IRB review for another institution, the IRB office shall consider the following criteria:

- Whether other institution has the capacity to meet the standards of the University of Montana's Human Research Protection Program (HRPP).
- Where the human subjects research activities would take place.
- Which institution's facilities and personnel would be involved.
- The University of Montana's capacity to be sufficiently informed about the other institution's local research context and local applicable laws and rules.

The IAA must set forth the University of Montana's FWA number and, for research subject to federal regulations, the FWA of the other party to the Agreement. The IAA should identify by title respective PIs, sponsorship, and the human subjects research scope of the IAA. The IAA should clearly state which party is relying on the other for IRB review, and how the relying party will be kept informed of the reviewing IRB's actions. Further details should be included in an appropriate template for use by the UM IRB and IO.

The University of Montana shall facilitate communication with the relying institution about UM IRB actions on the human subjects research that is subject to the IAA, in accordance with its specific provisions.

Records of IAAs shall be kept by the UM IRB Office.

### **4. Research Conducted at Multiple Sites and Multiple IRBs**

For research that takes place at more than one site in which all of the sites are engaged in research, reliance by one IRB on another is not required. Frequently each site's IRB will review the protocol for the research to be conducted at its site.

Effective September 25, 2017: NIH-funded multi-site, domestic, human subjects research must be overseen by a single IRB, with the exception of tribal IRBs. Researchers should consult their IRB during the grant application process.

Effective January 20, 2020: Common Rule Agency-funded multi-site, domestic, human subjects research must be overseen by a single IRB, with the exception of tribal IRBs. Researchers should consult their IRB during the grant application process.

## **5. UM Engaged in Research at Another Site Whose Personnel is Not Engaged**

Occasionally, the University of Montana may conduct research at a non-University of Montana site that has an IRB and FWA, but personnel at that site are not engaged in the research. In such cases, the University of Montana PI must provide the UM IRB documentation from the non-University of Montana IRB to the effect that its approval is not required. The University of Montana should also require evidence of permission granted by the other institution to the University of Montana investigators to conduct the research at their site.

## **6. UM Serving as IRB of Record for Entity that Does Not Have Its Own IRB**

The UM IRB may serve as the IRB of record for an entity that does not have its own IRB if (a) the University of Montana is involved in the conduct of or funding of the human subjects research at the entity; (b) the IO or Chair approves of the arrangement in advance; (c) the UM IRB can develop appropriate means by which to consider the local context of the research; and (d) if the research involved is being supported by a federal agency, and the entity is engaged in research, then the entity must have an appropriate FWA in effect. If the appropriate criteria are met, then the UM IRB may enter into an appropriate IAA.

## **7. UM IRB as Coordinating Center for a Multi-Center Protocol**

When the University of Montana serves as the coordinating center for a multi-center human subjects research protocol, the UM IRB will require the University of Montana PI to ensure that IRB approval has been obtained from the IRB at each participating site prior to the initiation of human subjects research at that site or, alternatively, that appropriate authorization agreements have been entered into by all sites. At the time of initial review of the protocol, the UM IRB will assess the procedures for dissemination of protocol information (e.g., Unanticipated Problems, protocol modifications, interim findings, etc.) to all participating sites.

# Chapter 6: Reviews Requiring Special Consideration

## 1. Projects Involving Indigenous Peoples

As a research institution, the University of Montana has far-reaching potential to collaborate with and conduct research, outreach, and instructional activities with a variety of indigenous peoples, including the recognized American Indian Tribes located within the State of Montana.

The University of Montana recognizes that property for indigenous people may have intangible, spiritual manifestations and that it, along with knowledge and traditional resources (such as plants, animals, and other material objects with sacred, ceremonial, heritage, or aesthetic qualities), are central to the maintenance of identity for indigenous people.

Any research conducted with indigenous people or on sovereign tribal land comes under the indigenous people's individual governing authority. This includes, but is not limited to, the Tribal Council, Tribal Cultural Committee, and Tribal IRB. UM involvement must comply with all applicable tribal, federal, state, and University regulations, policies, and procedures.

Montana is home to twelve federally recognized tribal nations and seven reservations. Each tribal government has differing requirements to conduct research on its lands. It is extremely important for researchers to build a positive relationship with the tribal entities with which they plan to work and to learn what the tribal requirements are to conduct research. Equally critical is that researchers and tribal entities work together to build a clear understanding of what is to be researched and how this information will be used. It is the Tribes' legal right to stop any and all research and to control how any information will be used. Information collected may become the Tribes sole property. Ultimately, Tribes have the right to say no to any type of research on items that fall under their legal sovereign right.

IRB proposals for research that may impact the resources or interests of a federally or state recognized American Indian or Alaska Native Tribal Nation (Tribal Nation) will not be approved without prior written approval from the official(s) designated by the relevant Tribal Nation(s). For purposes of this provision, references to "resources or interests of a Tribal Nation" are limited to resources and interests connected to Tribal Nation lands or those aspects of Tribal life that are within the domain of a Tribal Nation, (including, but not limited to, Tribal languages and subsistence rights on Tribal Nation lands) as opposed to individual Tribal Nation members.

If the activity is externally sponsored, the UM PI will follow OSP guidelines to ensure compliance with sponsor, state, and University requirements. If appropriate, UM may informally involve tribal members as UM employees or independent contractors, or may issue a subaward to the tribal entity. Subrecipients function as co-investigators on a sponsored activity and are involved in a creative way in designing or conducting the sponsored activity.

**IRB proposals that seek to involve Indigenous peoples as human subjects in research must:**

1. Seek guidance from the potentially impacted Tribal Nation(s) regarding which activity/activities require(s) review and prior approval from an authorized designee(s) of the Tribal Nation(s); and
2. Based on the guidance received, submit a written request to the relevant Tribal Nation(s), for approval to carry out the proposed activity(ies) that require(s) Tribal Nation review and approval. Examples of such activities may include, but are not limited to, the following:
  - a. research or projects that involve Tribal Nation members and would invoke the Tribal Nation in any way (including but not limited to referencing a Tribal Nation in materials, public forums, or publications). Note that this type of proposal may also require a separate Tribal IRB or other mechanism that a Tribal Nation may have in place to review proposed research (this would exclude cases where Tribal Nation members voluntarily participate in the proposed research as individuals, not as members representing a Tribal Nation);
  - b. carrying out studies or research on Tribal Nation reservations, territories, and other locations where Tribal Nations have legally protected rights to resources or to engage in activities; and
  - c. using Tribal Nation-controlled information or data in research.

As a research university, the University of Montana most often collaborates with Indigenous people in the role of research subjects. All UM employees and students doing research on human subjects must follow requirements per UM's Institutional Review Board (IRB) for the Protection of Human Subjects and meet any course requirements for human subjects protection. Tribes are sovereign nations and establish their own rules, policies, and procedures for conducting research on their respective reservations. When UM undertakes activities affecting American Indian tribal rights or interests, such activities should be implemented in a knowledgeable, sensitive manner that is respectful of tribal sovereignty and reflects tribal cultural protection and preservation concerns.

## **Timing**

When planning projects, UM researchers should allow adequate time to obtain the proper approvals. Each tribal nation reviews projects differently and according to their own internal policies, procedures, and cultural customs. The UM IRB urges UM researchers to plan months in advance if you plan on seeking tribal approval for a project. Tribal approval for research may come from a tribal IRB or its equivalent, such as the tribal council, tribal cultural committee, or another alternative culturally-appropriate body that is authorized to make decisions on behalf of the tribal nation.

## Research and Indian Health Services (IHS) Facilities

Any proposed research at an Indian Health Service (IHS) facility, whether on or off a reservation, will require additional review by the IHS IRB or its designee.

## UM IRB Expectations of PIs When Working with Indigenous Peoples

The UM PI will, at a minimum:

- Ensure compliance with University, tribal, and federal guidelines, policies and/or regulations.
- Work effectively with indigenous people and respect tribal cultural and intellectual property, and recognize the rights the involved Tribe(s) retains over all shared information (e.g., cultural knowledge, practices, and traditions).
- Comply with tribal requirements regarding cultural and data ownership, and adhere to the feedback of the involved Tribe(s) regarding collection or handling of materials, information, data, and samples.
- Collaborate with the involved Tribe(s) to identify what information should be protected, and establish and agree upon safeguards.
- Secure appropriate written permission from the involved Tribe(s) that details any expectations of the Tribe regarding reports or involvement.
- Work closely with the involved Tribe(s) and provide - in layman's terms - reports, presentations, or other updates as requested and entertain feedback and suggestions.
- Update the tribal governing body on research progress as requested (quarterly is recommended).
- Provide the tribal governing body a yearly written report, unless the involved Tribe(s) requests more frequent reports, that contains a full summary of all research activities.
- Request and secure permission to disseminate research findings in academic or popular literature, conferences, and/or any other endeavors that will involve the presentation of the research findings (e.g., submission of abstracts, poster presentations, oral presentations, and publication).

## Approvals and Agreements

Any employee, adjunct faculty member, or student who, on behalf of the University of Montana, conducts research using human subjects must receive IRB approval prior to recruiting or screening human subjects. The UM IRB will conduct its own review of protocols involving Indigenous peoples as human subjects but will not issue final approval until all of the appropriate tribal permissions have been obtained and submitted in writing to the IRB. Tribes are not required to follow single IRB (sIRB) requirements as outlined in 45 CFR 46.114.

The UM IRB may conduct a review at the tribe's request, or it may enter into a reliance agreement with the tribal IRB, such that the tribal IRB assumes oversight. When the UM IRB conducts the review, separate written permission must be obtained from the collective tribal governing body to conduct research on the reservation. UM IRB approval or an approved reliance agreement and tribal IRB approval must be finalized before any research is conducted. If the research does not involve human subjects, collective written permission by the tribal governing body may be adequate. Consult with the UM IRB to determine appropriate documentation.

## Memorandums of Understanding (MOU)

In some cases, a Memorandum of Understanding (MOU) may be executed between a tribe and UM. Typically initiated by the tribe, an MOU may be written in addition to IRB review and an IRB reliance agreement. The MOU will be signed by the UM IRB manager or other authorized institutional official. Components may include:

- a collaborative scope of work, timeframe, target population, and materials, information, data, and/or samples collected;
- a description of how the research process will benefit the tribal community or tribal members (e.g., financial benefits, social benefits, economic development, increased knowledge and innovation, capacity building);
- a description of any required progress reports to be supplied by UM, whether verbal or written, and the level of detail required;
- an expectation that the UM PI will conduct presentations to interested tribal entities to inform the community of project findings and to garner feedback and suggestions;
- procedures for UM dissemination of research findings;
- ownership of materials, information, data, and/or samples is typically retained by the involved Tribe(s);
- procedures for returning, storing, and/or destroying materials,

- information, data, and/or samples to the involved Tribe(s), specifying any agreed-upon confidentiality requirements;
- an expectation that all sensitive materials, information, data, and/or samples have been destroyed, or disposed of in accordance with involved Tribe(s) instructions upon the completion of the research project.

## 2. Vulnerable Populations Under 45 CFR 46

When some or all of the participants in a protocol are likely to be vulnerable to coercion or undue influence, the IRB will include additional safeguards to protect the rights and welfare of these participants. Some of the vulnerable populations that might be involved in research include children, pregnant women, fetuses, neonates, prisoners, adults who lack the ability to consent, students, employees, unhoused persons, and other groups deemed vulnerable by the IRB.

If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about or experienced in working with these participants. For example, the IRB will include one or more individuals who are knowledgeable about or experienced in working with children, prisoners, or adults with limited decision-making capacity, when reviewing research that involves individuals from these populations.

The Department of Health and Human Services (HHS), Code of Federal Regulation, Title 45 Public Welfare, Part 46 Protection of Human Subjects, contains additional safeguards designed to provide extra protections for vulnerable populations. These provisions provide for additional requirements for IRBs. Relevant subparts include:

- Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects'
- Subpart D - Additional Protections for Children Involved as Subjects' in Research

Research that involves any of these populations must comply with the requirements of the relevant subparts. In addition, although research funded by other federal agencies may or may not be covered by the subparts, these additional agencies may impose additional requirements for the protection of human subjects in research.

### Children

Federal regulations mandate when and how children may be involved in human subjects research (45 CFR 46 Subpart D). Children are defined in the Common Rule as “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 46.402a). All child subjects are to be given a clear and complete picture of the research in which they are asked to participate, together with its attendant risks and benefits, as their developmental status and competence will allow them to understand. Emancipated minors (16 years or older) and married minors are not considered children under this policy as per the State of Montana’s statutory definitions.

## Minor Assent

The Common Rule requires that a child whose age, maturity, and psychological state make it possible for him or her to make an independent decision to participate in a study must have the chance to give assent. Assent should be an ongoing dialogue between the researcher and the child.

All children from 10 to 17 years of age are required to give written assent. Children under 10 years old only need to give verbal assent if appropriate for their age. The IRB proposal must clearly describe acceptable procedures for informing the child subjects of the nature of the research and of its risks and benefits, as well as how the level of competence to understand and assent will be ascertained. This assessment must consider the child’s age, maturity, psychological, and emotional state.

### *Waivers of Documentation of Child Assent*

In some cases, the IRB may consider a researcher’s request for a waiver of documentation of minor assent. This means that assent is still being collected, but there is no signed document involved. This may be appropriate in cases where the child is too young to sign an informed consent form, and in cases when there is risk involved with having a participant’s name linked to a study via a signature (e.g., illegal drug/alcohol use, child abuse, etc.).

### *Full Waivers of Child Assent*

The UM IRB may consider a full waiver of a child’s assent to participate in research if: the child is incapable of providing or communicating assent and the study offers clear promise of benefit through a treatment that is not available outside the research setting; or the research is no more than minimal risk, the waiver would not adversely impact the rights or welfare of the participants, the research would be impracticable without the waiver, and appropriate information about the study will be provided to the child.

## Parental Consent

Federal regulations mandate when and how parental consent must be collected when children are involved in research (45 CFR 46.408). Parental consent is required for children ages birth through 17 years to participate in a research study. Often children, particularly young children, are unable to understand the full scope of the decision put before them. Therefore, it is important that a parent/legally authorized representative be the primary person to give consent in order to act in the child’s best interests.

For studies involving minimal risk, or more than minimal risk with the prospect of direct benefit to the child, the IRB may find that the permission of one parent is sufficient for enrollment in the research project. Otherwise, the permission of both parents is required 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. Parental permission is required for all survey research, including online surveys, unless the investigator can make a compelling argument to the contrary.

### *Active vs. Passive Parental Consent*

Active (opt-in) consent is typically required before conducting research with human participants. In most cases, parents or legal guardians must affirmatively communicate their approval before their child may participate in research.

In limited cases, the IRB may allow an opt-out consent process (passive consent), where a parent or guardian's consent is assumed unless they communicate otherwise. This is limited to cases where **all** of the following are true: (1) the study poses minimal risk; (2) the research cannot practicably be carried out otherwise; and (3) the IRB agrees that opt-out consent is appropriate under the circumstances. If research is conducted in a school setting, the school must agree that an opt-out model is consistent with their internal policies. Additional considerations include:

1. **Justify waiver of active consent:** Since active consent is expected, you must justify your use of opt-out consent as necessary and ethically appropriate. The IRB will want to know: if the research is part of regular classroom activities; the expected duration of the children's participation; whether the research could pose any risk, such as sensitive questions that may upset or embarrass; and whether identifying information will be collected.
2. **Document school approval:** For research in schools, include in your IRB application a letter of support for using opt-out consent, signed by the principal or another senior administrator.
3. **Develop a robust plan for informing parents:** Inform parents/guardians about the study and give them an opportunity to state that they do not want their child to participate. Ensuring that information is actually received can be a challenge - a flyer sent home may never make it there. Therefore, use more than one method to contact parents/guardians, if possible.
4. **Make it easy to opt out:** Similarly, the IRB recommends providing multiple ways for a parent/guardian to inform the researcher that they do not want their child to participate.
5. **Build in sufficient time:** Make sure to give sufficient time for parents/guardians to review the information and act (at least a week), and include a due date for responses.

6. **Set the right tone:** Be helpful and respectful in your communications. Describe the study activities clearly and in detail.
7. **Have a plan to address concerns:** If a parent/guardian expresses a concern you should address it immediately, beginning by informing the IRB office.
8. **Consider non-English speakers:** In situations where the researcher expects that a substantial number of parents/guardians are illiterate or do not read English, offer an appropriate alternative method of communicating information about the study.

### *Waivers of Documentation of Parental Consent*

A waiver of documentation of parental consent means that the researcher does not have to have a physical, signed copy of parent permission. Federal regulations allow the IRB to waive documentation of parental consent when the following is true: (1) the research is minimal risk; (2) no procedures are involved for which written consent is normally required; and (3) the only record linking the subject to the research is the consent form. The Common Rule also allows the IRB to waive documentation of parental consent when the subjects are members of a distinct cultural group in which signing forms is not the norm.

### *Full Waivers of Parental Consent*

Although rare, there may be circumstances under which the IRB may consider a full waiver of parental consent. The investigator must make a compelling and persuasive argument to the IRB for why a full waiver is necessary for the conduct of the research. Waivers of parental consent are usually granted in circumstances when parent permission is not a reasonable requirement to protect the child, such as in cases of abuse or neglect. Requests for waivers of parental consent must demonstrate that the waiver will not adversely affect the rights or welfare of the child and that the research would be impracticable without the waiver. The waiver must also not be inconsistent with federal or state law. Sometimes the IRB may require that parental consent is substituted with something else, such as permission from a legal guardian or an advocate. When research takes place within a school district, school officials must agree to the waiver of parental permission.

## **Wards of the State**

Research with wards is regulated by the Common Rule (45 CFR 46.409). Children who are wards of the state or any other agency, institution, or entity can be included in research only when (1) the research is related to their status as wards, or (2) the research is conducted in a setting where most children involved as subjects are not wards (e.g., school, camp, hospital). When wards are specifically enrolled in research, the IRB requires that an advocate is appointed for the child in addition to any other individual who acts on behalf of the child as a guardian. Advocates must have the background and experience to act in the best interest of the child and may not be associated with the research, the investigator(s), or the guardian organization in any way.

## **Pregnant People, Fetuses, and Neonates**

The University of Montana IRB requires adherence to DHHS regulations regarding additional protections required for research involving pregnant individuals, fetuses, and neonates. In addition to the other responsibilities assigned to the IRBs under 45 CFR Part 46 Subpart A, the University of Montana requires the IRB to review research involving these participants by applying the protections of 45 CFR 46 Subpart B for HHS supported research. The IRB will provide for equivalent protections when the research is not supported by HHS. Montana law may place additional restrictions on research on the fetus. The IRB will consult with UM Legal Council on a case-by-case basis for research protocols involving this class of participant.

## **Prisoners**

If an investigator indicates that incarcerated persons will participate in the research, or that participants may reasonably be expected to be incarcerated at some time point during the study, the IRB will adhere to the requirements found at 45 CFR 46, Subpart C. A majority of the IRB (exclusive of incarcerated person members) will have no association with the prison involved apart from membership on the IRB. At least one IRB member who is an incarcerated person or incarcerated person representative with appropriate background and experience to serve in that capacity will be present at the meeting.

### **When Participants Become Prisoners During a Research Protocol**

This policy applies whenever any human participant in a research protocol becomes an incarcerated person at any time during the protocol, e.g., after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the participant. If a participant becomes an incarcerated person after enrollment in research, the Principal Investigator is responsible for reporting in writing this situation to the IRB immediately. Each incarcerated person will be informed in advance that participation in the research will have no effect on his/her/their parole.

At the earliest opportunity after receiving the Principal Investigator's notice or otherwise becoming aware of the incarcerated person status of a participant the IRB will review the protocol again with an incarcerated person representative as a member of the IRB.

The IRB will take special consideration of the conditions of being an incarcerated person. Upon this review, the IRB can either (a) approve the involvement of the incarcerated person-participants in the research in accordance with this policy and all applicable regulations; or (b) determine that this participant must be withdrawn from the research.

Additionally, the IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the participant's participation by the investigator without regard to the participant's consent.

### **3. Other Vulnerable Populations**

Federal regulations require that the IRB consider additional protections for other vulnerable populations such as but not limited to persons lacking decision-making capacity and economically or educationally disadvantaged individuals. The IRB will consider these additional protections as part of the criteria for approval.

Although the federal regulations do not list all vulnerable groups, the IRB considers vulnerable groups to also include students, employees, and those within potentially compromised autonomy. The IRB will determine special protections for these groups on a case-by-case basis taking into account the risks and benefits and other protections afforded by institutional policies and state and federal law.

#### **Adults with Impaired Decision-Making Capacity**

Cognitively impaired adults are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals may be considered decisionally-impaired or have limited decision-making ability because they are under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill, or have severely disabling physical handicaps.

There are no federal regulations specific to research involving adults with impaired decision-making capacity. The IRB takes special care to consider issues such as the selection of participants, privacy and confidentiality, undue influence, and risk-benefit analysis. Decisions should be made with the utmost deference to the ethical principles underlying human research as set forth in the Belmont Report.

The National Bioethics Advisory Commission (NBAC) has issued 21 recommendations for IRBs, the research community, and Federal regulators to consider regarding the decision-making capacity of particularly vulnerable participants.

The following criteria may be taken into consideration for adult participants with impaired decision-making capacity involved in a research protocol:

- The objectives of the research cannot be met by conducting the research in a population that does not have the disorder that may affect decision making capacity.
- The research is designed for a disease or condition relevant to the vulnerable population under study.
- The research is either minimal risk, more than minimal risk with a prospect of direct benefit, or more than minimal risk without a prospect of direct benefit, but of vital importance to the vulnerable population.

- Adequate provisions are made for obtaining consent from the participant's legally authorized representative. The use of a legally authorized representative will be consistent with applicable state law(s).
- Adequate provisions are made for obtaining assent from the participant, unless the IRB determines that assent is not appropriate as a condition of participation or that some or all participants are not capable of providing assent.
- The protocol must describe when and how the participants will be assessed for capacity for formal consent or assent and understanding of the proposed research, and the process for a second confirming assessment. Competency should be evaluated on an individual basis to avoid incorrect assumptions as to an individual's ability to make decisions. Criteria for determining competence might vary according to the degree of risk or discomfort presented by the research procedures and the extent to which therapeutic gain can be anticipated. Mentally disabled or cognitively impaired participants for additional considerations the IRB may make surrounding informed consent.

The IRB may also consider additional safeguards to protect participants. These include:

- Requiring the involvement of participant advocates
- Requiring independent monitoring
- Requiring waiting periods
- Appointing a monitor to supervise the informed consent process

Such decisions may be based on the amount of risk involved in the research and the likelihood that participants will derive health benefits from their participation.

## Students

If an investigator will be conducting research with students as research participants, the IRB application should provide the following basic information where prompted:

- A rationale for recruiting students as research participants that demonstrates that students are the logical choice for answering the research questions (e.g., the research is related to student issues, academics, curriculum, instructional strategies, instructional techniques, classroom management methods, or program evaluation). If a study topic does not necessitate the recruitment of students specifically, then researchers should recruit from the general population. Students may be included as part of the general population, but they should not be singled out for recruitment.
- Whether the PI is a university faculty member, a teacher in a primary school setting (perhaps the PI is a student working on a degree program at UM), an administrator, or other service provider in the education setting and:
  - Information about the PI's specific role(s) at the school or institution,

- Whether or not the PI intends to recruit students who are enrolled in their courses/classes or students to whom they provide direct services. If PIs want to recruit students whom they teach or directly serve, the IRB application must provide a strong justification for pursuing an approach where there is an interpersonal conflict of interest. A clear explanation about why the research questions cannot be answered any other way needs to be provided. In addition, the PI must provide a strategy for mitigating an interpersonal conflict of interest.

## Strategies for Minimizing Interpersonal Conflict of Interest

If PIs plan on recruiting students whom they teach or directly serve, the application may not state that there is no interpersonal conflict of interest. When the subject pool is the researcher's own class or client roster, participants are often recruited out of convenience, and there may be more benefit to the researcher than to the participants. Past history and a continuing relationship with students can also bias a researcher and affect whether or not free informed consent and assent can truly be achieved.

The protocol application must address the PI's dual role and the resulting power imbalance. A description of the tangible measures that will be used to mitigate the conflict of interest needs to be provided where prompted. A tangible strategy is not merely stating that participation is voluntary and will not affect course grades or other services to which students are entitled.

The following options are available to mitigate interpersonal conflicts of interest:

- Ensure that data collection is anonymous and that the PI would not be able to trace individual responses. This option is not feasible if the class or client roster is small and if the responses provide enough contextual information that could result in the identification of students. As well, this option is not feasible if PIs wish to access FERPA-protected data for which written consent is required. See the heading Secondary Data below for more information about FERPA requirements.
- Ask a neutral third party not involved in the research to recruit students and collect consent and assent forms (if applicable) on the PI's behalf. The third party may also need to collect the data if doing so could result in the identification of participants (e.g., interviews); the data would then either be de-identified by the third party, if possible, or provided to the PI after a grade in the course has been assigned or after the students are no longer under the PI's supervision if de-identification is not possible.
- Conduct the study in another course not taught by the PI.
- Conduct recruitment, consent, and data collection after grades have been assigned.

## Addressing Inequitable Subject Selection and Stigmatization

Every effort should be made to recruit students who would most benefit from participation in the study. This must be balanced by an equal effort to avoid singling out students from their

classmates, especially in primary and secondary education settings where students may not have a choice about which classes they are enrolled in. The following three examples outline some problematic subject selection strategies that have been presented in IRB protocols in the past as well as some alternative strategies that can be employed.

- Research targeting specific groups of students in a specific class. Concerns are raised when investigators target a specific sub group of students in a class in a way that could cause stigmatization (e.g., low performing students, minority students). You can't isolate students within a class based on their race, ethnicity, gender, or academic performance.

**Alternative:** invite all students to participate (after obtaining parental consent if students are minors) and design data instruments with screening criteria built in, so that your target group is evaluated in the analysis stage and not during the recruitment stage.

**Alternative:** Keep the decision to participate private by handing out materials to all students - some of which may include the research instruments, some of which may include alternative activities.

- Cherry picking a representative sample from a group of eligible participants to be subjects of the research. This practice lends itself to researcher bias and does not yield generalizable results. If the research questions are broad, but the sample size is too small, conclusions can only be made about those particular subjects.

**Alternative:** invite all students to participate and allow for a control group, if feasible, to support conclusions and eliminate alternate explanations for results.

- Research that withholds educational benefits to students who do not participate. You cannot apply an intervention to a small group of students who agree to participate in the research if the intervention could benefit all students.

**Alternative:** either apply the intervention to all students who stand to benefit or ensure that the intervention will be applied to the rest of the group after the research is concluded.

## What Does Research Participation Mean in a Classroom Setting?

When conducting research in a class setting, the IRB protocol needs to make a distinction between required classroom work and research. Data cannot be used for research without consent, even if students are required to complete the class assignments and curriculum.

From the beginning, the research methods described in the protocol should clearly delineate between school-driven versus investigator-driven research and between normal educational practices and special, research-specific interventions. The protocol should explain whether the planned activities were designed by the school or department and would occur regardless of whether the research takes place or whether the planned activities are designed by the study team to be done exclusively as part of the research.

### *Normal educational practices*

If PIs plan on investigating the effectiveness of normal educational practices such as instructional strategies, instructional techniques, curricula, or classroom management methods, the research summary in the IRB application needs to explain the difference between choosing and not choosing to participate in the research. This information should also be communicated in the consent and assent documents and procedures. For example, if the research entails analyzing class assignments that students are required to complete, the consent/assent language should indicate that all students are required to do the work but that the research team will only analyze the work from those students from whom consent/assent has been obtained.

The burden of demonstrating whether an activity is part of normal educational practices is on the researcher. If a proposed research project appears to place participants at risk or has no precedent in previous, published research, the IRB will likely question the “normalcy” of the activity. For this reason, the PI should be prepared with a brief literature review that provides enough background information for the IRB to determine whether the proposed work falls within what is typical in the context of a specific classroom setting. What is considered to be normal in one classroom may not be in another. For example, curriculum and interventions for special education students in the primary or secondary school setting are tailored to each student, so normal classroom activities in a special education environment are student-specific in a way that they would not be in a general education environment. Be prepared to provide the contextual information about the school environment in which you intend to conduct the research in the IRB protocol – do not assume that IRB members will automatically know this.

### *Special, research-specific interventions*

If the PI plans on conducting a special investigation or intervention that goes beyond assessing normal classroom practices, the consent and assent language must explain what those who choose not to participate will be doing in the meantime. An alternate assignment or activity may need to be designed, and non-participating students cannot be singled out by either their peers or their teacher (see above sections on interpersonal conflict of interest and stigmatization). The research must be designed so that neither the participating group nor the non-participating group forego any educational benefits because of their choices. That is, participating students should not be made to devote time to the research at the expense of their learning or in a way that is disruptive to the classroom environment, and non-participating students should not be excluded from the potential educational benefits that might be provided by an intervention. In the former instance, the PI should consider setting aside non-classroom time for participating students to complete research tasks, or come up with a research design that keeps information about who is and who is not participating private. In the latter case, when students might stand to benefit from the intervention but may not want to participate in the research, the PI can offer to apply the intervention to all students after the research is concluded.

## **Secondary Data**

The IRB has oversight over the use of secondary data that contain identifying information. In most cases, consent and assent are also required for the use of individually identifying

educational records in research, even if a school has given permission to access and use the information for other purposes. If a PI have access to educational records as part of their job function, this does not automatically mean that they may use the records for research purposes.

Educational records are protected under the Family Educational Rights and Privacy Act (FERPA), and there is no statute of limitations on the privacy of uniquely identifying educational records. FERPA still applies to students' records even if they have graduated or are no longer enrolled at the school. FERPA may also apply to counseling and medical records. Teachers and administrators cannot be asked to share information about specific students without the student's and (for minors) a parent's consent.

School permission alone is only acceptable if it confirms that the research team will not access educational records or the school will provide the PI with information from which all of the identifying information has already been removed.

In the protocol materials, please also avoid false claims about anonymity. If a researcher has access to individual student information and if he/she knows who participated in the research and who did not participate, the subjects are not anonymous. Efforts should be made to maintain confidentiality – such as through the use of pseudonyms – but anonymity cannot be guaranteed. Do not use the word “anonymous” in the protocol submission if it does not apply.

## Observations in the Classroom

If the classroom environment will be observed, the IRB application must provide details about what information the research team wishes to gather from the observations and how the observations will help to answer the research questions. The IRB often receives educational research submissions that contain vague language about classroom observations. A rationale, justification, and details must be provided in order for proposed observations to be approved. In addition to explaining the nature of the observations, the IRB application must also explain who will conduct observations, when they will occur and how frequently they will occur, whether or not any information that could identify individual students will be recorded, and what data elements will be recorded. The PI may wish to create an observation intake sheet to record specific data elements to be gathered from observations.

### *Audio and Video Recording in the Classroom*

If the classroom environment will be recorded, an explanation should be provided in both the IRB application and on the consent form about why the recordings are needed to carry out the research. A video-recording may be able to catch more than what a teacher could observe. In a primary or secondary school setting, the teacher/researcher role can become conflated when recordings capture behavior that may require disciplinary action on the part of the teacher but that may not be relevant to the research. The teacher's role may interfere with the researcher's promise that participation will not negatively impact the student. The protocol should explain how such situations will be handled. As with individually-identifying secondary data, video recordings by default are not anonymous. The protocol should explain how recordings will be handled in a classroom where some students may have provided consent/assent for participation

in the research and some have not. If the purpose of the recording is to focus on the teacher and not the students, this needs to be outlined in detail, including the procedures for ensuring that students will not be video recorded. The protocol application should also explain who will have access to recordings, whether or not they will be disseminated, how long the recordings will be kept, where they will be stored, and when and how they will be destroyed.

## Extra Credit as an Incentive for Participation in Research

The decision about whether or not to participate in research should not affect a student's grade in a course. For this reason, **extra credit may only be offered as an incentive for participation in research if an alternative, equivalent form of extra credit is offered** for those students who want to obtain extra credit but who do not want to participate in research. In a college setting many institutions, including UM, use Sona Systems for advertising studies and credit management for college student subject pools. At UM, the department of Psychology uses Sona Systems; this tool is not available to all researchers. Where there is no system in place, researchers must describe the alternative extra credit in their IRB application. In addition, all researchers offering extra credit must specify the amount. For example, Sona allows assignment of credit hours in 15-minute increments. Researchers should not offer extra credit from differing instructors unless they can guarantee all students will receive the same amount and that an alternative is available. Extra credit may not be a feasible option if you are trying to maintain anonymity of subjects. Researchers using Sona cannot and should not guarantee anonymity for their participants since names must be known in order to assign credit to the correct student.

## Validity of Data Instruments

The data instruments selected should be age and developmentally appropriate if they will be distributed to students in primary or secondary education settings and should be relevant to the research questions posed in the IRB application. While the selection of data instruments pertains to research design, if the instruments are too complex or cannot possibly answer the research questions posed, the IRB may request that they be revised or replaced. Inappropriate data instruments can contribute to additional risks for participants; at best the research can be a waste of the subjects' time and, at worst, the research may lead to false conclusions that affect student learning. It is important that the instruments are not only reliable and well-established, but that they are designed to address the issue that is being studied and that they are used as they are designed for the specific research context.

## Student Athletes

When specifically recruiting student athletes at the University of Montana or any of its affiliate campuses, investigators must first obtain permission from the appropriate campus's Athletic Director.

## Employees

University of Montana employees may enroll in research protocols approved by the IRB. However, additional considerations and safeguards should be considered.

Employees, including University of Montana and affiliate employees (e.g., full-time, part-time, temporary, visiting, student employee appointments, etc.) may be recruited for research participation; however, an employee may not be required to participate in research as a condition of employment. Employees (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion.

Recruitment of potential participants who are employees must be designed to minimize the possibility of coercion or undue influence. In general, potential participants should be solicited from a “broad base” of individuals meeting the conditions for study, rather than from individuals who report directly to the investigator(s). Strategies to minimize the potential influence of an investigator when recruiting his/her own employees include recruitment through a third party unassociated in a supervisory relationship with the employee, postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the investigator(s).

Investigators and IRBs must consider strategies to ensure voluntary participation when the subjects of research include employees who are directly supervised by the investigator(s). An employee’s decision about research participation may not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors. Investigators may act as participants in their own studies if they meet the inclusion/exclusion criteria and all procedures including consent are completed by a Co-Investigator or Coordinator.

Except in unusual circumstances, investigators should not enroll employees under their direct supervision into research studies that involve greater than minimal risk without the prospect of direct benefit. Such studies should proceed only where the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and the research is of significant importance and cannot be conducted without the enrollment of these employees.

Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for investigators to keep an individual’s participation confidential, which could pose risks to participants, e.g., when stigma is associated with the condition or question under study or when peer pressure is a component of the research. In such situations, research should be conducted off-site and/or outside of regular work hours when possible to minimize potential risks.

Protecting the confidentiality of research participants’ personal information when the participants are employees may also present additional challenges. The extent to which medical information and/or research data may be accessible to supervisors or others not directly involved in the research must be considered and disclosed to potential participants in the informed consent process.

In cases where regular workplace activities are also the topic of research, investigators must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would take place even without the research. When access to

individuals or the facilities of the site is needed for recruitment and/or research activities, a letter of support from someone authorized to speak on behalf of the employees/site may be required.

## **Self-Experimentation**

Researchers can be subjects in their own studies. However, UM policy regards this type of research (investigator self-experimentation) as research with human participants, and generally requires the same review and approval as research that recruits other people as subjects.

Though investigator self-experimentation may not raise the conventional ethical concerns outlined in the Belmont Report, all human research projects should undergo ethical review to assure the safety of people involved and the integrity of the research at the university. While researchers may be aware of the risks of self-experimentation, they may also be more willing to accept risks that are ill-advised. Application for review with the IRB office allows a neutral third party to raise concerns and/or propose measures to promote the welfare of researchers.

The Common Rule and FDA regulations also require that informed consent be obtained from all research participants unless certain conditions are met. The IRB recommends researchers provide a consent document based on the template provided on the UM IRB website, with their IRB application, which will serve as the basis for documentation of informed consent for participation in human subjects research when the experimentation involves the researcher.

## **Other Vulnerable Populations**

The context of the research is an important consideration for the IRB when reviewing research that involves potentially vulnerable participants. Members of the following groups may be considered potentially vulnerable. The IRB will consider the context of the research and determine whether additional protections may be needed if members of the following groups are a targeted study population:

- Members of disenfranchised racial or ethnic communities
- Members of disenfranchised groups, such as the LGBTQ+ community
- Members of the Armed Forces and veterans
- Refugees, undocumented immigrants, etc.
- Educationally disadvantaged persons
- Economically disadvantaged persons
- People experiencing homelessness
- Institutionalized individuals
- Individuals with mental illness and/or substance use disorders

## **4. Reporting Suspected Abuse or Neglect of Children, Elderly Individuals, and Dependent Adults**

An investigator who knows of or reasonably suspects neglect or abuse of a child, elder, or dependent adult while engaged in university-approved research may need to report the abuse. An investigator who is classified as a mandated reporter under Montana law (e.g., teacher or medical practitioner) must report such abuse or neglect to appropriate authorities unless otherwise directed by the Associate Vice President (AVP) for Research and Creative Scholarship. An investigator who is not otherwise classified as a mandated reporter under Montana law and who knows or reasonably suspects that a child, elder, dependent adult has been abused or neglected, should seek guidance from the AVP who will consult with University Legal Counsel to determine an appropriate course of action. Investigators also must report such incidents of abuse or neglect to the IRB.

Examples of abuse and neglect that researchers may be legally and/or ethically required to report to authorities include, but are not be limited to:

- **Physical neglect** - a parent or caregiver is not caring for a dependent's physical needs, such as the need for food, water, or shelter. Signs of physical neglect may include frequent complains of hunger/thirst; signs of malnourishment, such as low body weight; hygiene issues, such as unwashed skin, hair, or clothing; and untreated wounds, dental issues, or medical conditions.
- **Physical abuse** – a parent or caregiver uses physical violence against a dependent, including hitting, kicking, burning, pinching, or corporal punishment. Signs of physical abuse may include visible injuries such as bruises, especially if they are at different stages of healing, cigarette burns, cuts, or lash marks; jumpiness or fearful behavior; and emotional outbursts.
- **Emotional abuse** – a parent or caregiver insults, intentionally humiliates, manipulates, gaslights, isolates, threatens, or coercively controls a dependent. Signs of emotional abuse may be hard to distinguish and researchers should be aware of this when working with vulnerable participants. Signs of emotional abuse may include but are not limited to lack of eye contact, expressions of fear or anxiety, withdrawal, and talk of death or dying.
- **Sexual abuse** – sexual abuse is any inappropriate touching, contact, or exposure of sexual content or nature by a parent or caregiver to a dependent. This includes but is not limited to rape, incest, sexual coercion, sex trafficking, or exposing children to sexual content. Signs of sexual abuse may be hard to distinguish and researchers should be aware of this when working with vulnerable participants.
- **Financial abuse** – a caregiver is stealing a dependent's money, seizing control of it, or preventing them from having their own. There are many signs of financial abuse but some may include, but are not limited to, preventing someone access to their bank account; preventing someone from working and/or interfering with job performance in some way; forcing someone to account for all money spent by, for example, looking at receipts; and forcing someone to turn over their paychecks.

## IRB Responsibility

The IRB is required to determine whether the risks to subjects are sufficiently minimized, informed consent is appropriate, vulnerable research subjects are adequately protected, and that privacy and confidentiality protections are adequate. If the IRB believes that a reportable observation or revelation of suspected harm to a child or other vulnerable person, such as a dependent adult or elder, might occur during the research, it may require that the informed consent statement include a warning of the limits to research confidentiality and advise subjects of the investigator's duty to report known or suspected incidents of abuse or neglect to appropriate authorities, including law enforcement.

## Investigator Responsibility

Each proposal for research that includes procedures which might lead to the disclosure of known or suspected child, dependent adult or elder abuse, OR will be conducted in subjects' homes (where signs of abuse may be observed), should include the following in the application for IRB review:

1. An investigator should explain to the IRB whether he/she is a "mandated reporter" as defined by Montana law governing child or elder and dependent adult abuse and neglect.
2. An investigator who is not a mandated reporter should clarify whether he/she intends to report information about alleged, probable, or known sexual or physical abuse of a child, dependent adult or elder which may be disclosed during the research.
3. The investigator should delineate in the IRB application any conditions under which confidential information might be disclosed, should specify what information will be reported to the authorities, and describe the procedures which will be followed. (i.e., who will make the report, to whom the report will be made, etc.)
4. The investigator should create and submit for IRB review an informed consent document that accurately reflects the conditions under which confidential information might be disclosed, including any voluntary disclosure by the researcher about alleged, probable, or known abuse or neglect of a child, dependent adult or elder.

The informed consent and assent form confidentiality section should include a description and examples of the types of information which the research team may report to authorities.

### **Consent form requirements for investigators who ARE in mandated reporter classifications:**

*Consent form: Under Montana law, the researcher(s) will not maintain as confidential, information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect. If any researcher has or is given such information, he or she may be required*

*to report it to the authorities...* [provide description and examples of types of information which would be reported ...]

Assent Form: *We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else. If you tell us that someone is or has been hurting you, we may have to tell that to people who are responsible for protecting children so they can make sure you are safe.*

### **Consent form requirements for investigators who are NOT in mandated reporter classifications:**

Consent form: *The researcher(s) may not be able to maintain as confidential, information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder, including, but not limited to, physical, sexual, emotional, and financial abuse or neglect. If the researcher is given such information, he or she may report it to the authorities* [provide description and examples of types of information which would be reported ...]

Assent Form: *We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else. If you tell us that someone is or has been hurting you, we may have to tell that to people who are responsible for protecting children so they can make sure you are safe.*

## **5. Certificates of Confidentiality**

Certificates of Confidentiality are an important tool to protect the privacy of research subjects. Certificates are issued by the National Institutes of Health (NIH) and other HHS agencies (such as the Centers for Disease Control and Prevention, and the Food and Drug Administration) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Certificates of Confidentiality may be granted for studies collecting information that if disclosed could damage their financial standing, employability, insurability, or reputation or have other adverse consequences for the subjects. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects.

The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects). Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects.

Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered "sensitive" if it involves the collection of:

- information about sexual attitudes, preferences, practices;
- information about personal use of alcohol, drugs, or other addictive products;
- information about illegal conduct;
- information that could damage an individual's financial standing, employability, or reputation within the community;
- information in a subjects' medical record that could lead to social stigmatization or discrimination;
- genetic information;
- tissue samples; or
- information about a subjects' psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the IRB office for help in applying for a certificate.

Certificates are granted sparingly. The study's funding source, if any, is not relevant to the decision. The IRB may require investigators to apply for a Certificate of Confidentiality.

## **Statutory Basis for Protection**

Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d): "The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

## **Limitations**

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures.

For example, a Certificate does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse or a subject's threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the informed consent form that research subjects are asked to sign.

In addition, a Certificate of Confidentiality does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if:

- the subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
- authorized personnel of the Department of Health and Human Services (HHS) request such information for audit or program evaluation, or for investigation of HHS grantees or contractors and their employees; or
- release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act.

## **Mandatory Reporting**

While any person may make a report if they have reasonable cause to believe that a child or elder was abused or neglected, Montana law mandates that certain persons who suspect child or elder abuse or neglect report this to the appropriate authorities.

## **6. International Research**

Research with international subjects requires sensitivity, as different cultural contexts may indicate certain classes of people are more vulnerable to being coerced or influenced to participate in human subjects research. There may also be increased risks to breaches of confidentiality or the consequences of such a breach. Therefore it is recommended that the IRB seek the expertise of someone familiar with the culture of the country where the investigator is proposing to conduct research.

Additional considerations when conducting international research include ensuring that all consent documentation are translated into the native language of the target population. The monitoring plan needs to include someone in-country for subjects to contact with their questions and concerns.

Finally, the investigator needs to be aware of local laws which may limit contact with subjects or indicate different privacy regulations than what are expected in the United States. For example, people residing in the European Union Economic Area (EEA) have rights in the *General Data Protection Regulations* (GDPR) which determine what is considered private information and how a researcher can collect, transport, analyze, and share personal data.

## **7. Research with Test Articles (FDA)**

Certain categories of research involve either methodologies that might require additional considerations or for which there are federally mandated determinations that IRBs are required to make and document. These categories of research include, but are not limited to:

- Clinical investigations involving drugs or biologics
- Clinical investigations involving medical devices
- Gene therapy research
- Prospective research in emergency settings
- Expanded access of an investigational drugs or devices, including single patient treatment use and compassionate use requests
- Emergency use of an investigational article or product
- Humanitarian use devices

## Research Involving Drugs or Biologics

All research involving use of FDA regulated drugs or biologics require submission of an Investigational New Drug Application to the FDA unless the research meets the criteria for exemption from the requirements as outlined below or the research involves the use of a drug other than the use of a marketed drug in the course of medical practice.

For sponsored research, applications for research on the use of a drug, unless that research is exempt from the IND regulations, must be accompanied by documentation from the FDA that includes a valid IND number. The IND number must either match the number on the sponsor protocol with the same title as the proposed research or be listed on communication from the sponsor specific to the proposed research, or on communication with the FDA. The research must not begin until a valid IND is in effect. This includes recruiting, obtaining consent, and screening participants for a specific study that is subject to an IND.

A study may qualify for IND exemption if it meets one of the FDA exemptions from the requirement to have an IND:

- Exemption 1: A clinical investigation of a drug product that is lawfully marketed in the United States if all the following apply:
  - The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
  - If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
  - The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
  - The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

- Exemption 2: A clinical investigation involving an in vitro diagnostic biological product if all the following apply:
  - The diagnostic involves one or more of the following: blood grouping serum, reagent blood cells, and anti-human globulin;
  - The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and
  - The diagnostic test is shipped in compliance with 21 CFR 312.160.
- Exemption 3: A drug intended solely for test in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.
- Exemption 4: A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND

When an exemption determination is needed, this assessment will be based on the information provided by the investigator and/or the sponsor. If information provided by the investigator and/or the sponsor is unclear or incomplete, the IRB staff may request submission of the

It is the responsibility of the investigator and/or sponsor to provide accurate information. Exemption determinations may be made by the IRB or may be determined by the FDA.

## Research Involving Medical Devices

Research with medical devices falls into four categories:

- Investigations of significant risk devices
- Investigations of non-significant risk devices
- Investigations exempted from the IDE regulations
- Research involving medical devices for the collection of data but where the medical device is not under investigation to evaluate the safety and effectiveness of the device

When a device risk determination is needed, the convened IRB will determine whether the study presents a significant risk or a non-significant risk of harm to study participants. This assessment will be based on the information provided by the investigator and/or the sponsor. It is the responsibility of the investigator and/or sponsor to provide accurate information.

The IRB's risk determination will be documented in the IRB meeting minutes. If an investigator submits a Non-Significant Risk research protocol that is determined by the IRB to be a Significant Risk study, the investigator and the Sponsor, if necessary, will be notified in writing. No further action will be taken by the IRB on the research until the sponsor or investigator has met the requirements for a SR study described in 21 CFR 812.

## Significant Risk Device Investigations

Applications for research on the use of a significant risk medical device must be accompanied by documentation from the FDA that includes a valid IDE number.

The IDE number must either match the number on the sponsor protocol with the same title as the proposed research or be listed on communication from the sponsor specific to the proposed research, or on communication with the FDA.

## Non-significant Risk Device Investigations

When research involves use of a medical device and the investigators/sponsor indicates that the device may qualify as non-significant risk, the IRB either confirms (1) that appropriate documentation is provided from the FDA to classify the device as non-significant risk or (2) the device does not qualify as a significant risk device, according to the following regulatory criteria outlined below. A significant risk device is an investigational device that presents a potential for serious risk to the health, safety, or welfare of a participant AND:

1. Is intended as an implant; or
2. Is purported or represented to be for a use in supporting or sustaining human life; or
3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or
4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

If the above criteria above are not met, the device may be designated as non-significant risk. No application is required to be submitted to the FDA. If the IRB cannot determine the risk of the device, the IRB may defer the determination to the FDA.

When research is conducted to determine the safety or effectiveness of the non-significant risk device the following abbreviated IDE requirements must be ensured by the designated Sponsor (or the Principal Investigator, if there is no sponsor):

- The device is not a banned device.
- The sponsor labels the device in accordance with 21 CFR 812.5.
- The sponsor obtains approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device and maintains such approval.
- The sponsor ensures that each investigator participating in an investigation of the device obtains from each participant entering investigator's care, consent under 21 CFR 50 and document it, unless documentation is waived.
- The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- The sponsor maintains the records required under 21 CFR 812.150 (b) (1) through (3) and (5) through (10);

- The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140 (a) (3) (i) and make the reports required under 812.150 (a) (1), (2), (5), and (7); and
- The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

## Investigations Exempted from IDE regulations

Clinical investigations that are exempt from IDE regulations still require IRB review and approval. An investigation of a medical device in human subjects research that is exempt from the IDE regulations must fall into one of the following categories and will be determined along with the review and approval of a submission:

- A device legally marketed in the US that is used or investigated in accordance with the indications in the FDA-approved labeling.
- A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
- A diagnostic device (that is, an in vitro diagnostic device) if the testing:
  - Is noninvasive
  - Does not require an invasive sampling procedure that presents significant risk,
  - Does not by design or intention introduce energy into a participant, and
  - Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.
- A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

When an exemption determination is needed, this assessment will be based on the information provided by the investigator and/or the sponsor. It is the responsibility of the investigator and/or sponsor to provide accurate information. Exemption determinations may be made by the IRB or may be determined by the FDA.

## Research Involving Medical Devices for the Collection of Data

Expedited review category 4 allows for the “collection of data through noninvasive procedures” and specifically notes: “Where medical devices are employed, they must be cleared/approved for marketing.” Studies intended to evaluate the safety and effectiveness of the medical device do not qualify under this category of review. The use of marketed medical devices for the collection of data on research studies may be part of a research protocol undergoing expedited or convened review. This type of use is generally considered not to be FDA regulated as it does not meet the definition of a clinical investigation intended to evaluate the safety and effectiveness of the medical device. In essence, the device is not the participant of the investigation.

## Gene Therapy Research

Gene therapy research may require special considerations. If the project involves gene transfer (administration of recombinant vectors) to human participants for other than clinical purpose review by the NIH Recombinant DNA Advisory Committee (RAC) may be required. The FDA must review any such study prior to final IRB approval. In addition, the protocol will require review by the University of Montana Institutional Biosafety Committee.

# Chapter 7: Informed Consent

No investigator may involve a human being as a subject in research without obtaining the legally effective informed consent (providing enough information that a reasonable person would want to have) of the subject or the subject's legally authorized representative. In general, the IRB considers individuals who are unable to consent for their own clinical care to be unable to consent for research participation.

Investigators must obtain consent *prior* to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.

Consent must always be sought using procedures that (a) provide the prospective subject or the subject's legally authorized representative sufficient opportunity to consider whether or not to participate; *and* (b) minimize the possibility of coercion or undue influence.

In determining the appropriateness of the consent process, the IRB will consider:

- the timing and location where the consent process will take place;
- the individual who will be obtaining consent (e.g. the investigator, collaborator, or qualified designee) and his or her training;
- the age, language, literacy, and cognitive capacities of the prospective participant;
- pre-existing role relationships between the researcher and the prospective participant; and
- any factors that might be perceived as coercive or present undue influence to participate in the research.

The IRB will require an alternative process to obtain consent when it determines that a potential subject's understanding of the research may be impaired due to the timing, location, or the individuals participating in the proposed consent process.

The information that is given to a subject or the legally authorized representative must be in a language understandable to the subject or the representative.

A person (i.e., a member of the project's research team) knowledgeable about the consenting process and the research to be conducted must obtain the informed consent. If someone other than the investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility. The person to whom the responsibility is delegated must have received appropriate training to perform this activity.

No informed consent, whether oral or written, may include exculpatory language through which a subject or a 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.

# 1. Basic Elements of Informed Consent

Informed consent must be sought from each potential subject or the subjects' legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. The informed consent process must *begin* with key information and this part of the informed consent must be organized and presented in a way that facilitates comprehension.

The **basic elements** of informed consent are:

1. a statement that the **study involves research**;
2. an explanation of the **purposes** of the research;
3. the **expected duration** of the subjects' participation;
4. a description of the **procedures** to be followed, and identification of any procedures which are experimental;
5. a description of any reasonably foreseeable **risks** or discomforts to the subject;
6. a description of any **benefits** to the subject or to others which may reasonably be expected from the research;
7. when a protocol involves medical or other therapeutic treatments, it must include a disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;
8. a statement describing the extent, if any, to which **confidentiality** of records identifying the subject must be maintained;
9. for research involving more than minimal risk of physical, emotional, or psychological harm, information about the **availability of professional services will be provided**;
10. **contact information** for the person who can answer pertinent questions about the research;
11. **contact information** for the person to notify in the event of a research-related injury to the subject;
12. **contact information** for the UM IRB, so that subjects can report concerns or complaints about the research or obtain answers to questions about their rights as research participants; and
13. **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.**

14. a place for participants to initial, when voice, video, digital, or image recording is involved.
15. a statement about the **future** use of the subject's identifiable private information or biospecimens:
  - a. Identifiers might be removed and the de-identified information or biospecimens used for future research without additional informed consent from the subject; **or**
  - b. The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.
16. a statement about the potential for publication or presentation of the study results, and an explanation about how potential identifying information will be managed in those situations.

**Additional elements of informed consent to be applied, as appropriate, are as follows:**

- **Anticipated circumstances under which the subjects' participation may be terminated by the investigator without regard to the subjects' consent.** The IRB will carefully review the protocol to determine whether there might be situations where participants should be withdrawn from the research, or if it is reasonable to expect that participants may be withdrawn from the research, without their consent. For example, in a dietary study in which the participants have to follow a strict dietary regimen, there is a reasonable likelihood that some participants may not adhere to the regimen. Thus, such a situation might reasonably occur and the termination statement should be added to the consent form.
- **Additional costs to the participant that might result from participation in the research.** Whenever the protocol information indicates a situation in which it is reasonable to expect that subjects will incur travel or non-travel expenses as a result of participating in the research, an additional cost statement should be included in the consent document. For example, if subjects are traveling from outside of the immediate area in which they live in order to participate in the research, they are likely to incur gas expenses for which they won't be compensated.
- **Consequences of a participant's decision to withdraw from the research.** A statement indicating any consequences that will be imposed if subjects end their participation in the research prematurely should be included on all consent documents. For example, any protocol involving UM students, staff, or faculty as subjects should indicate that their decision to withdraw from the study will have no effect on their current status or future relations with the University of Montana. Protocols that involve any form of remuneration (e.g., monetary, gift card, course credit) must include a statement on the consent form indicating whether the subject will still receive the full token, a reduced amount, or nothing if they withdraw from the study.

- **Procedures for orderly termination of participation by the participant.** Consent forms should include an explanation of what will happen to the subjects' data if he or she withdraws from the research (e.g., data will be excluded from the research and destroyed). Such statements are particularly important for protocols involving more than one data collection session or the collection of sensitive information.
- **Risks related to pregnancy.** Information regarding potential risks related to pregnancy is important when a research procedure may pose a risk to an embryo or fetus, but the applicability of the risks may not be apparent at the time of consent. For example, a female subject may not be pregnant at the time of consent but may become pregnant during the data collection or treatment phase of the research. Thus, such a statement would be important and required for MRI studies for which the MRI procedures may or may not pose a risk of harm to a developing embryo or fetus.
- **New findings developed during the course of the research which might affect the subjects' willingness to continue participation.** Research protocols involving multiple data collection phases extending over time can generate preliminary findings that have risk implications for new or continuing subjects. Subjects must be informed of any significant findings that might affect their willingness to continue participation, and this is particularly important when the research conditions or procedures involve more than minimal risk of harm to the subjects.
- **Number of participants involved in the study.** When the number of subjects is relatively small (10 or less) and the information being collected from the participants is uniquely identifiable in nature, the need to protect confidentiality is particularly acute. Concern about protecting confidentiality is also magnified when data collection involves sensitive information. Under such circumstances, participants should be informed about the number of subjects expected to participate in the research, procedures taken to ensure confidentiality, and any limitations on the researcher's ability to protect confidentiality.
- **Limitations on the researcher's ability to protect confidentiality.** When research data are collected under group conditions involving oral responses or behavioral observation (e.g., focus or intervention groups), the researcher cannot guarantee confidentiality. Research participants should be informed about the steps the researcher will take to protect confidentiality, but must also be informed of the limitations on the researcher's ability to protect confidentiality.
- 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.
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

- 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).

## Consent Language and Reading Level

The individuals communicating information to the prospective participant, or to the legally authorized representative, during the consent process must provide the information in language understandable to the participant or representative. The language of the consent form should match the estimated reading level of the participants. Researchers may request a waiver or an alteration of the signed consent process for vulnerable populations who have cognitive impairments and/or low literacy levels, and provide additional assistance in reading the consent document and understanding the consent process. Options include using oral consent, providing short summary documents of the main consent documents that highlight the important points in a brief manner, etc.

## Consent and Language Barriers

Researchers should prepare both English language and translated consent forms for proposals that include non-English-speaking subjects. An explanation of the translations and evidence of the comparability of the English and non-English consent forms is requested. The IRB may consult with language experts or require a "back-translation" into English. The translation should provide documentation to verify the accuracy of the translation and back-translation.

If a non-English-speaking subject is enrolled unexpectedly, researchers may rely on an oral translation of the English language consent form, but should take extra care in the informed consent process to ensure that the subject has understood the project. A statement in the research records (and on the English language consent form) should indicate that the translation took place, identify the translator, and document the translator's belief that the subject understands the study and the consent process. If the subject is a patient, a note about the translation should be made in the patient's research records as well. Researchers should try to provide a written translation of the vital emergency contact information.

Sometimes a subject understands English but does not read or write English. Again, an impartial witness should document that the subject understands the research and the consent process and consented to participate. Whenever the protocol involves a significant number of participants for whom English is not the primary language, reasonable efforts must be made by the investigator to provide translation services and to offer translated consent documents whenever necessary.

## Exculpatory Language

The information communicated to the prospective participant, or the participant's representative, during the consent process may not include exculpatory language through which the participant or the legally authorized representative was made to waive or appear to waive any of the participant's legal rights.

The information being communicated to the participant or the legally authorized representative during the consent process may not include exculpatory language through which the participant or the legally authorized representative release the investigator, the sponsor, UM or its agents from liability for negligence. Research studies involving human subjects that involve more than minimal risk of physical harm (for example, studies that require the participant to engage in moderate or higher levels of physical exercise) may contain the following liability statement. However, even this statement makes clear that any legal obligation would be honored if required by law:

*The University of Montana does not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Montana provide compensation for any injury sustained as a result of participation in this research study, except as required by law.*

## 2. Broad Consent

Broad consent is the seeking of prospective consent from subjects to unspecified future research for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. It is an alternative to the standard informed consent process described in 45 CFR 46.116(d). The UM IRB currently does not allow the use of this alternative consent method. Investigators are advised to obtain standard consent or apply to the IRB for a waiver of informed consent.

## 3. Waivers or Alterations of Informed Consent

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

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration for access to identifiable information and/or biospecimens; *and*
- whenever appropriate, the subjects' must be provided with additional pertinent information after participation;

or

- the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - public benefit or service programs;
  - procedures for obtaining benefits or services under those programs;
  - possible changes in or alternatives to those programs or procedures; or

- possible changes in methods or levels of payment for benefits or services under those programs;

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

## 4. Parental Permission and Child Assent

Please see Chapter 4 for policies concerning parental consent and child assent.

## 5. Surrogate Consent

Unless waived by the IRB, informed consent must be obtained directly from the individual subject. Under appropriate conditions, investigators also may obtain informed consent from a *legally authorized representative* of a subject (surrogate consent). The provision allowing surrogate consent is designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who have an impaired decision-making capacity or who are not otherwise competent to provide consent.

The IRB will require investigators to provide evidence of a completed competency assessment whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects. The IRB will assess whether the proposed plan to evaluate capacity to consent is adequate.

If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study. The IRB will evaluate (a) whether the assent of the subjects is required, and (b) whether plan for obtaining assent is adequate.

**Legally authorized representative** means an individual or judicial or other body authorized under applicable law or institutional policy to consent on behalf of a prospective subject to the subjects' participation in the procedure(s) involved in the research [45 CFR 46.102(i)].

Legal Counsel of the University has determined that, in Montana, the following meet the definition legally authorized representative and, thus, can give surrogate consent:

- a court appointed guardian of the person.
- a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) that specifies that the individual also has the power to make decisions of entry into research.

Investigators should consult with UM Legal Counsel when conducting research outside of Montana to determine the requirements for a legally authorized representative in the jurisdiction in which the research will occur.

## Conditions for Requesting Surrogate Consent

Such consent may be requested and accepted only when the prospective research participant is not competent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements:

1. A medical practitioner may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
2. Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.

## 6. Documentation of Informed Consent

Informed consent must be appropriately documented in accordance with, and to the extent required by policy and federal regulations, as follows:

1. Informed consent is documented using a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. Electronic signatures are allowed.
2. A copy shall be given to the person signing the form. The consent form may be either of the following:
  - a. a written consent document that embodies the elements of informed consent may be read to the subject or the subjects' legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed, or
  - b. a short form written consent document (when the elements of informed consent have been presented orally to the subject or the subjects' legally authorized representative). When this method is used, *all* of the following requirements must be met:
    - i. there must be a witness to the oral presentation;
    - ii. the IRB must approve a written summary of what is to be signed by the subject or representative;
    - iii. the witness must sign both the short form and a copy of the summary;
    - iv. the person actually obtaining consent must sign a copy of the summary;  
*and*
    - v. a copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

## 7. Waiver of Documentation of Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects' if it finds that:

1. the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated; or
2. the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality [NOTE: Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. For example, domestic violence research where the primary risk is discovery by the abuser that the subject is talking to researchers]; or
3. 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. Procedures such as non-sensitive surveys, questionnaires, and interviews generally do not require written consent when conducted by non-researchers; or
4. the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide, in the application materials, a written summary of the information to be communicated to the subject, and the IRB will consider whether to require the investigator to provide subjects with a written statement regarding the research.

## 8. Review and Approval of the Informed Consent Process

The IRB is responsible for the review and approval of the informed consent form prepared by the investigator. The informed consent form must contain all of the required elements and meet all other requirements as described in this section. If the informed consent has been initially prepared by an external entity other than a UM Principal Investigator, the IRB needs to ensure that the consent meets all the requirements of this policy.

IRB approval of the consent must be documented through the use of a certification stamp on each page that indicates the expiration date. If the consent form is amended during the protocol approval period, the date on the modified form will be the original expiration date.

In the case of federally-funded clinical trials, the investigator must post the consent form document for the trials on a publicly available federal website 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. Posting only a single consent form from a single site is required to satisfy the requirement for a multi-site study.

The investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative. IRB staff and IRB board members may use reviewer checklists that include an element designed to prompt consideration of this issue. Particular emphasis is placed on this issue to ensure that the assent of any individual under age 18 is accompanied by some form of consent from the child's parent(s) or guardian(s). This is also a focus of concern for any situation where the subject (even if an adult age 18 or over) experiences a cognitive impairment that makes it essential that a guardian serve as a witness to a signature or that a proxy for that individual provides consent. Further guidance on this issue is offered in 45 CFR 46 Subpart D.

The circumstances of the consent process must provide the prospective participant or the legally authorized representative sufficient opportunity to consider whether to participate. The consent process should be carefully detailed on the IRB application. The information provided should detail how each potential participant will have an opportunity to ask questions prior to any signature of consent or other form of agreement when a waiver/alteration of signed consent is sought.

## **Risk of Coercion and/or Undue Influence**

The circumstances of the consent process must minimize the possibility of coercion or undue influence. In particular, the IRB must determine that there is no coercion or undue influence in relation to the following situations:

- **Remuneration:** The IRB must determine that there is no monetary compensation/gift certificate/prize, or other award or remuneration that is out of proportion to the amount of time and effort that participants would expend during their involvement in the research. This must be carefully assessed to determine whether remuneration might make participation in the study difficult to reject. This would be of particular concern when remuneration is being offered to individuals from vulnerable populations who have minimal financial resources.
- **Dual Relationships:** The researcher(s) should disclose any dual relationship, or potential dual relationship, that might be involved in the research process. Dual relationships of concern exist when the investigator or the individual administering the research is in a position of power or influence over the research subjects for a reason not connected with the research. For example, when the investigators are course instructors or supervisors of University of Montana students who are being recruited to participate in the research, students may feel coerced to participate in the research in order to please the professor and/or avoid retribution related to grading. The same issue would arise when a University of Montana researcher is recruiting participation from UM faculty, staff, or students who

are also being supervised by the researcher. Similar relationships could exist in contexts outside the university.

# Chapter 8: Additional Laws

## 1. Health Insurance Portability and Accountability Act (HIPAA)

Whenever a research project involves obtaining protected health information (PHI) from a “Covered Entity,” as defined by HIPAA, proper authorization must be obtained from each subject.

Responsibility for obtaining authorization rests with the Principal Investigator. Before the UM IRB approves a study involving collection of HIPAA protected health information, the Principal Investigator will supply a written assurance that all subjects will provide appropriate, signed authorization forms to the Covered Entity providing the information. The authorization (or Permission to Gather Health Information) form can be downloaded from the IRB website.

Covered Entities at the University of Montana include:

- Curry Health Center Services Pharmacy
- MonTech - Montana Accessibility and Assistive Technology Center
- New Directions Program
- The Nora Stael Evert Physical Therapy Clinic
- RiteCare Clinic
- UMPT Sports and Orthopedics

The Security Rule, an important part of HIPAA, went into effect April 20, 2003. The rule's intention is to protect the confidentiality, integrity, and availability of electronic protected health information, which the University creates, accesses, transmits, or receives in both research and patient care settings. It sets forth specific requirements for the adoption of administrative, physical, and technical safeguards for the protection of electronic protected health information.

Since April 14, 2003 all research that will enroll subjects (including existing studies) AND obtain subjects' PHI must comply with HIPAA regulations.

### What is Protected Health Information (PHI)?

PHI is health information transmitted or maintained in any form or medium that:

1. identifies or could be used to identify an individual; and
2. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
3. relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.

## Exempt Records

The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information:

1. student records maintained by an educational institution, and
2. employment records maintained by an employer related to employment status.

If your study uses these kinds of records, it is not subject to HIPAA. However, existing IRB rules on informed consent and confidentiality still apply.

## Ways researchers can perform HIPAA-compliant research with PHI

1. **Obtain Subject Authorization** — use of an authorization form that includes required HIPAA authorization language (it must be approved by the IRB prior to use - similar to a consent form).

### Using HIPAA Authorization Forms

If a study using/disclosing PHI is going to use/disclose this PHI by means of a subject authorization (the most common and recommended means), investigators should be aware of the following:

- The authorization form needs to be submitted to the IRB along with the IRB checklist/application. Use our Authorization Form template (IRB website) filled in with your study specifics.
  - Two authorization forms require the subject's or authorized representative's signature:
    - A copy for the subject to keep, and
    - A copy for the investigator's records.
  - It is the responsibility of the PI to keep this authorization form in their records for 6 years and assure that it is completed correctly.
2. **Obtain an IRB alteration or waiver of subject authorization** — if the research is minimal risk to subjects and meets criteria for waiver or alteration.

### Obtaining HIPAA Authorization Waivers or Alterations

For research uses and disclosures of PHI, an IRB may approve a waiver or an alteration of the Authorization requirement in whole or in part. A complete waiver occurs when the IRB determines that no Authorization will be required for a covered entity to use and disclose PHI for a particular research project.

If a researcher has used or disclosed PHI for research with an IRB approval of waiver or alteration of Authorization, documentation of that approval must be retained by the researcher for 6 years from the date of its creation or the date it was last in effect, whichever is later.

### *How do I qualify for a waiver of authorization?*

Approvals for waivers or alterations will be rare and in most cases researchers are advised to use an Authorization Form with their subjects to use/disclose PHI. IRB approval is required for this Authorization Form - similar to consent forms.

The following criteria must be met to qualify for a waiver:

The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

1. An adequate plan to protect the identifiers from improper use and disclosure;
2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
4. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
5. The research could not practicably be conducted without the alteration or waiver or alteration; and
6. The research could not practicably be conducted without access to and use of the protected health information.

The IRB maintains the authority to make the final decision if a study meets the aforementioned criteria.

3. **Use a Limited Data Set** — PHI that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual.
4. **Use De-identified Data** — health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. (see below, “Using data that is De-identified”)

### **Using Data that is De-Identified**

Researchers may use or disclose health information that is de-identified without restriction under the Privacy Rule.

Covered entities seeking to release this health information must authorize that the information has been de-identified using either statistical verification of de-identification OR by removing the 19 identifiers from each record as specified in the Rule. These identifiers are:

1. Name
2. All geographic subdivisions smaller than a state (street address, city, county, precinct)  
Note: zip code or equivalents must be removed, but can retain first 3 digits if the geographic unit to which the zip code applies if the zip code area contains more than 20,000 people
3. For dates directly related to the individual, all elements of dates, except year. (date of birth, admission date, discharge date, date of death)
4. All ages over 89 or dates indicating such an age
5. Telephone number
6. Fax number
7. Email address
8. Social Security Number
9. Medical Record Number
10. Health Plan Number
11. Account Numbers
12. Certificate or license numbers
13. Vehicle identification/serial numbers, including license plate numbers
14. Device identification/serial numbers
15. Universal Resource Locators (URL's)
16. Internet Protocol addresses (IP's)
17. Biometric Identifiers
18. Full face photographs and comparable images
19. Any other unique identifying number, characteristic or code

## **2. Family Educational Rights and Privacy Act (FERPA)**

The Family Educational Rights Privacy Act (FERPA) was established in 1974 to protect the rights of students (20 U.S. Code 1232g). The law applies to all schools (i.e. elementary, secondary, and higher education institutions) that receive funds under an applicable program of the U.S. Department of Education. FERPA impacts researchers in that data not included in the student directory information cannot be used in research without the permission of the IRB and the research participant. Keep in mind, however, that the IRB cannot overrule the institution's decision to deny access, and if the IRB disapproves the proposed research, the institution may not approve disclosure of information associated with the research.

### **What information is protected by FERPA?**

Items that do not fall under student directory information cannot be used in research without going through the proper channels. FERPA requires that students be given the option to “opt out”

of allowing directly information to be shared, and if students choose to opt out, this information may not be disclosed (99.37). **Note:** For a general definition of the term “directory information” please see 34 CFR 99.2 and 1232g(a)(5)(A). To see what UM considers directory/non-directory information please refer to the UM Registrar’s website.

Researchers need to receive consent from student research participants in order to use information that falls under FERPA’s definition of education records (for definitions of “education record” or “records” please refer to 34 CFR 99.2 and/or 1232g(b)(3),(b)(5)(a)(4)). This includes – but is not limited to – end-of-course grades or any other grades or assignments produced within a class. In other words, instructors cannot use information to which they might have natural access for purposes other than instruction and evaluation without informed consent. Course grades are considered part of the students’ official records and thus belong to the student, and permission of the student should be obtained through informed consent. Other information not typically in a student directory could include race, sex birthdate, GPA, country of citizenship, social security number, residency status, and financial aid (including PELL Grants or HOPE Scholarship) or academic status. This list, however, is not exhaustive.

## **Does this mean that I cannot use my students’ grades or coursework in my research without IRB approval?**

Yes, FERPA regulations apply even when using your “own” records. You must receive IRB approval and student consent to use any grades and/or work completed within your class, including assignments such as papers, journals, projects, and tests (34 CFR 99.2). In practical terms, this means that you will need to obtain student consent either by securing access to educational records contained in UM’s directory or – if this is not possible – by obtaining consent via established informed consent procedures. Irrespective of the consent route, however, student research participants need to be informed about the following three issues so they know what they are consenting to: (1) nature of records that will be disclosed/used, (2) the purpose of the disclosure, and (3) the identification of the part of class or parties to whom the disclosure may be made (34 CFR 99.30).

## **What if my study is large-scale and consent for release of data not included in student directory information is difficult to obtain?**

For large-scale research projects where consent is difficult and/or impossible to obtain, you may want to consider applying for a waiver of consent. While the IRB will consider requests for waivers on a case-by-case basis, all requests should be made during the regular IRB application process. Keep in mind, however, that your ability to use this data will remain contingent upon IRB approval and student consent. Note: If the IRB grants the waiver, a designated school official will strip any personally identifiable information (PII) before the dataset will be shared with you (for a definition of the term “PII” please see federal regulations [34 CFR 99.3](#) or [20 U.S. Code 1232g](#)). Examples of PII include – but are not limited to – student names, student identification numbers, grade lists, place of birth, ethnicity, course schedules, academic status, and advisor names. The waiver, however, does not absolve you of the responsibility to notify the

students of the possibility to opt out of research project. Students retain this right to their educational records even if they no longer attend UM (34 CFR 99.37).

## **How does FERPA apply to proposed prekindergarten through 12-grade research?**

FERPA applies to all research projects conducted within local PK-12 schools and school districts. The PI is responsible for obtaining IRB approval from the University of Montana, and s/he also needs to comply with any additional safeguards that have been put into place by individual school districts. Also, keep in mind that the IRB cannot override a school district's decision to deny access to certain information to the researcher. Investigators will need to obtain written FERPA authorization from the parent/guardian of the child/children involved in the research.

## **Are there research projects involving access to data not typically included in student directory information that do not require informed consent from participants?**

Educational institutions may disclose, without consent, student data to those conducting studies for, or on behalf of, educational institutions to (1) develop, validate, or administer predictive tests; (2) administer student aid programs; or (3) improve instruction (34 CFR 99.31). Educational records may be released, as well, for institutional research; however, individuals proposing to publish or publicly disseminate such research would need IRB approval before proceeding.

## **3. Protection of Pupil Rights Amendment (PPRA)**

The Protection of Pupil Rights Amendment (PPRA; 20 U.S.C. § 1232h; 34 CFR Part 98) applies to any “local educational agency” that receives funding from the U.S. Department of Education. A “local educational agency” means an elementary school, secondary school, school district, or local board of education that is the recipient of funds from the U.S. Department of Education (ED). It does not include postsecondary institutions. PPRA also applies to research funded by the Department of Education. The focus of PPRA is on the requirement for parental consent for the collection of certain sensitive information, such as medical data or sexual attitudes or practices from school children via surveys and evaluations.

### **Description**

Researchers conducting studies in a “local educational agency” that receives any funds from the U.S. Department of Education must ensure that their protocol complies with the PPRA.

Parental consent is required for studies involving surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

- Political affiliations or beliefs of the student or the student's parent
- Mental and psychological problems potentially embarrassing to the student or his or her family
- Sex behavior or attitudes
- Illegal, anti-social, self-incriminating and demeaning behavior
- Critical appraisals of other individuals with whom the student has close family relationships
- Legally recognized privileged and analogous relationships, such as those of lawyers, physicians and ministers
- Religious practices, affiliations, or beliefs of the student or student's parent
- Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program

The IRB does not have the authority to issue a waiver of informed consent on any of the areas of inquiry set forth above, or to overrule school district policies for implementing PPRA. Researchers whose studies are subject to PPRA should review the policies of the local educational agency early in the study design process and should consider multiple methods to provide information to parents about their planned study. Parents should be given the opportunity to review the study materials before making a decision to permit their child to participate in the research.

For research not funded by the U.S. Department of Education but conducted in a local educational agency, the investigator must provide the IRB with a letter of agreement from a school official or the School IRB approval letter (when applicable), indicating that the school has adopted policies required by PPRA, and that the school agrees that the proposed study complies with those policies, which must include the following:

1. The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students.
2. Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the same eight items of the information noted above.
3. The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students.
4. The administration of physical examinations or screenings that the school may administer to students.

## 4. General Data Protection Regulation (GDPR)

The General Data Protection Regulation ("GDPR" 2016/679) is a European law that enhances data privacy by imposing strict requirements on the use of personal data ("data processing") and by making data privacy laws more uniform across the European Economic Area ("EEA"). The GDPR became effective on May 25, 2018.

The European Union (EU) consists of 27 countries:

- Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.
- EEA - EU countries and Iceland, Liechtenstein, Norway.
- Similar protections apply to the United Kingdom.
- For a full list of territories within the European Economic Area, please see [here](#).

"Personal data" under the GDPR refers to any identifiable information about a natural person (i.e., an individual, not a company or other entity), also known as a "data subject." Examples include a person's name, email address, government-issued identification, other unique identifiers such as IP addresses or cookies, and their personal characteristics, including photographs.

In addition, "special categories" of personal data merit a higher level of protection due to their sensitive nature and consequent risk for greater privacy harm. This includes information about a data subject's health, genetics, race or ethnic origin, biometrics for identification purposes, sex life or sexual orientation, political opinions, religious or philosophical beliefs, or trade union membership. Although criminal convictions and records are not considered special categories of personal data, this information is also subject to greater protection under the GDPR.

### Where Does GDPR Apply?

1. The physical location of a data subject determines the applicability of the regulation. Personal data of an individual who is physically located within the EEA countries at the time of data collection (whether or not the participant is not a citizen or resident of an EEA country), is covered under the GDPR.
2. Personal data of an individual who is physically located anywhere outside of the EEA at the time of data collection (even if the participant is a citizen of an EEA country) is not covered under the GDPR. However, if the personal data of this individual is subsequently processed (e.g., used, stored, or shared) after their return to the EEA, such data may be within scope of the GDPR.

## What research data are in scope of the GDPR?

### 1. GDPR and Identifiable Data

Personal data collected from individuals who are, at the time of data collection, physically present in any of the EEA countries, is subject to GDPR. The GDPR can apply to data collected by a UM person, or data collected by a third party and sent to UM researchers for analysis as part of a collaboration, from a data bank or repository, or pursuant to any other agreement or arrangement.

### 2. GDPR and Coded Data

Under the GDPR, “pseudonymized data” (coded data) is considered personal data even where one lacks access to the key-code/coding system/crosswalk required to link data to an individual data subject.

**Example:** A non-UM entity collects personal data from subjects who are located in the EEA, codes the data, secures the key, and sends only the coded data to UM, such that UM researchers have no means of accessing the identifiers. This data is considered personal data in the hands of the UM researchers, and is therefore subject to GDPR regulations.

In this scenario, the non-UM entity is considered the “controller” of the data, and harbors greater liability and responsibility for protecting the data, including the management of consent, options for withdrawing consent, coding the data appropriately, and conveying to UM the conditions under which the data are to be used. UM researchers, in most of these cases, would be considered a “processor” of the data under the GDPR. As a processor, a UM researcher is responsible for ensuring that they comply with the controller’s terms for using and safeguarding the data.

**Note: Under the US regulations for human subjects research, this type of coded data would not be considered to be human subject research and therefore would not require IRB review.** Because the GDPR imposes significant new requirements for coded data, researchers are urged to consult the IRB office if their research is or may be subject to these regulations.

### 3. GDPR and Anonymized Data

The GDPR does not apply to data that have been anonymized. In order for data to be considered completely anonymized, there can be no key code in existence anywhere that could re-identify the data. Essentially, any record of identifiable information about participants must be destroyed, whether in a system or on paper.

**Example:** A survey conducted using Qualtrics or another third-party online survey tool where the researcher receives assurances that the data is not linked to any IP address or

other identifiable information; or paper records where no information about the participant is collected or recorded.

## What are the data processing requirements under the GDPR?

1. Under the GDPR a so-called “**lawful basis**” is needed. This justifies the processing of personal data, and establishes the circumstances under which it is lawful to collect, use, disclose, retain, destroy, or otherwise process personal data. For research involving human participants, informed consent is considered the lawful basis for collecting and processing personal data.
2. If the GDPR applies, **explicit informed consent** must be obtained from data subjects at the point of collection. The consent process must include a description of how a participant’s personal data will be processed, and with whom it may be shared. This consent must describe any planned or expected use of the data. Please see the section of this document on specific consent documentation requirements.
3. If data is subject to the GDPR, **data subjects must be able to exercise certain rights** with respect to the data they provide. Data subjects have the right to access, amendment, erasure (“right to be forgotten”), restriction, and objection to processing. The “controller” of the data (which may or may not be the UM researcher, as explained above) is responsible for responding to these requests from study participants.
  - a. If UM is the controller: In cases where a UM researcher is directly collecting personal data from data subjects (i.e., when UM is acting as the controller), consult with the UM IRB if granting the participants the ability to withdraw data is not feasible for the study and can compromise analysis and outcomes. Otherwise ensure that the data is managed in a way that allows you to honor a request for withdrawal. The study consent form must include an explicit statement about withdrawal and contact information for the IRB.
  - b. If UM is the processor: In cases where a UM researcher is the recipient of coded data from third parties and does not have the key or other mechanism to link data to individuals, contact information for the controller must be provided to participants.
4. The GDPR also requires researchers to implement appropriate technical and organizational **security measures** to ensure a level of data security that is appropriate to the risk of harm to the research participants.
5. In the event of a security breach, timely breach notification is required. If a breach occurs in the course of a study involving data that may be protected by the GDPR, the PI must inform the UM IRB and:
  - a. either notify the appropriate EEA data protection authorities within 72 hours following the discovery of a personal data breach; or

- b. without undue delay, notify the applicable controller of the data.
6. Contractual documentation is required when personal data is transferred from EEA countries to other jurisdictions that, in the eyes of the EEA, lack adequate data protection laws. The United States is one such jurisdiction. Documentation is required when:
    - a. controllers provide GDPR-classified data to UM researchers; or,
    - b. UM researchers use third parties to support their research (e.g. Qualtrics, Skype) where participants may be located in the EEA.

## How does this affect my research with human participants?

If your research involves any of the following, your project may be subject to the GDPR:

1. Recruitment through social media, such that some participants may be located in the EEA;
2. Use of a third-party “processor” (e.g., Qualtrics, Skype) to collect data from participants who may be located in the EEA;
3. Direct receipt of data from individuals (participants, collaborators, etc.) located in the EEA;
4. Receiving data from third parties that have identified the data as being subject to the GDPR.

## What can I do to make my project GDPR compliant?

1. Collect the **absolute minimum** personal/demographic data needed. Consider designing the study such that it can be done anonymously, or record no identifying information. Many online survey sites collect personal information, including IP addresses, by default. Since IP addresses are considered identifiable information, make sure that you need to collect this information for your study. If not, disable this feature. We strongly recommend using Qualtrics as an online survey platform. If other electronic systems are used, consult the IRB office for guidance.
2. Use an active (“opt-in”) informed consent. Under the GDPR, consent must be freely given, specific, informed, unambiguous, and explicit. In your consent, include:
  - a. a description of the data processing and how data will be transferred (electronically or via any other means) to non-EEA jurisdictions. NOTE: Following informed consent language, a button stating “click to proceed to the survey” or similar is considered active consent for these purposes. Silence, pre-ticked boxes, and inactivity do not meet the standard for active consent under the GDPR.
  - b. details on how to withdraw consent and whom participants may contact to exercise rights under the GDPR (for UM researchers: [irb@umt.edu](mailto:irb@umt.edu)). Feel free to contact the IRB to ensure that your consent form is GDPR compliant.

3. Verify that contracts with any third-party website or software applications include language clarifying GDPR roles and responsibilities and specifying mechanisms to be used for global data transfers. Consider that many centrally offered services at UM already have these contractual requirements in place. If you wish to use any other services or software solutions, a data processing agreement will need to be in place. If the third party does not have this agreement language, UM can provide appropriate language.
4. For research where identifiable data will be collected, include an executable plan to restrict processing or remove data in the event participant requests to have their data removed. The informed consent document must notify the participant that their participation is voluntary and that they may leave the study at any point; however the informed consent need not describe how the data erasure will take place if requested. It is sufficient if these procedures be in place and available internally.
5. Use appropriate administrative and technical safeguards to protect the personal data collected.
6. In the event of a data breach or suspected loss of data, immediately notify the UM IRB so that appropriate steps can be taken at the University level and proper, timely response and support may be provided.

## **How is informed consent affected by the GDPR?**

Consent records, which must include the time and date of consent, must be maintained for each study participant. In the case of verbal, online, or other undocumented consent, the Principal Investigator is responsible for maintaining a consent log indicating each participant (either by name or study ID number) and the date and time that they provided consent.

Consent must be explicit, and provided in clear, plain language. If a consent form or script serves multiple purposes (as in, a recruitment email that doubles as a consent form), the request for consent must be clearly distinguishable within the document or script.

Participants must be given the right to withdraw consent at any time. Each subject must be informed of this right prior to giving consent. Withdrawing consent must be as easy as giving consent. If you believe that a participant withdrawal would jeopardize your research, consult the IRB.

Consent must be an affirmative action. This means that opt-out procedures or pre-checked boxes indicating consent cannot be used.

Consent must be freely given. Individuals in a position of authority cannot obtain consent, nor can consent be coerced. For example, faculty cannot obtain consent from their own students.

Consent forms must contain the following information:

1. The identity of the Principal Investigator;
2. The purpose of data collection;
3. The types of data collected, including listing any of the following special categories of information that will be gathered:
  - a. Racial or ethnic origin;
  - b. Political opinions;
  - c. Religious or philosophical beliefs;
  - d. Trade union membership;
  - e. Processing of genetic data;
  - f. Biometric data for the purposes of unique identification;
  - g. Health data; and/or
  - h. Sex life or sexual orientation information;
4. The right to withdraw from the research and the mechanism for withdrawal;
5. Data access and data security, including storage and transfer of data;
6. Information regarding automated processing of data for decision making about the individual, including profiling;
7. How long data will be stored (can be indefinite);
8. Whether and under what conditions data may be used for future research, whether or not related to the purpose of the current study.

## **Does recruiting participants or collecting data online fall under the GDPR?**

It might, if you are seeking participants from the EEA countries. However, in cases where a survey is sent to potential participants without a geographical preference, where there is no mechanism by which the location of the participants will be identified, GDPR does not apply. Consult with the IRB office for clarification if you are seeking participants from the EEA countries, and are collecting identifiable personal information.

## **What is right to erasure (“the right to be forgotten”)?**

When consent is used as the lawful basis for processing personal data, mechanisms for the withdrawal of consent must be accessible. Under the GDPR, withdrawing consent for research participation includes the right to erasure of data. If an individual covered by the GDPR contacts you at any point after data collection and asks for their data to be erased, please contact the UM IRB immediately.

## **If there is a data breach, what needs to happen?**

The GDPR has strict rules and timelines for the reporting of data breaches. If you identify that a data breach has occurred involving GDPR-covered research, immediately report the breach to the UM IRB and include the following information:

1. Type of breach and timeline of events
2. Nature, sensitivity, and volume of personal data

3. Severity of consequences for individuals
4. Number and characteristics of affected individuals
5. Ease of identification of individuals, in light of the breach
6. IRB Protocol number

# Chapter 9: Department of Defense (DOD) Research

Human subjects research is subject to Department of Defense (DoD) oversight when one or more of the following applies:

- the research is funded by the DoD,
- the research involves cooperation, collaboration or other type of agreement with the DoD (including subawards),
- the research uses property, facilities, or assets of the DoD, and/or
- the subject population will intentionally include military personnel and/or civilian personnel employed by the DoD.

These regulations do not apply when DoD personnel incidentally participate as research subjects where they are not the intended research population.

Involving a detainee as a human subject is prohibited in DoD-regulated research.

In addition to its Common Rule regulations at 32 CFR 219, DoD provides specific instructions for human subjects research in DoD Instruction 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.” Investigators are encouraged to consult the granting agency with questions about additional requirements for specific DoD-regulated projects. DoD agencies may provide additional guidance about regulations specific to each agency. After the IRB has approved a research project, the project may also be subject to additional review or approval by the Secretary of Defense.

Investigators intending to survey or interview military or civilian DoD personnel should note that the survey or interview instrument(s) may require specific review and approval by the DoD.

For research conducted in an international setting, all applicable national laws and requirements of the foreign country must be met. The IRB may request documentation to this effect from the research team. During its review, the IRB must also consider the cultural sensitivities in the setting where the research will take place.

For multisite research, the research involving human subjects must be approved by all required organizations before human subjects research activities begin. The IRB may approve a protocol contingent upon approval by other organizations.

## 1. Training Requirements

DoD requires continuing research ethics training for research personnel involved in the design, conduct, or approval of human subjects research. For certain DoD-sponsored research, UM

training requirements meet the DoD requirements. However, for research specifically sponsored by the Under Secretary of Defense for Personnel and Readiness, training is required on an annual basis. For research specifically sponsored by the Department of Navy, training specific to Department of Navy-Supported Extramural Performers is required. For other military branches, researchers are advised to consult the appropriate program officer for any applicable training requirements. The IRB may require documentation of appropriate training for personnel, as applicable.

## 2. IRB Review Requirements

DoD regulations place certain limitations on IRB review of certain research, including that DoD research intending to include prisoners as subjects cannot be reviewed by the IRB through an expedited review procedure.

When evaluating risk to subjects, the IRB must consider the risk to the average person, and not the specific risks of the everyday life of a person inherent in the work environment (e.g., emergency responder, pilot, soldier in a combat zone) or associated with a medical condition (e.g., frequent medical tests or constant pain).

### Recruitment and Enrollment

Officers are not permitted to influence the decision of their subordinates.

- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

For greater than minimal risk research involving DoD-personnel, when recruitment and consent occur in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

- Must not have a conflict of interest with the research or be a part of the research team.
- Must be present during the HSR recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary, and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.
- Should be available to address DoD-affiliated personnel's concerns about participation.

### Consent

If the research involves DoD-affiliated personnel as participants, in addition to the basic and required consent disclosures, the IRB or component HRPO must confirm that the consent documents must include:

- If the research involves risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.
- If applicable, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty.
- A statement that the DoD or a DoD organization is funding the study.
- A statement that representatives of the DoD are authorized to review research records.

For greater than minimal risk research:

- Consent documents must include the disclosure that participants may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants' participation in the study to such time after the study has ended.
- Written materials must document how organizations will care for participants with research-related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel in studies that are collaborative with a non-DoD institution.

Unless specifically agreed to by the DoD, the IRB cannot approve a waiver of consent for research where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Informed consent must be obtained in advance from the experimental subject or the subject's legal representative.

If consent is to be obtained from the experimental subject's legal representative rather than the subject, the research must intend to benefit the individual subject. The determination that research is intended to be beneficial to the individual experimental subject must be made by the IRB.

## Compensation

In general, federal personnel enrolled in DoD-supported research may be compensated up to \$50 for a blood draw and may not be otherwise compensated while on duty. If the personnel are off duty, and if the research is not federally funded, the human subjects may be compensated for blood draws in a reasonable amount as approved by the IRB. Additionally Federal personnel while off duty may be compensated for research participation other than blood draws in the same way as human subjects who are not Federal personnel. However, payment to off-duty Federal personnel for general research participation must not be directly from a Federal source.

Non-Federal personnel may be compensated for participation in DoD-supported research in a reasonable amount as approved by the IRB. Payment for non-Federal personnel for research participation may come directly from a Federal or non-Federal source.

## **Scientific Merit Review**

The UM IRB Chair is authorized to write a Scientific Merit Review letter on behalf the UM IRB.

# **3. Specific Subject Protections**

## **Service Members**

Service members and DoD-affiliated personnel are considered to be vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization. Therefore, additional protections for DoD-affiliated personnel are required, as follows (DoDI 3216.02 section 3.9 (f)):

- If the research involves DoD-affiliated personnel as participants and if the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.
- If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research.
- Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research.
- Military and civilian supervisors, officers, and others in the chain of command must not be present at any participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable.
- Service members and all Reserve component and National Guard members in a federal duty status are considered to be adults. If a Service member, Reserve component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human participant.

## **Research with Prisoners**

Research involving incarcerated persons cannot be reviewed by the expedited procedure.

When the IRB reviews research involving incarcerated persons, at least one incarcerated person representative must be present for quorum. In addition to allowable categories of research on incarcerated persons in Subpart C, epidemiological research is also allowable when:

- The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
- The research presents no more than minimal risk.
- The research presents no more than an inconvenience to the participant.

If a participant becomes an incarcerated person, and if the researcher asserts to the IRB that it is in the best interest of the incarcerated person-participant to continue to participate in the research while an incarcerated person, the IRB chair may determine that the incarcerated person-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the incarcerated person-participant (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

The convened IRB, upon receipt of notification that a previously enrolled human participant has become an incarcerated person, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human participant, now an incarcerated person, are not in jeopardy.

The IRB should consult with a participant matter expert having the expertise of an incarcerated person representative if the IRB reviewing the research protocol does not have an incarcerated person representative. If the incarcerated person-participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the incarcerated person-participant's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this incarcerated person-participant to continue to participate in the research. This approval is limited to the individual incarcerated person-participant and does not allow recruitment of incarcerated persons as participants.

Research involving a detainee as a human participant is prohibited. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

If consent is to be obtained from the experimental participants' legal representative, the research must intend to benefit the individual participant. The determination that the research is intended to be beneficial to the individual experimental participant must be made by an IRB.

Research involving a prisoner of war is prohibited. A prisoner of war is a person captured in war; especially: a member of the armed forces of a nation who is taken by the enemy during combat.

## 4. Institutional Requirements

The University of Montana is required to notify the DoD Human Research Protection Official when significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review, if the IRB used to review and approve the research changes to a different IRB, when the institution is notified by any Federal department or agency or national organization that any part of its human research program is under investigation for cause involving a DoD-supported research protocol, and all unanticipated problems, suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects.

Records maintained by the institution that document compliance or noncompliance are accessible for inspection and copying by authorized representatives of the Department of Defense. The DoD Components may rely on the institution to keep the required records that were generated by the institution, or the DoD Components may make arrangements to transfer the records.

There may be additional requirements that the institution must comply with when conducting DoD regulated research.

# Chapter 10: Non-Compliance and Suspension or Termination of IRB Approval of Research

The following is the University of Montana (UM) Institutional Review Board (IRB) policy for noncompliance investigation procedures, in accordance with the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), and the IRB's Federal Wide Assurance (FWA).

**Non-Compliance** is a failure to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB that results in harm to subject's rights, safety or welfare, or on the integrity of the data. Non-compliance results from the action or inaction of anyone conducting protocol procedures.

Reported incidents will be considered *possible* noncompliance until a final determination is made by the IRB Chair and/or Committee. The IRB will assess the severity of the event and, if necessary, require corrective action. Serious and continuing noncompliance will be reported to the appropriate institutional officials and regulatory agencies.

When noncompliance has occurred, federal regulations and UM policy require the IRB to determine whether the incident is minor, serious, continuing, or a combination. The level of noncompliance is dependent upon intent, context, and other circumstances taken into account by the IRB.

Examples of noncompliance may include, but are not limited to, the following:

- Failure to obtain informed consent or inadequate procedures for obtaining informed consent from subjects;
- Conducting human subjects research without a UM IRB-approved protocol;
- Inadequate supervision of research that involves potential risks to subjects and others
- Conducting research, including enrollment of subjects, when a UM IRB approval has expired or has been suspended or terminated;
- Initiating changes to the research protocol without prior IRB approval unless the change is necessary to eliminate apparent immediate hazards to the subject (Note: Both the discovery of unforeseen risk and a request to update the protocol must be reported to the IRB as soon as possible);
- Failing to adhere to the conditions of approval of a protocol as specified by the UM IRB;
- Starting research under a protocol before meeting the conditions required by an IRB and receiving an IRB notification of approval;
- Failure to add research personnel to the IRB-approved protocol, including document a change in Principal Investigator (PI);
- Failing to take UM-required CITI human subjects protection training;

- Enrolling significantly more subjects than approved by IRB;
- Enrolling subjects from populations not previously approved by IRB;
- Enrolling subjects who should have been screened out from the project based on the defined exclusion criteria approved by IRB;
- Failing to have research participants sign a new consent form when new and relevant risks are discovered or failing to provide this new information to participants;
- Altering an IRB-approved consent process or an IRB-approved recruitment process without prior IRB approval.

Graduate student PIs, student Co-PIs and faculty mentors share accountability for upholding ethical standards, mitigating risk, and following approved protocol requirements. In the event that a graduate student is the PI/Co-PI in a project under investigation for noncompliance, the student and faculty will be separately contacted to gather information related to the investigation. Research misconduct investigations are handled separately from academic misconduct issues. Academic misconduct will be handled per university policy.

## 1. Definitions

**Non-Compliance** - Failure to comply with applicable laws, regulations, or UM institutional policies pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB, including deviation from the IRB-approved/exempt study procedures.

**Minor Non-Compliance** – Minor noncompliance is neither serious nor continuing and is a single instance of noncompliance that does not affect the rights and welfare of participants or put participants at risk of harm. Examples include, but are not limited to:

- A single instance of failing to add researchers to an IRB-approved protocol;
- Failure to secure IRB approval before beginning research for research that constitutes minimal or no risk to the participants;
- Introducing protocol changes when those changes constitute minimal or no risk to the participants;
- Making minor wording changes to recruitment materials and/or study instruments without IRB approval;
- Or first occurrences that are believed to be the result of ignorance and/or misinterpretation of the IRB regulations.

Please note that these occurrences should be reported to the IRB and corrected as soon as possible. The IRB will investigate minor non-compliance incidents in the same manner as other non-compliance events, with possible post-investigation actions listed below. Even though minor non-compliance events do not have to be reported to federal oversight agencies, the UM IRB still takes minor non-compliance seriously and will investigate accordingly.

**Serious Non-Compliance** - Non-compliance that has a significant adverse impact either on the rights or welfare of participants or on the integrity of the study data. This involves one or more of the following: substantive harm or genuine risk of substantive harm to the safety, rights and welfare of research participants or others; decreases potential benefits; or compromises the

integrity of the human research protection program. Examples of serious noncompliance include, but are not limited to:

- One or more instances of conduct defined above as noncompliance that exposes subjects or others to risks of harm that are not an inherent part of the approved research protocol;
- Conduct defined as noncompliance above, even though subjects or others have not been exposed to risks of harm not inherent in the approved protocol, where the IRB finds that the lack of risk exposure was incidental;
- Misrepresentation of information related to the human subjects research protocol or performance of the research;
- Conducting non-exempt research without IRB approval;
- Making substantive changes to a previously approved protocol without IRB approval, and
- Conduct that adversely affected the integrity or effectiveness of human subjects protections or subjects rights or welfare.

Whether the conduct was inadvertent, careless, reckless, or intentional may be taken into consideration by the IRB in a determination of seriousness. Serious noncompliance is required to be reported to the Office of Human Research Protections (OHRP) if it is nonexempt research supported by US Human Health Services (HHS) or covered by a Federalwide Assurance (FWA).

**Continuing Non-Compliance** - Continuing noncompliance is multiple or repeated instances of noncompliance, particularly after written notice from the IRB that the investigator must take action to correct noncompliance. The multiple or repeated instances of noncompliance may occur on one or more protocols and may occur simultaneously or independently. The IRB will determine if the continuing noncompliance also constitutes serious noncompliance. Continuing noncompliance is required to be reported to the OHRP if it is nonexempt research supported by HHS or covered by a FWA.

**Unanticipated Problems (UPs)** - any incident, experience, or outcome that meets all of the following criteria: (1) Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; (2) Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); AND (3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated Problems occurring in research do not in and of themselves constitute IRB noncompliance or research misconduct. However, if a PI fails to report an unanticipated problem in a timely manner to the IRB, or if an unanticipated problem is caused by a failure to follow IRB approved research protocols, these actions may represent noncompliance with IRB policy. **Breaches of confidentiality are always unexpected, even if outlined in the informed consent.**

## 2. Procedures

### Reporting Requirements

Investigators, research staff and any other member of the UM IRB or IRB office are required to report any potential, observed, suspected, or apparent non-compliance to the IRB. This refers to all non-compliance, whether or not it may be serious and/or continuing non-compliance. All institutional members, research participants and others are encouraged to report any potential, observed, suspected, or apparent non-compliance.

Reports of non-compliance may also arise from: (i) calls or online reports to the Montana University System Compliance Hotline, the confidential institutional hotline for reporting compliance concerns; or (ii) as a result of internal or external audits; or (iii) through direct communication to the IRB. Regardless of how reports arise, all allegations of non-compliance related to research with human participants must be referred to the IRB. The allegation may be referred to other institutional offices for evaluation and management as appropriate.

Reports of non-compliance must contain enough information to determine whether the report is sufficiently credible and specific so that potential documentation of non-compliance may be identified and acted upon.

Protocol deviations and noncompliance should be reported to the IRB as soon as possible. An initial report should be made to the IRB Office by email within one (1) week (7 calendar days) of when the investigator became aware of the event. Any event involving serious injury or danger to the subject must be reported immediately. The initial report must be followed by a formal Incident Report submission in Cayuse Human Ethics within no more than two (2) weeks (fourteen (14) calendar days) of when the investigator became aware of the event. Reports of possible noncompliance should include a complete description of the event and include sufficient detail to allow the IRB to make an assessment.

In some cases, reporting requirements may be met by submitting a preliminary report to the IRB office, IRB, and other officials/agencies involved, with a follow-up report submitted at a later date when more information is available. These determinations will be made on a case-by-case basis, with the IRB Chair, Associate Vice President (AVP) for Research Compliance, institutional official(s) and/or others involved as appropriate. The primary consideration in making these judgments will be the need to take timely action to prevent avoidable harms to research subjects and others.

### Investigation

Upon receipt of the noncompliance report the IRB office will notify the IRB Chair of the alleged noncompliance and determine if the report requires further investigation with immediate action, further investigation but no immediate action, or no action. The IRB will attempt to resolve alleged instances of noncompliance without interrupting the conduct of the study, especially if the rights, safety, and welfare of subjects may be jeopardized by the interruption. All reports of

potential noncompliance as well as the outcome of investigations that are substantiated will be noted in the protocol record.

If a determination of further investigation with immediate action is made an emergency IRB meeting will be scheduled to:

- discuss an allegation of noncompliance and/or serious adverse event;
- or determine whether an activity should be suspended. The UM IRB may appoint a delegate and/or subcommittee to proceed with an investigation.

If an investigation is warranted, the IRB may collect information through:

- interviews with people affiliated with the allegation;
- interviews with human participants or participating organizations; and
- consent records, data records, and any other relevant documentation.

If the IRB Chair has an actual or perceived conflict of interest, the Institutional Official will delegate the responsibility of the investigation to an IRB member who does not have a conflict of interest. The Institutional Official, legal counsel, complainant, and the person against whom the allegation is being made may be invited to participate in the investigation.

The IRB will fully investigate and review reports of possible non-compliance to determine if the event was not non-compliance, minor non-compliance, serious non-compliance, or continuing non-compliance. If necessary, the IRB will require corrective action.

## **Findings and Corrective Actions**

If the IRB finds that no noncompliance occurred because: (1) the reported non-compliance was unsubstantiated, (2) the investigator deviated from the protocol in order to eliminate immediate and apparent hazards to subjects, or (3) continued participation of enrolled subjects in research for which approval has expired was necessary to protect the best interests of enrolled subjects, the following actions by the IRB may include but are not limited to:

- Requiring no further action.
- Requiring submission of an amendment to the protocol or consent form.
- Requiring submission of a continuing review application.
- Permitting or disallowing use of data collected during (2) and (3) above.

If minor non-compliance is found to have occurred, action by the IRB may include but are not limited to:

- Requiring a corrective action plan to be submitted which includes a detailed explanation of the non-compliance event and actions taken or proposed to prevent reoccurrence.
- Requiring remedial training (e.g., online educational program, attendance at workshop, one-on-one training).
- Requiring re-consent of subjects.
- Requiring the submission of an amendment to the protocol or consent form.
- Not permitting publication or dissemination of the results of the research.

- Requiring the destruction and disposal of data collected while the protocol was non-compliant.

Whenever appropriate, investigators will be assisted so that they can achieve compliance without the need for more serious sanctions. However, if the investigator fails to cooperate with IRB requests to correct minor non-compliance, this inaction will be treated as continuing non-compliance and potentially research misconduct.

If serious and/or continuing non-compliance is found to have occurred, actions by the IRB may include but are not limited to:

- Establishing a corrective action plan.
- Asking the investigator to voluntarily halt the research until the investigator is in compliance.
- Requiring the investigator to participate in and complete further training.
- Requiring more frequent review of the project.
- Implementation of monitoring of the research and/or the informed consent process.
- Requiring the investigator(s) to provide additional information to current and/or past participants and/or re-consenting of participants.
- Disallowing use of the data collected during noncompliance.
- Not permitting publication or dissemination of the results of the research.
- Limiting the investigator's human subject research privileges.
- Writing letters of censure.
- Making recommendations to the Institutional Official (IO) for further sanctions, stipulations, or restrictions to the Investigator's privilege to conduct human subjects research.
- Sharing information of noncompliance with other institutional units as deemed necessary, including for a Research Misconduct investigation.
- Suspension of the research.
- Termination of the research.

The IRB and, when appropriate, the institution will act promptly to ensure remedial action regarding any breach of regulatory or institutional human subject protection requirements. The IRB also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or deviates from the approved protocol.

All serious and/or continuing noncompliance must be reported promptly to the AVP for Research, the Institutional Official and, for federally funded research, the appropriate department, agency head or sponsor. Reports will only be made to OHRP for research that is regulated by these oversight agencies per FWA. Sponsor reporting requirements may apply if required by project terms and conditions or applicable regulations.

## IRB Reporting Obligations

It is the responsibility of the IRB Manager and/or Chair, in consultation with the IRB office, to compile a final report for the AVP for Research and, if necessary, the Institutional Official. The Institutional Official may need to submit the final report to OHRP. The final report to OHRP must include:

- the name of the institution;
- the research project title and/or grant proposal that was originally suspended;
- the name of the principal investigator of the protocol;
- the research project number assigned by the IRB; and
- any corrective actions the institution is taking to remediate the immediate problem and ensure that the incident will not happen again with that principal investigator or with other researchers.

In the report, the IRB will determine one of the following actions:

- There was no evidence to support the allegation.
- The allegation was not supported; however, it may require additional action by administration.
- The allegation was valid and requires additional action.

Unanticipated problems involving risks to subjects or others, any serious and/or continuing noncompliance, and any suspension or termination of IRB approval are reportable to the appropriate federal department or agency head(s) and to the UM Institutional Official. The Institutional Official may need to report the suspension to OHRP or another regulatory agency. HHS regulations require that any suspended human participant research that is conducted or supported by HHS be reported to OHRP immediately (HHS regulations, 45 CFR 46.103(a) and (b)(5)).

## Regulatory Background

HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to regulatory requirements pertaining to research conducted under an OHRP- approved assurance are promptly reported to OHRP: any unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and any suspension or termination of IRB approval.