Institutional Review Board (IRB)

Handbook

2018

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University of the Rockies

www.rockies.edu

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1.0 Introduction

The University of the Rockies (UoR) Institutional Review Board (IRB) is responsible for protection of human participants involved in research. This *Institutional Review Board Handbook* is designed to help student, faculty, or staff researchers affiliated with UoR in planning their research study and applying for IRB approval prior to conducting their study. This handbook may be especially useful for students who are seeking approval of their doctoral proposal to understand the IRB portion of the process and is designed to be used in conjunction with the *Dissertation Handbook* and the *Applied Doctoral Project (ADP) Handbook*. Students should refer to the UoR Dissertation and ADP Handbooks for information about the entire doctoral project process.

Researchers who are conducting a study, including students, are referred to as "principal investigators." Other definitions related to the IRB process are provided in *7.0 Definitions Related to the IRB Process*. All doctoral project Chairs and non-student principal investigators are encouraged to consult the IRB Chair with any questions through the email address, IRB@rockies.edu. See *Section 5.0 Submission Procedures* for submission instructions. A list of forms and other helpful tools can be found in *Section 11.0 Links to Forms and other Helpful Tools*.

2.0 Principles of Research Involving Human Participants

UoR is committed to the highest ethical standards in conduct of research. For projects involving humans as participants, UoR is guided by the ethical principles set forth in the Declaration of Helsinki, the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research's Ethical Principles, and Guidelines for the Protection of Human Participants of Research: The Belmont Report. In addition, UoR is committed to ensuring that all human participant research, regardless of funding source, follows the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). The UoR IRB for Human Participants is registered with the federal government.

IOrg Number: IORG0003731

IRB Number: IRB00004424

FWA Number: FWA00021730

The IRB Policies and Procedures apply to all research involving human participants, funded or unfunded, sponsored or not sponsored, carried out by UoR students, faculty, and staff on or off campus, whenever human participants are included. The IRB will also review research that meets the requirement for exempt approval.

3.0 Statement of Ethical Principles

The following broad principles are the basis for UoR policy concerning review of research involving humans:

- Whereas the participation of humans in research projects may raise fundamental ethical and civil rights questions, all such research, funded and unfunded projects, sponsored and not sponsored, which is carried out by UoR students, faculty, or other UoR employees, on or off campus, shall be covered by the UoR Institutional Review Board (hereinafter referred to as IRB) for the Protection of Human Participants in Research Policies and Procedures covered by this document.
- All activities involving humans as participants must provide for the rights, safety, health, and welfare of each individual.
- The direct or potential benefit to the participant and the importance of the knowledge gained must outweigh any inherent risk to the individual.
- Participation in research must be voluntary and informed consent procedures must conform to the IRB Policies and Procedures.
- An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to refuse to participate or may withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled.
- Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the principal investigator.
- The primary responsibility for protection of human participants rests with the principal investigator and with support, approval, and monitoring by UoR as set forth in the IRB Policies and Procedures.

4.0 Institutional Review Board General Information

The purpose of University of the Rockies' IRB is to ensure ethical research practices among its students and faculty. Anyone affiliated with UoR who is pursuing a research project must receive approval from the IRB before commencing the study, including solicitation of any human participants and collection of any data, including a pilot study. For the purposes of students completing a dissertation or ADP, the IRB must approve ***every*** dissertation/ADP regardless of the research methodology to be employed before the study can be conducted.

4.1 Membership

The IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities. The President of UoR shall appoint the Chair and members of the IRB. The IRB shall be sufficiently qualified through the experience and expertise of its members; their diversity, including consideration of race, gender, and cultural backgrounds; sensitivity to issues such as community attitudes; and promoting respect for its advice and counsel in safeguarding the rights and welfare of human participants. Members must also possess the necessary professional competence to review specific institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Every effort will be made to ensure that the members of the IRB represent diverse backgrounds. The IRB shall not consist of members of a single profession or discipline; shall include at least one member whose primary concerns are in scientific areas; and include at least one member whose primary concerns are in non-scientific areas. The IRB will have at least one member who is not otherwise affiliated with UoR, and at least one member with legal expertise.

4.2 Training in Human Participants' Protection

All IRB members and primary investigators are required to complete the Collaborative Institutional Training Initiative (CITI) online training in human participants' protection, which can be accessed electronically at https://www.citiprogram.org/default.asp. The CITI training is an intensive process and researchers are cautioned to begin and complete this training in a timely manner. A Completion Report, obtained at the conclusion of the training, must be included in any IRB application. The CITI certification, which is valid for 3 years, must be in force throughout the data collection and analysis process. **Faculty must have an active CITI Completion Report on file. The CITI requirement is the same for all investigators – faculty, staff, or student (or external research partners) and doctoral project chairs.**

The following courses are required for all investigators (faculty, staff, students) and doctoral project chairs:

- Social & Behavioral Research Investigators Basic/Refresher Course
- Information Privacy and Security (IPS)

Researchers collecting protected health information (PHIs) are required to complete the following course:

- Health Information Privacy and Security (HIPS) Course – Information for Students or Investigators
    - Health Privacy Issues for Students and Instructors (ID: 1420)
    - Basics of Health Privacy (ID: 1417)
    - Basics of Information Security, Part 1 (ID: 1423)
    - Basics of Information Security, Part 2 (ID: 1424)

Each course must be completed while attaining a minimum score of 90%.

4.3 Meeting Dates

IRB meetings are held once a month. It is at these meetings that any Full reviews are conducted. ***Requests for reviews and resubmissions may be handled more often.*** The IRB Chair may convene additional meetings as necessary to handle business. The Chair may cancel meetings when no new IRB, renewal, or change requests are pending.

4.4 Meeting Procedures

Quorum A majority of IRB members must be present to conduct a Full IRB Review, or to conduct business related to IRB functioning. Members present may, by simple majority vote, defer agenda items if they believe requisite members of IRB are not present. Requests for non-full reviews and resubmissions may be reviewed solely by the IRB Chair or his/her appointee.

Order of Business The agenda for IRB meetings shall be:

a) Review of and action on minutes of previous meetings.
b) Review and discussion of, and action on, new exempted or expedited IRB requests (in order of submission).
c) Review and discussion of, and action on, resubmitted IRB requests (in order of submission). Review and discussion of, and action, on renewal requests.
d) Review and discussion of, and action, on substantive changes to previously approved IRB requests.
e) Review and discussion of, and action, on Close-Out forms of any completed studies.
f) Old and new business related to IRB functioning.
g) Other business.

Actions IRB requests shall be approved, approved with conditions, deferred, or disapproved. Reviews may also be halted until a future date by majority vote of those members present.

Attendance by Non-IRB members IRB meetings are generally open to all members of the University community and the community at large.

a) The IRB members may, on majority vote, close meetings for compelling reasons, as long as such closure is not in conflict with 45 CFR Part 46 or other applicable federal, State, or local law and regulations.
b) Anyone may speak for or against an IRB request, but remarks must be based only on the Criteria for Approval as stated for each criterion of the IRB paperwork.
    i. The Chair may limit the duration of comments or the number of speakers for and against a proposal to serve the best interest of committee functioning.

ii. Written comments received by the Chair prior to the meeting will be read into the minutes or distributed and appended to the minutes only if the requester makes a formal request for doing so and insofar as they address the Criteria for Approval.

c) The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that represented by the regular IRB members.

VOTING Only IRB members may vote. All voting will take place in a closed session and any guests will be dismissed.

CONFLICT OF INTEREST IRB members, and anyone speaking or submitting written comments, must declare any potential conflict(s) of interest or commitment in advance. Members may speak for, but may not vote on their own IRB requests, IRB requests of students for which they are on the committee, or any IRB request for research in which an IRB member is or is likely to be a participant. Written comments shall explicitly address any conflict of interest or its absence (in the event of a perceived conflict of absence that could be addressed for clarity).

MINUTES The IRB will keep minutes of the proceedings. The minutes must show attendance; actions taken by IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

4.5 IRB RECORDS

The IRB Chair shall keep the following documentation of IRB activities on file for at least 5 years:

1. Written procedures for the IRB;
2. A list of IRB members including name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations, and employment or other relationship between each member and the institution;
3. Minutes of IRB meetings;
4. Copies of all IRB reviewer forms completed for new IRB, renewal, and change requests;
5. Copies of all proposals received, scientific evaluations (if any) that accompany the proposals, copies of all internal and external correspondence related to each submitted IRB request, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants (if any);
6. Copies of all correspondence between the IRB and the primary investigator for any study;
7. Records of continuing review activities;
8. Records of change requests and documentation; and

9. Statements of significant new findings provided to participants as required by the consent documents.

5.0 Submission Procedures

All investigators, including faculty, staff, and students, must submit a *Request for IRB Review* form regardless of whether human participants are used in the study. Students who have passed their Preliminary Oral Defense should submit the *Request for IRB Review* form with supporting documentation to the IRB Chair through the IRB Administrator at IRB@rockies.edu. For most efficient consideration, submissions should be made by the 15th of the month.

Supporting documentation included with the *Request for IRB Review* form should always include a *Research Summary* that follows the prescribed outline (see section 11.0 for exemplar and template), and a copy of the principal investigator's CITI completion report (see section 4.2). Other supporting documentation may include: a signed *Organizational Permission* form for permission to access participants or data, or use the premises; a signed *Permission to Use or Modify an Existing Instrument* form; an unsigned sample *Informed Consent Form*; an unsigned sample *Assent Form*; all data collecting instruments (such as a survey, or an interview script). The format for submission of these documents is specified in *Instructions for IRB Application*.

All requests to conduct research involving human participants must be submitted to the UoR IRB. Only research consistent with university policy will be reviewed (e.g., no medical research or animal research; See Dissertation and ADP Handbooks for specifics). Requests from individuals other than dissertation/ADP students should be made to IRB@rockies.edu. The investigator, whether student or faculty, must obtain IRB approval before undertaking the research and beginning data collection. ***Absolutely no solicitation of human participants or data access or collection may occur prior to IRB approval.***

All three types of reviews use the same submission form; researchers will submit a *Request for IRB Review* form and indicate the type of review (Exempt, Expedited, or Full) the researcher believes is warranted. See Sections 5.1 – 5.3 below for criteria for each type of review. After submission, the IRB will consider the researcher's requested review type and make the final determination regarding the type of review (Exempt, Expedited, or Full) warranted. Any IRB member may request that research be reviewed at a more extensive level. If a full review is required, the IRB will contact the researcher.

5.1 Criteria for Exempt Review

Research in this category involves risks or stressors that are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

The IRB Chair must determine that a project qualifies for an exempt review. ***Researchers must not proceed with the research until written IRB approval has been received. Absolutely no solicitation of human participants or data collection is allowed prior to receipt of IRB approval, including pilot studies.***

Action on Exempt research is generally taken within 5-7 working days of receipt by the IRB Chair. Incomplete requests will be halted and returned.

Research qualifies as Exempt if it falls in one of the following six (6) categories (note that not all types of research described below are, or are permitted to be, conducted at the UoR):

1. Research conducted in established or commonly accepted educational settings, involving normal education practices.
    a) Special note for research in schools: In order for a project involving educational research (research conducted in classrooms) to be reviewed under the Exempt category, the investigator must supply a letter from the appropriate school district official that certifies that the project meets the following conditions. The research activities will:
        i. Not differ in any significant way from the normal range of activities of the classroom, school, or district;
        ii. Involve only customary and non-controversial instructional goals;
        iii. Not deny any students' educational benefits they would otherwise receive;
        iv. Promise direct benefits (at least in the form of evaluative information) to the classroom, school, or district;
        v. Incorporate adequate safeguards to protect the privacy (e.g., anonymity or confidentiality) of all individuals who might be participants of the research; or
        vi. Involve only existing data on students which are not identity-specific.
2. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, and achievement tests), survey procedures, interview procedures, or observation of public behavior, unless specific individual human participants can be identified, directly by or through identifiers linked to the participants, and disclosure of their identity could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
3. Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, and achievement tests), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 of this section, if the human participants are elected or appointed public officials or candidates for public office, or federal statute(s) require(s), without exception, that the confidentiality of the personally identifiable information will be maintained through the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information

is recorded by the investigator in such a manner that participants cannot be identified directly or through identifiers linked to the participant.

5. Research and demonstration projects that are conducted by or subjected to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
    a) Public benefit or service programs;
    b) Procedures for obtaining benefits or services under those programs;
    c) Possible changes in or alternatives to those programs or procedures; or
    d) Possible changes in methods or levels of services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains an ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

5.2 Criteria for Expedited Review

Research with minors (as defined by state statutes) may not be reviewed under the Expedited category. Note that not all types of research described below are, or are permitted to be, conducted at the UoR. Research that poses only minimal risk to adult human participants and does not pertain to sensitive or personal aspects of the participants' behavior or involve concealment or deception may be granted an Expedited review under one or more of the conditions listed below (if carried out through standard methods):

1. Recording of data from participants who have reached the age of majority in their state (not all states use 18 years of age as the age of majority) using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the participant or an invasion of the participant's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).
2. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from participants who have reached the age of majority or older and who are in good health and not pregnant.
3. Voice or video recordings made for research purposes.
4. Moderate exercise (not including stress testing) by healthy volunteers.
5. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

6. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research will not involve stress to participants beyond that routinely experienced in daily life or during the use of noninvasive procedures routinely employed in clinical practice.
7. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

An expedited review requires review by one or more members of the IRB and action generally takes 12 to 18 working days. Incomplete requests will be halted and returned. ***Researchers must not proceed with the research until written IRB approval has been received. Absolutely no solicitation of human participants or data collection is allowed prior to receipt of IRB approval, including pilot studies.***

5.3 Criteria for Full Review

Research involving more than minimal risk or vulnerable human participants* must undergo a Full IRB review. Examples of research that may involve more than minimal risk (mental or physical), include:

1. Surveys or questionnaires that solicit information regarding personal or sensitive aspects of the participants' behavior, including sexual practices, instances of child or sexual abuse suffered by the participant, criminal activities, drug and alcohol use, or eating disorders.
2. Stress testing, drug and alcohol use by the participants for research purposes, and studies in which participants are asked to do more than moderate physical exercise, which could result in injury to the participant.
3. Use of concealment or deception (see "7.0 Definitions Related to the IRB Process").

* See "7.0 Definitions Related to the IRB Process" for definition of "vulnerable human participants."

Incomplete requests will be halted and returned. A Full review requires a meeting of the IRB and generally takes 15 to 25 working days. For most efficient consideration of the Request for Full Review, all forms and materials must be submitted by the 15th of the preceding month. The IRB will review the submission and provide the researcher a list of issues one (1) week prior to the meeting. At the IRB meeting the IRB Chair will facilitate the review of the issues and the researcher should be prepared to address each one. The IRB reserves the right to explore other issues besides those provided to the researcher. ***Researchers must not proceed with the research until written IRB approval has been received. Absolutely no solicitation of human participants or data collection is allowed prior to receipt of IRB approval, including pilot studies.***

5.4 Criteria for Approval

The IRB uses eight (8) specific review criteria when reviewing proposals:

1. Risks to participants are minimized. Risks can be minimized in the following ways:

a) Using procedures that are consistent with sound research design;
b) Not exposing participants to unnecessary risk; and
c) Using procedures already being performed on the participants for diagnostic or treatment purposes, whenever appropriate.

2. Risks to participants are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result.
    a) In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research).
    b) The IRB does not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as a research risk that falls within its purview.
3. Selection of participants is equitable.
    a) In making this assessment, the IRB takes into account the purposes of the research and the setting in which it will be conducted.
    b) The IRB is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative.
    a) Except as provided elsewhere in this policy, no investigator may involve a human being as a participant in research, unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative.
    b) An investigator must seek consent under circumstances that provide the prospective participant or the participant's representative sufficient opportunity to consider whether or not to participate and that minimizes the possibility of coercion or undue influence.
    c) The information given to the participant or the representative must be in language understandable to the participant or the participant's representative.
    d) No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or that appears to release the investigator, the sponsor, the institution or its agent from liability for negligence.
5. Required elements of informed consent are present.
    a) The IRB may waive or modify this requirement under certain circumstances. Any modification to informed consent procedures must be fully justified in writing.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

7. Whenever appropriate, there are provisions to protect the privacy of participants and to maintain the anonymity and confidentiality of data.
8. When some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, mentally disabled persons), or concealment or deception will be used, additional safeguards and supports have been included in the study to protect the rights and welfare of these participants.

5.5 Meeting with the IRB

A meeting between the IRB and the student proposing a dissertation/ADP may be required only in cases of a Full Board Review, at the discretion of the IRB. The meeting, if required, could take place in person or by teleconference. Exempt and Expedited Reviews do not necessitate that the student meet with the Board. In cases of an Exempt or Expedited Review, the student may proceed with solicitation of participants and data collection after receiving formal approval from the IRB Chair.

Following a Full Board Review, the IRB will take one of the following actions regarding the proposal: "approved," "approved with conditions," "deferred," or "disapproved." Details regarding the possible actions are found in section 5.6.

5.6 Actions by the IRB

The following are the possible actions the IRB can take following a review of an IRB proposal.

Approved. The IRB will provide the principal investigator a letter indicating the start date and end date of the approval. Researchers will need to submit an *IRB Close-Out Form* upon completion of the research. If the researcher anticipates that the research will not be completed by the expiration date, the researcher should submit a *Request for Renewal* form (see section 5.7 for details).

Approved with Conditions. IRB requests that are approved with conditions necessitate that revisions and/or clarifications that address the issues raised by the IRB be submitted to the IRB. The IRB will also provide a list of documents required for resubmission (see section 5.6.1). The IRB Chair may act on revisions, depending on the extent of them. ***The investigator must wait for written notification of approval after revisions are made before proceeding with solicitation of participants and data collection.***

Deferred. A deferred decision is rendered when insufficient information is provided to make an evaluation of the risk/benefit ratio and to ensure protection of human participants. A complete re-application needs to be submitted to the IRB.

Halted. Requests that are missing vital information, e.g., the Research Summary, current CITI Completion Report, or other instrumentation and/or documentation pertinent to the proposed research – will be halted, resulting in the need to resubmit the IRB Request.

Disapproved. Applications are disapproved if the research does not meet the criteria for protecting participants and substantial changes would be required. No IRB request will be disapproved until it has been reviewed in accordance with the full review procedures set forth in this document. If the IRB disapproves a request for review of a research study, a written statement of the reasons for its decision will be given to the principal investigator. The principal investigator will have an opportunity to respond in person or in writing. Review of a previously disapproved protocol requires a Full IRB review.

Parallel IRB and Organization Permission. If approval of another IRB is required, the UoR IRB will generally review the proposal first and when satisfied with the proposal, the UoR IRB will "approve with conditions" the study with the only condition being that the researcher secures the necessary permission(s) from the other IRB(s). Once permission from the other IRB(s) has been obtained and submitted to the UoR IRB, the UoR IRB will issue a full approval. The researcher can share that full approval with the other IRB if the other IRB(s) desires to have a copy it.

5.6.1 Resubmission Procedures

If an IRB application is **Approved with Conditions** then a partial resubmission is necessary. The "approved with conditions" letter will specify what documents need to be changed and resubmitted. One of those documents will be an *IRB Change Matrix* detailing changes in response to the issues raised in the letter. A second document will be a completed and signed *IRB Change Matrix Chair Authorization* form where the doctoral research chair signs a statement verifying that the student has addressed all issues adequately and the new submission meets all IRB requirements. The *Research Summary* is also likely to be updated and resubmitted. See *Instructions for IRB Application* for details on formatting the resubmission.

If an IRB application is **Disapproved**, a full resubmission is necessary, with the addition of the *IRB Change Matrix* detailing major differences between the original submission and the resubmission.

5.7 Continuing Review

Federal regulations require re-evaluation of approved research at intervals that are appropriate to the degree of risk. At the time of its initial review, the IRB will determine the renewal date of the IRB approval. If the project is going to continue past the expiration date, then the investigator must submit a *Request for Renewal* form. The principal investigator must submit the request for renewal in time for review and approval by the one-year anniversary date of the previous approval. The researcher should provide all information requested on the form; incomplete requests will be halted. If a researcher fails to provide continuing review information to the IRB or the IRB has not reviewed and approved a request for renewal by the continuing review date specified by the IRB, then the research study may not continue. No enrollment of new participants or data collection is allowed after the expiration of IRB approval.

The IRB may require continuing review of any research at more frequent intervals than 12 months whenever the degree of risk justifies such review. Additionally, the IRB has the authority to observe or have a third-party observe the consent process and the research process for a given study. These third-party observers are required to comply with confidentiality standards governing the ongoing research.

5.8 Changes to Approved Research

Any changes to previously approved research, including, but not limited to, those that may change the risk/benefit ratio, must be approved by IRB prior to implementing the changes. In addition, the IRB must be notified of any changes in principal investigator(s) or faculty sponsorship. Principal Investigators must submit changes in writing to the IRB Chair on the *Report of Change* form. Incomplete requests will be halted.

5.9 Deviations from Protocol

Principal Investigators must report **any and all** deviations from the approved research protocol to the IRB immediately by emailing the IRB at IRB@rockies.edu. If the research is supervised by a Faculty chair (e.g., dissertation or ADP Chair), the Principal Investigator should copy the chair on the email. The IRB Chair may appoint an ad hoc panel of three IRB members to investigate the deviations with regard to any substantive effect on human participant protection. The panel will make recommendations to the IRB Chair. Outside IRB experts may be consulted.

5.10 Adverse Events

Principal Investigators must report **any and all** adverse events to the IRB immediately by emailing the IRB at IRB@rockies.edu. If the research is supervised by a Faculty chair (e.g., dissertation or ADP Chair), the Principal Investigator should copy the chair on the email. The IRB Chair may appoint an ad hoc panel of three IRB members to investigate the adverse event with regard to any substantive effect on human participant protection. The panel will make recommendations to the IRB chair. Outside IRB experts may be consulted.

6.0 Data Collection

Note: This section is only applicable for those studies in which data will be collected. Solicitation of human participants and/or data collection in any study may commence only *after* the request by the principal investigator has been approved by the IRB. When conducting research, the participants must agree to be a part of the research prior to collection of any data, including for screening purposes, and the privacy and security of their information must be ensured.

6.1 Informed Consent

A consent form signed by each participant, or the parent/guardian of each participant, is normally required for all non-exempt studies. Active informed consent must be obtained prior to collection of any data, except where Waiver of Consent is appropriate, and necessary in order to conduct the research. Active consent may be obtained in ink or through a web-based survey portal, as the first page of a web-hosted survey. When use of Waiver of Consent is approved by the IRB, oral consent must include all of the elements of written consent.

For any study in which children have not reached the age of majority in their domiciled state (unless emancipated) will be participating, informed consent must be obtained from their parents or legal guardians. Informed assent must be obtained from minor participants if they are between ages 7 and the age of majority. An assent form is a written document used to inform the child of the study using age-appropriate language so he or she can determine whether or not to participate in the research. An assent form is generally presented to children older than 6 years of age. If the child is not yet able to read, procedures may be used to present the information orally to obtain oral assent. Certain studies may be exempt from the permission requirement (e.g., if the research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants, such as neglected or abused children; Source 45 CFR 46.408). Proposals of research to be conducted in an educational or other institution must include a letter of approval from the school district, hospital, or other institution.

Informed consent or assent must be obtained ***before*** participation of any participants or collection of any data, including pilot tests. The informed consent and/or assent document must contain the following elements (please see *Sample Informed Consent Form, Sample Parent/Legal Informed Guardian Consent Form,* and *Sample Assent Form* for suggested wording):

1. Identification of investigator's name, institution, status, mailing address, and telephone number. If the researcher is a student, the name, address, and telephone number of the Doctoral Project Chair must be included.
2. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures that are experimental. The *Informed Consent*

Form should tell the potential participant all she or he will encounter, how long it will take, where it will take place, etc. The information should be written at a reading level appropriate for the particular participant. Consent forms should provide a description of the types of questions to be asked (e.g., "In this study, we are exploring whether some people are 'at their best' at different times of the day. We will be asking you questions about your daily activities, your personality, and some basic demographic characteristics, such as your age, gender, and race.").

3. A description of any reasonably foreseeable risks or discomforts to the participant. The following risks, if foreseeable, must be thoroughly explained:
    a) When sensitive questions are to be asked, either examples of the most sensitive questions or an explicit description of these questions should be given (e.g., "We will be asking you questions, the most sensitive of which might be: Have you ever considered committing suicide? Have you ever made yourself throw up after a meal? Do you enjoy looking at people of the same sex?").
    b) When research gathers information about a participant's involvement in illegal activities and no Certificate of Confidentiality is held by the researcher, the researcher must provide a statement that questions regarding illegal activities will be asked as part of the research study. The researcher must state in the consent form that the possibility exists, although it is not probable, that the researcher's data could be subpoenaed and used against the participant.
    c) Suspected child abuse/neglect: When applicable, a statement should be included in the consent form that the researcher may report to appropriate legal authorities known or suspected child abuse or neglect, and circumstances or conditions which might reasonably result in abuse or neglect that become apparent as a result of a parent's participation or their child's participation in a research study.
    d) If the participant incurs or may incur expenses as a result of participating in the project (e.g., medical or transportation expenses), the researcher must clearly state whether the participant will be reimbursed for those expenses or if there will be no reimbursement for participating in the research.
    e) In a situation where a participant could be injured while participating in a project, the researcher must clearly explain any limitations of liability on the part of the researcher.
4. A description of any benefits to the participant or to others that may reasonably be expected from the research. The following benefits, if mentioned, must be accurately described:
    a) Possible benefits to society: Societal benefits should not be overstated. There may be no direct benefit to the participant, other than a sense of helping the public at large.
    b) Payment of participants: Only include information on payment if payment is available. Any conditions for receiving the payment must be included in the consent form (e.g., if only partial payment will be made to a participant who withdraws from the study, the researcher must clearly explain the formula for partial payment). If payment is given to

defray the incurred expense of participation, it must not be coercive in amount or method of distribution.

5. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant. For example, in drug studies, the medication(s) may be available through a family doctor or clinic without the need to volunteer for the research activity.
6. A statement describing the extent to which confidentiality of records identifying the participant will be maintained. Federal Regulations stipulate that, where appropriate, proposals should include adequate provisions to protect the privacy of participants and to maintaining the confidentiality of data. When a proposal does not explain if and how privacy will be maintained, participants cannot know the future status of their contributions to the study, and so they cannot provide truly informed consent. The section on privacy and confidentiality should include the following statements:
    1. Explaining how the participant's participation will either be known, kept confidential, or anonymous: Anonymity means that there is no way to identify an individual participant's responses. Confidentiality implies participants' identities are known, but will be protected by the investigator (to the best of his or her ability). For example, if participants sign a consent form and their names are tied to their responses through a master list of names and code numbers, and in addition the coded responses are kept in a secure location, the participants' responses may be considered confidential, but are not anonymous.
    2. Describing how individual privacy will be maintained in publications or presentations, including the thesis or doctoral project.
       Note: Transcripts of interviews or observations and raw responses to survey questions are raw data and should not be appended to the doctoral project.
    3. Explaining how and where all consent documents, participant lists, and data will be stored and for how long (APA recommends a minimum of 5 years).
    4. Explaining what the disposition of audio or videotapes will be at the conclusion of the storage period (e.g., destroyed, erased, given to participants, used for other purposes, such as advertising a product or procedure).
    5. Explaining what the disposition of master lists (linking participants' names with data) will be at the conclusion of the storage period.
7. If protected health information is to be collected or transferred, including all required elements for an authorization (see IRB Policy for HIPAA Compliance). For research involving more than minimal risk, an explanation as to whether any compensation will be given, whether medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
   Note: Federal regulations (see CFR 46.102[g]) do not limit injury to "physical injury."

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled, and that the participant has the right to refuse to answer questions.
9. Identification of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant. The email address of the IRB Chair (IRB@rockies.edu) should be included should the potential participant wish to contact the IRB, should he or she have questions or concerns.
10. All studies funded by federal agencies that require demographic information about gender and race or ethnicity must include the following statement: "This study is being funded by a federal agency which requires that data be collected in a form that may be analyzed for differences between men and women and races or ethnic groups."

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

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

An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the participant's representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive, or appear to waive, any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agent from liability for negligence.

The IRB may approve waiver of the requirement of a signed consent form in the following cases:

- The only record that links the participant to the research is the signed consent form, and the principle risk to the participant would be a breach of confidentiality that would expose the participant to risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. In this case, participants must be asked if they want to sign a consent form that links them to the research.

In these cases, the IRB may require the investigator to provide participants with information sheets to retain (e.g., an information letter that contains the information normally included in a consent form, but with no signature line).

6.1.1 Cultural Considerations Regarding Informed Consent

Any research to be conducted outside the United States may be subject to human participants' protections and legislation in the host country. The investigator is responsible for providing information to the IRB about human participants' requirements in the international setting, as pertinent to the IRB request.

In some cultures, an investigator may enter a community to conduct research or approach prospective participants for their individual consent only after obtaining permission from a community leader, a council of elders, or another designated authority. Such customs must be respected. In no case, however, may the permission of a community leader or other authority substitute for individual informed consent. In some populations, the use of a number of local languages may complicate the communication of information to potential participants and the ability of an investigator to ensure that they truly understand it. Investigators should develop culturally appropriate ways to communicate information that is necessary for adherence to the standard required in the informed consent process. They should describe and justify in the research protocol the procedure they plan to use in communicating information to participants. When consent forms need to be translated into different languages, the IRB will need to see copies of those translated forms, along with evidence (through back translation) that the pertinent information has been included.

Cultural and linguistic considerations must also be addressed when selecting, modifying, or creating instrumentation to be used with persons from a different culture or in a language other than English. If a given instrument is not normed for the population of interest, then the instrument's appropriateness for the population must be face validated in a pilot study following IRB approval.

6.2 Considerations for International Research with Human Participants

Investigators must consider a range of issues when conducting research in international settings. Culturally appropriate and responsive procedures are an important component of human participant protection in research studies. Investigators proposing to conduct research outside the United States must review specific rules to be followed in that country, as well as, any local customs that may not be

considered in typical IRB review in the United States. The following list contains an overview of the range of issues that must be considered when proposing and conducting research with human participants in international settings:

1. Translation of research documents from English into other languages: The investigator should submit a copy of all documents (solicitation letters, informed consent, instrumentation) in English and in the language to be used. The investigator (or the translator) should verify that the translated version of each document is complete and accurate, does not contain any information that is not present in the English version of the document, and is not misleading in any way.
2. Participation of minors: Parental or guardian permission is required for human participants who have not yet reached the age of majority as defined by their government; however, in some cultures, obtaining active parental or guardian consent may be culturally inappropriate due to local customs and regulations. In such situations, the investigator must provide evidence to the IRB of the cultural inappropriateness of obtaining parental or guardian consent. For example, the investigator may provide accurate copies of specific regulations in English that indicate that such permission is not required; a letter from a government official in that country indicating such permission is not culturally appropriate; or a signed statement from a UoR faculty member who can attest to the cultural inappropriateness of requiring active parental permission. Based on sufficient evidence of the cultural inappropriateness of seeking active parental permission for participation of minors in the research and an assessment of the possible risks, the IRB has the discretion to waive such permission. The minor participants must retain(s) the right to withdraw, without penalty, at any time during the research. If the IRB grants a waiver of active parental permission, the investigator must provide the parents or guardian with a letter informing them of the research, written at an appropriate literacy level in the parents/guardians' language.
3. Documentation of compliance with local human participants protections: The investigator should submit documentation from the appropriate official(s) (e.g., government officials, school officials, community officials, etc.) indicating that the research protocol and any and all instruments to be used (including any biomedical equipment) have been reviewed and are acceptable. The certification letter should be on organizational letterhead and include an original (ink) signature.
4. Verification of cultural responsiveness: Unless the investigator is highly familiar with and/or a member of the international culture to be studied, the investigator should consult with an individual who is of or highly familiar with the culture to review the research protocol for cultural responsiveness and appropriateness. Cultural and linguistic considerations must be addressed when selecting, modifying, or creating instrumentation. If a given instrument is not normed for the population or language of interest, then the instrument's appropriateness for the population must be face validated in a pilot study following IRB approval.

5. Research assistance: If participants will be recruited by someone other than the researcher, or any data will be collected or analyzed by someone other than the researcher, that individual or individuals must have a high level of familiarity with the culture of interest. These individuals must be identified in the IRB request and each individual must sign a *Non-Disclosure Form,* including contact information.
6. Anonymity and confidentiality: Specific processes for ensuring anonymity and/or confidentiality of all data in the host country must be specified.
7. Transporting data: The processes for transporting data from the international location to the investigator's location, if outside that location, must be described clearly, including the processes for maintaining confidentiality and anonymity.

6.3 Policy for HIPAA Compliance

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was written to allow for insurance portability, but also as a Privacy Rule to protect the privacy and security of a person's identifiable health information. The purpose of this policy is to provide researchers with the information they will need to comply with the Privacy Rule associated with HIPAA. All HIPAA guidelines must be followed in order to conduct ethical research with human participants. **Studies that do not involve protected health information (PHI) as defined below do not need to request HIPAA Authorization**.

The following are definitions of important terms associated with HIPAA compliance.

HIPAA (Health Insurance Portability and Accountability Act) HIPAA is the 1996 Act to regulate the transfer and collection of protected health information (PHI) between and within covered entities defined as (a) health care plans, (b) health care clearinghouse, and (c) health care providers who electronically transmit any health information.

Protected Health Information (PHI) All individually identifiable health information that is either created or received by a health care entity that includes information about the past, present, or future physical or mental health of a person, the provision of health care to a person, or payment for care is considered to be Protected Health Information (PHI). This includes information in written, electronic, or oral form. This includes information created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse.

Authorization Authorization is the HIPAA equivalent of consent for use or disclosure of a person's PHI. Required elements for an authorization form include:

- Specific description of what PHI will be used or disclosed;
- Who may use or disclose PHI;
- Who may receive the PHI;
- Purpose of the use or disclosure of PHI;

- Statement of how long the use or disclosure will continue ("No expiration date" is allowed for research purposes);
- Right to revoke authorization;
- Notice that the information may be disclosed to others not subject to the Privacy Rule;
- Right to refuse to sign authorization; and
- Participant's signature.

The participant must sign the form and receive a signed copy for the authorization to be valid.

The HIPAA authorization can be a separate document from the consent form, or the required elements can be incorporated into the consent form. The UoR approved HIPAA authorization form is Sample *HIPAA Authorization Form A: Enrollment into Research*.

Authorization should be obtained in each of the following circumstances:

1. When requesting permission from research participants to have their name, address, and phone number or other health information released to an investigator for recruitment into a research study; or
2. When enrolling participants into a specific research study that will collect their PHI as part of the research study. This second circumstance occurs simultaneously with the consent process.

If PHI data is to be obtained by a third party, the participant must give authorization for that information to be released through the *Authorization to Release Health Information* form.

WAIVER OF AUTHORIZATION: A Waiver of Authorization can be obtained if the following three criteria have been met:

1. The research is no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    a) An adequate plan to protect the identifiers from improper use and disclosure;
    b) An adequate plan to destroy the identifiers at the earliest opportunity; and
    c) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity.
2. The research cannot be carried out without a waiver; and
3. The research cannot be done without this specific PHI.

When applying for a waiver of authorization, the investigator must complete the *Waiver of HIPAA Authorization* form. Uses and disclosures of PHI pursuant to the waiver must be limited to the minimum necessary to achieve the research purpose. This means that if you use a waiver to collect PHI, you must only collect the bare minimum of information from patient records deemed necessary to answer the research question.

DE-IDENTIFIED DATA Health information is considered de-identified when it does not identify an individual and the health care entity has no reasonable basis to believe that the information can be used to identify an individual. ***Research involving de-identified data will not be required to adhere to HIPAA regulations requiring authorization.*** De-identified data includes **none** of these 18 identifying links:

- Name
- Address including city, county, precinct, zip code
- All elements of dates (except year) for dates directly linked to an individual (birth date, admission date, discharge date, date of death) [For all participants over 89 years, all elements of dates including year that are indicative of their age cannot be used; however, age can be aggregated into a category of age 90 or older.]
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social Security Numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license number
- Vehicle identifiers
- Device identifiers
- Web Universal Resource Locators/Identifiers
- Internet Protocol address numbers
- Biometric identifiers including finger or voice prints
- Full face photographs and comparable images
- Any other unique identifying number, characteristic, or code

LIMITED DATA SET Limited Data Sets include research that falls under HIPAA regulations but does not require researchers to obtain authorization or waiver of authorization. Researchers can collect data that retains the following types of identifiers:

- Admission, discharge, and service dates
- Birth date
- Date of death
- Age (including over age 89)
- Geographic information (except street addresses) such as city, state, and five-digit zip code

Researchers using a limited data set will be able to use the data only for research purposes but may not use the limited data set to contact participants.

RECRUITMENT OF PARTICIPANTS No researcher may contact potential participants with whom the researcher does not have a clinical relationship without authorization: If a researcher wishes to recruit participants into a study, then the researcher must request that a physician who does have a clinical relationship with these participants obtain authorization from the participants to release information to the researcher. Alternatively, the care-providing physician can give the patient the contact information about the study.

6.4 ORGANIZATIONAL PERMISSION

Collecting data often involves obtaining data or recruiting participants from one or multiple organizations. The *Organizational Permission Form*, signed by a person in authority, may be used as evidence that permission has been granted. Permission from organizations must be obtained for:

- Permission to solicit participants on property or through the organization (e.g., lists of members and contact information, subscribers, listserv, etc.);
- Permission to collect data through that organization or from participants associated with that organization;
- Permission to conduct interviews on the organization's premises;
- Permission to use organizational name; and
- Permission to access organizational data and/or documents not in the public domain.

In addition to obtaining informed consent from individuals, any organization from which participants are recruited must give permission for that recruitment, including through social media. An example of using social media would be the use of a LinkedIn Group for potential participants for a doctoral study. The researcher will need to obtain permission to solicit participants online from the founder, administrator, or organization responsible for the social media site, utilizing the *Organizational Permission Form*. If the End User License Agreement (EULA) of the sites allows for such solicitations, the researcher can instead submit the EULA and highlight where such solicitations are permitted.

The *Organizational Permission Form* is also used to document permission to use a site for conducting physical interviews. Since the researcher will need to obtain permission from the location(s) in which **physical** face-to-face interviews will be conducted, the researcher may want to consider some type of **electronically-mediated** (e.g., Skype; Facetime, etc.) face-to-face interview thereby avoiding the need to seek permission from each location(s).

6.5 USING EXISTING INSTRUMENTS

Researchers may use existing instruments (e.g. psychological or other tests) to collect data if permission is granted using the *Permission to Use or Modify an Existing Instrument* form. Written or emailed permission may be used to document permission if the signed form cannot be obtained. Proof of permission to use or modify existing instruments must be submitted along with the *Request for IRB Review* form.

6.6 Non-Disclosure

All service providers who have access to raw data and/or implicit or explicit participant information should sign a *Non-Disclosure Form*. Examples of such persons may include someone who: is helping to solicit or recruit participants; administers surveys or tests; conducts interviews or observations; video records participants; transcribes video or audio recordings; or assists with data analysis where participants may be implicitly or explicitly identified.

If interview data are to be transcribed by someone other than the researcher, the researcher should have the transcriber sign a *Non-Disclosure Form*. The researcher should address how confidentiality will be maintained in the *Research Summary*. Also, the information regarding transcription should be provided to the participants as part of the *Informed Consent Form*.

7.0 Definitions Related to the IRB Process

Applied Doctoral Project (ADP): A culminating research project that is equivalent in research rigor to a traditional dissertation, but allows students more flexibility in designing and conducting a research project with an applied focus that is more in line with practitioner-scholar philosophy.

Archival data: Also known as **existing data**. This is data that have already been collected for purposes other than the proposed research. Archival data are complete and available to the principal investigator at the time of the IRB application.

Coercion: The persuasion of an otherwise unwilling person to do or agree to something by use of obvious or implied force or threats.

Concealment: When using concealment, the researcher intentionally does not reveal to the participant all details of the study before engaging them in the study. The researcher withholds certain information from the participants.

Debriefing: Researchers who use deception in their study are ethically bound to disclose the deception to the study participants and explain why its use was necessary. Debriefing in person or by telephone, when possible, provides the opportunity to answer participants' questions and learn about their experiences as a participant in the study. Preparing and memorizing a script can build in consistency when debriefing research participants.

Deception: When using deception, the researcher intentionally tells the participants something untrue, disguising the nature of the study, for example.

Dissertation: A formal, comprehensive report that details the purpose, background research, methodology, data collection and analysis, and conclusions of an original research study; undertaken after all coursework is completed.

Doctoral Project: The culminating task in the doctoral degree program that allows students to demonstrate pertinent knowledge, skills, research expertise, and practical applications in their discipline and serves as a requirement for graduation. The University has two types of doctoral projects: 1) dissertation (required for all Ph.D. students, and 2) Applied Doctoral Project (ADP) (for Psy.D. students and all non-Ph.D. doctoral students).

Exempt Review: Research that generally involves risks or stressors that are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations may be granted an exempt review.

Existing data: Also known as **archival data**. These are data that have already been collected for purposes other than the proposed research. Existing data are complete and available to the principal investigator at the time of the IRB application.

Expedited Review: Research that poses only minimal risk to adult human participants and does not deal with sensitive or personal aspects of the participant's behavior may be granted an expedited review under certain conditions.

Full Review: Research involving more than minimal risk or vulnerable human participants must undergo a full IRB review.

HIPAA: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was written to allow for insurance portability, but also as a Privacy Rule to protect the privacy and security of a person's identifiable health information. All HIPAA guidelines must be followed in order to conduct ethical research with human participants.

Human participant: A living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable private information through intervention or interaction with the individual.

Informed Assent: A minor participant's affirmative agreement to participate in research.

Informed Consent: An adult participant's affirmative agreement to participate in research, or the affirmative agreement for one's minor child to participate in research.

Interaction: Communication or interpersonal contact between investigator and participant.

International research: International research pertains to studies to be conducted in countries outside of the United States of America.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

IRB Change Matrix: A detailed description, in matrix form, produced by the principal investigator to document changes between submissions to the IRB. The IRB Change Matrix simplifies the IRB review process by indicating to the chair, committee, and IRB reviewer that the Principal Investigator has demonstrated a clear and thorough response to comments.

Principal investigator: The individual who has primary responsibility for designing and carrying out the research project. In the case of a student project such as a dissertation or ADP, this is not the Doctoral Project Chair but rather the student who is conducting the research.

Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It also includes that which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (e.g., the

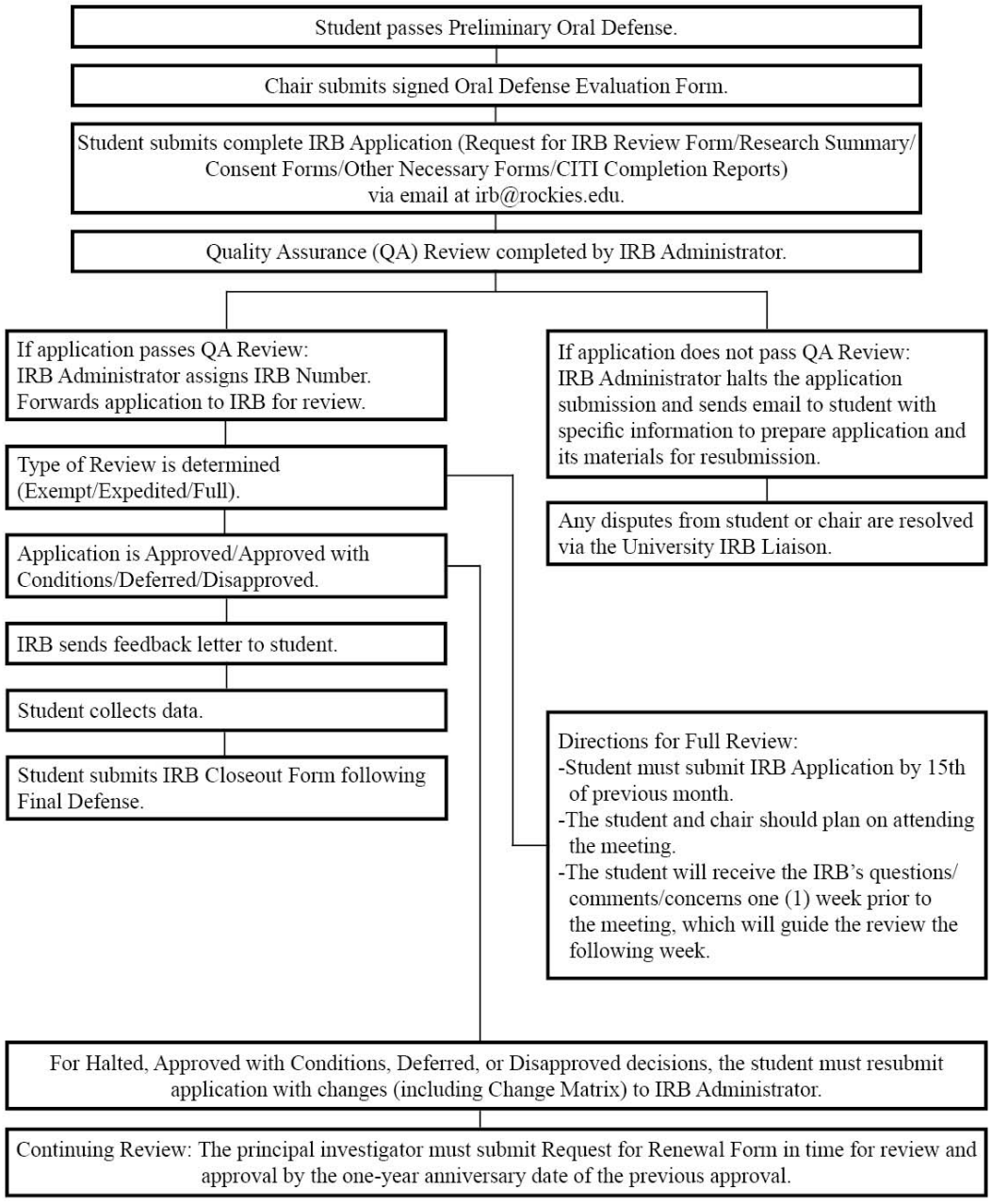
identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Protected Health Information (PHI): Defined as individually identifiable health information that a health care provider, health plan, health care clearinghouse, or employer creates or receives. This includes information about the past, present, or future physical or mental health of a person, the provision of health care to a person, or the payment for the provision of care to that person.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the development of generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Vulnerable persons/participants: Those who are relatively (or absolutely) incapable, or at risk of being incapable, of protecting their own interests. Vulnerable participants include children under 18 years, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, persons not proficient in the language of the research study, and any participants likely to be vulnerable to coercion or undue influence.

8.0 Process Map for the IRB Application Process



9.0 Common Comments Found in IRB Reviews

Taking a close look at each of these phrases can be useful as you prepare to submit your IRB Application and could help you have a successful review by avoiding common pitfalls:

"The 'age of majority' varies across individual states. The researcher should revise to require participants to have reached the ""age of majority"" in their domiciled state. Using the minimum age of 21 will cover the 'age of majority' in all states."

"The IRB's preference would be for the researcher to secure permission to use the 'Permission to Use or Modify and Existing Instrument' form for instruments. The IRB understands that this may not be possible, but if possible, the preference would be for a completed 'Permission to Use or Modify and Existing Instrument' form for each instrument."

"The following is awkward. The researcher should review and revise."

"The researcher will need to submit the required CITI Course Completion Report and ensure 1) the completion reports are valid through the end of the study 2) are associated with the University of the Rockies, and 3) at least the minimum score for each course is obtained."

"The researcher should determine whether there is the possibility for coercion in the selection of participants."

"The researcher should provide information regarding his/her relationship with the company and any potential participants."

"The researcher should provide information about the data analysis plan beyond the limited information already provided."

"The researcher should revise the consent form to inform participants that the doctoral project chair and/or IRB may access the data."

"The researcher should provide a literature based context in which to place the proposed study so that the IRB can better assess the benefits and risks of the study relative to the literature. Additionally, the researcher should provide the most relevant references in support of the research."

"It is not clear if the participants' responses will be audio or audio/video recorded. The researcher should include a specific statement and check off box on the *Informed Consent Form* for the participant to indicate that they agree to the recording of their responses."

"The researcher should include a specific statement and check off box on the *Informed Consent Form* for the participant to indicate that they agree to the recording of their responses."

“The researcher should inform participants they have a right to refuse to answer any question, for any reason, and without penalty for doing so.”

"The researcher should inform participants they have a right to withdraw from the study at any time, for any reason, and without penalty for doing so."

“The researcher must provide the participant some indication of benefits and risks of participation. There are always risks though they may not exceed those found in everyday life.”

“The researcher will need to obtain permission to solicit participants online from the founder, administrator, or organization responsible for the site, utilizing the UoR *Organizational Permission Form*. If the End User License Agreement (EULA) of the sites allows for such solicitations, the researcher can submit the EULA and highlight where such solicitations are permitted."

“The researcher should review the requirements for anonymous/anonymity. The current study does not fit the requirement given the researcher will know the identity of the participant.”

"The researcher should indicate who will be transcribing the data utilizing the UoR *Non-Disclosure Form*. If not the researcher, the researcher should address how confidentiality will be maintained. Also, the information regarding transcription should be provided to the participant as part of the informed consent. Please see the *Non-Disclosure Form*."

"The IRB notes that another IRB is requesting UoR IRB approval before they will approve the study. In situations like this, the UoR IRB will conditionally approve the study with the only condition being that the researcher secures permission from the other IRB. The researcher will then secure permission from the other IRB and submit it to the UoR IRB which will then issue a full approval. The researcher can share that full approval with the other IRB if they desire to have a copy of the full approval."

“The researcher should review the *Sample Informed Consent Form* to guide the necessary revisions to the one submitted. The revised consent form should address the issues below as well as to present a detailed and clearly worded consent form that participants can unambiguously understand.”

“The researcher should reflect upon using social media accounts directly linked to friends or direct professional associates as they may result in an unintended level of coercion. The researcher should review and revise.”

“The researcher will need to obtain permission (see *Organizational Permission Form* below) from the location(s) in which the **physical** face-to-face interviews will be conducted. The researcher may want to consider some type of **electronically-mediated (e.g., Skype; Facetime, etc.)** face-to-face interview thereby avoiding the need to seek permission from each location(s).”

Another good source to consider when preparing your IRB Application is "The Top 10 Ways to Persuade an Institutional Review Board to Reject Your Research Proposal" from David Lopatto and Ann Ellis from Grinnell College. It can be found at the link below:

http://www.cur.org/assets/1/7/spring10lopatto.pdf

10.0 IRB 101- Items every Student should know

1) The Institutional Review Board (IRB) ensures that any doctoral project design protects human participants. **All doctoral studies MUST be approved by the IRB before any data is collected for the study and/or any participants recruited for the study**.
2) Before designing a doctoral study, students should be familiar with the *IRB Handbook*, and particularly what types of studies are acceptable in relation to protecting human participants. Part of planning a study is to choose a topic, design, and set of participants that meets the ethical principles as set by the IRB Handbook.
    a. Research that involves protected classes is discouraged as IRB approval may take many months in order to set up appropriate safeguards. Protected classes would be: minor children (usually below age of 18); prisoners; people with mental disabilities; or others that may not be free or capable of giving consent to participant in the study.
    b. Research where risk outweighs benefits may be disapproved or deferred. Students should make sure that their study has documented benefits and that risks to participants are minimal.
    c. Informed Consent must be obtained from all participants in the study. Make sure your study design includes ways to recruit participants that does not involve perceived or actual coercion. One example of coercion could include the following: an instructor telling prospective participants in a class that they will lose grade points if they do not participate in the research.
    d. In addition to Informed Consent, any organization from which participants are recruited must give permission for that recruitment, including social media. An example of using social media would be the use of a LinkedIn Group for potential participants for your doctoral study. Make sure that you can get permission from organizations using the *Organizational Permission Form*.
    e. Additional permission from organizations must be obtained for:
        i. Permission to collect data through that organization or from participants associated with that organization;
        ii. Permission to use organizational name; and
        iii. Permission to access organizational data and/or documents not in the public domain.
3) All researchers (termed Principal Investigators, or PIs) must have a current CITI certificate before and throughout the study. Obtain the CITI certificate by taking the trainings associated with University of the Rockies at www.citiprogram.org. Students will usually take the trainings during their Dissertation Planning II/ADP Planning II course.
4) IRB submission occurs after the student has passed their Preliminary Oral Defense, and their Chair has submitted the *Oral Review Evaluation* form.
5) There are three categories of review that the IRB considers:
    a. Exempt-- Does not involve human participants; will not require a review, but must still be submitted to the IRB;

b. Expedited Review– Most research that involves interviews, observations, and/or focus groups; and
c. Full Review -- Involves participants who are part of a protected class or involves risk to participants that may override the benefit.

There is one form for submission to the IRB that covers all three categories of review. The IRB will determine the category of review and communicate that back to the applicant within seven (7) working days.

6) IRB Submission starts with the *Request for IRB Review* form and should always include a *Research Summary* that follows the prescribed outline, and a copy of the principal investigator's CITI completion report (see section 4.2). Other supporting documentation may include: a signed *Organizational Permission Form* for permission to access participants or data, or use the premises; a signed *Permission to Use of Modify an Existing Instrument* form; an unsigned sample *Informed Consent Form*; an unsigned sample *Assent Form*; and all data collecting instruments (such as a survey, or an interview script). The format for submission of these documents is specified in *Instructions for IRB Application*.
7) If it is necessary to change your study design after IRB approval, submit a *Report of Change* form (see section 5.8).
8) If your data collection exceeds the expiration date on the IRB Approval letter (one year), you will need to submit a *Request for Renewal* form (see section 5.7).
9) You will be asked to complete the *IRB Close-Out Form* after completion of your overall study.

11.0 Forms and Other Helpful Tools

The following forms and templates can be found in the Rockies Research Center.

Request for IRB Review – form for principal investigator to submit to the Institutional Review Board (IRB) that covers all three categories of review (see section 5.0).

Research Summary – document intended to provide guidance to the principal investigator for the completion of the Research Summary to be included with the *Request for IRB Review* form.

Research Summary Exemplar – PDF document that offers specific information necessary to help principal investigator successfully complete the Research Summary required for the IRB application.

Research Summary Template – Word document that serves as a template and guide to help the principal investigator format the Research Summary required to complete the IRB application.

Request for Renewal – form for the principal investigator to submit to secure continuing approval of protocols requiring IRB review (see section 5.7).

Report of Change – form for principal investigators to submit for any modifications of previously approved research by the IRB (see section 5.8).

Sample HIPAA Authorization Form A: Enrollment into Research – sample document for principal investigators to use when project involves gaining consent for a study involving participants and their protected health information (HIPAA).

Waiver of HIPAA Authorization – document for principal investigators to use to provide protocol-specific responses to specific items describing why a waiver is being requested for a study involving participants and their protected health information (HIPAA).

Sample: Authorization to Release Health Information – sample form to send to participants to sign to authorize a third party to release protected health information (HIPAA).

Sample: Informed Consent Form – sample document intended for principal investigators to use to create an informed consent form tailored to their own specific research project.

Sample: Parent/Legal Guardian Informed Consent Form – sample document intended for principal investigators to use to create a Parent/Legal Guardian Consent Form for parents and/or legal guardians to give permission for their child to participate in a research study.

Sample: Assent Form – sample document intended for principal investigators to use to create a document for gaining legally valid informed consent from an individual not competent to participate in research (e.g., a child or cognitively impaired person).

Organizational Permission Form – form that principal investigators can use to obtain permission from a specific organization giving permission to conduct research at their facility and/or with their employees.

Permission to Use or Modify an Existing Instrument – form that principal investigators can use to obtain permission for a specific instrument from the author to use or modify their instrument for their research study (see section 6.5).

Non-Disclosure Form – Form intended for principal investigators to send to, and receive back signed, others who may see raw data and/or explicit or implicit participant identifying information (see section 6.6). The non-disclosure agreement protects the confidentiality of any participant in the study.

IRB Close-Out Form – document that is required to be completed by the principal investigator when all data collection has ended.

IRB Change Matrix – a change matrix is required with every IRB resubmission. The principal investigator fills out the Change Matrix to indicate what has been changed in response to issues with the prior submission. Re-submissions will not be accepted without a completed change matrix and a signed *IRB Change Matrix Chair Authorization Form* (see section 5.6.1).

IRB Change Matrix Chair Authorization Form – to be signed by the doctoral research chair and included as one of the documents in an IRB resubmission. By signing this document, the chair signifies that he/she carefully reviewed the *Change Matrix* and the changed documents, and that they adequately address the previously noted issues: (see section 5.6.1).

Instructions for IRB Application – details the format of documents for inclusion with a *Request for IRB Review* form (see section 6.0) or for a resubmission (see section 5.6.1).