# Institutional Review Board (IRB)

# Handbook

# 2014-2015

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## 1.0 Introduction

The University of the Rockies (UoR) Institutional Review Board (IRB) Handbook is designed to help students who are seeking approval of their dissertation proposal to understand the IRB portion of the process. The IRB is responsible for protection of human subjects involved in research. The IRB may also be used by faculty hoping to conduct a research study while affiliated with UoR. Definitions related to the IRB process are provided in Appendix A. All investigators and dissertation chairs are encouraged to consult the Chair of the IRB Committee about any questions. This IRB Handbook is designed to be used in conjunction with the Dissertation Handbook. Students should refer to the Dissertation Handbook for information about the entire dissertation process. Throughout this IRB Handbook, there are numerous references to contacting the IRB Chair or making a submission to the IRB Chair. To facilitate interactions with the IRB Chair, online dissertation students can email dissertation.online@rockies.edu and Colorado Springs campus and Denver Instructional Site students can email dissertation.ground@rockies.edu. Others interested in contacting the IRB Chair can email irb@rockies.edu.

## 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 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). 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.

Additional information on acceptable types of research is outlined in the following *University of the Rockies Academic Catalog* policy on *Academic Integrity Violations*. To see the full policy in context, please see the *Student Rights and Responsibilities* section of the *Academic Catalog*.

## 2.1 Academic Integrity Violations

Academic dishonesty can take a number of forms. It includes, but is not limited to, cheating on a test or examination, claiming the work of another as one's own, plagiarizing any paper, research project, or assignment, or falsely submitting material to fulfill course requirements.

***Unapproved Research***

Unapproved research is any research that is undertaken without approval by the university or the Institutional Review Board (IRB), including any solicitation of or interaction with human subjects or accessing any data. In the case of dissertation research, unapproved dissertation research is any research that is started before officially enrolling in dissertation course work, any research for which the Research Review Board (RRB) has not approved the dissertation proposal, and for which the Institutional Review Board has not approved the IRB request. Conducting dissertation research without RRB/IRB approval is an Academic Integrity violation and could result in sanctions.

# 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 subjects and collection of any data, including a pilot study. For the purposes of students completing a dissertation, the IRB must approve ***every*** dissertation 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 subjects' protection, which can be accessed electronically at https://www.citiprogram.org/default.asp. The CITI training is a very intensive and time-consuming process. Students are cautioned to begin and complete this training in a timely manner. A Completion Certificate, obtained at the conclusion of this training, must be included in the Request for Exemption, Expedited, or Full review (see Appendix B, Appendix C, or Appendix D). The CITI certification, which is valid for 2 years, must be in force

throughout the data collection and analysis process. **Faculty must have an active CITI Certificate on file. The requirement is the same for all investigators – faculty, staff, or student (or external research partners) and dissertation chairs.**

The following modules are required for all investigators (faculty, staff, students) and dissertation chairs:

- Social & Behavioral Research Investigators Basic/Refresher Course
- Health Information Privacy and Security (HIPS) Course – Information for Students or Investigators
- Social and Behavioral Responsible Conduct of Research Course

Each module must be completed with a passing score of 90% or higher.

## 4.3 Meeting Dates

Full IRB meetings are held once a month during the year. ***Requests for exemptions, expedited reviews, and resubmissions may be handled more often.*** The Chair of the IRB 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 exemptions, expedited 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) Old and new business related to IRB functioning.
c) Review and discussion of, and action on, new IRB requests (in order of submission).
d) Review and discussion of, and action (if needed), on exempted or expedited requests.
e) Review and discussion of, and action, on continuing requests.
f) Review and discussion of, and action, on substantive changes to previously approved IRB requests.
g) Other business.

**Actions** IRB requests shall be approved, approved with revisions, disapproved, or tabled until a specified 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, 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.

**CONFLICT OF INTEREST** IRB members, and anyone speaking or submitting written comments, must declare any potential conflict(s) of interest 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 Chair of the IRB 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, master's, and dissertation students, must submit the appropriate Request for Review (Exempt, Expedited, or Full) to the IRB regardless of whether human subjects are used in the study. Students who have passed the Preliminary Oral Defense should submit the appropriate Request for Review with supporting documentation to the Chair of the IRB through the Dissertation Administrator (DA) at dissertation.online@rockies.edu (online) or dissertation.ground@rockies.edu (Colorado Springs campus and Denver Instructional Site students). For most efficient consideration, submissions should be made by the 15th of the month.

All requests to conduct research involving human participants must be submitted to the UoR IRB. Requests from individuals other than dissertation 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 subjects or data access or collection may occur prior to IRB approval.***

The three different kinds of IRB requests depend on the nature of the student's dissertation methodology (e.g., original research, archival research, etc.). Investigators may request that research be reviewed using one of the three processes: Exempt, Expedited, or Full; however, any IRB member may request that research be reviewed at a more extensive level than requested by the investigator.

***Important note: The investigator (and the student's master's advisor or dissertation chair) should review the criteria for Exempt, Expedited, and/or Full review carefully to determine which Request for Review to submit. If the study meets Exempt criteria, the Request for Exempt Review should be submitted. If the study does not meet Exempt criteria, then the study should be evaluated as to whether Expedited criteria are met. If Expedited criteria are not met, then the investigator should submit the Request for Full Review. Request for Full Review should only be submitted when the study does not meet the criteria for Exempt or Expedited Review. Any research with protected classes or vulnerable subjects falls under Full IRB Review. If you are unsure of which request to submit, you (or your dissertation chair) should consult with the Chair of the IRB Committee to ensure the proper request is submitted.***

## 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. ***Do not proceed with the research until you have received written IRB approval. Absolutely no solicitation of human subjects or data collection is allowed prior to receipt of IRB approval, including pilot studies.***

Action on Exempt research is generally taken within five (5) to seven (7) days of receipt by the IRB Chair. Incomplete requests will be deferred. For research in this category, investigators must submit to the IRB Chair (through the Dissertation Administrator) one copy of the following:

1. A completed Request for Exemption (Appendix B), including a narrative response to all open-ended questions on the Request Form;
2. A Research Summary (Appendix E), the thesis or dissertation proposal should NOT be submitted;
3. Informed consent document(s), if applicable (Appendices L & M);
4. Copies of any survey or assessment instruments or interview/focus group/observational protocols; and

5. All other relevant materials: copies of any communications to be used to solicit subjects; organizational permission form(s) to access subjects, data, or use premises; permission to use or modify instrument form(s) for instruments not in the public domain; and non-disclosure agreements, if applicable (Appendices N, O, & P). Note: permission is not necessary to use without modification instruments that are available for purchase. The student should provide information documenting the availability of any instruments available for purchase, such as copies of a purchase estimate or receipt.

Research qualifies as Exempt if it falls in one of the following six categories (note that not all types of research described below are 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 US Department of Agriculture.

## 5.2 Criteria for Expedited Review

Research with minors (children aged 17 years and under) may not be reviewed under the Expedited category. 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 18 years of age or older 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 18 years of age 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.

For research in the Expedited review category, submit to the IRB Chair (through the Dissertation Administrator) one copy of the following:

1. A completed Request for Expedited Review form (Appendix C), including a narrative response to all open-ended questions on the Request Form;
2. A Research Summary (Appendix E), the thesis or dissertation proposal should NOT be submitted;
3. Informed consent document(s) (Appendices L & M);
4. Copies of any survey or assessment instruments or interview/focus group/observational protocols ; and
5. All other relevant materials: copies of any communications to be used to solicit subjects; organizational permission form(s) to access subjects, data, or use premises; permission to use or modify instrument

form(s) for instruments not in the public domain; and non-disclosure agreements, if applicable (Appendices N, O, & P). Note: permission is not necessary to use without modification instruments that are available for purchase. The student should provide information documenting the availability of any instruments available for purchase, such as copies of a purchase estimate or receipt.

A request for 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 deferred. ***Do not proceed with the research until you have received written IRB approval.***

## 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 definitions in Appendix A).

* See Appendix A for definition of "vulnerable human participants."

For research in the Full Review category, submit the following to the IRB Chair (through the Dissertation Administrator):

1. A completed Request for Full Review form (Appendix D), including a narrative response to all open-ended questions on the Request Form;
2. A Research Summary (Appendix E), the thesis or dissertation proposal should NOT be submitted.
3. Informed consent document(s) (Appendices L & M);
4. Copies of any survey or assessment instruments or interview/focus group/observational protocols ; and
5. All other relevant materials: copies of any communications to be used to solicit subjects; organizational permission form(s) to access subjects, data, or use premises; permission to use or modify instrument form(s); and non-disclosure agreements, if applicable (Appendices N, O, & P). Note: permission is not necessary to use without modification instruments that are available for purchase. The student should provide information documenting the availability of any instruments available for purchase, such as copies of a purchase estimate or receipt.

Incomplete requests will be deferred. 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, submit a draft of all forms and materials by the 15th of the month. ***Do not proceed with the research until you have received written IRB approval.***

## 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 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 Review 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 Chair of the IRB Committee.

Following a Full Board Review, the IRB will make one of the following decisions regarding the proposal: "approved," "approved with specific changes," or "disapproved," in which case suggestions for major revisions will be given to the researcher. If the request is approved with specific changes, the researcher may not proceed with the research until documentation of the requested changes is reviewed and approved by the IRB.

## 5.6 Actions by the IRB

The principal investigator may proceed with the research study only after written notification of approval from the IRB. IRB requests that are approved subject to revisions necessitate that revisions and/or clarification be submitted in writing to the IRB Chair. The IRB may give the Chair authority to act on revisions, depending on their extent; this information will be included in the IRB decision. ***The investigator must wait for written notification of approval after revisions are made before proceeding with solicitation of subjects and data collection.***

Incomplete Requests are requests that are missing the Research Summary, current CITI certificates, or other instrumentation and/or documentation pertinent to the proposed research. These will be deferred, resulting in the need to revise and resubmit the IRB Request.

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 Exempt, Expedited, or Full 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.

## 5.7 Continuing Review

Federal regulations require reevaluation 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 (Appendix F) to the IRB Chair. 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. Please provide all information requested on the form; incomplete requests will be deferred. If an investigator has failed 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, IRB has the authority to observe or have a third party observe the consent process and the research process for a given study. These individuals are required to comply with confidentiality standards governing the ongoing research.

### 5.8 Changes to Approved Research

Minor changes in previously approved research that do not increase risk to participants during the period for which the research is approved or involve a change in the population or its source do not need to be submitted for additional IRB approval. Any changes that affect the risks to participants or involve a new population or source 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 (Appendix G). Incomplete requests will be deferred.

## 6.0 Data Collection

Note: This section is only applicable for those studies in which data will be collected. Solicitation of human subjects 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 studies, whether submitted for Exempt, Expedited, or Full review. 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 up to 17 years (unless emancipated) will be participating, informed consent must be obtained from their parents or legal guardians (Appendix L). Informed assent must be obtained from minor participants if they are between ages seven (7) and 17 (Appendix M). 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 six (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 subjects or collection of any data, including pilot tests. The informed consent and/or assent document must contain the following elements:

1. Identification of investigator's name, School within the institution, institution, status, mailing address, and telephone number. If the researcher is a student, the name, address, and telephone number of the Dissertation 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 dissertation.
       Note: Transcripts of interviews or observations and raw responses to survey questions are raw data and should not be appended to the dissertation.
    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.
    6. If protected health information is to be collected or transferred, including all required elements for an authorization (see IRB Policy for HIPAA Compliance).
7. 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

name and telephone number of the IRB Chairperson 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 subjects' financial standing, employability, or reputation. In this case, subjects 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 subjects protections and legislation in the host country. The investigator is responsible for providing information to the IRB about human subjects 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 under the age of 18; 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 subjects 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 agreement.
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.

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 can be found in Appendix H: 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.

**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 (Appendix I). 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 (Appendix J: Sample HIPAA Authorization Form B: Research Recruitment). Alternatively, the care-providing physician can give the patient the contact information about the study.

# APPENDIX A: DEFINITIONS RELATED TO THE IRB PROCESS

**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.

**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 subject 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.

**Exempt Review:** Research in this category 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.

**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.

**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, this is not the Dissertation 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.

UNIVERSITY of the ROCKIES

# Institutional Review Board Handbook
# Appendix B: Request for Exemption

Revised 10/10/12

Use this form to request a protocol you believe to be exempt in accordance with federal regulations and highlighted in the IRB Policies and Procedures. Only the IRB Chair or designee may determine if a protocol is exempt. In the case of exemption, need for HIPAA authorization or waiver may still apply.

## A. Principal Investigator (PI) Information:

First Name: _____ Last Name: _____

Check one: ☐ Faculty/Staff ☐ Graduate Student *

Mailing Address: _____

Phone: _____ Fax: _____ E-mail address: _____

## B. Dissertation Chair Information (* Required for Students)

First Name: _____ Last Name: _____

Phone: _____ E-mail address: _____

## C. Dissertation Title

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| |

**D. Proposed Starting and Ending Dates**: _____ to _____
(Please identify a 1-year period. Please use the following format: MM/DD/YYYY)

**E. Which Human Subjects online training have you completed?** ☐ HHS ☐ CITI
(Please attach Completion Certificate, which should be in force throughout the data collection period).

**F. CONFLICTS OF INTEREST** shall be considered to include:

- Stock (holdings or options) in a sponsoring organization;
- Director, advisor, or consultant to the sponsoring organization; or
- Other vested interests such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested.

1. Does the PI or any Co-PIs have an actual, potential, or perceived conflict of interest as included above?
   ☐ Yes ☐ No

   If YES, please list: _____

2. Has this project been submitted to any other IRB? ☐ Yes ☐ No
   If YES, describe the IRB and action taken on your proposal:

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3. Is this project currently sponsored? ☐ Yes ☐ No
   If YES, describe the source:

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**G. The following questions will help the IRB to determine whether or not your project will be exempt from IRB review:**

1. Will existing or archived data, documents, records, or biological specimens be used? (Existing is defined as data which have been collected for purposes other than the proposed research and is on the shelf at the time of this application).
   ☐ Yes (Please answer 1a. and 1b.) ☐ No (Please proceed to #2)
   a. Is the source publicly available? ☐ No ☐ Yes (describe where or provide URL of website)
   b. Is the information recorded in such a manner that subjects can be identified, directly or through identifying links?
      ☐Yes ☐ No (If YES, your research does not qualify for exemption)

2. Will surveys/interviews/tests/observations of public behavior be used? ☐ Yes ☐ No (If no, please proceed to #3)
   a. Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? ☐ Yes ☐ No
      i. Will subjects be videotaped? ☐ Yes ☐ No
   b. Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation? ☐ Yes ☐ No

IF YOU ANSWERED "YES" TO BOTH 2a AND 2b, THEN YOUR RESEARCH DOES NOT QUALIFY FOR EXEMPTION.

IF YOU ANSWERED ONLY ONE AS "YES" (OR BOTH AS "NO"), THEN ANSWER 2c, 2d, 2e, AND 2f.

   c. Will any of your subjects be under the age of 18? ☐ Yes ☐ No
   d. Is the research an observation of public behavior? ☐ Yes ☐ No
   e. Will you participate in the activities being observed? ☐ Yes ☐ No
   f. Does your research involve members of any protected classes? ☐ Yes ☐ No

IF YOU ANSWERED "YES" TO 2c, 2d, AND 2e, THEN YOUR RESEARCH DOES NOT QUALIFY FOR EXEMPTION AND YOU WILL NEED TO COMPLETE THE REQUEST FOR EXPEDITED REVIEW FORM (APPENDIX C).

IF YOU CHECKED 2f, YOU NEED TO COMPLETE THE REQUEST FOR FULL REVIEW FORM (APPENDIX D).

3. Is Protected Health Information (PHI) being collected for this project? ☐ Yes ☐ No

   (If YES, please attach a waiver of HIPAA Authorization (Appendix I). Protected Health Information is defined as "individually identifiable health information that a health care provider, health plan, health care clearinghouse, or employer creates or receives and 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."

4. Select one of the following applicable categories for exemption of this project: _____

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

5. Project Summary: Briefly describe the involvement of human subjects in your research re: what will happen to or with them so that the IRB may evaluate the level of risk.

   a. Will your study involve persons from different cultures or international contexts?
   ☐ Yes ☐ No.
   If yes, briefly describe steps to be taken to ensure cultural responsiveness throughout the research process.

   b. Identify how data will be collected (e.g., Internet or pencil and paper assessment or survey, individual interviews, focus groups, observation with field notes, etc.).

   c. Will an existing instrument be used and/or modified? ☐ Yes ☐ No.

   If yes, please append the signed permission form or proof of purchase of access to the instrument.

   d. Append the Research Summary and copies of all data collection instruments

6. Population: briefly describe the population for the study and how they will be accessed.

   a. Is permission needed to access the population? ☐ Yes ☐ No

   b. If yes, please append the signed permission form (see Appendices)

7. Briefly describe how subjects will be recruited to participate in the study. Append copies of any communications to be used to recruit or solicit participants.

8. Briefly describe how active informed consent will be obtained from subjects prior to collection of any data.

9. Briefly describe how subjects may withdraw from the study should they choose to do so.

10. Attachments: (check all that apply)

- ☐ Research Summary
- ☐ Human Subjects Certificate
- ☐ Permission to Access Subjects or Data
- ☐ Permission to Use or Modify Existing Instrument
- ☐ Subject Solicitation or Recruitment Documents
- ☐ Informed Consent Form
- ☐ Data Collection Instruments
- ☐ Other (identify below):

**SCIENTIFIC MISCONDUCT SHALL BE CONSIDERED TO INCLUDE:**

- Fabrication, falsification, plagiarism, or other unacceptable practices in proposing, carrying out, or reporting results from research.
- Material failure to comply with Federal requirements for the protection of human participants, researchers, and/or the public.
- Failure to meet other material legal requirements governing research.
- Failure to comply with established standards regarding author names on publications.
- Failure to adhere to issues of patient confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46).

**INVESTIGATOR'S CONTINUING RESPONSIBILITY TO IRB**

Once the protocol has been approved, it is the Principal Investigator's (PI) responsibility to:

- Report changes in research activity related to the project;
- Provide the IRB with all protocol and consent form amendments and revisions. IRB must approve these changes prior to their implementation. All advertisements recruiting study participants must also receive prior approval by the IRB;
- Promptly report all adverse and serious adverse events (including death, hospitalization or prolongation of hospitalization, and unanticipated adverse side effects);
- Renew protocols with the IRB prior to expiration. All projects must have a continuing review at least annually to renew the approval for the protocol. Some projects will have the continuing review more frequently as determined in the initial review and approval;
- Notify the IRB if the protocol is complete.

***Failure to comply with these federally mandated responsibilities may result in suspension or termination of the project.***

## Investigator Acknowledgement

I have read the definitions of Scientific Misconduct and listed all potential Conflicts of Interest. I have read the Investigator's Continuing Responsibilities to the IRB. I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB. My signature below attests to my agreement to conduct this research study in such a manner that acts of scientific misconduct and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UoR IRB. I will conduct my study in compliance with the UoR IRB Handbook.

Principal Investigator Signature: _____ Date: _____

## Dissertation Chair Acknowledgement

I acknowledge that the information contained in the protocol is accurate to the best of my knowledge. I verify that I am the Dissertation Chair for this protocol and that I shall be responsible for the oversight of the conduct of the research and adherence to all applicable UoR IRB policies and procedures.

Dissertation Chair Signature: _____ Date: _____

**For office use only:**

IRB #: _____ Date Received: _____

Action: ☐ Approved ☐ Approved with Revision ☐ Disapproved

Signature of IRB Chair: _____ Date: _____

UNIVERSITY of the ROCKIES℠

# Institutional Review Board Handbook
# Appendix C: Request for Expedited Review

Revised 10/10/12

(If you are requesting an Exempt or Full Review, please fill out the appropriate form)

**A. Principal Investigator (PI) Information:**

First Name: _____ Last Name: _____

Check one: ☐ Faculty/Staff ☐ Graduate Student *

Mailing Address: _____

Phone: _____ Fax: _____ E-mail address: _____

**B. Dissertation Chair Information** (* Required for Students)

First Name: _____ Last Name: _____

Phone: _____ E-mail address: _____

**C. Dissertation Title**

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**D. Proposed Starting and Ending Dates**: _____ to _____
(Please identify a 1-year period. Please use the following format: MM/DD/YYYY)

**E. Which Human Subjects online training have you completed?** ☐ HHS ☐ CITI
(Please attach Completion Certificate, which should be in force throughout the data collection period).

**F. Conflicts of interest. Conflicts of interest shall be considered to include:**

- Stock (holdings or options) in a sponsoring organization
- Director, advisor, or consultant to the sponsoring organization
- Other vested interests, such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested.

1. Does the PI or do any Co-PIs have an actual, potential, or perceived conflict of interest as included above?
   ☐ Yes ☐ No

   If yes, please identify which and explain:

**G. Has this project been submitted to any other IRB?** ☐ Yes ☐ No
If YES, identify the other IRB and their action taken on your proposal:

**H. Is this project currently sponsored?** ☐ Yes ☐ No
If YES, describe the source and any potential conflicts:

**I. Will you be collecting or sharing Protected Health Information?** ☐ Yes ☐ No

**J. Will your research involve any of the following protected classes?**
If you answer yes to a, b, c, or d, please submit the Request for Full Review (see Appendix D).

| Category: | Yes | No |
|---|---|---|
| a. Children/minors under age 18 | ☐ | ☐ |
| b. Prisoners | ☐ | ☐ |
| c. Pregnant women | ☐ | ☐ |
| d. Cognitively impaired or mentally disabled | ☐ | ☐ |
| e. Educationally or economically disadvantaged | ☐ | ☐ |

**K. Will your study involve collecting personal or sensitive information that, if disclosed, may place your subjects at personal or professional risk?** ☐ Yes ☐ No
If yes, please submit the Request for Full Review.

**L. Will your study involve the use of deception or concealment?** ☐ Yes ☐ No
If yes, please submit the Request for Full Review.

**M. Research Project**

1. Project Summary: Briefly describe the involvement of human subjects in your research re: what will happen to or with them so that the IRB may evaluate the level of risk.
    a. Will your study involve persons with clinical diagnoses or research in clinical settings?
    ☐ Yes ☐ No
    b. If yes, briefly identify possible consequences, and/or additional stress and consequences of participating in research, and what supports or referrals you will have in place to address them. Elaborate in the Research Summary.
    c. Will your study involve persons from different cultures or international contexts?
    ☐ Yes ☐ No
    d. If yes, briefly describe steps to be taken to ensure cultural responsiveness throughout the research process. Elaborate in the Research Summary.
    e. Identify how data will be collected (e.g., Internet or pencil and paper assessment or survey, individual interviews, focus groups, observation with field notes, etc.).
    f. Will an existing instrument be used and/or modified? ☐ Yes ☐ No
    g. If yes, please append the signed permission form or proof of purchase of access to the instrument.
    h. Append the Research Summary and copies of all data collection instruments
2. Population: briefly describe the population for the study and how they will be accessed.
    a. Is permission needed to access the population? ☐ Yes ☐ No
    b. If yes, please append the signed permission form
3. Briefly describe how subjects will be recruited to participate in the study. Append copies of any communications to be used to recruit or solicit participants.
4. Briefly describe how informed consent be obtained from subjects prior to collection of any data.
5. Briefly describe how subjects may withdraw from the study should they choose to do so.

6. Briefly describe procedures for protecting participants' anonymity and maintaining confidentiality in data collection, storage, and reporting.

7. Attachments: (check all that apply)

   ☐ Research Summary

   ☐ Human Subjects Certificate

   ☐ Permission to Access Subjects or Data

   ☐ Permission to Use or Modify Existing Instrument

   ☐ Subject Solicitation or Recruitment Documents

   ☐ Informed Consent Form

   ☐ Data Collection Instruments

   ☐ Other (identify below):

**SCIENTIFIC MISCONDUCT SHALL BE CONSIDERED TO INCLUDE:**

- Fabrication, falsification, plagiarism, or other unacceptable practices in proposing, carrying out, or reporting results from research.
- Material failure to comply with Federal requirements for the protection of human participants, researchers, and/or the public.
- Failure to meet other material legal requirements governing research.
- Failure to comply with established standards regarding author names on publications.
- Failure to adhere to issues of patient confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46).

**INVESTIGATOR'S CONTINUING RESPONSIBILITY TO IRB**

- Once the protocol has been approved, it is the Principal Investigator's (PI) responsibility to:
- Report changes in research activity related to the project;
- Provide the IRB with all protocol and consent form amendments and revisions. IRB must approve these changes prior to their implementation. All advertisements recruiting study participants must also receive prior approval by the IRB;
- Promptly report all adverse and serious adverse events (including death, hospitalization or prolongation of hospitalization, and unanticipated adverse side effects);
- Renew protocols with the IRB prior to expiration. All projects must have a continuing review at least annually to renew the approval for the protocol. Some projects will have the continuing review more frequently as determined in the initial review and approval; and
- Notify the IRB if the protocol is complete.

***Failure to comply with these federally mandated responsibilities may result in suspension or termination of the project.***

## Investigator Acknowledgement

I have read the definitions of Scientific Misconduct and listed all potential Conflicts of Interest. I have read the Investigator's Continuing Responsibilities to the IRB. I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB. My signature below attests to my agreement to conduct this research study in such a manner that acts of scientific misconduct and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UoR IRB. I will conduct my study in compliance with the UoR IRB Handbook.

Principal Investigator Signature: _____ Date: _____

## Dissertation Chair Acknowledgement

I acknowledge that the information contained in the protocol is accurate to the best of my knowledge. I verify that I am the Dissertation Chair for this protocol and that I shall be responsible for the oversight of the conduct of the research and adherence to all applicable UoR IRB policies and procedures.

Dissertation Chair Signature: _____ Date: _____

**For office use only:**

IRB #: _____ Date Received: _____

Action: ☐ Approved ☐ Approved with Revision ☐ Disapproved

Signature of IRB Chair: _____ Date: _____

UNIVERSITY of the ROCKIES

# Institutional Review Board Handbook
# Appendix D: Request for Full Review

Revised 10/15/12

(If you are requesting an Exempt or Expedited Review, fill out the appropriate form)

**A. Principal Investigator (PI) Information:**

First Name: _____ Last Name: _____

Check one: ☐ Faculty/Staff ☐ Graduate Student *

Mailing Address: _____

Phone: _____ Fax: _____ E-mail address: _____

**B. Dissertation Chair Information (* Required for Students)**

First Name: _____ Last Name: _____

Phone: _____ E-mail address: _____

**C. Dissertation Title:**

| |
|---|
| |

**D. Proposed Starting and Ending Dates:** _____ to _____
(Please identify a 1-year period. Please use the following format: MM/DD/YYYY)

**E. Which Human Subjects online training have you completed?** ☐ HHS ☐ CITI
(Please attach Completion Certificate, which should be in force throughout the data collection period).

**F. Conflicts of interest. Conflicts of interest shall be considered to include:**

- Stock (holdings or options) in a sponsoring organization
- Director, advisor, or consultant to the sponsoring organization
- Other vested interests, such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested.

1. Does the PI or do any Co-PIs have an actual, potential, or perceived conflict of interest as included above?
   ☐ Yes ☐ No

   If YES, please identify which and explain: _____

**G. Has this project been submitted to any other IRB?** ☐ Yes ☐ No

If YES, identify the other IRB and their action taken on your proposal:

**H. Is this project currently sponsored?** ☐ Yes ☐ No

If YES, describe the source and any potential conflicts: _____

**I. Will you be collecting or sharing Protected Health Information?** ☐ Yes ☐ No

**J. Will your research involve any of the following protected classes?**

| Category: | Yes | No |
|---|---|---|
| a. Children/minors under age 18 | ☐ | ☐ |
| b. Prisoners | ☐ | ☐ |
| c. Pregnant women | ☐ | ☐ |
| d. Cognitively impaired or mentally disabled | ☐ | ☐ |
| e. Educationally or economically disadvantaged | ☐ | ☐ |

If you checked YES to any protected classes, briefly justify the appropriateness of conducting research on this population and what additional protections will be in place to mitigate risks.
Elaborate in the Research Summary.

**K. Will your study involve collecting personal or sensitive information that, if disclosed, may place your subjects at personal or professional risk?** ☐ Yes ☐ No

If YES, briefly describe and justify the risk and describe protections to be put in place to minimize this risk. Elaborate in the Research Summary.

**L. Will deception or concealment be used?** ☐ Yes ☐ No

If YES, briefly describe and justify its use. Elaborate in the Research Summary.

**M. Will your study involve persons with clinical diagnoses or research in clinical settings?** ☐ Yes ☐ No
If YES, briefly discuss possible consequences; and/or additional stress and consequences of participating in research, and what supports or referrals you will have in place to address them. Elaborate in the Research Summary.

**N. Will your study involve persons from different cultures or international contexts?** ☐ Yes ☐ No
If YES, briefly describe steps taken to ensure cultural responsiveness. Elaborate in the Research Summary.

**O. Research Project**

1. Project Summary: Please describe the involvement of human subjects in your research re: what will happen to or with them so that the IRB may evaluate the level of risk.
   a. Identify how data will be collected (e.g., Internet or pencil and paper assessment or survey, individual interviews, focus groups, observation with field notes, etc.).

   b. Will an existing instrument be used and/or modified? ☐ Yes ☐ No
      If yes, please append the signed permission form or proof of purchase of access to the instrument.

   c. Append the Research Summary and copies of all data collection instruments

2. Population: briefly describe the population for the study and how they will be accessed.

   a. Is permission needed to access the population? ☐ Yes ☐ No

   b. If yes, please append the signed permission form

3. Describe how subjects will be recruited to participate in the study. Append copies of any communications to be used to recruit or solicit participants.

4. Describe how informed consent be obtained from subjects prior to collection of any data. If the subjects will be minors or other persons who are not legally able to provide informed consent, please identify who will consent on their behalf and the assent process, if applicable.

5. Describe how subjects may withdraw from the study should they choose to do so.

6. Describe procedures for protecting participants' anonymity and maintaining confidentiality in data collection, storage, and reporting.

7. Attachments: (check all that apply)

   ☐ Research Summary

   ☐ Human Subjects Certificate

   ☐ Permission to Access Subjects or Data

   ☐ Permission to Use or Modify Existing Instrument

   ☐ Subject Solicitation or Recruitment Documents

   ☐ Informed Consent Form

   ☐ Informed Assent Form (if applicable)

   ☐ Data Collection Instruments

   ☐ Other (identify below):

## SCIENTIFIC MISCONDUCT SHALL BE CONSIDERED TO INCLUDE:

- Fabrication, falsification, plagiarism, or other unacceptable practices in proposing, carrying out, or reporting results from research.
- Material failure to comply with Federal requirements for the protection of human participants, researchers, and/or the public .
- Failure to meet other material legal requirements governing research.
- Failure to comply with established standards regarding author names on publications
- Failure to adhere to issues of patient confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46).

## INVESTIGATOR'S CONTINUING RESPONSIBILITY TO IRB

Once the protocol has been approved, it is the Principal Investigator's (PI) responsibility to:

- Report changes in research activity related to the project;
- Provide the IRB with all protocol and consent form amendments and revisions. IRB must approve these changes prior to their implementation. All advertisements recruiting study participants must also receive prior approval by the IRB;
- Promptly report all adverse and serious adverse events (including death, hospitalization or prolongation of hospitalization, and unanticipated adverse side effects);
- Renew protocols with the IRB prior to expiration. All projects must have a continuing review at least annually to renew the approval for the protocol. Some projects will have the continuing review more frequently as determined in the initial review and approval;
- Notify the IRB if the protocol is complete.

***Failure to comply with these federally mandated responsibilities may result in suspension or termination of the project.***

## Investigator Acknowledgement

I have read the definitions of Scientific Misconduct and listed all potential Conflicts of Interest. I have read the Investigator's Continuing Responsibilities to the IRB. I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB. My signature below attests to my agreement to conduct this research study in such a manner that acts of scientific misconduct and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UoR IRB. I will conduct my study in compliance with the UoR IRB Handbook.

Principal Investigator Signature: _____ Date: _____

## Dissertation Chair Acknowledgement

I acknowledge that the information contained in the protocol is accurate to the best of my knowledge. I verify that I am the Dissertation Chair for this protocol and that I shall be responsible for the oversight of the conduct of the research and adherence to all applicable UoR IRB policies and procedures.

Principal Investigator Signature: _____ Date: _____

**For office use only:**

IRB #: _____ Date Received: _____

Action: ☐ Approved ☐ Approved with Revision ☐ Disapproved

Signature of IRB Chair: _____ Date: _____

# APPENDIX E: RESEARCH SUMMARY

**Instructions:** Please follow this numbered outline by specifically addressing 1-9 when preparing the Research Summary. Remember to use layperson terms and if a section does not apply, simply state this. When complete, this Research Summary should be attached to the appropriate Request for IRB Review form (see Appendix B, C, or D).

**1. Purpose/Significance**

Briefly describe the proposed study, including its purpose and the research question. Please minimize technical language not readily understood by persons outside your discipline.

Criteria for IRB approval: The proposal is clear as to what the researcher wishes to accomplish. It is clear why the purpose is important enough to warrant participation of human subjects.

**2. Methodology**

Describe the research design and procedures to be used. It is clear what the participant will encounter: when, where, and how long. The proposal describes the population to be studied (including sample size), how the population is to be approached, and what subjects will experience. Investigatory tools (surveys, questionnaires, etc.) are appended to the proposal.

Criteria for IRB approval: Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, AND, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. All necessary permissions to access the population or data, recruit subjects, or use or modify existing instruments are documented using required forms.

Cultural and linguistic considerations re: must also be addressed when selecting, modifying, or creating instrumentation. If a given instrument is not normed for the population of interest, then the methodology should include a plan to examine the instrument's appropriateness for the population via face validation in a pilot study following IRB approval.

**3. Risks/Benefits**

a. Describe all risks (physical, mental, emotional, and legal) to the subjects. If deception is to be used, describe what the deception will be and why it is necessary in order to conduct the research. The researcher must include a process for debriefing the participants no later than the conclusion of the research study. Describe safeguards (e.g., medical consultation, counseling, etc.) that will be taken to reduce risks.

b. Describe all benefits to the subjects, whether direct or indirect.

c. Describe how the risks are reasonable in relation to anticipated benefits.

Criteria for IRB approval: Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying

knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Examples of research that may potentially involve more than minimal risk (mental or physical) include:

- Surveys or questionnaires that solicit information regarding personal or sensitive aspects of the subjects' behavior, including sexual practices, instances of child or sexual abuse suffered by the subject, criminal activities, drug and alcohol use, or studies of eating disorders.
- Stress testing, drug and alcohol use by the subjects for research purposes, and studies where subjects are asked to do more than moderate physical exercise that could result in injury to the subject.
- Use of concealment or deception.

Examples of Mistakes:

a. Risks involved in the procedure are not mentioned in the proposal. For instance, if the following risks are involved in the course of research, they must be explicitly mentioned:
    - Sensitive questions which may cause discomfort;
    - Expenses incurred by subjects;
    - Possible injury to subject;
    - Questions about illegal activities;
    - Questions/situations which may uncover suspected child abuse which would then be reported; or
    - Retaliation which may occur when results of study become public.

b. Risks are understated or benefits (if any) are overstated, coercive, or excessive. For instance, a researcher describes subjects as greatly benefited by knowing they have contributed generally to scientific knowledge.

c. Risks are not reasonable in relation to the expected benefits. For instance, by answering questions, participants risk prosecution by law enforcement officials.

d. Steps that could be taken to minimize risks are not taken. For instance, a researcher does not provide referral to a psychologist when very disturbing reactions to questionnaires or interviews may occur.

e. Proposal involves risk or benefit which accrues unfairly. For instance, when a proposal offers a treatment (benefit) to participants in the study, the narrowing of the population of the study to exclude some particular group must be justified (such as, women or ethnic groups).

f. Concealment or deception is proposed but the use is not justified adequately or is not appropriate or necessary

g. Deception is used but debriefing is not proposed or the process of debriefing is not described adequately.

**4. Subject Recruitment**

Describe how subjects will be recruited, selected, and, if part of the design, placed into groups.

Criteria for IRB approval: Selection of subjects is equitable. Equity requires that no group or class of persons should bear more than its fair share of the burdens of participation in research. Similarly, no group should be deprived of its fair share of the benefits of research, short-term or long-term; such benefits include the direct benefits of participation, as well as, the benefits of new knowledge that the research is designed to yield. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons.

**5. Individual Informed Consent**

Describe how informed consent will be obtained from each subject or the subject's legally authorized representative.

Criteria for IRB approval: Informed consent will be sought from each prospective subject or the subject's legally authorized representative. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy, unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject 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 subject or the representative shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the 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 agent from liability for negligence.

There are three types of Informed Consent:

1. **Written Consent**. A Consent Form (see sample in Appendix K) signed by each subject is normally required for protocols submitted for all exempt, expedited, and full reviews. 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.
2. **Assent**. Projects involving children (up to 17 years, unless emancipated) undergo full review. In addition to written consent forms for parents (see Appendix L), these proposals require written assent forms from children aged 7 to 17 (see Appendix M). "Assent" means a child's affirmative agreement to participate in research. Minors aged 15 to 17 cannot give adult consent but are normally asked to sign an assent form using the same language and information contained in their parents' consent form. Any projects involving minors require a signed consent form from either the child's parents or legal guardians before approaching the child for assent. Certain studies may be

exempt from the permission requirement (e.g., if the research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., 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.

3. **Oral Consent**. A statement of oral consent must include the elements of a Written Consent Form. The IRB should be provided with the oral statement and a strong rationale for requesting oral consent.

The IRB may approve waiver of the requirement of a signed consent form, if it finds:

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

- In this case, subjects must be asked if they want to sign a consent form that links them to the research.

- If the research involves more than "minimal risk," then no waiver or alteration of informed consent is allowed.

In these cases, the IRB may require the investigator to provide subjects 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).

Cultural considerations must be addressed regarding solicitation and consent. In some cultures an investigator may enter a community to conduct research or approach prospective subjects 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 subjects and the ability of an investigator to ensure that they truly understand it. Many people in all cultures are unfamiliar with, or do not readily understand, scientific concepts such as those of placebo or randomization. Investigators should develop culturally appropriate ways to communicate information that is necessary for adherence to the standard required in the informed consent process. Also, they should describe and justify in the research protocol the procedure they plan to use in communicating information to subjects. 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.

**6. Informed Consent Document**

Attach an informed consent document that contains the following items:

A. General Elements of Informed Consent:

1. Identification of investigator's name, School within the institution, institution, status, mailing address, and telephone. If the researcher is a student, the name, address, and telephone number of the faculty advisor 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 subject'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 he or she will encounter, how long it will take, where it will take place, etc. It should be written at a reading level appropriate for the particular subjects. 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 subject. 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 subject's involvement in illegal activities and no Certificate of Confidentiality is held by the researcher (see Question 8), the researcher must provide a statement that questions regarding illegal activities will be asked as part of the research study. Also, 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 subject.
    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 subject 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 subject will be reimbursed for those expenses or if there will be no reimbursement for participating in the research.
    e. In a situation where a subject 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 subject 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 subjects: Only include information on payment if payment is available. Then any conditions for receiving the payment must be included in the consent form (e.g., if only partial payment will be made to a subject 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 subject. For example, in drug studies, the medication(s) may be available through their 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 subject will be maintained. Federal Regulations stipulate that, where appropriate, proposals should include adequate provisions to protect the privacy of subjects and to maintaining the confidentiality of data. When a proposal does not explain if and how privacy will be maintained, subjects 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:

   a. Explaining how the subject's participation will either be known, kept confidential, or anonymous. Anonymity means that there is no way to identify individual subjects' responses. Confidentiality implies subjects' identities are known, but will be protected by the investigator (to the best of his or her ability). For example, if subjects 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 subject's responses may be considered confidential, but are not anonymous.

   b. How individual privacy will be maintained in publications or presentations.

   c. Explaining what the disposition of audio- or video-tapes will be at the conclusion of the study (e.g., destroyed, erased, given to subjects, used for other purposes such as advertising a product or procedure).

   d. Explaining what the disposition of master lists (linking participants' names with data) will be at the conclusion of the study.

   e. If Protected Health Information is to be collected or transferred, include all required elements for an authorization (see IRB Policy for HIPAA Compliance).

7. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Note that the 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 subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled, and that the subject has the right to refuse to answer questions.
9. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. The name and telephone number of the IRB Chairperson should be included should the potential participant wish to contact the IRB, should he or she have questions or concerns.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

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

Criteria for IRB approval: Each required item is present, or an explanation is provided for any elements that have been omitted or modified. The IRB may waive or modify this requirement under certain circumstances. For projects where no written consent is obtained, provide a written assurance that the subjects will be informed of their rights (e.g., the right not to participate, the right to omit answers to any questions, and the right to withdraw from the study at any time).

**7. Data Monitoring**

Describe how the data will be monitored to ensure the safety of the subjects.

Criteria for IRB approval: When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

**8. Privacy and Confidentiality**

Describe how the privacy of research subjects and the confidentiality of the data will be maintained. Describe whether subjects will be identifiable in the data, who will have access to the data, and how access will be limited. Describe how anonymity and confidentiality will be protected in reporting, whether in the dissertation or subsequent papers or presentations. Identify how data and consent forms will be stored prior to destruction. As per the American Psychological Association (APA) recommendation, data should be stored for a minimum of 5 years.

If Protected Health Information is to be collected or transferred, researchers must comply with the Privacy Rule associated with HIPAA.

Some studies require disclosure of information to other parties; describe any limits to confidentiality. If research is contemplated on a topic which is likely to be subject to legal proceedings, the federal government can issue a "Certificate of Confidentiality" which shields the data from required disclosure by the researcher. Information on certificates of confidentiality is available at http://www.hhs.gov/ohrp/policy/certconf.html and http://grants.nih.gov/grants/policy/coc/index.htm.

**9. Protection of Subjects' Rights**

If the research involves any subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons, or involves the use of concealment or deception, describe the additional safeguards that have been included in the study to protect the rights and welfare of these subjects.

Criteria for IRB approval: When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. When concealment or deception will be used, subjects must be debriefed at the end of the study.

Additional risks for persons with clinical diagnoses/ research in clinical settings: Describe risks of disclosure and possible consequences; and/or additional stress and consequences of participating in research. Describe how these risks will be minimized or attenuated through safeguards and supports.

Criteria for IRB approval: Appropriate safeguards, supports, or referrals must be included in the study.

International research: Research to be conducted in countries other than the United States may be subject to human subjects protections and legislation in those countries.

Criteria for IRB approval: The student must review human subjects requirements in the country in which the research will be implemented and demonstrate that the study meets human subjects protection statutes, as applicable.

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# Institutional Review Board Handbook
# Appendix F: Request for Renewal Form

Revised 10/15/12

Investigator Name: _____

Investigator Signature: _____

Dissertation Chair Name: _____

Dissertation Chair Signature: _____

Investigator's Address: _____

Telephone: _____ E-mail: _____

**Title of Project**:

| |
|---|
| |

IRB #: _____ Original Level of Review: ☐ Exempt ☐ Expedited ☐ Full

**University of the Rockies and federal government regulations require review at least annually of all projects that are currently active.**

1. Is your project still active? ☐ Yes ☐ No

2. If not active, what is the disposition of the project and the data resulting from the project? You are reminded that informed consent forms are privileged institutional records and must be protected for confidentiality of information on individual subjects (use additional pages to respond).

3. If active, is the project proceeding as originally approved with no substantial modifications?

   ☐ Yes ☐ No

   If no, please attach additional information regarding changes to project.

4. If yes, when did you last complete Human Subjects training? If you have not completed this training within 18 months of the date of this application, please complete the CITI training and submit a copy of the completion report within 30 days of IRB approval.

5. Has anything happened to change your estimate of risk to subjects? ☐ Yes ☐ No

   If yes, please attach an explanation.

6. The Institutional Review Board is required by the federal government to obtain the following information in order to approve a request for a renewal of approval and/or conduct a continuing review of a research project. Please use the following checklist when submitting your request for a renewal of approval for your project (use additional pages to respond).
    a. The approximate number of subjects accrued.
    b. A description of any adverse events or unanticipated problems involving risks to subjects or others, withdrawal of the subjects from the research, or complaints about the research.
    c. A summary of any recent literature, findings, or other relevant information about risks associated with the research.
    d. A copy of the current informed consent document.

7. Is this project currently funded? ☐ Yes ☐ No

    If yes, please indicate funding source(s) and whether a certification to an external agency will be requested.

**Office use:**

IRB#: _____ At IRB: _____

☐ Action: Approved ☐ Approved with Revision ☐ Disapproved

Signature of IRB Chair: _____

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# Institutional Review Board Handbook
# Appendix G: Report of Change Form

Revised 10/16/12

Investigator Name: _____

Investigator Signature: _____

Dissertation Chair Name: _____

Dissertation Chair Signature: _____

Address: _____

Telephone: _____ E-mail: _____

**Title of Project**:

| |
|---|
| |

IRB #: _____

**Please describe any intended changes to your project** (e.g., change in principal investigator(s) or faculty sponsorship, change in procedure affecting risk/benefit ratio, significant change in study population or recruitment method, nature of the involvement of human subjects, etc.).

| |
|---|
| |

**Please describe, as appropriate, changes to informed consent, confidentiality, or other procedures to address increased risks.**

| |
|---|
| |

**Office Use:**

IRB#: _____ At IRB: _____

Action: ☐ Approved ☐ Approved with Revision ☐ Disapproved

Signature of IRB Chair: _____

# APPENDIX H: SAMPLE HIPAA AUTHORIZATION FORM A: ENROLLMENT INTO RESEARCH

To do the research described in the attached consent form, we have to collect health information about you. By law, we have to tell you how we will do this, and get your permission. We will collect the following health information about you for this research project:

1. [example] Demographic information (age, sex, ethnicity).
2. Results of medical or psychological tests performed on you.

[If releasing health information to others] This information may need to be collected or examined by:

1. People from the UoR Institutional Review Board, which approves and monitors research at this school.
2. People from the US Food and Drug Administration (FDA), if it decides to examine the way the research was done.
3. People from [Company X]; the drug company sponsoring this research.
4. People from [University X], who will be analyzing the data for this research.

These people are not allowed to record any information in a way that will allow anyone else to know you are a participant in this study.

[If not releasing health information] No personally identifiable health information about you will be disclosed to others.

To be in this research, you have to sign this form, giving us permission to gather (and share) the information. You do not need to sign this form. If you decide not to sign this form, then you cannot be in the research study.

If you change your mind later and do not want us to collect (or share) your health information, send a letter to _____ telling us that you have changed your mind and do not want us to collect (or share) your health information. If you cancel your authorization, the researchers will be able to use the information already collected, but they won't get any more information about you. If you cancel it, then you may no longer be able to be in the study.

You will be given a copy of this form after you have signed and dated it.

I do___ do not____ want my health information to be collected and used by the researchers and their staff described in this form and the attached consent form.

Printed Name of Participant: _____ Date: _____

Signature of Participant: _____

This authorization will expire on: _____(date) OR

__ the end of the research study.

__ will not expire.

# APPENDIX I: WAIVER OF HIPAA AUTHORIZATION

Protected Health Information is defined as "Individually identifiable health information that a health care provider, health plan, health care clearinghouse or employer creates or receives and 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."

1. Describe the protected health information (PHI) that will be collected.

IN ORDER FOR THIS WAIVER TO BE APPROVED, THERE MUST BE NO MORE THAN MINIMAL RISK TO PRIVACY OF THE SUBJECT, BASED ON THE ANSWERS TO THE FOLLOWING QUESTIONS:

2a. How will subject identifiers be protected?

2b. What is the plan to destroy the identifiers ASAP? [Please state if there is a health or research justification for retaining the identifiers or if retention is required by law.]

2c. Will the data be made available to anyone other than the study personnel? If so, to whom? And if so, why?

3. Can this project be done without PHI?

4. Why is it not possible to get the authorization of the subjects whose PHI you want to use?

CONFIRMATION:

I confirm that the Protected Health Information (PHI) will not be re-used or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research or for other research that has been reviewed and approved by the IRB with specific approval regarding access to this PHI.

_____ _____

Signature of PI Date

This protocol has been reviewed under expedited procedures and the use and disclosure of PHI and:
__ it meets the above criteria. Alteration, or waiver, in whole or in part, of authorization has been satisfied by the presence of the above criteria and is granted.
__it does not meet the criteria for approval of Waiver of Authorization

_____ _____

Signature of IRB Chair Date

# APPENDIX J: AUTHORIZATION TO RELEASE HEALTH INFORMATION: SAMPLE AUTHORIZATION FORM B: RESEARCH RECRUITMENT

I _____ (Patient's Full Name) authorize _____ (PI or Physician Name) and staff members of _____(Facility name) working for him or her to use or give the following health information about me for the purpose of research recruitment:

___ Name, Address, and/or Telephone number

___ Other (Specify) (e.g., laboratory or test results)

---

This information will be given to: _____

I give my authorization knowing that:

- I do not have to sign this authorization. If I do not sign it, my information will not be released for research recruitment.
- I can cancel this authorization any time.
- I have to cancel it in writing.
- If I cancel it, the researchers and the people my information was given to may have already used the information, but they will not use it in the future.
- I can read the Notice of Privacy Practices at the facility where the research is being conducted to find out how to cancel my authorization.
- The records given out to other peop0le may be given out by them and might no longer be protected.
- I will be given a copy of this form after I have signed it.

This authorization will [not expire] OR [expire on: ____]

Additional information: _____

_____ _____

Patient's Signature Date

# APPENDIX K: SAMPLE CONSENT FORM

Informed Consent Form for (insert Project Title)

You are being invited to participate in a research project conducted by (insert name), who is a (graduate student/faculty member) at University of the Rockies.

You are invited to participate in a research study about (describe project in language the subject can easily understand).

You will be asked to (explain specifically what the subjects are going to be asked to do) that will take about (give time commitment) of your time. (If applicable, sample questions or description should be inserted here.)

The potential risks associated with this study are (include any foreseeable risks or discomforts to subject). We expect the project to benefit you in these ways (include any foreseeable benefits including class credit, etc.). You will receive (describe any reimbursement) as compensation for your participation (describe any conditions associated with reimbursement; e.g., payment for discontinuing or not completing tasks). (If there are no direct benefits to participants, explain other benefits of the research study.)

If you have decided to participate in this project, please understand that your participation is voluntary and that you have the right to withdraw your consent or discontinue participation at any time with no penalty. (Explain the process by which participants may withdraw from the study.) You also have the right to refuse to answer any question(s) for any reason with no penalty.

In addition, your individual privacy will be maintained in all publications or presentations resulting from this study. (Describe the methods you intend to take in order to protect your subjects' confidentiality and anonymity or explain that subjects' names may be used in the final research document. If you conduct an experiment where the subjects will be audio and/or video tape-recorded, you must explain what the disposition of the tapes will be at the conclusion of the study.)

(If federally funded, include the following.) 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.

If you have any questions regarding this project, you may contact the researcher at (insert email address and/or phone number). If you have questions regarding your rights as research participant or any concerns regarding this project, you may contact my advisor, (insert Dissertation Chair name), at (insert Dissertation Chair's email address and/or phone number), or you may report concerns – confidentially, if you wish – to the UoR Chairperson of the Institutional Review Board by emailing IRB@rockies.edu.

A copy of this consent form will be provided to you.

I understand the above information and voluntarily consent to participate in the research. I further attest that I am at least 18 years of age.

Signature of Participant: _____ Date: _____

IRB Approval Number: _____ IRB Expiration Date: _____

# APPENDIX L: SAMPLE PARENT/LEGAL GUARDIAN CONSENT FORM

Parent/Legal Guardian Consent Form for (insert Project Title)

Dear Parent or Guardian:

Your child is being invited to participate in a research project conducted by (insert name), who is a (graduate student/ faculty member) at University of the Rockies.

The purpose of this project is to (describe project in language the parent or guardian can easily understand).

Your child will be asked to (explain specifically what the subjects are going to be asked to do) that will take about (give time commitment) of their time. (If applicable, sample questions or description should be inserted here).

The potential risks associated with this study are (include any foreseeable risks or discomforts to subject). We expect the project to benefit your child in these ways (include any foreseeable benefits). (If there are no direct benefits to participants, explain other benefits of the research study.)

Your child's individual privacy will be maintained in all publications or presentations resulting from this study. (Describe the methods you intend to take in order to protect your subjects' confidentiality/anonymity or explain that subjects' names may be used in the final research document. If you conduct an experiment where the subjects will be audio and/or video tape-recorded, you must explain what the disposition of the tapes will be at the conclusion of the study.)

If you agree to allow your child to participate in this project, please understand that his/her participation is voluntary and that you and your child have the right to withdraw your consent or discontinue participation at any time with no penalty. Your child will also have the right to refuse to answer any question(s) for any reason with no penalty. (Explain the process by which participants may withdraw from the study.)

If you have any questions regarding this project, you may contact the researcher at (insert email address and/or phone number), or the researcher's supervisor, (insert Dissertation Chair name), at (insert email address and/or phone number). If you have questions regarding your or your child's rights as a research participant or any concerns regarding this project, you may report them—confidentially, if you wish—to the University of the Rockies Chairperson of the Institutional Review Board at IRB@rockies.edu.

A copy of this consent form will be provided to you.

I understand the above information and voluntarily consent to have my child participate in the research. I further attest that I am at least 18 years of age.

Signature of Parent: _____ Date: _____

Name of Child: _____

IRB Approval Number: _____ IRB Expiration Date: _____

# APPENDIX M: SAMPLE ASSENT FORM

Assent Form for (insert Project Title)

Note to Investigators: If minor children (under age 18) will be included in the study it is necessary to document the child's affirmative agreement to participate in research. 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 over six years of age. If the child is not yet able to read, procedures may be used to present the information verbally to obtain verbal assent.

NOTE: Parents (or legal guardians or legally authorized officials) must sign separate consent forms permitting the minor to participate in research. Any project involving minors requires a signed consent form from either the child's parents or legal guardians before approaching the child for assent.

The following is a template for use in creating an assent form. Use language that targets the child's age and maturity level.

**ASSENT TO BE IN A STUDY**

1. Introduce yourself and others who may interact with the child. My name is (insert name).
2. Describe the study purpose. We are asking you to take part in a research study. We are trying to learn more about _____.
3. Describe what the child will be asked to do. If you agree to be in this study, you will be asked to: [Describe what will happen using language appropriate to the age-group targeted. If many tasks are involved, use a bullet format to list the tasks. Include the amount of time and number of sessions that are involved.]
4. Describe risks (if any) associated with participation and how the risks are managed (e.g., will the study hurt? The stick from the needle will hurt, but the hurt will go away after a while.).
5. Describe benefits (if any) that the child may experience from participation (e.g., this study won't make me feel better or get well, but the doctors might find out something that will help other children like me later.).
6. Make sure the child has discussed his or her participation with his or her parents (e.g., please talk to your parents about this study before you decide whether to participate. We will also ask your parents if it is all right with them for you to take part in this study. If your parents say that you can be in the study, you can still decide not to participate.).

7. Invite questions about the study (e.g., you can ask me any questions that you have about this study and I will try to answer them for you. If you have questions that you think of later, you can call me at _____ ).

8. Discuss Voluntary Participation (e.g., taking part in this study is up to you. You do not have to be in the study. No one will be mad at you if you don't want to do this. If you want to be in the study, you can say yes. If you say yes, but change your mind later, you can stop any time you want.).

**Please mark one of the choices below to tell us what you want to do:**

**___ No, I do not want to be in this study.**

**___ Yes, I want to be in this study.**

Write your name here: _____Date:_____

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# Institutional Review Board Handbook
# Appendix N: Organizational Permission Form

Revised 10/16/12

**Name of Student**: _____

**Title of Dissertation**:

| |
|---|
| |

Name of Organization or Entity: _____

Type of Organization or Entity: _____

Organizational Address: _____

**Please check all permissions that apply:**

- ☐ Permission to solicit subjects on property or through the organization (e.g., lists of members and contact information, subscribers, listserv, etc.)
- ☐ Permission to collect data through organization, whether in person, by phone, or electronically
- ☐ Permission to use organizational name
- ☐ Permission to access organizational data and/or documents not in the public domain

**Name of Authorizing Person**: _____

Job Title: _____

Signature: _____ Date: _____

**Electronic Signature not Accepted**

(valid for 2 years)

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# Institutional Review Board Handbook
# Appendix O: Permission to Use or Modify an Existing Instrument

Revised 10/16/12

Student First Name: _____ Last name: _____

**Title of Dissertation**:

| |
|---|
| |

**Name of Instrument**: _____

**Developer/Author**: _____

Address: _____

**Please check all permissions that apply**:

- ☐ Permission to use this instrument in the above-referenced dissertation research.
- ☐ Permission to modify this instrument for use in the above-referenced dissertation research.

Please identify any restrictions on the use of the above-referenced instrument or write N/A.

| |
|---|
| |

- ☐ I would like a copy of the dissertation.

**Name of Authorizing Person**: _____

Job Title: _____

Signature: _____ Date: _____

**Electronic signature not accepted**

(valid for 2 years)

UNIVERSITY of the ROCKIES℠

# Institutional Review Board Handbook
# Appendix P: Non-Disclosure Form

Revised 10/16/12

Student First Name: _____ Last Name: _____

**Title of Dissertation**:

| |
|---|
| |

Name of Service Provider: _____

Address: _____

**Type of Assistance**: (check all that apply)

- ☐ Soliciting and/or recruiting subjects
- ☐ Administering or collecting surveys or tests
- ☐ Web hosting of survey
- ☐ Conducting interviews or observations
- ☐ Video- or audio-taping
- ☐ Transcribing audio- or video-tapes
- ☐ Qualitative data analysis support
- ☐ Statistical analysis support

I hereby agree not to disclose or share any confidential information pertaining to the above-referenced research study obtained in the process of providing the services identified above. Confidential information includes but is not restricted to research participants' names, demographic characteristics, or any other personally identifying information; assessment instrument responses or scores; participants' ratings, narrative responses, or comments, whether in response to questions or spontaneous; and/or any other information that might compromise the confidentiality or anonymity of the participants. I hereby agree to refrain from discussing with or disclosing any confidential information regarding research participants to any persons other than the researcher, the members of the UoR dissertation committee, or the UoR IRB. All research materials in my possession will be stored securely and no other parties will have access to them. I agree to report immediately to the UoR IRB any breach, whether suspected or known, of this confidentiality statement regarding the above research project.

Signature: _____ Date: _____

**Electronic Signature not accepted**

(valid for 2 years)