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: _____