UNIVERSITY of the ROCKIES

Request for IRB Review

Revised 02/23/18

Submission Instructions

Please complete the following form to request an Institutional Review Board (IRB) Review. Based on the information you provide below and the documents you submit, the IRB will determine the appropriate level of review (Exempt, Expedited, or Full Review). Complete this form in its entirety and submit via IRB@rockies.edu or e-sign.

Expected Level of Review

My expected level of review: ☐Exempt ☐Expedited ☐Full

Principal Investigator (PI) Information

Name:_____ Researcher Status: ☐Student ☐Faculty

Mailing Address:_____ City:_____ State:_____ Zip:_____

Phone:_____ Fax:_____

Email:_____

Doctoral Research Information (if applicable)

Chair Name:_____

Chair Phone:_____ Chair Email:_____

A. Doctoral Research Title:_____

B. Proposed Starting and Ending Dates:_____ to_____ (MM/DD/YY)
(Please identify a 1-year period)

C. Have you completed the required CITI online training? ☐Yes ☐No
(Please attach Completion Certificate, which should be in force throughout the data collection period.)

D. 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; or
- Other vested interests, such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested.

Does the PI or do any Co-PIs have an actual, potential, or perceived conflict of interest as outlined above?
☐Yes ☐No **If Yes, please identify which and explain below:**

E. Has this project been submitted to any other IRB? ☐Yes ☐No
If yes, please identify the other IRB and their action taken on your proposal below:

F. Is this project currently sponsored in full or partially by an entity outside of the University? ☐Yes ☐No
If yes, describe the source and any potential conflicts below:

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

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

- Children/minors under age 18: ☐Yes ☐No
- Prisoners: ☐Yes ☐No
- Pregnant women: ☐Yes ☐No
- Cognitively impaired or mentally disabled: ☐Yes ☐No
- Educationally or economically disadvantaged: ☐Yes ☐No

If you selected yes to any of the categories above (i.e., protected classes), **briefly** justify the appropriateness of conducting research on this population and what additional protections will be in place to mitigate risks below (Elaborate in the Research Summary section):

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

If yes, below **briefly** describe and justify the risk and describe protections to be put in place to minimize this risk below (Elaborate in the Research Summary Section):

J. Will deception or concealment be used? ☐Yes ☐No
If yes, **briefly** describe and justify its use below (Elaborate in the Research Summary):

K. Will your study involve persons with clinical diagnosis or research in clinical setting? ☐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 below (Elaborate in the Research Summary):

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

M. Research Projects

1. Project Summary: **Briefly** describe below the involvement of human participants in your research regarding what will happen to or with them so that the IRB may evaluate the level of risk:

   a. **Briefly** describe below 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 below the population for the study, and how they will be accessed:

   a. Is permission needed to access the population? ☐Yes ☐No
      If yes, please append the signed permission form.

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

4. **Briefly** describe below how informed consent will be obtained from participants prior to collection of any data. If the participants 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. Provide both the consent and assent forms.

5. **Briefly** describe below how participants may withdraw from the study should they choose to do so:

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

7. Attachments: (Check all that apply)
   - ☐ Research Summary
   - ☐ Organizational Permission Form
   - ☐ Permission to Use or Modify Existing Instrument Form
   - ☐ Participant Solicitation or Recruitment Documents
   - ☐ Informed Consent Form
   - ☐ Informed Assent Form (if applicable)
   - ☐ Data Collection Instruments
   - ☐ Other (identify below):

Scientific Misconduct

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.

Signature:_____ Date:_____

You have provided your consent to receive documents from University of the Rockies in electronic form as part of your Online Application. For more information, please refer to the Electronic Communication section of the Catalog.

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 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.

Chair Signature:_____ Date:_____