“We need to draw the line on unethical behavior. But let’s draw it with an Etch-a-Sketch and don’t be afraid to shake it a little.”

Demystifying the Research Ethics Board
Agenda

• Overview of research ethics principles & procedures
• Overview of the research ethics approval process at the U of R
• Advice on completing the ethics application.
Core Principles

• Tri-Council Policy Statement 2 – Ethical Conduct for Research Involving Humans (2010; revisions in 2014)
• Respect for persons
• Concern for welfare
• Justice
Research Requiring Review

- Human participants
- Human biological materials

- Approval must be obtained PRIOR to data collection
Research Exempt from Review

- Publicly available information
- Observation of people in public places
- Secondary use of anonymous information
Ethics Review

• REB exists to
  – protect participants and researchers
• REB works with (not against) researchers to ensure their research plan is ethically sound
Assessing Risk

• Determined on the basis of
  • the participants (vulnerability)
  • research requirements (emotional, legal, social, physical)

• Minimal Risk
  - research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life.

• Above Minimal Risk
Minimal Risk Applications

- Applications are reviewed by 2 REB members (Random selection)
- Also reviewed by the Chair
- Comments are returned to the applicant
- Either approved, approved with amendments or needs resubmission
Above Minimal Risk

• Applications are reviewed by the full REB at a monthly meeting
• May require a scholarly review

• 1 meeting per month
Multi-jurisdictional Research

• Reciprocity Agreement
  – University of Saskatchewan
  – Saskatchewan Health Authority
  – Saskatchewan Polytechnic
Ethics Review Process

• Submit your completed (and signed) application to research.ethics@uregina.ca
• Ensure your supervisor has reviewed and signed off on your application
• Review process usually takes about – 4 weeks. Plan for it!!
REB Application Form

• Before you begin
  – Opening the application
REB Application Form

• Before you begin
  – Read the entire application through
  – Dynamic Form
  – Refer to the guidance notes
REB Application Form

• Part 1  Identification

PART 1: IDENTIFICATION

1.1 Project Title

1.2 Principal Investigator
   Full Name
   Mailing Address
   Email
   NSID Number (U of S faculty only)
   Position
   Department
   Division

1.3 University/Institutional Affiliation of Principal Investigator

1.4 If this is a student/graduate/resident project, please provide the following information:
   a) Student Name(s) and Student ID or NSID(s)
   b) Supervisor Name

1.5 Project Personnel (Include graduates/post graduates/residents)
   Full Name
   Position/Role
   University/Institutional Affiliation
   Email
   Phone

1.6 Primary Contact Person for Correspondence (If different than Section 1.2)

1.7 Research Site(s) where project will be carried out

1.8 Proposed Project Period
   From (MM/DD/YYYY)
   To (MM/DD/YYYY)

1.9 Has this project applied for and/or received ethical approval from any other Research Ethics Board? Will you be seeking REB approval through the Sask. ethics harmonization process?
   Yes  No

1.10 Status of Funds
   Awarded  Pending  Unfunded
# REB Application Form

## Part 2 Conflict of Interest

<table>
<thead>
<tr>
<th>PART 2: CONFLICT OF INTEREST</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.1.1 Is there any real, potential or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)?</strong></td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
</tbody>
</table>

### 2.1.2 Will any of the researcher(s), members of the research team and/or their immediate family members:
- Receive personal benefits in connection with this project over and above the direct costs of conducting the project, such as remuneration or employment?
- Receive significant payments of other sorts from the sponsor such as grants, compensation in the form of equipment or supplies or retainers for ongoing consultation and honoraria?
- Have a non-financial relationship with a sponsor (such as unpaid consultant, board membership, advisor or other non-financial interest)?
- Have any direct involvement with the sponsor such as stock ownership, stock options or board membership?
- Hold patents, trademarks, copyrights, licensing agreements or intellectual property rights linked in any way to this project or the sponsor?
- Have any other relationship, financial or non-financial, that if not disclosed, could be construed as a conflict of interest?

|  |  
| --- | --- |
| Yes | No |

Please describe the personal benefits or relationship.

| 2.2 Have any restrictions regarding access to or disclosure of information (during or at the end of the project) been placed on the investigators? This includes controls placed by the sponsor, funding body or advisory committee. |  
| --- | --- |
| Yes | No |

| 2.3 Please describe the arrangement and discuss the implications of any potential conflict of interest. Please describe how the conflict will be reduced, managed or eliminated as well as what additional protections have been put in place to protect project participants. The conflict of interest and how that conflict is being managed should be disclosed in the letter of information consent to participants. |  
| --- | --- |
REB Application Form

• Part 3 Brief Overview of Research Project

<table>
<thead>
<tr>
<th>PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
</tr>
<tr>
<td>3.2</td>
</tr>
<tr>
<td>3.3</td>
</tr>
</tbody>
</table>

- Questionnaire
- Individual Interviews
- Group Interview
- Video/audio recording
- Home Visits
- Other: 

- Participant Observation
- Focus Groups
- Non-invasive physical measurements
- Secondary use of data or analysis of existing data
- Ethnography
# REB Application Form

## Part 4 Project Details

### 4.1 Will you have any internet-based interaction with participants? **ON 4.1**
- [ ] Yes
- [x] No

4.1.2 If you are using a third party research tool, website survey software, transaction log tools, screen capturing software, or masked survey sites, how will you ensure the security of data gathered at that site?

4.1.3 Describe how permission to use any third party owned site(s) will be obtained, if applicable:

4.1.4 How will you protect the privacy and confidentiality of participants who may be identified by email addresses, IP addresses, and any information that may be captured by the system during your interactions with these participants?

4.1.5 If you do not plan to identify yourself and your position as a researcher to the participants, from the onset of the research study, explain why you are not doing so, at what point you will disclose that you are a researcher, provide details of debriefing procedures, if any, and if participants will be given a way to opt out, if applicable:

### 4.2 Will your research involve Aboriginal Peoples including First Nations, Inuit and Métis peoples? **ON 4.2**
- [ ] Yes
- [x] No

4.2.2 Please outline the plans to obtain community engagement for this project. Describe the nature, and extent of the community engagement as determined jointly by the researcher and relevant community. If no community consent is being sought, please justify.

4.2.3 Describe any relevant customs and codes of research practice that apply to the particular community or communities affected by the research:

4.2.4 Will a research agreement between the researcher and community be prepared?

### 4.3 Will the project involve community-based participatory research? **ON 4.3**
- [ ] Yes
- [x] No

4.3.2 Please outline the plans to obtain community engagement for this project. Describe the nature, and extent of the community engagement as determined jointly by the researcher and relevant community. If no community consent is being sought, please justify.

4.3.3 Describe the organizational structure and community processes required to obtain approval within the specific community or communities:

4.3.4 Will a research agreement between the researcher and community be prepared? This should outline the goals of the project, principles of partnership, decision-making processes, roles and responsibilities of partners and guidelines for how the partnership will handle and disseminate data.

4.3.5 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research findings before the completion of any reports or publications? How will final results of the project be shared with the participating community?

### 4.4 Will disclosure of any kind be necessary in this project? **ON 4.4**
- [ ] Yes
- [x] No

4.4.2 Please explain and describe the protocol for debriefing and re-consenting of participants upon completion.

### 4.5 Will participants be compensated? **ON 4.5**
- [ ] Yes
- [x] No

4.5.2 Please provide details:

4.5.3 Will participants be anonymous in the data gathering phase of the study? (Anonymous means that no link can be established between the participant and the research, e.g., name of the researcher who has participated in the research).
- [ ] Yes
- [x] No

4.5.5 If yes, are there any limits to confidentiality:

- [ ] Limits due to the nature of group activities (e.g., focus groups): the researcher cannot guarantee confidentiality
- [ ] Limits due to context: individual participants could be identified because of the nature or size of the sample or because of their relationship with the researcher.
- [ ] Limits due to selection: procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g., participants are referred to the study by a person outside the research team).
- [x] Other:
### PART 5: ESTIMATION OF RISKS AND BENEFITS

8.1.1 Do you consider this project to be: [ ] Minimal Risk [ ] Above Minimal Risk

8.1.2 Indicate if the participants might experience any of the following:

- Risk of psychological or emotional harm or discomfort (e.g. trauma, anxiety, stress)
- Legal repercussions for participating in the study (e.g. possibility of being sued, charged with criminal activity, disclosure of past or future criminal activities, etc.)
- Social repercussions (e.g. ostracized, being negatively judged by peers or employer, fired from your job)
- Risk of physical harm or discomfort (e.g. falling, muscle pain, tiredness, weakness, nausea)

8.1.3 Describe how the risk will be managed (including an explanation as to why an alternative approach could not be used). If appropriate, identify any resources, e.g. physician or counselor, to which participants can be referred. [ ]

8.1.4 If above minimal risk, what are the likely benefits of the research to the researcher, participant, the research community and society that would justify asking participants to participate? [ ]
## Part 6: Participant Recruitment

<table>
<thead>
<tr>
<th>Part 6: Participant Recruitment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.1</strong> Describe the participants and the criteria for their inclusion or exclusion. Indicate the number of participants and a brief rationale for the intended number of participants.</td>
</tr>
<tr>
<td><strong>6.2</strong></td>
</tr>
<tr>
<td>6.2.1 Provide a detailed description of the method of recruitment.</td>
</tr>
<tr>
<td>6.2.2 How will prospective participants be identified?</td>
</tr>
<tr>
<td>6.2.3 Who will contact prospective participants? Describe the source of the contact information, how they will be contacted and as applicable, who originally collected the contact information. Ensure any letters of initial contact or other recruitment materials are attached, e.g. advertisements, flyers, telephone script, etc.</td>
</tr>
<tr>
<td><strong>6.3</strong> In cases where the research involves special or vulnerable populations, distinct cultural groups, or in cases where the research is above minimal risk, the researcher should describe their experience or training in working with the population. If none of these criteria apply, this section may be omitted.</td>
</tr>
<tr>
<td><strong>6.4</strong> Where relevant, please explain any relationship (pre-existing, current or expected to have) between the researcher(s) and the researched (e.g. instructor-student, manager-employee, co-workers, family members/intimate relationships, etc). Please pay special attention to relationships in which there may be a power differential. Describe any safeguards and procedures to prevent possible undue influence, coercion or inducement.</td>
</tr>
</tbody>
</table>
### PART 7: CONSENT PROCESS

Describe the process that will be used to obtain informed consent. Please note that it is the content of the consent, not the format that is important. If the research involves collection of personally identifiable information from a research participant or extraction of personally identifiable information from an existing database, please describe how consent from the individuals or authorization from the data custodian will be obtained. If there will be no written consent, please provide a rationale for oral or implied consent (e.g., cultural appropriateness, online questionnaire, etc.) and explain how consent will be recorded.

<table>
<thead>
<tr>
<th>7.1</th>
<th>Describe the consent process. [GN 7.1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1.2</td>
<td>Who will ask for consent?</td>
</tr>
<tr>
<td>7.1.3</td>
<td>Where, and under what circumstances will consent be obtained?</td>
</tr>
<tr>
<td>7.1.4</td>
<td>Describe any situation in which the renewal of consent for this research might be appropriate and how this would take place (e.g. longitudinal studies, multiple data collection events, etc.).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.2</th>
<th>If any or all of the participants are children and/or are not competent to consent, describe the process by which capacity/competency will be assessed, the proposed alternate source of consent - including any permission/information letter to be provided to the person(s) providing the alternate consent - as well as the assent process for participants. [GN 7.2]</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3</td>
<td>Describe your plans for providing project results to the participant? [GN 7.3]</td>
</tr>
<tr>
<td>7.4</td>
<td>How and when are participants informed of the right to withdraw? What procedures will be followed for participants who wish to withdraw at any point during the study? [GN 7.4]</td>
</tr>
</tbody>
</table>
# REB Application Form

## Part 8  Data Security and Storage

<table>
<thead>
<tr>
<th>PART 8: DATA SECURITY AND STORAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicate the procedures you plan to implement to safeguard and store the data. Identify the person who will be assuming responsibility for data storage (University policy requires the researcher or the supervisor, in the case of student research, to securely store the data at the University for a minimum of five years upon the completion of the study. For more information see U of S Responsible Conduct of Research Policy or U of S Records and Information Management Policy.</td>
</tr>
</tbody>
</table>

| 8.1 Who will conduct the data collection? GN 8.1 |
| 8.2 Who will have access to the original data of the study? GN 8.2 |

| 8.3 How will confidentiality of original data be maintained as well as preserving or destroying data after the research is completed. For all data (e.g. paper records, audio or visual recordings, electronic recordings), indicate the: |
| 8.3.1 Person responsible for data storage: |
| 8.3.2 Data security during transportation from collection site: |
| 8.3.3 Means and location of storage (e.g. a locked filing cabinet, password protected computer files, encryption): |
| 8.3.4 Time duration of storage (Must be > 5 Years): |
| 8.3.5 Final disposition (archive, shredding, electronic file deletion): |

| 8.4 Indicate how the data collected is intended to be used (thesis, journal articles, conference presentation, media, etc). GN 8.4 |
The Consent Form
For more information ...

- TCPS 2

- TCPS 2 Course on Research Ethics (CORE)
  - [http://tcps2core.ca/welcome](http://tcps2core.ca/welcome)

- CIHR Guidelines for Health Research Involving Aboriginal People
  - [http://www.cihr-irsc.gc.ca/e/29134.html](http://www.cihr-irsc.gc.ca/e/29134.html)

- The First Nations Principles of OCAP®
  - [https://fnigc.ca/ocap](https://fnigc.ca/ocap)