# Human Research Ethics Board – Trinity Western University

# Reviewer Guide

This guide is intended to assist HREB reviewers in considering ethical issues pertaining to research with human participants. It may also be used to assist HREB applicants in anticipating matters of potential significance to reviewers. Prompts in each section are guidelines only and HREB reviewers are free to include other relevant considerations.

When writing review comments, reviewers are asked to address remarks to the researcher.

## Elements for Consideration

### Scholarly Review

* What level of review has the project received? (e.g. thesis proposal approval, departmental review, external committee?) Commensurate with complexity/level of risk?
* Is the project funded? Funding linked to external review?
* Unusual circumstances? High risk may require review by external expert. Second opinion recommended?
* Experience
* Do researchers have the experience or expertise to work with the groups or methods involved? (e.g. clinical expertise to use the Beck Depression Inventory)
* Is adequate training provided for assistants/volunteers? Appropriate supervision?

### Conflict of interest

* Are conflicts of interest identified/mitigated?
* Are there any co-existing roles (e.g. instructor, minister, manager)?
* Who recruits, who is aware who’s in/who’s out/what’s said during power-over relation?
* Are commercial/corporate interests declared/participants informed? Agreements appended?
* In extreme cases(e.g. sensitive, and conflict unmanageable), should one interest be abandoned?

### Rationale

* Why this group, this topic? Citations? Would a reasonable person consider the scholarly motivation clear enough to justify any apparent risks?
* Would a reasonable person accuse it of wasting people’s time or giving academia a bad name?

### Methods

* Has sufficient information been provided to enable a coherent understanding of methods/analysis?
* Are the type, number, and duration of observations/interactions clear?
* Is there any serious disconnect between research questions, methods, and analysis?
* Are instruments appended? Are they appropriate, e.g. does an ostensibly non-clinical study of well-being ask about suicidality and clinical depression? Does any requested information appear to be unrelated to the research focus?

### Participants

* Are inclusion/exclusion criteria clear, justified? Does the application demonstrate an adequate grasp of complex constructs, e.g. gender, sexual orientation, religion, culture?
* Is the sample size reasonable in light of methods?
* Is requested time involvement reasonable?

### Recruitment

* Are power-over relationships managed? Who approaches whom? Who knows who is in/out?
* Is recruitment public? Confidential? Snowball, cold call, voice messages, unintentional outing?
* Is sufficient information provided? (e.g. affiliation, study title/topic, inclusion/exclusion criteria, procedures, contact)
* Ad/flyer/circular/script appropriate in language/tone? Documents appended?

### Risks

* Are reasonably foreseeable risks/harms identified and mitigated? (e.g. physiological, cognitive, emotional, social, legal, location)?
* Are risks and management strategies accurately/clearly described in consent documents?
* Is deception/non-disclosure involved? Justifiable?

### Benefits

* Are there reasonable foreseeable benefits to one or more stakeholders? (e.g. participant, community, society, knowledge, student)
* Are benefits accurately represented in consent documents? (e.g. no direct personal benefit to participant, but contribution to knowledge in particular area of study). Overstated? (e.g. contribution to policy development process?)

### Incentive/Compensation

* Is incentive/compensation appropriate to study and context? Too much? Too little? Pro-rated? Appropriate in form?
* In light of study context/location, could it result in undue pressure to participate? Put participants at risk? (e.g. assault/robbery in economically deprived settings)

### Participant Consent

* Is the process appropriate to the group/study design (e.g. written, verbal?)
* Is the language/readability appropriate to group (e.g. middle school, non-native speakers of language used in research process)
* Are explanations clear/tone appropriate, not legalistic, contractual (i.e. not “I understand that…the above terms and conditions…I the under-signed…”)?
* Is it clear that potential participants are free not to participate, not to answer any questions, to withdraw at any time without consequence? Are related procedures clear?
* Appropriate sign off (study explained, questions answered, agree to begin)?
* Parental or other proxy consent?
* Age-appropriate child assent?
* Consent documents appended? See Consent Form Checklist. Are any aspects not handled appropriately?

### Institutional/Agency/Community Consent

* Are all levels of necessary approval/permission addressed?
* Is additional review required by other REBs or permission from other agencies/authorities? (e.g. hospital, school board, university, church, aboriginal group)
* Is administrative consent needed? (e.g. school principal, NGO, business)? Not always required, but researchers should be aware of administration’s position, e.g. hostile. Risks for participant?
* Does the study involve community consultation? Will it be initial? Ongoing throughout? (e.g. aboriginal group, religious community)
* If the study is located internationally, what permissions are needed and/or accountability measures are in place? (e.g. local review, host, supervision, supporting/partnering agency). Are such considerations addressed?
* Are Certificates of Approval/permission letters attached? Pending?

### Privacy, Anonymity, Confidentiality

* Are issues of privacy/anonymity/confidentiality accurately assessed?
* Is recruitment anonymous? confidential? maintained, e.g. snow ball, voice messages?
* Is privacy maintained throughout research process, with safeguards relative to sensitivity? Waived? (e.g. participants want intellectual property acknowledged)
* Are promises of privacy/anonymity/confidentiality consistent with data collection procedures? (e.g. interview versus focus group, notes versus audio/video, use of online technologies)
* Are there limits? (e.g. use of transcriptionist/interpreter, key informants, duty to report, possibility of subpoena). Are limits clearly communicated?
* Is the data management plan adequate and clearly articulated to participants? (e.g. separate identifiers from data, double lock, password protected electronic data, retention/destruction schedule appropriate given sensitivity and standard for discipline)
* Will the use of data in dissemination maintain the standard of privacy promised to participants? (e.g. pseudonyms, generics, aggregates)

### Debriefing and Dissemination

* Are debriefing procedures commensurate with sensitivity/complexity of study?
* Where relevant, is use of deception or non-disclosure revealed and explained? In such cases do participants have the option of re-consenting/withdrawing data after debriefing?
* Are there plans for reports back? courtesy copies?

### Overall Risk Assessment and Review Type

* Expeditable? i.e. group vulnerability and research risk no greater than low-low, low-medium, or medium-low (See p. 4 of this guide)
* Complex, large-scale, or unusual? Second opinion? Escalate to full HREB?

## Assessing the Risk Level of Research [[1]](#footnote-1)

The risk matrix is a tool designed to help researchers and reviewers determine the level of risk involved in a study and the level of ethics review required (expedited or full board review). An overall risk ranking is arrived at by considering the vulnerability of intended research participants in light of the risks associated with the research process.

Vulnerability is based on a range of factors that occur along a continuum. This includes, but is not limited to, participant capacity (cognitive, mental, emotional), age, health status, power relationships, gender, socioeconomic status, legal status, situational conditions.

Research risk is based on an assessment of the type, probability, and magnitude (size/amount) of harms participants are likely to experience as a result of research methods to be used and data to be collected. This includes, but is not limited to, psychological/emotional conditions such as embarrassment, stress or anxiety; physiological conditions such as physical discomfort, pain, bodily harm; social, financial, and legal ramifications such as stigma, loss of privacy, status, or reputation, loss of employment, deportation, criminal investigation (e.g. in cases of duty to report, breech of confidentiality).

Factors of participant vulnerability and research risk should be summarized with an overall assessment (low, medium, high). These should then be then located on the matrix to arrive at an overall risk ranking.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Research Risk:  Physical, Emotional Psychological, Financial, Social, Legal, etc. | | |
| Participant  Vulnerability | Low | Medium | High |
| Low | 1  Minimal Risk Review | 1  Minimal Risk Review | 2  Full Board |
| Medium | 1  Minimal Risk Review | 2  Full Board | 3  Full Board |
| High | 2  Full Board | 3  Full Board | 3  Full Board |

1. Adapted from:

   Guidance Notes for the Application of Behavioural Ethical Review (Version: Oct. 2008), available at: http://www.ors.ubc.ca/ethics/behavioural/b-forms.htm

   *Using the Risk Matrix*, available at: http://reportal.jointcentreforbioethics.ca/institution/view/id/16 [↑](#footnote-ref-1)