

Is Your Research Ethics Application Complete? A Researcher Checklist

Research Ethics, Dalhousie University

The following is a list of requirements and questions that must be addressed in your research ethics submission. These are questions that the Research Ethics Board (aka REB reviewers) will be asking as they review your submission. This may be used as a companion to the *Guidance for Submitting an Application for Research Ethics Review* document and the Tri Council Policy Statement *Ethical Conduct for Research Involving Humans*.

Is the application complete and submitted on time? This includes:

- a) Following the submission instructions described on the Research Ethics website.
- b) A complete application form. Complete **all sections** of the application form and address each **sub-section** explicitly. If a section is not relevant to your proposed research, please indicate “not applicable”.
 - All pages in the application including any appendices must be submitted in a single document
 - Text must be in a legible font size, normally no smaller than 11 pts.
- c) Relevant documents in clearly labelled appendices, including:
 - Recruitment documents
 - Screening documents
 - All consent forms (and assent forms) and/or consent scripts (for oral consent)
 - Research instruments
 - Debriefing forms
 - Permission/support letters (Aboriginal Band Council, School Board, Director of a long-term care facility)
 - Confidentiality agreements

1.0 ADMINISTRATIVE INFORMATION

- Is the **administrative information** complete?
 - Does the lead researcher have a current affiliation with Dalhousie?
 - Has the researcher provided an official Dalhousie e-mail address?
 - Student research: Is a Dalhousie supervisor identified? Has the supervisor reviewed the submission?
 - Does the project require research ethics review anywhere else?
 - Is the study funding identified?
 - Are attestations complete?

2.1 LAY SUMMARY [500 words]

- Does the **summary** describe the rationale, purpose, study population and methods?
- Does the summary offer **context** and **justification** for the study?

2.2 RESEARCH QUESTION

- Are the **hypotheses/objectives/research questions** described?

2.3 RECRUITMENT

- Are the **source and number** of participants clearly stated?
- Is the rationale for the **sample size** clearly stated?
- Is the **recruitment plan** appropriate for the target sample?
 - Are the eligibility criteria (**inclusion/exclusion**) clearly described? Are they appropriate? Is the group of research participants appropriate for the research objectives?
- Are the **screening procedures** fully explained and any relevant documents included with the protocol?
- Are the **recruitment instruments** included (posters, invitation emails, media advertisement, etc.)?
- Is it clear **who** will be doing the recruitment and what actions they will take?
- If participants are recruited from a member of the research team's employment circle (e.g., university staff), courses (e.g., university students), or client list (e.g., clinical research), are real or potential **conflict of interests** recognized and addressed in 2.9?
- Is the **permission of organizations** is needed (e.g., Aboriginal Band Council, School Board) for the researcher to be able to conduct recruitment and research activities and are these described? Are any **permission letters** attached?

2.4 INFORMED CONSENT PROCESS

- Is the informed consent process described? Are all copies of all consent forms appended? Is the **procedure for obtaining informed consent** appropriate?
- If **non-written** consent is proposed, is it described? Is the script appended?
- Are there special considerations (e.g., vulnerable population, capacity)? If **third party** consent is sought, is it appropriate? Is **assent** properly sought (either in writing or orally)?
- Are plans for **ongoing** consent described? Are plans for **community** consent described? (if applicable)
- Is information provided about participants' opportunity to **withdraw participation**?
- Is information provided about participants' opportunity to **withdraw data**? Is the information appropriate?
- Is a **waiver** of informed consent is sought? Are the criteria listed in the guidance document met?

2.5 METHODS AND ANALYSIS

- Is the **study design** appropriate for the research objectives?
- Are the **methods/procedures** clearly described? Is it clear what participants will be asked to do? Is it clear what **instruments** will be used? Have these been submitted (or examples of the stimuli fully described)? Are randomization or blinding procedures clear? Are the methods/ procedures appropriate to achieve the intended results?
- Is it clear **where** the research will be conducted and **who** will be doing it?
- Is the **time** for each task and the total time commitment noted? Is it realistic? Is this consistent with what is stated on the consent form?
- Is it clear what **data** will be recorded?
- Are the planned **data analyses** described? Are they appropriate/relevant for the research questions? Are they consistent with the data collected?
- Are participants **compensated or reimbursed** for their participation? Is this appropriate? Is

information provided about what happens for those who withdraw?

- Are **incentives** to participants used? Are they appropriate? Is information provided about what happens for those who withdraw?
- Is **deception** involved or information withheld from participants and, if so, is it justified and are there appropriate arrangements for debriefing of participants?
- Is the **debriefing** form included if deception involved or information is withheld?
- Are the **members of the research team** described? Are their qualifications/training relevant to this study?

2.6 PRIVACY & CONFIDENTIALITY

- Are details about how **data** will be **stored and handled** provided? Is it stored in a confidential manner? Is access restricted?
- Is information provided on how **long** it will be retained? Will it be destroyed? If so, how and why? [Note that the REB does not require data to be destroyed, only that it be stored securely. Electronic data should be password protected and encrypted, especially if data is identifiable]
- Will stored data be stripped of **personal information**? Will identifying and/or personal information be stored securely elsewhere? If not, are measures undertaken to limit possible breaches to confidentiality?
- Will **dissemination** of research results identify participants directly or indirectly?
- Is information provided about use of participants' **quotes**? Is the information appropriate?
- Are any **limits on confidentiality** addressed (e.g., duty to disclose abuse or neglect if applicable)?
- Will participants' **personal information** be **accessible outside Canada**? If so, has the researcher described how compliance with the *University Policy for the Protection of Personal Information from Outside Canada* has been met?

2.7 PROVISION OF RESULTS TO PARTICIPANTS

- Are plans for **sharing study results** with participants discussed?
- If applicable, will participants be informed of results that may indicate they **may be at risk**? If so, is the plan for doing so adequate?

2.8 RISK & BENEFIT ANALYSIS

- Has the researcher **identified the risks** for participants associated with their participation in the research, their **estimated probability** and how these will be **mitigated** or addressed?
- Are there any **community**-related risks involved? Have these been addressed?
- Has the researcher identified the benefits (direct and/or indirect) that may be derived from the research? Are **direct benefits** (if any) to participants (other than compensation) explained? Are **indirect benefits** of the study (i.e., contribution to new knowledge) explained?

2.9 CONFLICT OF INTEREST

- Are there any researchers on the research team who hold **dual roles** (e.g., TA / student)? Is this addressed? Is there the potential for **financial conflicts of interests**? Have the researchers taken steps to mitigate any real or potential conflict of interests with respect to dual roles and financial conflicts of interests?

2.10 RESEARCH WITH ABORIGINAL PEOPLES

- Has the researcher presented the plan for **community engagement**? If not, has the researcher

requested an exception or explained why it does not?

- Has/is the research been/being reviewed by an Indigenous ethics review group? If not, is it clear why it is not necessary?
- Are plans for **sharing study results** with participants discussed? Are there plans for sharing data with the community as well? If so, are participants properly informed of who will have access to identifiable data?

2.11 CLINICAL TRIALS

- Has the researcher provided a **rationale**, if the clinical trial does not need **registration**?
- Has the choice of **control** (including placebo) been justified? Participants should not be deprived of effective treatment due to study participation.
- Is it clear what is known about **safe use** of the proposed intervention, and how the proposed use differs? Is it clear what additional risks this may occasion?
- Has **randomization** and blinding been used where possible? Randomization reduces selection bias, blinding reduces bias in data collection and analysis. When blinding is used, plans for breaking blinding if needed for individual care become important.
- Has the researcher indicated clearly how **safety** will be monitored in an ongoing way, and what steps will be taken if concerns arise? Have potential risks of stopping been addressed?

2.12 USE OF PERSONAL HEALTH INFORMATION

- Will personally identifiable health information collected for the purposes of providing healthcare services be used? If so, has the information **source** been identified? Has the information been **fully described**?
- Has the researcher **justified** why the research cannot be conducted without personal health information? Is the information in the most **de-identified form** possible?
- Will personal health information be **combined** with information from other sources? If so, has this been justified?
- Have **foreseeable risks** to privacy been described and mitigated?

APPENDICES

- **Are all necessary appendices included? Are they all appropriate?**
 - Recruitment documents
 - Screening documents
 - **All** consent forms (and assent forms) and scripts
 - Research instruments
 - Debriefing forms
 - Permission/support letters (Aboriginal Band Council, school board, director of a long-term care facility)
 - Confidentiality agreements

In the consent form, reviewers look for the following when reviewing your submission:

- a) **Format**
 - Does the consent form appropriately identify the **affiliation** of the researcher?
 - Identification of document as **Consent Form**
 - Is the consent form **simply written** for a lay reader (normally at a grade 8 comprehension level, with no acronyms or technical jargon)?

- Is it appropriately **formatted**: legible font size (min 11 pt), headings, page numbering?
 - Are the **title** for the study and **names**/contact information for researchers included on the **first** page and on the **signature** page?
- b) **Invitation to Participate in Research**
- Is there an introduction explaining that this is a research study, and that **participants are invited to participate in research**?
 - Is there a statement that assures **voluntariness and right to withdraw** without consequence?
- c) **Who Is Conducting the Research Study**
- **Identity, affiliation** and contact information of researchers
 - Information about any **sources of funding** for the study
 - Are any **conflicts of interest** explained?
- d) **Purpose and Outline of the Research Study**
- Is the **purpose** of the study clearly described?
 - Is the **study design** clearly described and how many **participants** are involved?
- e) **Who Can Participate in the Research Study**
- Are **inclusion and exclusion** criteria described?
- f) **What Participants Will Be Asked to Do**
- Are the participants appropriately told what they will be **asked to do** based on the description in the protocol?
 - Are the **procedures or tasks** that the participants will be asked to carry out described?
 - Is the **time** that participation will involve described?
 - Are **other requirements** on the part of participants explained (e.g., special clothing, fasting, etc.)?
- g) **Possible Benefits, Risks and Discomforts**
- Are **direct benefits** (if any) to participants (other than compensation) explained?
 - Are **indirect benefits** of the study (e.g., contribution to new knowledge) explained?
 - Are the foreseeable **risks** identified? Are their **probabilities** estimated? Are the means to **mitigate the risks** described?
- h) **Compensation / Reimbursement**
- If the participants are to be **compensated**, are the conditions and amount of compensation described?
- i) **Privacy and Confidentiality**
- Is there a statement regarding the **confidentiality** of participant data (e.g., storage of data, access, method of publication)
 - Is there a statement regarding how the identity of the participant will be safeguarded?
 - Are any **limits on confidentiality** (if applicable) described (e.g., duty to disclose abuse or neglect)?
 - If participants will be **quoted** in reports from the data, is this addressed in the consent form

(e.g., whether they will see quotes in advance and whether quotes will be attributable)?

j) **Participant Withdrawal**

- Are participants given information about the opportunity to **withdraw participation**?
- Are they given information about the opportunity to **withdraw data**? Is the information appropriate?
- Are those providing consent informed about how **assent** of participant will be sought when third parties give consent?

k) **Sharing Research Findings with Participants**

- Description of how participants will **review transcripts of interviews**, if applicable
- Description of how **study results** will be provided to participants, if applicable

l) **Questions**

- Is there information about **whom** the participant may contact regarding the study?
- Is the **contact information** of that individual provided?
- Has a **Research Ethics** contact been identified should participants wish to raise concerns?

m) **Overall**

- Does the information on the consent form **match the information in the submission**? Are there any inconsistencies (e.g., participant age, time commitment, compensation amount)?
- Is there a clear distinction between **clinical care or service provision / research** procedures

n) **Signature Page**

- Are the appropriate signatures requested, in an acceptable format (signature, date)? That is, is there a signature **statement** indicating that **information has been provided**?
- Are all permissions **required** for *participation* and for data to be *useable* all included in a single signature? (e.g., audio/video taping, use of quotes)
- Are additional optional permissions (those that are **not required** for participation or for usability of the data) requested separately, and clearly indicated? (e.g., re-contact for future studies; transport data outside Canada)?
- Is contact information or other **personal information** beyond the participants' signature requested? If so, is the **purpose** for this clearly indicated or inferable? Is it appropriate to ask?