University of Manitoba | Human Research Ethics

Human Research Ethics - Fort Garry
66 Chancellors Circle
Winnipeg, MB R3T 2N2
humanethics@umanitoba.ca

Creating a Human Research Ethics Protocol in RAS – A Companion Guide

Research with human participants has a long history that has resulted in some significantly unethical behaviour by researchers. This history has resulted in a series of documents designed to protect participants from harm. The core principles of respect for persons, concern for welfare, and justice are key to conducting ethical research.

Preparing an ethics submission is not simply an exercise to get through. It requires thoughtful planning on your part and careful review by the Research Ethics Board. This is not an activity that can be done at the last minute. We expect submissions to be in final form. Any submissions that are missing information or are written in draft form will be returned to you to revise and finalize.

The ethics protocol is an exercise in justification. The onus is on the researcher to clearly justify the research methodology, design, data collection instruments, recruitment plan, data management plan, and dissemination plan. Researchers must also show that participants are providing fully informed consent.

The protocol submission is comprised of a series of questions. It is critical that you respond to each question. The purpose of this Guide is to clarify questions that appear in the Research Administration System ethics protocol form and to provide additional tips in completing your protocol. Not all questions in RAS are included in the Guide as not all questions require further clarification. Refer to this Guide as you craft your responses. It is equally important that your responses correspond to the question being asked. Do not repeat information in different places unless asked to do so. Repeating information across the questions leads to inconsistencies in the submission that are difficult for the REB to evaluate and complex to review during an audit process.

The text in **black** is the question as worded in the RAS system. The text in **green** clarifies what the Research Ethics Board (REB) is looking for. The text in **blue** provides information required in the consent form to help ensure greater consistency throughout the application. Text in **red** denotes things you should not do.

NOTE: As you move through the tabs, you will see a number of “Yes” or “No” questions. Your responses may open additional tabs or text boxes which require your attention. If you change your answer to the “Yes” or “No” questions, these additional tabs or text boxes may disappear. Any responses you entered will not be saved.

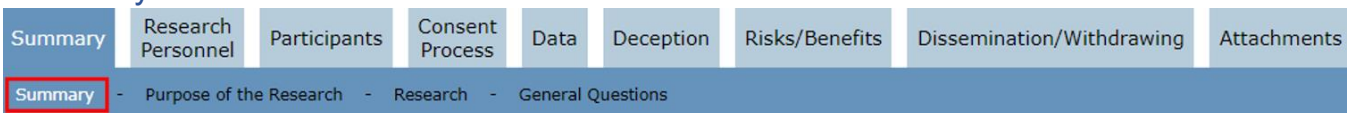
TIP: Read all the questions before completing the application. Only respond to the question being asked in each text box. This prevents duplication of information and ensures consistent responses throughout the protocol.

As the system’s text boxes do not allow for formatting, we recommend using spacing and capital letters to create headings.

Contents

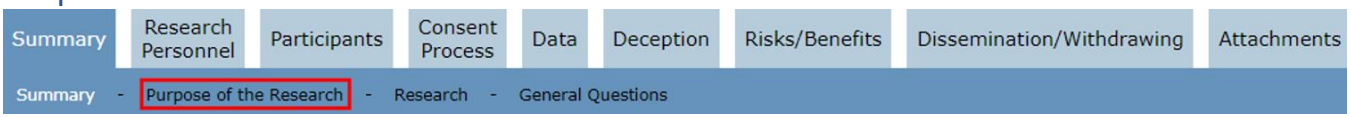
SUMMARY TAB:

Summary



- Primary Department
  - Please amend to your current department for which you are submitting your study. For students, please change the department from Faculty of Graduate Studies to the Department you are working within.

Purpose of the Research



- Provide a **brief** statement about the project written in **lay** language. Do not provide a technical summary. Do not cut and paste directly from the study[1] proposal.
  - Write for a general audience. Citations and references are not needed. Do not provide a technical summary.
- Describe the research methods.
  - Briefly describe the methods you will use.
  - If there are multiple phases of the study, describe the methods to be used in each phase.
  - Do not provide information on the recruitment and consent process here.
- Briefly describe chronologically what the research team will ask participants to do after the recruitment process and consent has been obtained. If there are multiple phases of the study, describe what participant will do in each phase.
  - Do not provide information on the recruitment and consent process here.
- Where will the study take place?
  - If data collection will take place on-line for focus groups, interviews, or observation, specify the platform to be used.
  - If data collection is happening in-person, specify where. If participants will choose the meeting place, state that and provide examples.
- How much time will study participants be expected to dedicate to the research?
  - Indicate the total amount of time participants will be expected to dedicate to the study including member-checking.

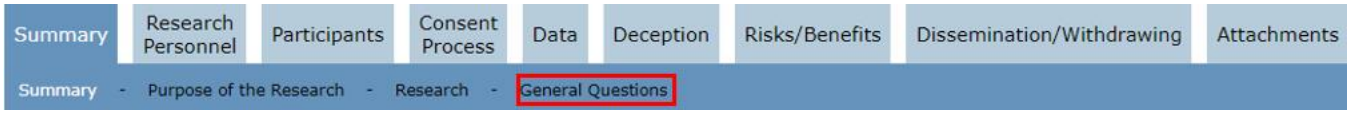
Research

- Type of Study
  - NOTE: if your study is a clinical trial, it must be registered. The ICMJE accepts registration in the following registries: www.anzctr.org.au (Australia),

[1] The term "study" is used to describe a research project or a research study.

www.clinicaltrials.gov (US), www.ISRCTN.org (UK), www.umin.ac.jp/ctr/index/htm (JAPAN), www.trialregister.nl (Netherlands), and https://eudract.ema.europa.eu/ (new registrations after June 20, 2011). In addition to the above registries, starting in June 2007 the ICMJE will also accept registration in any of the primary registries that participate in the WHO International Clinical Trials Portal (see http://www.who.int/ictrp/network/primary/en/index.html). Because it is critical that trial registries are independent of for-profit interests, the ICMJE policy requires registration in a WHO primary registry rather than solely in an associate registry, since for-profit entities manage some associate registries. Trial registration with missing or uninformative fields for the minimum data elements is inadequate even if the registration is in an acceptable registry.

General Questions

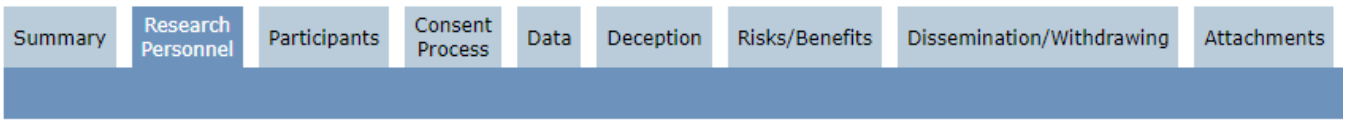


- Does the study involve participants who are not legally or practically able to give their valid consent to participate?
    - This question is not intended for participants under the age of 18.
- Does this study propose mature minor consent?
    - A mature minor is a child under 18 years old, who has the capacity to fully appreciate the nature and consequences of a proposed study and is capable of giving informed consent. It is not based primarily on age but on capacity to understand and make decisions.
    - Mature minor consent is used when participants under the age of 18 will consent for themselves, and the researcher will not seek consent from the parent/guardian.
- Are participants from a population that may be marginalized or vulnerable in the context of research?
    - This question will help the REB in determining potential level of risk.
- Does this research include the use of personal health information?
    - The **Personal Health Information Act (PHIA)** defines health as 'the condition of being sound in mind, body, and spirit'.
    - Personal Health Information (PHI) includes recorded information about an identifiable individual as it relates to the person's health or health care history, provision of health care, or payment for health care provided.
    - PHI includes self-reported health information by a participant.
- Does this study use deception (e.g. will participants be intentionally misled about the study's purpose, their own performance, or other features)?
    - This question is asking whether the study requires alterations to consent (e.g. partial disclosure, deception, exception to seek consent as described in **TCPS 2 Art. 3.7A**).
    - Withholding the research question from the consent form is not considered deception.

    - If you answer ‘yes’, a Deception tab will appear where you will be asked to provide further information.
- Will the majority of participants identify as First Nations, Inuit, and/or Metis?
    - In some cases, Indigenous People represent a large portion of a specific population. Even if you are indirectly recruiting Indigenous People, answer ‘yes’ if the majority of your study population will be First Nations, Inuit, and/or Metis.
- Will the analysis of the research results use First Nations, Inuit, and/or Metis identity as a variable?
    - If you plan to collect demographic information from your participants, and analyze Indigenous Peoples’ data separately, answer ‘yes’ to this question.
- Will the interpretation of research results refer to First Nations, Inuit, and/or Metis people, language, history or culture?
    - This question refers to both the primary collection of study data and secondary use of information collected originally for a purpose other than the current study purpose.
- Will participants be given the choice to waive their anonymity?
    - Answer ‘yes’ if participants will be given the opportunity to have their real names included in publications and presentations.
- Will this study include involvement or recruitment from a specific organization?
    - Answer ‘yes’ if you are recruiting and/or partnering with a group or organization outside of University of Manitoba.
    - If you answer ‘yes’, a tab will open under the “Dissemination/Withdrawing” tab (“Other Approvals”) where you will be asked to provide further information.

- Will permission be required to conduct the study outside the University of Manitoba?
    - If you answer ‘yes’, a tab will open under the “Dissemination/Withdrawing” tab (“Other Approvals”) where you will be asked to provide further information.

RESEARCH PERSONNEL TAB:

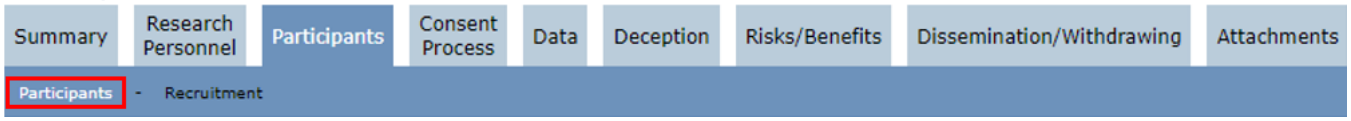


- Protocol Personnel Table
    - Include each research team member who will interact with participants and/or have access to individual data (line-level data).
- What type of data will each team member have access to?
    - Types of data include directly identifying, indirectly identifying, coded, anonymized and anonymous (see **Chapter 5 TCPS 2** pp. 79-80).
    - Indicate which team member will have access to which type(s) of data.
    - Advisors must have access to all data as per Faculty of Graduate Studies guidelines.
    - Example: *The PI will have access to directly identifying, coded, and anonymized data. The Advisor will have access to directly identifying, coded, and anonymized data. RA [insert name] will have access to anonymized data…*

    - Team members accessing directly identifying information, including advisors for student studies, should be named in the consent form. RAs, study coordinators, and those in similar roles should be identified by their role and should not be named directly.
- All team members who engage with participants and/or raw data are required to complete CORE training and PHIA training (if appropriate). All team members (other than the PI, Co-PI, and Advisor) must complete an Oath of Confidentiality. If any team member requires alternative training, provide a justification and describe the training that will be completed.
    - Each team members must upload their CORE certificate and UM Privacy training certificate/pledge into their RAS profile.
    - Template Oaths of Confidentiality are available **here**.
    - Contact humanethics@umanitoba.ca for advice if there are individuals who may interact with participants but are not part of the research team or are unable to complete CORE training (e.g., Elders, graphic artists, community members.)
    - It is the PI's responsibility to ensure all team members are educated on the protocol and how data will be properly stored and handled.

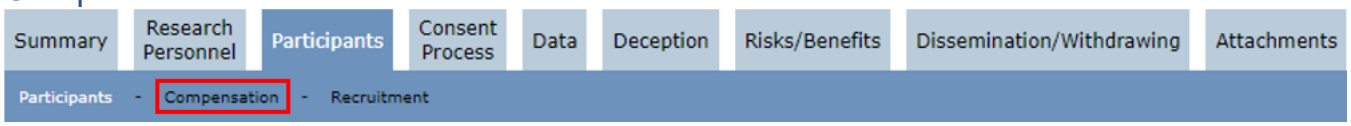
PARTICIPANTS TAB:

Participants



- How many participants do you expect to recruit?
    - Include the total number of participants you plan to recruit and a justification for why you chose that number.
    - If you have multiple data collection methods and will recruit different participants for each method, specify how many participants will be recruited for each method.
- What are the inclusion criteria to participate in the study?
    - In point form, list the characteristics or attributes that prospective participants must have to be included in the study. Common criteria may include demographic, clinical, and/or geographic characteristics.
- What are the exclusion criteria?
    - In point form, list the exclusion criteria based on the inclusion criteria.
- Will the participants in your study be UNAWARE that they are participants?
    - This may include participants in an observational study.

Compensation

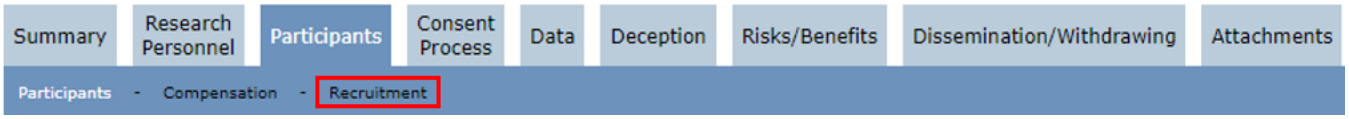


- Please provide justification for these compensation arrangements.

- The purpose of compensating study volunteers is to cover “out of pocket” expenses (such as parking, meals) and/or lost wages as a result of time spent in the study. Payment to participants should not constitute undue inducement.
- The REB will review both the amount of payment, the proposed method, and the timing of disbursement to ensure it is not coercive or an undue influence.
- Payment for participating in a study is not considered a benefit of that study.

- When will participants receive their compensation?
  - Participants must be compensated as soon as possible after consent has been given.
  - If the study has multiple phases, compensation may be provided at the start of each phase. If neither of these options is possible, explain and justify how compensation will be provided.
- Participants must be able to keep their compensation if they withdraw from the study. Describe how participants will be compensated if they withdraw from the study.
  - Participants should not suffer any disadvantage or reprisal for withdrawing, including the withholding of compensation.

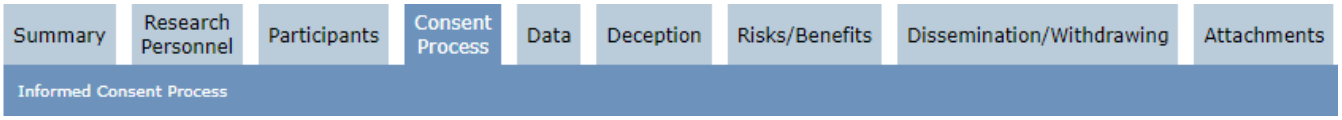
Recruitment



- *[For protocols indicating ‘Yes’ to recruiting participants who are not legally or practically able to give their valid consent*] Please describe how you will recruit potential participants who lack the capacity to decide for themselves whether to participate or continue to participate in the study.
  - Describe how you will recruit potential participants. Explain who you will reach out to first and how you will ensure participants do not feel any pressure or obligation from a third party to participate.
- *[For protocols indicating ‘Yes’ to recruiting participants who are not legally or practically able to give their valid consent]* Please indicate how you will recruit participants through those authorized to speak for them.
  - Specify how you will reach out to those authorized to consent on behalf of potential participants.
- *[For protocols indicating ‘Yes’ to recruiting participants who are under the age of 18].* How will you reach out to parents/guardians of participants under the age of 18?
  - Explain who you will reach out to first and how you will ensure participants do not feel any pressure or obligation from a third party to participate.
- Describe how prospective participants will be identified, who will contact them, and the process of doing so.
  - The REB does not allow contact information to be collected from third parties. For snowball recruitment, participants may forward recruitment material so interested parties can contact the PI directly.
  - Do not provide information on the consent process here.
- Attach copies of all material that will be given/read to participants and/or third parties:
  - This material may include email and telephone scripts, social media posts, captions, posters, letters, etc.

- Only final versions of the recruitment material should be uploaded, and these must be free from spelling and grammatical errors.
- Refer to the **Guidelines for Participant Recruitment** for more information.

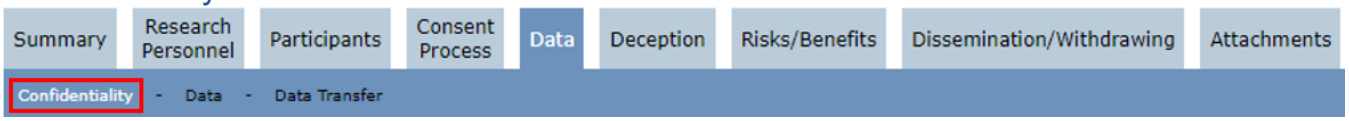
CONSENT PROCESS TAB:



- Describe the consent process including how consent will be obtained.
  - Consent must precede data collection. Although not all consent must be obtained in writing, the procedures to seek and document consent must be fully described.
  - For online surveys, the consent form should be embedded into the survey platform, not provided as a url link.
  - Only participants whose data or information is being collected are required to give their consent.
  - Consent forms should be in their final versions and free from spelling and grammatical errors.
  - The **Consent Form template** sets out the information required (see **Chapter 3 TCPS 2** pp. 36-37) and includes verbatim statements required by UM.
  - Do not discuss recruitment, data collection, or data storage here.
- For participants who are not able to provide their own consent, provide the steps for how informed consent from an authorized person will be obtained
  - Explain who you will reach out to first. Typically, consent from an authorized person such as a parent/legal guardian or caregiver is obtained before assent is obtained.
- How will you obtain assent from the participant themselves.
  - Although not all consent must be obtained in writing, the procedures used to seek and document consent must be fully described.

DATA TAB:

Confidentiality



- Are there conditions in which privacy or confidentiality cannot be guaranteed?
  - Examples include group settings, interviews in public spaces, when third parties might be aware of participant involvement, a small population where the public could identify a participant even without using names (e.g., mayor of a city).
  - Ensure that the consent form reflects that confidentiality may or cannot be guaranteed.
  - Where possible (e.g., focus groups) include Oaths of Confidentiality for participants to sign.
  - This is not asking whether the participants will be identifiable to the members of the research team.
- *[For protocols indicating 'Yes' to giving participants the choice to waive their anonymity]*

- Describe the options participants will be given to waive anonymity and how this information will be provided to them.
- Ensure that the consent form reflects what is outlined here.

Data (Safeguarding Information)

This section is about the researcher's/research team's obligation to safely store participant data. In developing the responses, researchers must consider the risks to participants should the data be inadvertently accessed, which is an increasingly common occurrence in today's world.

- Below are some **important general notes** for this section. Review the different information/data types and their definitions before completing these questions.
  - Privacy versus Confidentiality: Privacy refers to an individual's right to be *free from intrusion or interference* by others. Confidentiality refers to the *obligation* of an individual or organization *to safeguard entrusted information*.
  - Responses under this tab fall into several types of **data collection methods** (survey/questionnaire, interviews, focus groups, observations). Answers should refer only to the data collected within that method. If multiple methods will be used, provide details relevant to each method.
  - Refer to the **Data Storage Guidelines** for more information and for sample wording which can be used in the consent form.
  - If you will have different **data** (information) **types** over the course of the study, make sure you provide a response for each type (e.g. identifiable survey, anonymized survey).
  - There is no requirement to destroy any type of study data. When no longer needed, it is typically advised that **identifiable data** be destroyed (e.g., names, email addresses) to help maintain participant privacy. Ensure that you have enough time to complete all required study processes when indicating a destruction date (e.g. creating and sending a summary of findings to participants)
  - If you do not intend to destroy identifiable data, you must provide a justification.
  - If you intend to destroy data indicate the month and year in which you anticipate they will be destroyed – "X data will be destroyed by…(MMYY)."
  - Ensure the consent form reflects the same dates.

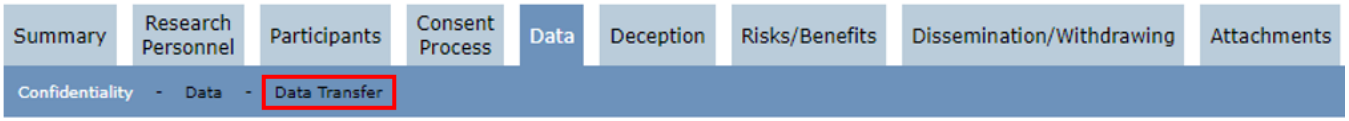
- Surveys/Questionnaires:
  - How will the survey/questionnaire be administered?
    - If conducted online, include platform to be used.
  - Describe the type(s) of data to be collected: anonymous, anonymized, coded, indirectly identifiable and/or directly identifiable.
    - The data type may change over the course of the study. Include all anticipated data types and indicate when the data type will change during the study. For example, "surveys will be identifiable, then anonymized once data collection is complete".
    - Ensure the consent form reflects the same information.

- Where will the survey/questionnaire data be stored in the short term and long term?
  - Discuss storage in both the short and long term. If the data will be transferred from one platform to another, discuss the process here. For example, transferring the data file from the survey platform (e.g., Qualtrics) to a UM One Drive account.

- Interviews and Focus Groups:
  - Who will conduct the interview/focus group?
    - Specify the individual(s) that will conduct the interview. Ensure all individuals are also listed in the personnel table.
  - Will any individual(s) other than the research personnel be present during the interview/focus group?
    - These people may be translators, support persons, elders, facilitators.
  - *[For protocols indicating 'Yes' to recording an interview/focus group]* List the procedures that will be recorded.
    - E.g. obtaining consent, preamble, interview/focus group itself.
    - Be specific about the type of recording (e.g., audio and/or video). If participants have the choice of recording type, outline the process here.
    - Ensure the consent form reflects the options.
  - Where will the recordings be stored? How will you maintain participant confidentiality?
    - If you will use multiple methods of recording, ensure you discuss all forms. For example, using a recorder and a recording app in a cell phone.
    - Discuss storage in both the short and long term. If the data will be transferred from one device to another, discuss the process here. For example, transferring the audio file from a recorder to a laptop.
  - Who will transcribe the recordings? Indicate if the recordings will be transcribed manually or identify the transcription service used.
    - NOTE: Contact humanethics@umanitoba.ca for a current list of IST approved transcription services.
  - Will the transcripts be anonymized, coded, or identifiable? Please explain.
    - The data type may change over the course of the study. Include all anticipated data types and indicate when the data type will change during the study.
  - Where will the transcripts be stored?
    - Discuss storage in both the short and long term.
  - *[For focus groups]* What will happen to the recordings and/or transcripts if one participant (or more) decides to withdraw?
    - If it is not possible/feasible to delete certain participants from the overall recording, ensure this is clearly indicated here and in the consent form.
    - It may be possible to delete certain participant quotes from a transcript.
    - Ensure the process is outlined here and in the consent form.
- Observations:
  - Please provide your observation plan.
    - Include information on how you will maintain participant confidentiality.

- Other Data Mediums:
    - If you will collect any other data or information from participants, click “Yes” and a table will be created for you to list further information.
        - Describe the type(s) of data to be collected: anonymous, anonymized, coded, indirectly identifiable and/or directly identifiable.
            - The data type may change during the course of the study. Include all anticipated data types and indicate when the data type will change during the study.
            - If you selected ‘other’ as a data medium, explain what it is in this question.
        - Where will the data be stored? Include information on both physical and electronic copies.
            - Discuss storage in both the short and long term.
            - Financial Services have more information on gift card use for study purposes and forms on their intranet.
                - Gift card and honorarium declaration forms must be kept for 7 fiscal years.

Data Transfer



NOTE: If you intend to share data with someone outside the UM and/or transfer data to location outside UM, contact the Contracts Office (researchcontracts@umanitoba.ca) for advice on the documentation required. All plans to share and/or and transfer of data must be clearly explained in the Consent Form.

- Will data be transferred from one site to another? This includes data collected in the field or off-site.
    - Select ‘yes’ for studies involving fieldwork where data will be physically moved from the collection site to the University.
    - Select ‘yes’ if data will be transferred outside the University (e.g., sent to a transcription company).
    - If ‘Yes’, a new question will open. Explain the process of transferring the data (physical and digital files) to the University. Include all safeguards you will take to ensure the data are secure during transfer.
- Will data be shared/transferred between research team members (e.g., student PIs/advisors, research assistant/PI, PI/co-Is)?
    - If ‘Yes’, a new question will open. Explain how the data will be transferred. Include information on who will transfer the data and in what forms. Include all safeguards you will take to ensure the data are secure during transfer.
- Will the data be archived or made accessible to the public and/or other researchers?
    - If ‘Yes’, a new question will appear. Explain what data will be shared and in what form. Include information on whether the data will be anonymous or anonymized.

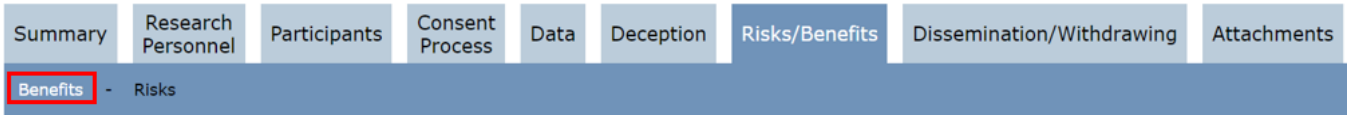
- Participants should be explicitly asked in the consent form if they want their data to be archived or made accessible to the public. Ensure that the information presented here is also included in the consent form.

DECEPTION TAB:

- Provide detailed information on the extent and nature of deception and why the research could not be conducted without it. This description must be sufficient to justify a waiver of informed consent.
  - More information on deception can be found in the TCPS 2 in Chapter 3.
- How will debriefing be provided to participants?
  - Examples may include via email, verbal communication, or a write up at the end of a survey.
- Outline when debriefing will be done and by whom. If no debriefing will be done, indicate N/A.
  - At what time in the study will participants be debriefed? Will it occur directly after participating? Participants should be debriefed as soon as possible.
  - Who will be debriefing? Specify the individual(s) and ensure they are listed on the personnel table.

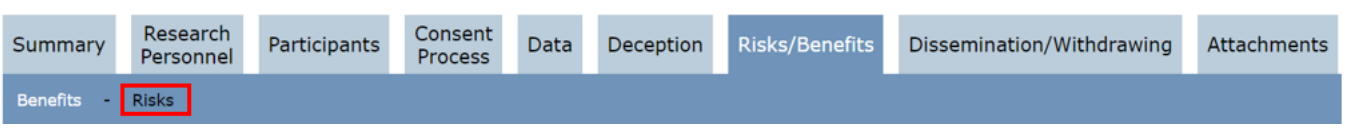
RISKS/BENEFITS TAB:

Benefits



- What are the expected benefits of the research?
  - List all of the potential benefits including those to the general public.
- What are the indirect benefits for participants participating in the research?
  - This may include enhancing/advancing knowledge of the study topic, which may be of particular interest to participants.
- What are the direct benefits for participants participating in the research?
  - This may include gaining access to care or information that they normally would not or learning information about themselves.
  - Note: compensation is not considered a benefit.

Risks



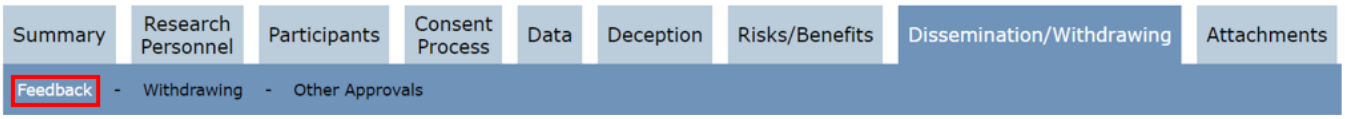
- What are the risks (psychological, physical, emotional, social, legal, economic, or political) to participants and others if applicable.

- Participation in all studies carries risk. Risks may be minimal or more significant. Include information about any mental or physical discomfort or negative feelings/associations that participants may experience due to study activities. Include details on any known side effects which may result from the study activities.
- Consider social and emotional discomforts that may be associated with questionnaires that evoke strong emotions, or have the potential to elicit responses of severe anxiety/depression, etc.
- Consider what risks participants may face should the data be inadvertently accessed or breached in relation to the type and level of sensitivity of the data you are collecting.

- Is there a possibility that abuse of children or persons in care might be discovered in the course of the study?
  - Although topics of abuse may not be related to your research question, select 'yes' if there is any possibility that participants may disclose information.
  - If 'Yes', a new question will open. Explain what you will do if a disclosure is made.
  - Ensure the consent form explains the requirements for disclosures and the process you will follow if a disclosure is made.

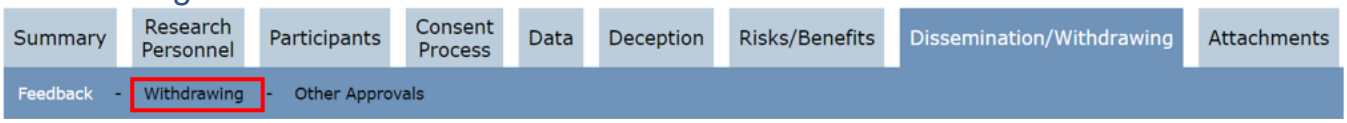
DISSEMINATION/WITHDRAWING TAB:

Feedback



- In oral and/or written dissemination, will you refer to individual participants?
  - If using real names, be consistent with the confidentiality section of your protocol and the consent form.
- Provide your plans for sharing the results of the research with your participants. Participants should be given a choice in how they wish to receive this information and approximately when to expect it (MMYY).
  - Results of the study should be made available to participants in a culturally appropriate and meaningful format.
  - Ensure that the consent form reflects what is outlined here.

Withdrawing

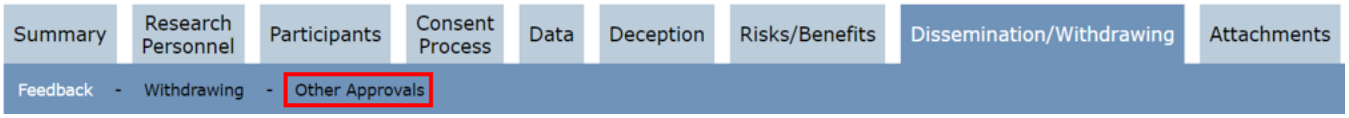


- How and when will you inform participants about the withdrawal process?
  - Keep the information here consistent with the consent form, which should clearly outline how participants can withdraw from the study.
- Indicate what will be done with the participants' data when they withdraw.
  - The REB default is to destroy all the data upon withdrawal. If you anticipate any limitations to your ability to destroy these data (e.g. focus groups, observation studies), indicate the limitations here and in the consent form.

- Address the destruction of partial data if applicable.

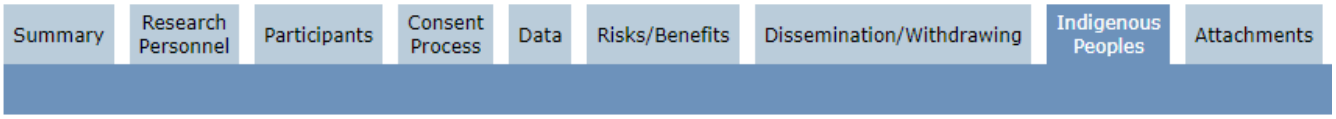
- Is there a deadline after which the nature of your data analysis would make it impossible for participants to withdraw? Please provide a MMYY.
  - There are often limitations to destroying data once they have been anonymized or pooled together. If there is a deadline to withdraw, ensure the consent form reflects this.

Other Approvals



- Attach any scripts that will be used to request permissions/approvals. Copies of communications or approval letters may also be attached. All attachments should be uploaded as individual documents.
  - If you do not have the required approval yet, attach a blank document as a place holder. When you receive the document, submit an amendment.

Indigenous Peoples



NOTE: Indigenous researchers may choose to describe their positionality in framing their responses to questions in this Tab.

- Explain how you have engaged or intend to engage the relevant community(ies) (e.g., chief and council, band councils, Elders, local associations, groups, committees, and organizations representing Indigenous people).
  - TCPS 2 describes **community** as a group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A community may include members from multiple cultural groups, may be territorial, organizational, or a community of interest. “Territorial communities” have governing bodies exercising local or regional jurisdiction (e.g., members of First Nations who reside on reserve lands). “Organizational communities” have explicit mandates and formal leadership (e.g., a regional Inuit association or a friendship centre serving an urban Indigenous community). In both territorial and organizational communities, membership is defined, and the community has designated leaders. “Communities of interest” may be formed by individuals or organizations who come together for a common purpose or undertaking. Communities of interest are informal communities whose boundaries and leadership may be fluid and less well- defined. They may exist temporarily or over the long term, within or outside of territorial or organizational communities. An individual may belong to multiple communities, both Indigenous and non-Indigenous. An individual may acknowledge being of First Nations, Inuit or Métis descent but not identify with any particular community. How individuals define

which of their community relationships are most relevant will likely depend on the nature of the research study being proposed.
    - **Community engagement** is defined by the TCPS 2 as a process that establishes an interaction between a researcher (or a research team) and the Indigenous community relevant to the study. It signifies the intent of forming a collaborative relationship between researchers and communities, although the degree of collaboration may vary depending on the community context and the nature of the study. The engagement may take many forms including review and approval from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. The engagement may range from information sharing to active participation and collaboration, to empowerment and shared leadership of the study. Communities may also choose not to engage actively in a study, but simply to acknowledge it and register no objection to it.
    - Respectful relationships, collaboration, and engagement are central to undertaking research by, with, and for Indigenous Peoples and communities. Such engagement does not require REB review and should occur BEFORE a protocol is submitted.
- Are you conducting research on lands under the jurisdiction of First Nations, Inuit or Metis authority?
    - A description of engagement with leaders of the community should be provided.
    - Where a researcher proposes alternatives to securing the agreement of formal leadership for research on First Nations, Inuit or Métis lands or in organizational communities, they should engage community processes and document the measures taken, to ensure due consideration has been given to complex community authority structures.
    - To the extent possible, the researcher should describe how they have taken into consideration the views of all relevant sectors within a community, including individuals and subgroups who may not have a voice in the formal leadership.
    - If 'Yes', attach any approvals you have from the community to conduct this study. This can be a formal communication, such as a letter of support, or an informal communication, such as an email.
    - If you do not have the required approval yet, attach a blank document as a place holder. When you receive the document, submit an amendment.
    - TCPS2 makes exceptions to seeking the engagement of leaders of a community. These include: (1) where there are complex authority structures (Art. 9.5), (2) when engaging with community members who may not have a voice in formal leadership or whose circumstances make them vulnerable (Art. 9.6), and (3) when critically examining public institutions, governments or organizations that have authority over the community.
- Is there a research agreement in place?
    - If 'Yes', attach the agreement.
    - If the agreement is not approved yet, attach a blank document as a place holder. When you receive the document, submit an amendment.

    - If 'No', a new question will appear. Indicate why you will not obtain an agreement with your participant population group.
    - The TCPS 2 encourages research agreements to ensure the terms and undertakings of both the researcher and community are set out before participants are recruited. Research agreements serve as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities. At a minimum, the agreement should address the ethical protections that would apply to securing individual consent for a comparable project and should specify any commitments regarding collective community participation and decision making, sharing of benefits and review, and updating of the agreement.
    - An agreement may be relatively brief, and subject to clarification as the project unfolds.
- Provide information on how the nature of the research is relevant to the needs and practices of that community, and how it might benefit the participating community. Include information on how the proposed study will support capacity building within the community(ies).
    - Where the form of community engagement and the nature of the study make it possible, the study should be relevant to community needs and priorities. Outline how the study is expected to benefit the participating community (e.g., capacity-building, reciprocal learning, extending/expanding skill transfer, local hiring, recognition of contributors, sharing of results), as well as how you plan to extend the boundaries of knowledge.
    - Outline how communities may benefit from of study activities (e.g., receipt of research funds, release time for study personnel, overhead levies on shared studies, or commercialization of research discoveries).
- Describe how representatives of the engaged community will be involved in the interpretation of data and review of research findings before finalization of any findings resulting from the data.
    - Researchers should provide communities access to study data that will allow them to address pressing issues through community-generated policies, programs, and services.
    - How will community representatives participate in the interpretation of the data and the review of study findings before the completion of the final report, and before finalizing all relevant publications resulting from the study?

Secondary Use of Data

- Who currently has custody of the records/database/materials to be used?
    - Describe where the data is and who has access to the data.
- Has the project for which the original data was collected reviewed by an external agency/institution or REB?

    - If ‘Yes’, a new question will appear. Outline when the original study was approved, by whom, and what the current status of that study is. Also, attach copies of any approval letters that were obtained and the consent forms that were used.
- Briefly describe the purpose of the original study.
    - Describe in lay language the original purpose for the data collection.
- What is the purpose and rationale of the proposed research? How does the proposed research differ from the original research?
    - Describe the research question and objectives for the proposed study.
    - Use point form for clarity.
- Describe how the data were initially gathered, when, and by whom.
    - Describe the process of the original data collection. Outline who gathered the data, when data collection occurred, and the current status of the data.
- Does the proposed research differ from what the participants originally consented to?
    - If ‘Yes’, a new question will appear. Explain how the proposed study is different from the original study. Provide a rationale for the proposed study.
- Describe the data set(s) (e.g., survey, audio/video recordings, photos, transcripts).
    - Describe the data you will be obtaining and the format it will be in.
- For each data set identified above, state the data type(s) (e.g., identifiable, or anonymized), and how those data will be used.
    - Describe the type(s) of data to be obtained: anonymous, anonymized, coded, indirectly identifiable and/or directly identifiable.
    - The data type may change over the course of the study. Include all anticipated data types and indicate when the data type will change during the study.
- Please indicate any strategies to be used to allow participants to object and/or communicate to relevant groups about the research (e.g., posting notices where participants may frequent, proxy consent).
    - If you do not intend to obtain consent from participants to use these data, explain the strategies you will use to reach these individuals to let them know the data will be used for a secondary purpose.
- Describe how you will have the data transferred to you.
    - Explain how the data will be transferred. Include information on who will transfer the data and in what forms. Include all safeguards you will take to ensure the data are secure during transfer.
    - NOTE**:** If you intend to share data with or obtain data from someone outside the UM, contact the Contracts Office (researchcontracts@umanitoba.ca) for advice on the documentation required.
- Describe the physical location(s) and safeguards that will be used to securely store all non-digital sources of data, such as written records, audio or video recordings, questionnaires, during the course of the study.
    - Discuss storage in both the short and long term. If the data will be transferred from one place to another, discuss the process here.
- Describe the location(s) and safeguards that will be used to securely store all digital sources of electronic data during the course of the study.

    - Discuss storage in both the short and long term. If the data will be transferred from one device to another, discuss the process here.
- Provide the date when the data will be destroyed (MMYY) or provide justification for keeping the data indefinitely.
    - There is no requirement to destroy any type of study data. When no longer needed, it is typically advised that **identifiable data** be destroyed (e.g., names, email addresses) to help maintain participant privacy. Ensure that you have enough time to complete all required study processes when indicating a destruction date (e.g. creating and sending a summary of findings to participants)
    - If you do not intend to destroy identifiable data, you must provide a justification.
    - If you intend to destroy data indicate the month and year in which you anticipate they will be destroyed – "X data will be destroyed by…(MMYY)."
- Indicate what type of data each team member will have access to.
    - List all the individuals who will have access to the data and outline what type of data they will each have access to (anonymous, anonymized, coded, indirectly identifiable or directly identifiable).
- Is there a research agreement in place between the University of Manitoba and the custodian of the data?
    - If 'Yes', attach the agreement. If the agreement is not approved yet, attach a blank document as a place holder. When you receive the document, submit an amendment.