



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

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.

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.

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SUMMARY TAB:

Summary

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Summary	-	Purpose of the Research	-	Research	-	General Questions		

- Is the Principal Investigator for this project a student?
 - Answer 'Yes' if you are a student or post-doctoral fellow.

Purpose of the Research

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Summary	-	Purpose of the Research	-	Research	-	General Questions		

- Provide a **brief** statement about the project written in **lay** language. **Do not cut and paste directly from the study¹ proposal.**
 - Write for a general audience. Citations and references are not needed. **Do not provide a technical summary.**
- Describe the research question(s) and objectives for this research study.
 - Use point form for clarity.
- 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.**

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

- Describe briefly in a step-by-step manner what the research team will be doing with participants, after they have been recruited and consented.
 - 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.
- Approximately how long will this study take for participants?
 - Indicate the total amount of time participants will be expected to dedicate to the study including member-checking.

Research

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Summary	-	Purpose of the Research	-	Research	-	General Questions		

- Type of Study
 - Note that the category “survey” also refers to questionnaires.

General Questions

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Summary	-	Purpose of the Research	-	Research	-	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 (i.e., will participants be intentionally misled about the purpose of the study, their own performance, or other features of the study)?
 - 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 this study occur in locations outside of the University of Manitoba?
 - Answer 'yes' if the study will take place physically outside the University of Manitoba (off campus), and permission will be required to conduct the study at that location.
 - 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:

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
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- Protocol Personnel Table
 - Include each research team member who will interact with participants and/or have access to individual data (line-level data).
- Describe each team member's role in the study (e.g. staff, research assistant, student statistician, supervisor etc.)
 - Describe how they will interact with study participants and/or access the data.
- Are any of the research team members affiliated with institutions other than the University of Manitoba?
 - If 'Yes', a new question will open below. Indicate how you will confirm whether approval from that institution/those institutions is required.
- What type of data will each individual 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.
- How will the PI ensure that all research team members are aware of their responsibilities regarding participants' privacy and confidentiality? Research coordinators and assistants must complete an Oath of Confidentiality.
 - All team members who engage with participants and/or data are required to complete CORE training and PHIA training (if appropriate) and upload certificates into their RAS profile.
 - All team members (other than the PI and Advisor) must sign an Oath of Confidentiality. Template Oaths 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.)
 - If any team member requires alternative training, provide a justification, and describe the training that will be completed.
 - 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.

- *[For protocols indicating 'Yes' to a study related conflict of interest]* Please describe. Please explain how you will ensure participants do not feel pressure or obligation to participate or perceive that they may be penalized for choosing not to participate.
 - Describe the conflict of interest and indicate how it will be mitigated to ensure participants do not feel pressure or obligation to participate or perceive that they may be penalized for choosing not to participate.

PARTICIPANTS TAB:

Participants

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Participants - Recruitment								

- 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 is 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 criteria would someone become ineligible to participate?
 - 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.
 - If 'Yes', a new question will open below. Provide a justification for why participants will not be aware they are in the study.
- Will information about the participants be obtained from sources other than the participants? If yes: Please describe.
 - This may include participants whose information is collected about them by a third party (e.g., a parent being asked to speak about their child, an organization providing information on their employees, obtaining contact information from public sources).
 - If 'Yes', a new question will open below. Indicate what sources will be used and what information will be collected from those sources.

Compensation

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Participants - Compensation - Recruitment								

- 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.
 - Participants should not suffer any disadvantage or reprisal for withdrawing, including the withholding of compensation.
 - Describe how participants will be compensated in the event they choose to withdraw from the study.

Recruitment

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Participants - 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 are not legally or practically able to give their valid consent to participate?
 - 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 recruit parents/guardians of participants under the age of 18?
 - Specify how you will reach out to parents/guardians of these 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.
- Provide a step-by-step description of how you will identify and recruit participants. Describe how prospective participants will be identified, who will contact prospective participants and by what means this will be done.
 - 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.
- 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.

CONSENT PROCESS TAB:

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Informed Consent Process								

- Describe the consent process. Where and how will consent 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.
 - 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 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

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Confidentiality	-	Data	-	Data Transfer				

- 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).
 - If 'Yes', a new question will appear below. Explain the precautions you will take to protect privacy and confidentiality.

- 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)

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Confidentiality - Data - Data Transfer								

- 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.
 - Are the data anonymous, anonymized, coded, indirectly identifiable or directly 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. For example, "surveys will be identifiable, then anonymized once data collection is complete".
 - [Ensure the consent form reflects the same information.](#)
 - Where will this data be stored?
 - 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 this data 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 data?
 - Indicate whether data will be transcribed manually or identify the transcription service that will be used. If manually, specify the individual(s) who will transcribe and ensure they are listed in the personnel table.
 - 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 this data be stored?
 - Discuss storage in both the short and long term.
 - 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 who will conduct the observation(s), whether any individual(s) other than members of the research team be present, identify and describe who will be present, the type of data that will be generated from the observation(s), and 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.
 - Is the data anonymous, anonymized, coded, indirectly identifiable or directly identifiable? Please explain.
 - 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 this data be stored?
 - Discuss storage in both the short and long term.
 - For more information on gift card use for study purposes and to access the forms, click [here](#).
 - Gift card and honorarium declaration forms must be kept for 7 fiscal years.

Data Transfer

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Confidentiality - Data - 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?
 - 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 transferred between research team members?
 - Select 'yes' for student studies as advisors will need access to all the data as per Faculty of Graduate Studies guidelines.
 - Select 'yes' if data will be shared with study staff and/or Co-Investigators.
 - 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:

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
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- 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.
- When and by whom?
 - 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

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
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Benefits - Risks

- 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

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Benefits - Risks								

- What are the risks (psychological, physical, emotional, social, legal, economic, or political) to participants, or to a third party?
 - 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.
- Provide a description of the risks, the steps that will be taken to reduce or eliminate them, and the steps that will be taken to improve any actual harm to participants, including (if appropriate) providing a list of helpful resources.
 - Ways to mitigate harm to participants might include having experts available to monitor body functions/reactions, providing a list of helpful resources, providing a safe space, having an Elder or counsellor available.
- 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

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Feedback - Withdrawing - Other Approvals								

- Will you be providing participants with the opportunity to review their data?
 - If 'Yes', a new question will appear. Indicate what data will be shared with participants as part of the member checking process (e.g. recording, transcript, field notes). Also outline when and how participants will receive the data, how

long they will have to review it, and what will be assumed if no response is received.

- Will your publications refer to individual participants?
 - This includes oral and/or written dissemination.
 - If 'Yes', a new question will appear. Indicate how you will refer to these individuals. If using pseudonyms/general descriptors, indicate the naming convention that will be used.
 - If using real names, be consistent with the confidentiality section of your protocol and the consent form.
- How will the research results be disseminated, to whom, and for what intended purpose?
 - What is your study's dissemination/knowledge mobilization plan? Include all potential avenues. Include who you will engage with and how you will engage with them (e.g. publications, presentations, articles, reports, theses, website, videos, creative works, community meetings). Ensure that your engagement strategies are appropriate for your stakeholder audiences(s).
- Steps should be taken to provide participants with a brief, non-technical summary of research results as soon as possible after the data collection phase of the study is completed should they want it.
 - Results of the study should be made available to participants in a culturally appropriate and meaningful format. Provide your plans for sharing this information with your participants. Participants should be given a choice in how they wish to receive this information and approximately when to expect it (by MMY).
○ Ensure that the consent form reflects what is outlined here.

Withdrawing

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Feedback	Withdrawing	Other Approvals						

- How and when are participants informed of their right to withdraw?
 - Keep the information here consistent with the consent form, which should clearly outline how participants can withdraw from the study.
- What procedures will be followed for participants who wish to withdraw at any point during the study?
 - Describe how participants can withdraw from the study at any point in time. Include information on who they contact and how the contact should be made.
- Please indicate what will be done with the participant's data when they request to 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 MMYYY.
 - 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

Summary	Research Personnel	Participants	Consent Process	Data	Deception	Risks/Benefits	Dissemination/Withdrawing	Attachments
Feedback - Withdrawing - Other Approvals								

- How will you obtain approval from the groups/organizations?
 - Who are the group(s)/organization(s) you will require approval from and how will you obtain this approval?
 - Attach any scripts that will be used to request permissions/approvals. Copies of communications or approval letters may also be attached.
 - 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

Summary	Research Personnel	Participants	Consent Process	Data	Risks/Benefits	Dissemination/Withdrawing	Indigenous Peoples	Attachments
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- As per Article 9.1 of the TCPS 2, please provide a plan on how you have and will engage the relevant community in your research plans (e.g., chief and council, band councils, tribe elders, local Metis associations, committees and organizations representing urban 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. A community may be territorial, organizational, or a community of interest. An individual may belong to multiple communities, both Indigenous and non-Indigenous (e.g., as a member of a local Métis community, a graduate students' society, and a coalition in support of Indigenous rights). 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 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?
 - 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.
 - Will the participants' personal information be disclosed to community members without their consent?
 - If 'Yes', a new question will appear. Explain how information will be disclosed. Outline how participants will be made aware that their personal identifiable data

- will be shared with community partners. Outline the safeguards that will be put in place to protect the confidentiality of identifiable data.
 - If 'No', a new question will appear. Explain why information will not be disclosed. Explain what type of data (if any) community partners will have access to.
- As per Article 9.13 of the TCPS 2, please provide information on how the nature of the research is relevant to the community needs and practices, and how it might benefit the participating community.
 - 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).
- Please describe how the community representatives will be engaged in the interpretation of data and review of research findings, before finalization of any relevant publications or reports 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

Summary	Research Personnel	Secondary Use of Data	Attachments
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- 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? Be sure to explain how the proposed research differs from the original research, if applicable.
 - 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.
- Has the purpose of the proposed research differed from what participants originally consented to in the informed consent process?
 - 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 you will be using and how (e.g., reviewing videotapes/transcripts or analyzing a dataset).
 - Describe the data you will be obtaining and the format it will be in.
- Describe the type of data you will obtain (e.g. identifiable, anonymized).
 - 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.
- Will you obtain consent from participants?
 - If 'Yes', a new question will appear. Explain how you will obtain consent from participants to use these data. Attach the new consent form.
- Will you disseminate the results of the study as well?
 - If 'No', a new question will appear. Explain why the results of the proposed study will not be disseminated/shared.
- 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.

- What will ultimately happen to this data? How long will you keep it? If you will destroy the data, when (MMYY)? Please provide justification for why the data will be kept 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).”
- Who will have access to the data? What data will they 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.