



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

The purpose of this Guide is to clarify questions that appear in the Research Administration System ethics protocol form under the Summary tab 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. 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.

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.

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

- 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.**
- 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.