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

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

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

Data (Safeguarding Information)

• Below are some important general notes for this section. Review the different information/data types and their definitions before completing these questions.
  o 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.
  o 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.
  o Refer to the Data Storage Guidelines for more information and for sample wording which can be used in the consent form.
  o 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).
  o 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).
  o If you do not intend to destroy identifiable data, you must provide a justification.
  o 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).”
  o Ensure the consent form reflects the same dates.

Surveys/Questionnaires:
  o How will the survey/questionnaire be administered?
    ▪ If conducted online, include platform to be used.
  o 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:
  o 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:
  o 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

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 transfer of data must be clearly explained in the Consent Form.

• Will data be transferred from one site to another?
  o Select ‘yes’ for studies involving fieldwork where data will be physically moved from the collection site to the University.
  o Select ‘yes’ if data will be transferred outside the University (e.g., sent to a transcription company).
  o 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?
  o Select ‘yes’ for student studies as advisors will need access to all the data as per Faculty of Graduate Studies guidelines.
  o Select ‘yes’ if data will be shared with study staff and/or Co-Investigators.
  o 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?
  o 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.
  o 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.