University of Manitoba | Research Ethics and Compliance

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Creating a Human Research Ethics Protocol in RAS – A Companion Guide: Secondary Use of Data Tab

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

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? 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.