University of Manitoba | Research Ethics and Compliance

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

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

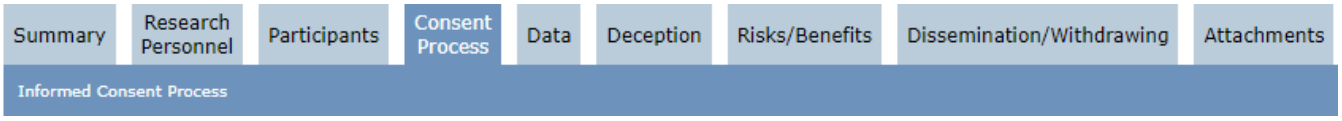
The text in **black** is the question as worded in the RAS system. The text in **green** clarifies what the Research Ethics Board (REB) is looking for. Text in **red** denotes things you should not do.

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.

CONSENT PROCESS TAB:



- 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.