



Creating a Human Research Ethics Protocol in RAS – A Companion Guide: Risks/Benefits Tab

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

RISKS/BENEFITS TAB:

Benefits

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