

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

The purpose of this Guide is to clarify questions that appear in the Research Administration System ethics protocol form <u>under the Participants tab</u> 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.

<u>TIP:</u> 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.

## PARTICIPANTS TAB:

## **Participants**



- How many participants do you expect to recruit?
  - Include the total number of participants you plan to recruit and a justification for why you chose that number.
  - If you have multiple data collection methods and will recruit different participants for each method, specify how many participants will be recruited for each method.
- What is the inclusion criteria to participate in the study?
  - In point form, list the characteristics or attributes that prospective participants must have to be included in the study. Common criteria may include demographic, clinical, and/or geographic characteristics.
- What criteria would someone become ineligible to participate?
  - In point form, list the exclusion criteria based on the inclusion criteria.
- Will the participants in your study be UNAWARE that they are participants?
  - This may include participants in an observational study.
  - If 'Yes', a new question will open below. Provide a justification for why
    participants will not be aware they are in the study.

- Will information about the participants be obtained from sources other than the participants? If yes: Please describe.
  - This may include participants whose information is collected about them by a third party (e.g., a parent being asked to speak about their child, an organization providing information on their employees, obtaining contact information from public sources).
  - o If 'Yes', a new question will open below. Indicate what sources will be used and what information will be collected from those sources.

Compensation



- Please provide justification for these compensation arrangements.
  - The purpose of compensating study volunteers is to cover "out of pocket" expenses (such as parking, meals) and/or lost wages as a result of time spent in the study. Payment to participants should not constitute undue inducement.
  - The REB will review both the amount of payment, the proposed method, and the timing of disbursement to ensure it is not coercive or an undue influence.
  - Payment for participating in a study is not considered a benefit of that study.
- When will participants receive their compensation?
  - Participants must be compensated as soon as possible after consent has been given.
  - If the study has multiple phases, compensation may be provided at the start of each phase. If neither of these options is possible, explain and justify how compensation will be provided.
- Participants must be able to keep their compensation if they withdraw from the study.
  - Participants should not suffer any disadvantage or reprisal for withdrawing, including the withholding of compensation.
  - Describe how participants will be compensated in the event they choose to withdraw from the study.

## Recruitment



- [For protocols indicating 'Yes' to recruiting participants who are not legally or practically able to give their valid consent] Please describe how you will recruit potential participants who are not legally or practically able to give their valid consent to participate?
  - Describe how you will recruit potential participants. Explain who you will reach out to first and how you will ensure participants do not feel any pressure or obligation from a third party to participate.

- [For protocols indicating 'Yes' to recruiting participants who are not legally or practically able to give their valid consent] Please indicate how you will recruit participants through those authorized to speak for them.
  - Specify how you will reach out to those authorized to consent on behalf of potential participants.
- [For protocols indicating 'Yes' to recruiting participants who are under the age of 18]. How will you recruit parents/guardians of participants under the age of 18?
  - Specify how you will reach out to parents/guardians of these participants.
  - Explain who you will reach out to first and how you will ensure participants do not feel any pressure or obligation from a third party to participate.
- Provide a step-by-step description of how you will identify and recruit participants.
   Describe how prospective participants will be identified, who will contact prospective participants and by what means this will be done.
  - o Do not provide information on the consent process here.
- Attach copies of all material that will be given/read to participants and/or third parties:
  - This material may include email and telephone scripts, social media posts, captions, posters, letters, etc.
  - Only final versions of the recruitment material should be uploaded, and these must be free from spelling and grammatical errors.
  - o Refer to the **Guidelines for Participant Recruitment** for more information.
  - The REB does not allow contact information to be collected from third parties.
     For snowball recruitment, participants may forward recruitment material so interested parties can contact the PI directly.