

## Creating a Follow On Submission in RAS A Companion Guide: REB Events

Follow on submissions include changes to study personnel, amendments (changes) to approved protocols, annual renewals, protocol closures, and reporting unanticipated issues and events (REB event).

TCPS2 (Art. 2.8) states that ethics review must continue throughout the study to ensure that all stages are ethically acceptable. This guide provides clarifications and helpful tips to ensure compliance with the requirements of continuing research ethics review within the RAS system. Not all questions in the Research Administration System (RAS) system are included as not all questions require further clarification. Please refer to this information as you craft your responses. The text in **black** is the question you will respond to. The direction in **green** clarifies what the Research Ethics Board (REB) is asking for. Text in **red** denotes things you should not do.

<u>NOTE:</u> 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 tabs or text boxes may disappear. Any responses you entered will not be saved.

As the system's text boxes do not allow for formatting, we recommend using spacing and capital letters to create headings.

## REB EVENT



- Description of Event
  - Describe in detail what occurred. Provide all relevant information, including dates, times, and names of research team personnel. Do NOT include the names of participants.
- What actions will be taken to rectify this event?
  - Outline any changes or actions to your study you plan to implement. These should be reviewed and approved by the REB unless there is a need to immediately address any risk of harm to participants. Do NOT implement any actions listed until the REB has acknowledged/approved them.
- Have you notified any other offices of this event (i.e., Privacy and Access Office)?
  - o In the box below, outline the office you have contacted. If you haven't contacted any offices, state your rationale.
- Does the protocol require changes to prevent this event from occurring again?

 'If Yes', a new box will appear. Outline briefly what you propose change and indicate that once the REB event is acknowledged, you will submit an Amendment with the proposed or REB-prescribed changes.