Working Within an Application 101

This document is designed to explain basic functions of RSS and working within an application.

1) Highlights of the main IRB menu:

   **New Protocol/sIRB Request**- click to create a new application
   **View/Edit**- click to view and/or edit existing applications you are personnel on
   **View sIRB Request**- click to view an existing sIRB request
   **Data Managers**- click to create a group that would be doing nothing more than administrative functions for a protocol (e.g. submitting continuing reviews, etc.)
   **Policy & Procedures**- this link leads to the UNMC HRPP Policies and Procedures manual
   **Chair/Vice-Chair Call Schedule**- here you can find the contact information for IRB chairs and vice-chairs

2) Within an application, answering questions a certain way will generate additional questions.

   Ex. Section II.25

   Here is the original question:

   25. Method of Subject Identification and Recruitment

   A. Will prospective subjects learn about the research and then contact the investigator about participation (for example, in response to a print, electronic, radio or television advertisement; referral by a clinician or other specifically for this research)?
   Collaborate/Comment (No comments exist)

   - Yes  ☐  No

   B. Will the investigator make the initial contact with the potential subject to tell him/her about the research (for example, by contacting existing or past previous patients or research participants; or by contacting prospective subjects thru school records, or thru support groups or other interest Groups; or thru use of the Hospital Opt-In Database)?
   Collaborate/Comment (No comments exist)

   - Yes  ☐  No

   C. Will this study be listed in the clinical trial registry at [www.clinicaltrials.gov]?  
   Collaborate/Comment (No comments exist)

   - Yes  ☐  No
If I answer “yes” to the first question (A), it generates the following follow-up question:

2. What is the statistical or other justification for the total number of subjects described above?

Note: Summarize briefly the statistical consideration or other considerations which determine the total number of subjects needed to achieve the scientific aims of the research, as well as the rationale for the anticipated number of screen failures and/or subject withdrawals. Details regarding the statistical considerations may reference a detailed protocol if available.
4) When offered selection bullets, **CIRCLE bullets** mean you will select ONE.

**SQUARE bullets** mean you will select all that apply.

5) When navigating through your application, click section titles to go straight to the section without scrolling or using the “previous” and “next” buttons:

6) Always hit **SAVE** to refresh a page. Hitting the refresh button on the browser may result in losing progress on an application.