

# 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

**RSS**

IRB

IBC

## APPLICATION

New Protocol / sIRB Request

View / Edit

View sIRB Request

Data Managers

Policy & Procedures

Chair/Vice-Chair Call Schedule

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](http://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:

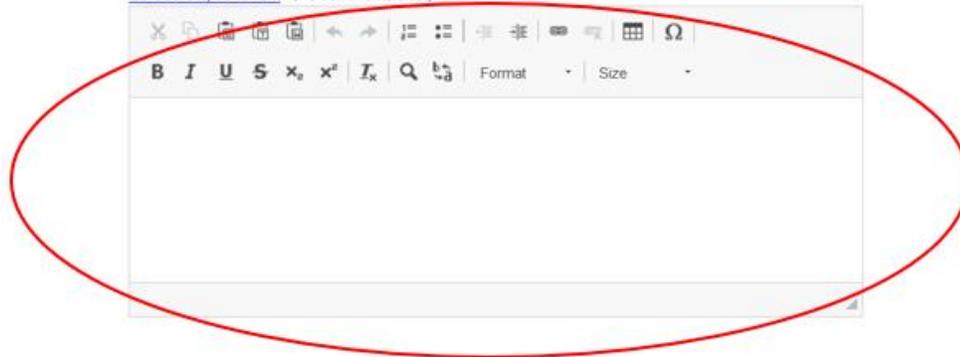
SECTION II

**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

**1. If so please describe how prospective subjects will become aware of the research (for example, by a print, electronic, radio or television advertisement, or thru another mechanism)?**  
[Collaborate/Comment](#) (No comments exist)



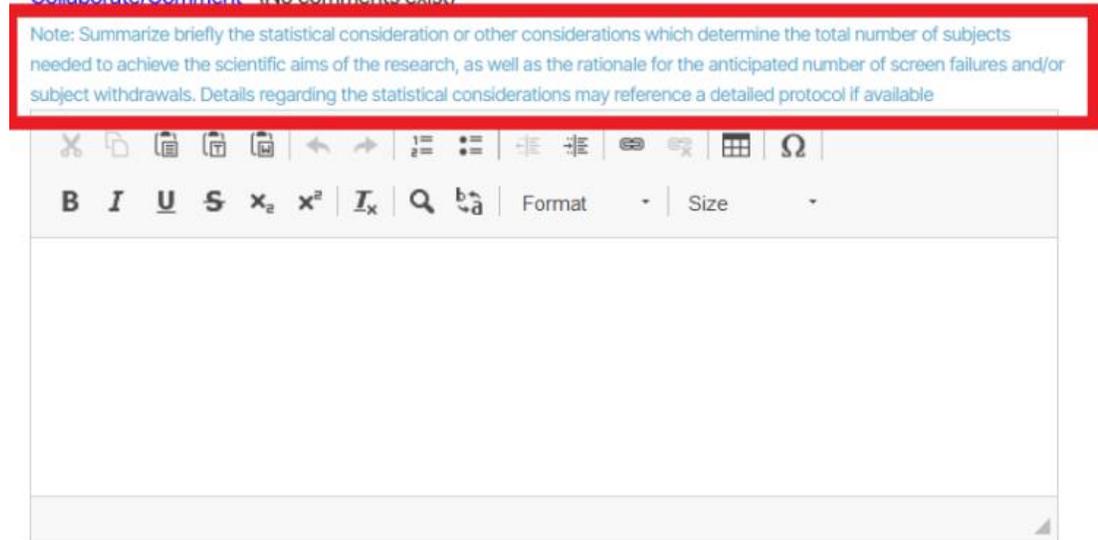
The image shows a rich text editor interface. At the top, there is a toolbar with various icons for text formatting and editing. Below the toolbar, there is a large, empty text area where the user can input their response. A red oval is drawn around the entire text editor area, including the toolbar and the text input field.

3) **Notes** within a question help instruct on how to properly answer the question on the application.

Ex.

**2. What is the statistical or other justification for the total number of subjects described above?**  
[Collaborate/Comment](#) (No comments exist)

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



The image shows a rich text editor interface. At the top, there is a toolbar with various icons for text formatting and editing. Below the toolbar, there is a large, empty text area where the user can input their response. A red box is drawn around the text area, highlighting the note text.

4) When offered selection bullets, **CIRCLE bullets** mean you will select ONE.

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

## 8. Vulnerable Subjects

### A. Will prisoners be included in the research?

[Collaborate/Comment](#) (No comments exist)

Yes  No

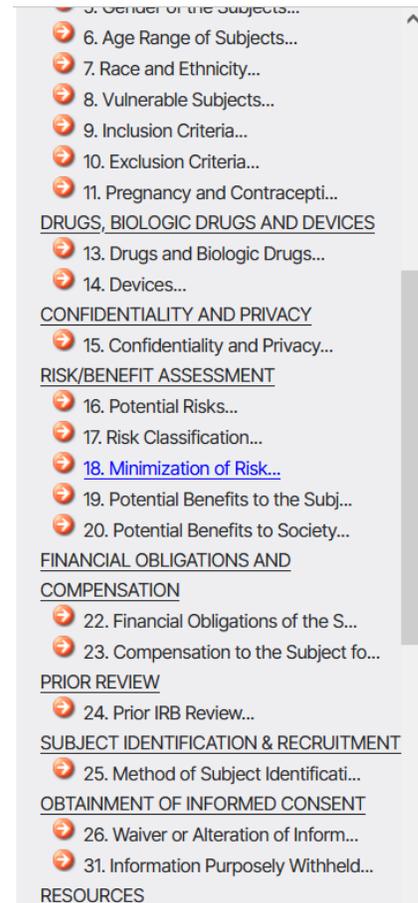
### B. Select from the list all of the vulnerable populations that will specifically be recruited to participate in this research.

[Collaborate/Comment](#) (No comments exist)

Note: This does not include subjects who are incidentally members of this group but who are not specifically recruited because they are members.

- Decisionally-impaired persons
- Critically ill patients
- Students of the investigator
- Employees of the investigator
- Educationally disadvantaged individuals
- Socially or economically disadvantaged individuals
- Individuals with a stigmatizing illness or condition
- Individuals from a marginalized social or ethnic group
- Other.
- No vulnerable subjects will be specifically recruited

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.