

Creating and Navigating a New Application in RSS

This document describes the basics of creating an application in RSS.

NOTE: only ONE person can be in an application making edits at one time.

- 1) Log in to your RSS account.
- 2) At the TOP of your home page is a black bar. On the FAR LEFT, there is a tab labeled **“IRB”**. Click this.



- 3) Under the red title “application” is a drop down listed **“New Protocol/sIRB Request”**. Click this.



- 4) You are now on a page listed as “New Application”. Here is where you select the TYPE of application you are submitting.

There is NO WAY TO TRANSFER YOUR APPLICATION to another application type later. If you do not select the correct application, you will be required to start from scratch on a brand-new application.

Click the **blue link** next to an application for a description and/or what kind of research may be submitted under that application type.

[CLICK HERE FOR A FULL BREAKDOWN OF THE TYPES OF APPLICATIONS](#)

New Application

INSTRUCTIONS: Carefully read the descriptions below and click on the one to which option to select, please contact the Office of Regulatory Affairs

If you are conducting a Clinical Trial at UNMC/NM, both IRB requirements. A detailed list of institutional requirements can be found at [UNMC IRB C](#)

Create New Application

- A. Biomedical Research OR Behavioral and Social Science Research
- B. Research involving the collection and/or use of human biological materials
- C. Exempt research (Note: only use this application if your research is exempt)
- D. Research involving medical records
- E. Tissue bank ONLY- the collection of human biological materials
- F. Humanitarian Use Device (HUD) [click here for description](#)
- G. Data Registry ONLY- the collection of information/data (typical of clinical research)
- H. Existing Paper Format Protocol
- I. Central IRB Application (CIRB)
- J. Single Patient Expanded Access Protocol (Drugs) [view](#)
- K. Single Patient Expanded Access Protocol (Device) [view](#)
- L. Emergency Use of a Test Article Report [view](#)

Create Single IRB Request

- A. Single IRB (sIRB) Request Form [view](#)

- 5) Once you click on an application type, you’ve opened up your new application!

- 6) From here you will complete all sections of the application marked with an **orange arrow**. You will see a breakdown of these sections on the LEFT side of your screen. You can navigate through your application using labels on the left side of the screen.

Answering parts of the application a certain way will spawn additional questions, sections, and/or addendums. These will continue to pop up in the menu on the left side of the screen.

SECTION I

- Therapeutic/Non-Therapeutic...
- 1. Title of Protocol:...
- 2. Responsible Personnel:...
- 3. Funding Source:...
- 4. Deadline for IRB Approval:...
- 5. Contract:...
- 6. Agreements:...
- 7. Study Sites:...
- 8. Principal Investigator Ass...
- 9. Principal Investigator Fin...

SECTION II

SECTION III

SECTION I

SECTION II

PROTOCOL ABSTRACT

- 1. Provide a brief (less than...

PURPOSE OF THE STUDY AND BACKGROUND

- 2. Purpose of the Study...
- 3. Background and Rationale...

CHARACTERISTICS OF THE SUBJECT POPULATION

- 4. Accrual...
- 5. Gender of the Subjects...
- 6. Age Range of Subjects...
- 7. Race and Ethnicity...
- 8. Vulnerable Subjects...
- 9. Inclusion Criteria...
- 10. Exclusion Criteria...
- 11. Pregnancy and Contraception Re...

DRUGS, BIOLOGIC DRUGS AND DEVICES

- 13. Drugs and Biologic Drugs...
- 14. Devices...

CONFIDENTIALITY AND PRIVACY

- 15. Confidentiality and Privacy...

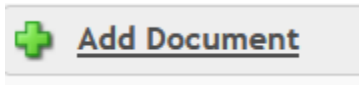
RISK/BENEFIT ASSESSMENT

The IRB recommends paying close attention to the **notes** provided throughout the application. This will assist with a potentially quicker turnaround from the assigned IRB analyst.

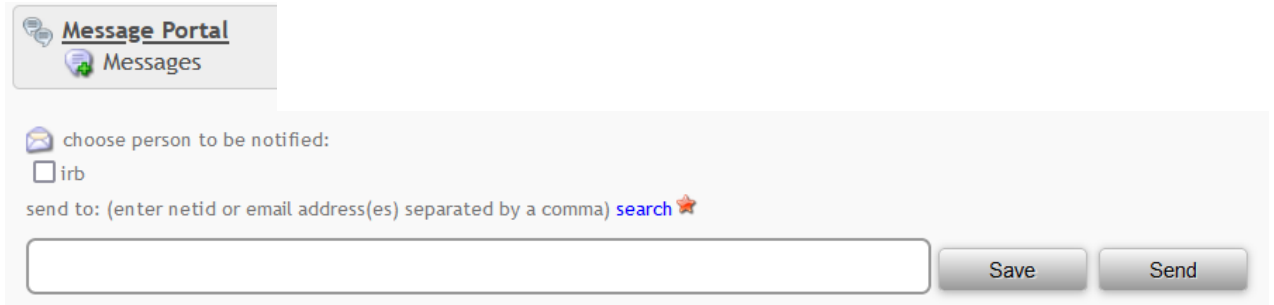
Be sure to **“SAVE”** your progress often while you progress through your application. This can be done by (a) **clicking “Save”**, (b) **clicking into a different section**, or (c) **using the “previous” or “next” options.**

We advise you **NOT** to hit refresh when working on your application as it could result in losing parts of an application. Please be patient when things are loading as this can sometimes take a little bit of time.

- 7) On the left side of the screen you will see a **green plus** with a link labeled **“ADD DOCUMENT”**. Click this to add any necessary documents (i.e. protocol, investigator brochure, advertisements, etc.)

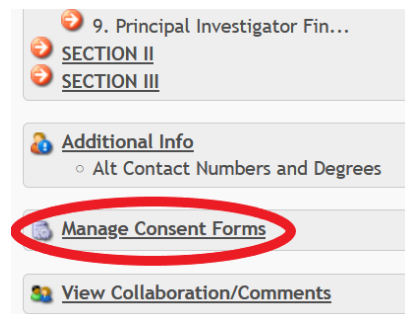


- 8) In the top, left corner is a link labeled **“MESSAGE PORTAL”**. Use this to send and receive messages with the IRB. This is not used to communicate with other study team members.

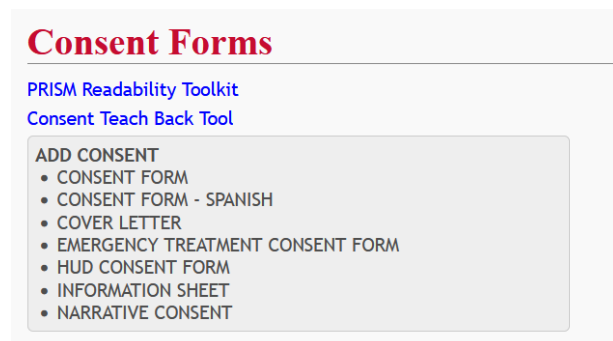


- 9) Unless a waiver of consent is requested, a **consent form must be created** before submitting the application. If you’re completing a cIRB application, attach the consent form/template provided by the sponsor, IRB of record, etc.

To create a consent form, click **“Manage Consent Forms”** in the left-hand menu:



Click the type of consent form you’d like to develop.



NOTE: details on the type of consent forms and how to create one can be found in the RSS education guide titled *“Consent Forms 101”*.

10) At the top, under the two rows of blue and green arrow tabs, are 5 buttons:



- “**Exit Application**”- use this to exit your application and work on it at a later date. NOTE: This button must be used to exit the application. **Exiting out of RSS will not automatically exit you out of an application.** Only one person can edit an application at a time, so if you forget to exit the application, no one else will be able to make edits until you do.
- “**Save**”- saves your progress- click often!
- “**Submit**”- click when you’re ready to submit. If you are missing any required items, the system will not allow you to submit.
- “**Delete**”- click to delete an application. You will receive an email confirming the deletion from IRBORA.
- “**Open PDF**”- this will open a PDF version of your application

NOTE: Once an application is submitted, there will be no edits until the IRB does their initial review.