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CHAPTER 1: Getting Started

1. HOW TO ACCESS AND LOG-IN TO THE SYSTEM
   
   A. WEBSITE: https://net.unmc.edu/rss
   
   B. LOG IN
      
      1) Enter your UNMC NetID or NHS Olympus ID username and password (*Figure 1A*)
      
      2) If you have a NHS Olympus ID (i.e. Nebraska Medical Center email), click the box labeled “@nebraskamed.com”. (*Figure 1B*)
      
      3) If you **do not have** a UNMC NetID or a NHS Olympus ID, click REQUEST ACCOUNT (*Figure 1C*)
C. REQUEST AN ACCOUNT

1) A separate window will open up with a form to complete. *(Figure 2)*

2) Enter in all required information.

3) In the section called ACCOUNT DETAILS *(Figure 2A)*, for the PRIMARY PURPOSE OF ACCOUNT *(Figure 2B)*, choose the option UNMC RSS- IRB Application *(Figure 2C)* from the drop down menu.

4) Once the form has been submitted, you will receive 2 emails from “ITS System Access”. These emails will have your UNMC NetID username and password. For questions regarding this process, please contact the UNMC HELP desk at (402) 559-7700.
2. IRB ON INITIAL SCREEN (Figure 3A)
   A. NEW PROTOCOL (Figure 3B)
      Choose this option to start an electronic application.
   B. VIEW/EDIT (Figure 3C)
      Choose this option to view and open any application that you have created or are listed on. This is also where you will find all additional forms (e.g., continuing review, protocol violation report etc.).

3. LINKS ON INITIAL SCREEN (Figure 4A)
   Choose this option (Figure 4B) to go to the RSS page where you can submit an Adverse Event report for a particular study.
4. ICONS & BUTTONS

A. SIGN OUT BUTTON (Figure 5A)
   This button logs you out of the electronic system. Signing out of the electronic system does not
   automatically sign you out of the application.

B. EXIT BUTTON (Figure 5B)
   This button MUST be clicked any time you exit an application. If you SIGN OUT of the system without using
   the EXIT button, the application will remain locked for 15 minutes. This means that the application cannot
   be signed or edited.

C. SAVE BUTTON (Figure 5C)
   This button saves any information you have entered or changed in the application.

D. SUBMIT BUTTON (Figure 5D)
   This button submits the application to the IRB.

E. DELETE BUTTON (Figure 5E)
   This button will erase the entire document. If application is in active status, the application will go back to
   the last approved version.

F. PRINT PDF BUTTON (Figure 5F)
   This button enables you to view, edit or print the .pdf version of the application.

G. NEXT/PREVIOUS BUTTONS (Figure 5G)
   This button advances you to the next or previous section in the application. All information in entered in a
   section will be saved when you move to another section.

H. ORANGE ARROW (Figure 5H)
   This icon indicates that questions within a particular section have not been answered. An application
   CANNOT be signed until all of the questions have been answered (i.e., there are no more orange arrows.
   NOTE: The orange arrows in Section I next to Principal Investigator, Scientific Reviewer and Faculty Advisor (if
   applicable) will ALWAYS be visible until the application has been signed.

I. MAGNIFYING GLASS (Figure 5I)
   This icon provides additional information about the application or questions within the application.
4. ICONS & BUTTONS (cont’d) (*Figure 6*)

**J. RED “X” (*Figure 6A*)**
This icon deletes information (e.g., text or personnel) that has been entered.

**K. GREEN “+” SIGN (*Figure 6B*)**
This icon indicates where to add study personnel (application) and standard statements (consent forms).

![Figure 6](image)

**L. LOCK ICON (*Figure 7A*)**
This icon will appear on the application VIEW/EDIT screen if someone else is logged into the application. ONLY one person can edit the application at a time. By placing the cursor over the lock, you will be able to see the name of the person who is logged into the application.

**M. GREEN PENCIL ICON (*Figure 7B*)**
This icon indicates that the application is ready to be signed.
CHAPTER 2: Starting a New Application

1. SELECTING THE CORRECT APPLICATION FOR YOUR RESEARCH (Figure 8)
   Choosing the correct application is VERY important! Placing the cursor over the name of each application will give you a brief description of the types of research that should be submitted using that application (Figure 8A). Also, by clicking on the magnifying glass you can read more information about that particular application. NOTE: Existing studies that are currently active, may need to be submitted on a different type of application than was initially used and approved by the IRB.

2. COMPLETING THE SECTIONS
   A. Section I
      1) Status(Figure 9)
         a) New Submission (Figure 9A)
            Choose this option when creating a brand new study.
         b) Revised electronic IRB Application(Figure 9B)
            Choose this option when submitting a change to an existing approved electronic application.
         c) Initial electronic submission of an existing expedited IRB approved protocol (Figure 9C)
            Choose this option when converting a paper application to the electronic system.
2) **Add Personnel (Figure 10)**

   a) Click the green arrow to take you to the Search Employee screen. *(Figure 10A)*

   b) **Search options**
      
      i. Enter part of or entire name *(Figure 10B)*
      
      ii. Search by department *(Figure 10C)*

   c) **Click** on the correct name(s) from the list. *(Figure 10D)*

   d) Once the name(s) appears in the Selected Employees box *(Figure 10E)*, click **OK** to have name(s) applied to the application. *(Figure 10F)*

   e) If you need to remove a name from the list, click **CLICK TO REMOVE**. *(Figure 10G),

   f) If the name of the person you are searching for is not found select **Request Name**, add the requested information and an email will be sent to the IRB. *(Figure 10H)*

   *Note: Only 1 person can be listed under a specific study role.*

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*Figure 10*
3) **Delete Personnel**

   Click **RED X** next to the name. (**Figure 11A**)

4) **Additional Info** (**Figure 11B**)

   Degree information must be provided for all study personnel (**Figure 12A**). An alternative contact # (e.g., cell phone or pager) is optional (**Figure 12B**).

   **NOTE:** This section will auto-fill with the information entered from previous applications.
B. SECTION II

1) **All questions** marked with an orange arrow must be answered. Depending upon the answers provided, additional questions may be asked and/or addenda attached.

2) **Navigating within Section II**
   a) Clicking on a particular sub-section header (e.g., Protocol Abstract) will take you to that particular sub-section of the application. Once in the sub-section, clicking on specific question numbers will take you directly to that question.
   b) Use your mouse to scroll up and down on the page.
   c) Use the NEXT or PREVIOUS options to go to the next/previous sub-section.

C. SECTION III (Figure 13)

Use the submission checklist to indicate all documents attached to the application. It is VERY important that you indicate any other review committees (e.g., P&T committee) that have to review and approve the application. (Figure 13A)
3. ADDENDUM

The response to certain questions may automatically attach an addendum (e.g. if you are enrolling Decisionally-impaired subjects in the research, then Addendum E will be attached) (Figure 14A). The addendum will show up in the left side of the screen. If you think that the addendum has been inadvertently attached, click on the magnifying glass next to the addendum (Figure 14B). This will pull up a dialogue box (Figure 15) that explains which question(s) and response(s) caused the addendum to attach.
4. MANAGE CONSENT FORMS
   A. Creating a consent form

   1) **Choose** the correct consent form under *ADD CONSENT*. *(Figure 16A)*

   2) **Optional information** (i.e. fields are not required)

      a) **Department**: A department name should be entered if the research is being conducted at UNMC or UNO. *(Figure 16B)*

      b) **Consent Identification**: If the study has multiple subject groups (e.g. control group vs. experimental group), the name of the particular group can be entered in this field. *(Figure 16C)*

         **NOTE**: You do not have to enter the IRB# in this field as it will automatically be generated on the consent form by the system.

      c) **Optional Version Info**: If there is any additional version information (e.g., date, amendment number) that you want displayed at the bottom of the consent form, it can be entered into this field. *(Figure 16D)*

   3) **Consent Headers**

      You must choose at least one consent header. *(Figure 16E)* This is the letterhead that will be displayed on the consent form. Choosing multiple consent headers will generate a consent form on each letterhead. **NOTE**: Selecting TNMC will generate the hospital letterhead which displays the medical record barcode.
4) **Save Button** *(Figure 17A)*

This function is used to **SAVE** the consent form.

5) **Delete Button** *(Figure 17B)*

This function is used to delete the consent form that you are working in. This button does not delete the entire application.

6) **Complete Button** *(Figure 17C)*

Once a consent form is finished, it must be moved from **EDIT** to **COMPLETED** status before the application can be submitted.

   a) Save the consent form.
   b) Click **COMPLETE**.

7) **Copy Button** *(Figure 17D)*

This function can be used when a study requires multiple consent forms of the same type but with slightly different information.

   a) Create the first consent form.
   b) Click **COPY**.
   c) A 2nd consent form is generated which then can be revised as necessary.

8) **Exit Button** *(Figure 17E)*

Click the **EXIT** button to leave the consent page.

9) **Draft Button** *(Figure 17F)*

This function is used to open the .pdf version of the consent form. Always review the .pdf version of the consent form prior to submission of the application for formatting and grammatical errors.

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**Figure 17**

![Consent Forms Diagram](image-url)
10) Standard Statements
Clicking on the green circle *(Figure 18A)* next to a statement will automatically enter it into the corresponding text box.

**NOTE:** When the green circle is clicked, a blue bar will appear at the bottom of the screen indicating that the text has been added. *(Figure 18B)*

![Figure 18](image)

11) Authorized Study Personnel
Click the box *(Figure 19A)* next to the study personnel that you want displayed on the bottom of the consent form.

**NOTE:** It is a requirement that all personnel authorized to document informed consent are listed on the consent form.

![Figure 19](image)
5. Add Documents *(Figure 20A)*

This function allows you to upload any document(s) (e.g., grant, advertisement) that need to be attached to the application.

A. Select the category that best corresponds with the type of document that is being uploaded *(Figure 21A)*

B. Click BROWSE to find file and attach. *(Figure 21B)*

C. Complete DESCRIPTION with the title of document added (example - IB Version 2.0 dated August 26, 2011). *(Figure 21C)*

D. Click UPLOAD to upload the document. *(Figure 21D)*

E. Click X to close the dialogue box when finished uploading. *(Figure 21E)*

6. IRB Email Utility *(Figure 20B)*

This function enables individuals working in the application to easily email other individuals also listed on the application.

A. Checking the box next to the person(s) that you want to email *(Figure 20C)* *(Figure 21A)*

B. Click IRB EMAIL UTILITY *(Figure 20B)*
7. Signing the application

All sections of the application, including the Conflict of Interest (COI) questions, must be completed in order for the PI (Scientific Reviewer or Faculty Advisor) to sign off. Once logged in and in the VIEW/EDIT Screen, the person signing will see a green pencil. (Figure 23A)

A. Click on the study next to the green pencil. (Figure 23A)
B. Perform a thorough review of the study, addressing any issues or concerns prior to signing.
C. Based on your role, click on the section you need to sign

1) Principal Investigator
   a) Go to the PRINCIPAL INVESTIGATOR FINANCIAL DISCLOSURE (Figure 22B)
   b) Once COI questions have been answered (Figure 22C), you must hit SAVE (Figure 22D) before you can sign.
   c) Scroll to the bottom of PRINCIPAL INVESTIGATOR FINANCIAL DISCLOSURE.
   d) Click CLICK TO SIGN next to your name (Figure 22E).

2) Scientific/Scholarly Merit and Resource Reviewer
   a) Go to the SCIENTIFIC/SCHOLARLY MERIT AND RESOURCE REVIEW CERTIFICATION Section (Figure 22G)
   b) Check the box next to your name to sign the application (Figure 24A)

3) Faculty Advisor
   a) Go to the CERTIFICATION OF FACULTY ADVISOR (Figure 22F)
   b) Check the box next to your name to sign the application (Figure 24A)
D. The IRB EMAIL UTILITY (Figure 25A) can be used to send an email to the PI, coordinator or anyone listed on the study that the application has been signed.

E. Hit EXIT (Figure 25B) at the top of the screen.

F. Once all signatures have been obtained, then the study is ready for submission to the IRB. Only hit the SUBMIT (Figure 25C) button when it is certain that the application is ready for IRB review.

8. Submitting the application

If all orange arrows have been addressed, all consent forms have been COMPLETED (Figure 26B) and are no longer in EDIT (Figure 26A) mode, and all signatures have been obtained, click the SUBMIT button.
9. Change Request for an approved application and/or consent form(s)

A. Go into the application

B. Select **RESET EDIT (Figure 27A)**. This creates a new version of the application and/or consent form(s) and archives the previous version.

C. Choose the status **REVISED ELECTRONIC IRB APPLICATION (Figure 28A)** and provide the IRB# (Figure 28B).

D. Make the necessary changes and click **SAVE (Figure 28C)**.

E. On the left hand side, a **CHANGE REQUEST (Figure 28D)** button will appear. Click this button to complete the Request for Change form.

F. Complete all questions marked with orange arrows and provide all required justifications.

G. The PI will sign the application and click **SUBMIT (Figure 28E)**.

*NOTE: Clicking the DELETE button on the application, will ONLY delete the new version that has been created and set the previous version to ACTIVE. It will not delete the entire application from the system.*
10. Finding Other Forms
   A. Go to the VIEW/EDIT screen.
   B. Click the NOTEPAD (Figure 29A) icon next to the corresponding study.
   C. Select the appropriate form from the list provided (Figure 30A).
   D. Address all of the questions.
   E. Once the PI has signed the form, click SUBMIT.

11. REMINDERS
   A. All ORANGE arrows must be gone prior to signatures being received.
   B. There is no order in which the application needs to be signed.
   C. When your consent forms are filled out, you must click COMPLETE.
   D. Once an application is active (status states ACTIVE), clicking DELETE will take you back to the last approved version.
   E. If changes need to be made when an application is in SUBMITTED or PENDING status, please contact IRB Office to reset the application to edit mode.
   F. Degrees must be entered in ADDITIONAL INFO but contact # is optional. If individual does not have a degree enter “n/a”.
CHAPTER 3: IRB Submission Procedure

1. Assigning IRB #
   This will be done once the application is submitted and the IRB Administrator receives the notice, they will then assign an IRB #.

2. Full Board Studies
   A. Once the IRB # has been assigned, an email will be sent to the PI and Lead Coordinator with the paper packet requirements.
   B. Packets must be delivered to the IRB Office. Once the IRB Office has received the packets, PI and Lead Coordinator will receive an email with date of full board meeting in which the study will be reviewed.

   Note: See IRB website (www.unmc.edu/irb) for list of submission and pre-review deadlines and meeting dates.

3. Expedited and Exempt Studies
   Once the IRB # has been assigned, an email will be sent to the PI and Lead Coordinator that the study has been accepted into the system and they will be notified regarding the review. No paper documents are required.

4. IRB Correspondence (e.g. approval letters)
   All correspondence/notifications from IRB office will be attached to the electronic application under the ADD DOCUMENT section under IRB CORRESPONDENCE. (Figure 31A)
CHAPTER 4: Tips & Tricks of Editing

1. To enter a single space in between paragraphs, hold down the SHIFT key and hit ENTER.

2. Do not try to copy and paste a table into the application. Use the TABLE function (Figure 32A) within the application itself.

3. Different browsers (i.e., Firefox or Internet Explorer) offer different functions. For example, Firefox has spell check where Internet Explorer does not. If you are having problems, try a different browser first before proceeding. NOTE: Firefox and Internet Explorer work better than Google Chrome or Safari. Also, older versions of Firefox and Internet Explorer do not support the application.

4. When making a bulleted list, you can increase or decrease the indent by using the appropriate buttons (Figure 32B). NOTE: Bulleted lists that are copied and pasted from a PDF document do not actually contain bullet points. Rather those are symbols which should be deleted. Once the text has been inserted you can create your own bulleted list within the text box.

5. Periodically open the PDF document to check the spacing of the document.

6. Copy and paste small sections of text from another document rather than very large sections.

7. ALWAYS first contact the IRB before spending hours working on trying to fix an editing issue. Most times these problems can be fixed quickly.
CHAPTER 5: Troubleshooting

I cannot open the Informed Consent Form (ICF) to make copies.

In the COMPLETED CONSENT Section, click on header (UNMC, UNO, etc.). It will become blue. Click to enter the ICF (Figure 33A). Once PDF opens, you can print the forms.

I cannot sign the application.

1. Check to make sure that all questions have been answered throughout the application and any attached addenda.

2. In the VIEW/EDIT screen, check to see if there is a LOCK icon (Figure 34A) next to the protocol. If so, someone is already in the application and must first hit EXIT before the application can be signed.
I cannot insert a graph into the application.

Graphs and figures can be attached as a document to the application but cannot be inserted into the application itself.

There is an addendum attached to my application but I don’t know where it came from.

Click on the MAGNIFYING GLASS icon next to the addendum (Figure 35A). This will pull up a dialogue box (Figure 36) that explains which question(s) and response(s) caused the addendum to attach.