eProST
(Electronic Protocol Submission and Tracking)

USER GUIDE
(This guide is designed for users whose academic departments have enabled the full electronic workflow within eProst)

University of Miami
Human Subjects Research Office
1500 NW 12th Avenue, Ste. 1002, Miami, FL 33136

Tel: 305-243-3195
Fax: 305-243-3328
Email: eprost@med.miami.edu
# Table of Contents

PREFACE ..................................................................................................................................................... 3  
CHAPTER 1: REQUESTING AN EPROST ACCOUNT ................................................................. 5  
CHAPTER 2 – LOGGING IN TO EPROST ................................................................................. 8  
CHAPTER 3: "HOME WORKSPACE" AND "PERSONAL FOLDERS" ..................................... 11  
CHAPTER 4: WORKING WITH FOLDERS ................................................................................. 13  
CHAPTER 5: USING 'SMARTFORMS' – GENERAL PRINCIPLES ........................................ 16  
CHAPTER 6: CREATING A NEW PROTOCOL ........................................................................... 20  
CHAPTER 7: CONFLICT OF INTEREST DISCLOSURES ....................................................... 23  
CHAPTER 8: SUBMITTING AMENDMENTS .............................................................................. 24  
  STEPS TO SUBMITTING AMENDMENTS ................................................................................. 24  
  STEPS TO EDIT THE AMENDED STUDY PROTOCOL FORM ........................................... 25  
CHAPTER 9: CREATING A CONTINUING REPORT ................................................................ 26  
CHAPTER 10: COMPLETING A "REPORTABLE EVENT" FORM ............................................ 28  
CHAPTER 11: CREATING A FINAL REPORT ............................................................................ 30  
CHAPTER 12: GUIDE FOR DEPARTMENTAL APPROVERS AND ANCILLARY COMMITTEE MEMBERS ................................................................................................................................................. 31  
CHAPTER 13: IRB MEMBER'S GUIDE TO REVIEWING STUDIES REQUIRING APPROVAL BY THE FULL IRB ................................................................................................................................. 33  
  STEPS TO REVIEWING/APPROVING A SUBMISSION AS A PRIMARY OR SECONDARY REVIEWER ................. 33  
  STEPS TO VIEW A SUBMISSION THAT WILL BE REVIEWED BY THE CONVENED IRB ..................... 34  
CHAPTER 14: IRB MEMBER'S GUIDE TO REVIEWING EXPEDITED AND EXEMPT STUDIES................................................................................................................................................................................. 37  
CHAPTER 15: FREQUENTLY ASKED QUESTIONS .................................................................... 39  
  WESTERN IRB ............................................................................................................................. 39  
  EPROST REDEPLOYMENT .......................................................................................................... 39  
APPENDIX 1: WORKFLOW DIAGRAM (SIMPLIFIED) ........................................................... 41  
APPENDIX 2: TABLE OF FIGURES ............................................................................................ 42
**Preface**

**eProst** is the Human Subject Research Office's (HSRO) web-based, computer system that automates the entire lifecycle of human subject research activity. eProst is designed to support both behavioral and biomedical research studies, including studies requiring IRB approval by the full panel or those that require expedited or exempt review. We have chosen the eProst system because it will provide more information while reducing the cycle time required to gain IRB approval of a newly submitted study, amendment and continuing/final report.

Through eProst, human subject research studies may be:

1) written and submitted to the University of Miami's Institutional Review Board (IRB)
2) reviewed by the IRB
3) tracked through the review process by Principal Investigators and others
4) modified as necessary to gain IRB approval
5) amended by investigators
6) managed by means of continuing reviews and reports such as those required for adverse events, study deviations, etc.

This step-by-step guide should facilitate the use of eProst to make the IRB process nearly paperless for investigators and reviewers. For additional information about the eProst system or about IRB policies, regulations and the review process, the UM Human Subjects Research Office maintains a home page at [http://hsro.miami.edu](http://hsro.miami.edu) and a help desk at 305-243-3195.

In writing and/or revising this eProst guide, a goal is to make it an easily comprehensible reference manual for investigators and their staffs, for IRB members, reviewers and oversight staff from the Human Subject Research Office, for other University offices and for individuals authorized to access the eProst system. Many of the chapters may be intuitive for some but necessary for others. We ask for flexibility in this regard since we sought to create a manual that avoids its sometimes definition as "an object that raises the monitor to eye level".

In writing this eProst guide, we also recognized that much information is repeated to fit different situations. This is deliberate to avoid pitfalls that may occur when computer jargon is misinterpreted (see Preface Figure 1). Investigators may find it helpful to read the chapters relevant to their specific activities while using reference information from other cited chapters.
Special thanks are due to HSRO Education Coordinator Joey Casanova who led in the development of this guide. He and the HSRO team emphasize that while much effort was expended to make this guide as complete and useful as possible, it remains a 'living document' that will be reviewed, revised and supplemented as needed to ensure that it accounts for policy changes, new concepts of organization and the questions and concerns of the community of eProst users. Comments and suggestions on the organization and contents of this guide are welcome. These may be addressed to IRB members or to the Human Subject Research Office (HSRO).

Myron Rosenthal, Ph.D.
Vice Provost for Human Subject Research
CHAPTER 1: REQUESTING AN ePROST ACCOUNT

Every eProst user must have his/her own eProst "account" with a unique username and password.

Having an eProst account allows the user to connect (i.e. "log-in") to the eProst system; and it allows the eProst system to identify the user.

**NOTE:** Users should not share their password or permit anyone else to access the eProst system under their account.

Steps to request an eProst account:

1) Click (i.e. "open") a standard internet browser

**NOTE:** The HSRO recommends the use of Internet Explorer by individuals with Windows as their computer's operating system and Safari for individuals using Apple computers.

NOTE: The browser must be set to allow "cookies" (pieces of information stored by web pages on your computer. Cookies are used to remember login information and other data). If "cookies" are not yet allowed on your computer, click on Tools in the browser's toolbar, then click on Options and then click on Privacy to access the necessary application.

2) When the internet browser screen appears on the computer, users should access the HSRO website. This is done by typing the following (underlined) address into the browser toolbar which is usually at the top of the screen:

   http://hsro.miami.edu

3) When the HSRO website has been accessed, the HSRO Home Page should appear. Figure 1 is a copy of this home page. Attention should be directed to the top right hand corner of the page under the heading Links of Interest where there is a link titled: New User? Request an eProst Account.

4) Click on New User? Request an eProst Account. This will bring up the eProst Account Request form which is shown in Figure 2.
5) Complete the **eProst Account Request form** by filling in all required information. When the form is completed, click the **Register** button located at the **bottom** of the form.

**NOTE:** Required fields are marked with a red asterisk (*). The form cannot be submitted until all of these fields have been completed.

6) Your eProst username and password will be sent within one business day to the email address you provide in the form.

**NOTE:** When you receive the email letter, read it carefully. It states that the password must be changed upon the first login to the eProst system.

**NOTE:** If you ever forget your username or password, please contact the eProst help desk at 305-243-3195 or send an email request to **eprost@med.miami.edu**.

![HSRO home page](www.hsro.miami.edu)

**Figure 1:** the HSRO home page from the website at www.hsro.miami.edu.
Figure 2: eProst Account Request Form

Account Request

To be granted access to eProst, you must be an employee, student, or authorized associate of the University of Miami (UM) or Jackson Health System (JHS). If you do not already have an eProst account, please complete the following account request form. You must submit a valid UM or JHS email address for your request to be processed. Your request will be forwarded to the Human Subjects Research Office (HSRO) for verification purposes. After verification, a username and temporary password will be issued to you via email.

Note: If you already self-registered, or you have already been notified of your eProst account but have forgotten your username and/or password, please do not complete this self-registration form; contact eProst Technical Support for further assistance.

eProst Account Request Form

Please complete the following information. All fields with a red asterisk (*) are required.

- First Name:
- Middle Name:
- Last Name:
- Title:
- E-mail address:
CHAPTER 2 – LOGGING IN TO ePROST

To access eProst, users must login (i.e. connect to the computer system by supplying a username and password).

Steps to login to eProst:

1) Ensure that you have an eProst account with a username and password (c.f. Chapter 1).

Figure 3: Perhaps this user did not read Chapter 1?

2) Click (i.e. "open") a standard internet browser

NOTE: The HSRO recommends the use of Internet Explorer by individuals with Windows as their computer’s operating system and Safari for individuals using Apple computers.

NOTE: The browser must be set to allow "cookies" (pieces of information stored by web pages on your computer. Cookies are used to remember login information and other data). If "cookies" are not allowed, click on Tools in the browser's toolbar, then click on Options and then click on Privacy to access the necessary application.
3) When the internet browser screen appears on the computer, users should access the HSRO website. This is done by typing the following into the browser toolbar which is usually at the top of the screen:


4) Press ENTER

5) When the HSRO website has been accessed, the HSRO Home Page should appear. Figure 1 (in Chapter 1) is a copy of this home page.

6) Click on Login in the upper right corner of the HSRO Home Page. Alternatively, you may click on Login To eProst which is found under Links of Interest on the right of the page. The Welcome to eProst page should be presented. A copy of this page is shown in Figure 3.

7) Enter your username and password and click the Login To eProst button.

   NOTE: As an added security measure, eProst has an automatic “Lock-Out” policy. Nine (9) unsuccessful login attempts will lock your eProst account. Please contact the eProst help desk at 305-243-3195 or send an email request to eprost@med.miami.edu.
Welcome to eProst

You are about to enter eProst, the University of Miami Electronic Protocol Submission and Tracking System. Please enter your username and password below.

- If this is your first time entering the system, you will be asked to change the password originally assigned to you via e-mail.
- If you do not have an eProst account, complete the Account Request form.

For technical support issues call 305-243-3195 and ask for the eProst helpdesk or e-mail our helpdesk at eprost@umiami.edu.

Figure 4: The "Welcome to eProst" login page
CHAPTER 3: "HOME WORKSPACE" AND "PERSONAL FOLDERS"

The HOME WORKSPACE is the page on the computer screen which serves as the user's main page (i.e. "home-page") for working with eProst.

PERSONAL FOLDERS are specific to the user's current role

When a user logs into the eProst system (c.f. Chapter 2), a home workspace page appears on the screen. This page is individualized for each eProst user. It is from this Home Workspace page that users control what they will accomplish within the eProst system.

A typical Home Workspace page (created for "Test PI") is shown in Figure 4. Controlling eProst from the Home Workspace page is straightforward once it’s the basic principles are understood.

The Home Workspace page is individualized to each user's privileges to provide necessary access to one or more personal folders. These folders are specific to the role(s) permitted to be assumed by users. The available roles may be selected by clicking from the list on the left side of the Home Workspace page.

For example, users who are submitting materials (i.e. studies, reports or amendments) to the IRB should click on Protocol Team. Users who are conducting reviews of someone else's study at the departmental level should click on Departmental Approver. Users who are conducting reviews for the IRB should click on the IRB Member role. Users who are conducting reviews for an ancillary committee should click on Ancillary Committee Member.
Once a "role" has been selected, a folder specific for that role will appear on the screen. This folder acts as the gateway to provide users with access to studies, information and work areas through tabs found in the center of the page. The function of these tabs will be explained in subsequent chapters.

**NOTE:** If studies or other items are expected but not seen on the selected folder, users should first ensure that the proper role has been selected.

The **Home Workspace** also contains a button to create a new study (protocol). Clicking on this button will provide users with a blank “SmartForm” necessary for submission to the IRB.

**NOTE:** Creation of continuing reports, amendments and reportable events documents must be initiated from within a study workspace (c.f. Chapter 6). This is because these items must be linked to an existing study.

![Figure 5: The "Home Workspace" page for the user "Test PI"](image-url)
This chapter uses the "PROTOCOL TEAM" folder as an example

This chapter describes functions and access available within folders. Since the most commonly used folder is that created for the Protocol Team (c.f. Figure 4), this will serve as the example folder.

Figure 6: For advice, call the HSRO 'help' desk at 305-243-3195 or use your discretion if children are available.

The Protocol Team folder should be used by principal investigators, co-investigators, collaborators and staff of a study. This folder contains only studies and other items on which the user is listed as a member of the study team.

NOTE: The specificity of studies and other items occurs in all folders. For example, if a user has access to and selects the Departmental Approver role, he/she will only see studies awaiting departmental approval.

The Protocol Team (or any other folder) can be accessed by
a) logging into eProst (Chapters 1 and 2)
b) clicking on Protocol Team (or other folder) from within the Home Workspace page (Chapter 3)
Information within the **Protocol Team** folder is by using the tabs found in the center of the page. Clicking on a specific tab will determine what information will become immediately available. The availability of tabs varies with the role selected. Tabs on the **Protocol Team** folder are:

1) **My Inbox:** This displays studies, continuing/final reports, amendments and reportable events that require the user's attention. An example of an “inbox” folder is shown in Figure 5.

   **NOTE:** If an expected item is not available within the user's **Protocol Team** folder, check that the PI has listed the user for access to that study.

   Items within the **My Inbox** folder may be accessed by clicking on the study title (“Name”).

   Items within the **My Inbox** folder may be sorted by clicking on the table headings (i.e. ID, Name, Principal Investigator, Date Modified, Type of Submission, State)

   ![Figure 7: An example of the "MY INBOX" tab](image)

2) **Protocols:** Displays all studies to which the user has been permitted access by the Principal Investigator. Information may be accessed and sorted as in the **My Inbox** tab

3) **Continuing Reports:** Displays all continuing reports and final reports for studies permitted to the user. Information may be accessed and sorted as in the **My Inbox** tab

   **NOTE:** eProst assigns separate IDs to protocols and continuing/final reports. Clicking the study (protocol) ID or title ("name") will access the study; clicking a continuing/final report ID or title ("name") will access that report.
4) **Amendments:** Displays all amendments for studies accessible by the user. Information may be accessed and sorted as in the My Inbox tab.

5) **Reports:** Allows access to reports of interest from the HSRO to the protocol team. Reports are generated by clicking on Run or the Name (title) of the report.

6) **Reportable Events:** Displays all reportable events for studies to which the user is permitted access.

    **NOTE:** The definition of "Reportable Events" is broad (c.f. IRB Written Policies and Procedures in the HSRO website). This definition includes (but is not limited to) items such as serious adverse events, IND safety reports, study deviations, updated investigator brochures and affirmations of translated documents.

Reportable events may be accessed by clicking on the ID number or Title of the event. The associated study is viewable by clicking on the Protocol ID or Protocol Title.
CHAPTER 5: USING 'SMARTFORMS' – GENERAL PRINCIPLES

Information is sent from the protocol team to the IRB via eProst's electronic "SmartForms". Specific forms exist for such items as study applications, continuing reports and amendments. These intelligent WebForms are specific for the desired task to capture study information from the research team through a standard browser.

Note to eProst users: Filling out "SmartForms" is not a complicated task and may be simpler than navigating through some of our local streets.

SmartForms utilize conditional branching logic to customize what questions are being asked based on prior answers and/or research procedures. What this logic does is guide users to the appropriate questions while bypassing unnecessary portions of the forms (i.e. investigators are required to complete only those questions that apply to his/her study).

Investigators can fill out smart- forms online without ever printing them.
There are five methods by which information is entered into eProst SmartForms. These methods are:

1) **Text Boxes:** users should enter text directly into these blank boxes

2) **Pull-Down Menus:** Users must select one option from a menu of possible options

3) **Selectable Check Lists:** Users should select multiple options from this pre-established list

4) **"Add Documents" Button:** Documents should be attached to the SmartForm in the same manner as attaching documents to an email

5) **Subforms:** These automatically become available to users when answers to questions define the need for additional forms and information

In all SmartForms, required fields are marked with an asterisk (*). These fields must be completed in order to continue to the next page or to submit the form.

The two primary methods of navigating through SmartForms are the BACK and CONTINUE buttons at the top and bottom of each page (c.f. Figure 6).

1) **BACK Button:** Clicking this button moves the user to the previous page.

   **NOTE:** *This is not the "Back" button on the browser window but rather an internal control within the eProst system*

2) **CONTINUE Button:** Clicking this button moves the user forward to the next page. When this next page is accessed, all previous pages are automatically saved.

Using the CONTINUE button enables eProst to select required questions based on previous answers. Users are advised that while they can navigate to subsequent pages using the Jump To function described later in this Chapter, the latter may not differentiate between questions that are applicable based on prior answer and those question that are not relevant to the submission (i.e. the Jump To function is not built on the SmartForm "branching logic").

**NOTE:** *Clicking the CONTINUE button will have result in an “error message” if all required fields on the current page have not been completed*
After the first time the user saves a "SmartForm", all pages will have the following links available at both the top and bottom (c.f. Figure 6):

1) **SAVE:** Clicking this link saves the previously entered data without moving the user to other sections of the application. It is recommended that users save their work at regular intervals to avoid computer malfunctions.

   **NOTE:** For security, the eProst system will log users out after 30 minutes of inactivity. If so logged out, work on the current page will be lost. It is recommended that users who leave their computer idle should save their work and lock their computer

2) **EXIT:** Clicking this link will close the current SmartForm and return the user to the workspace from which the submission is managed (i.e. the protocol workspace or the amendment workspace etc). These workspaces are described in sections below.

   **NOTE:** Clicking **EXIT** does not save the current SmartForm page. Users should first click **SAVE** before clicking **EXIT**

3) **HIDE/SHOW ERRORS:** Clicking this link will reveal a list of incomplete required fields. This link is most useful when the SmartForm has been completed but not yet validated or submitted. Its advantage is that it will define oversights and omissions by the user.

   **NOTE:** Users should be aware that this list will show fields as incomplete if those fields have not yet been addressed by the branching logic or the investigator; and it may not list required fields if the need for additional information has not yet been defined

4) **PRINT:** Clicking this link will print the current page of the SmartForm.

5) **JUMP-TO:** This function is driven by a pull-down menu from which users may select a page in the SmartForm and be taken directly to that page.

   In all SmartForms, the last page will provide instructions for submitting the form. The **FINISH** button replaces the **CONTINUE** button on this page. Clicking the **FINISH** button exits the form and directs the user to an appropriate workspace page (note – alternatively, the user may click the **EXIT** link to accomplish this same purpose).
1. General Information

PLEASE NOTE: If this is a Full Board Protocol, prior to completing this application, PIs should contact the Pre-Board Specialists at the HSRO (305-243-3195 or eprost@med.miami.edu) to determine whether the study will be reviewed by the UM IRB or by WHIR.

1.1. Title of Study/Project:

1.2. Additional (UM/HMS/SCCC etc.) Identifying Number:

   CINB Number (if applicable):

1.3. Principal Investigator:

   [Name] [State] [Medical License # (if applicable)]

1.4. Department: (This field will be populated automatically based on PI’s department once the page is saved)

   Major Sub-division: (If applicable)

   Research Center: (If applicable)
CHAPTER 6: CREATING A NEW PROTOCOL

Steps to create a new protocol are:

1) Log into eProst (Chapters 1 and 2)

2) Click on Protocol Team from within the Home Workspace page (Chapter 3)

3) Click New Protocol on the left side of the Home Workspace to access the forms that must be completed for study submission (c.f. Figure 6).

4) Complete the form using the principles detailed in Chapter 5.

When the "new study" SmartForm is complete, click on the FINISH button or EXIT link to be directed to the Study Workspace (c.f. Figure 7).

The Study Workspace is similar to the My Inbox workspace described in Chapter 6. However, the activities available from the Study Workspace are required for the user to accomplish the following:

a. Complete the study application and forms such as those for Conflict of Interest (c.f. Chapter 8) and the Principal Investigator's Assurance Statement required for study submission

**NOTE:** All study team members must complete the Conflict of Interest Disclosure in order for the system to permit the Principal Investigator to validate and submit the new study application

**NOTE:** The system requires the Principal Investigator to complete and electronically “sign” the Principal Investigator's Assurance Statement in order submit the new study application

b. Respond to requests from reviewers

c. Track the submission through the approval process

d. Manage the study (i.e. submit amendments, continuing reports etc) after its approval
5) When the eProst form and submission of all Conflict of Interest Disclosures are complete, the PI may forward the study for departmental approval by clicking Submit Protocol which is available within the My Activities section of the Study Workspace.

**NOTE:** The system will permit only the PI to submit the study.

6) When the Submit Protocol activity is selected, the Principal Investigator’s Assurance Statement will open in a separate window. The PI should read the statement and must select "yes" to acknowledge his/her agreement.

7) Click the OK button to submit the Principal Investigator’s Assurance Statement and submit the study.

**NOTE:** Study will be forwarded for approval from the academic department of the PI. After departmental approval, the study will be forwarded to any applicable Ancillary Committees for approval as required. The study will then be forwarded to the HSRO for IRB review.

**NOTE:** If reviewers request study modifications, these will be communicated to the PI and designees via email and the study will be listed in the My Inbox tab and the system will place the study into a state that allows editing.
Figure 9: The Study Workspace
CHAPTER 7: CONFLICT OF INTEREST DISCLOSURES

All members of the protocol team must complete a Conflict of Interest Disclosure. This may be accomplished at any time prior to study submission.

Steps to completing the COI disclosure are:

1) Log into eProst (Chapters 1 and 2)
2) Click on "Protocol Team" from within the Home Workspace page (Chapter 3)
3) Click on "My Inbox" from the tabs in the center of the screen
   
   **NOTE: The My Inbox view may be the user's default setting**

4) Within My Inbox is a list of studies requiring some action by the user. Click the appropriate study title to access the Study Workspace (c.f. Figure 7)

5) If there is an orange box on the left side of the Study Workspace titled Disclosures Required, this box will list all study team members who must submit a Conflict of Interest Disclosure (COI) form.

   **NOTE: The orange box will not appear once everyone on the study team has completed required disclosures**

6) Users may submit a COI form by clicking Submit Conflict of Interest under the My Activities heading on the left side of the Study Workspace.
7) Complete the COI form using the principles detailed in Chapter 5.
8) Click the check box to attest to the accuracy of COI answers
9) Click OK to submit the Conflict of Interest Disclosure.
CHAPTER 8: SUBMITTING AMENDMENTS

Steps to submitting amendments are:

1) Log into eProst (Chapters 1 and 2)
2) Click on Protocol Team from within the Home Workspace page (Chapter 3)
3) Click on Protocols from the tabs in the center of the screen
4) Within Protocols is a list of studies available to the user. Click the appropriate study title to access the Study Workspace (c.f. Figure 7)

**NOTE:** The Study Workspace will differ from that shown in Figure 7 because the current study has already been approved. Therefore, the Study Workspace will include a section entitled Create with buttons for accessing various activities such as reports and amendments

5) From within the Create section of the Study Workspace, click New Amendment button to access the amendment SmartForm.

6) Complete the amendment SmartForm using the principles detailed in Chapter 5.

7) Whenever the amendment SmartForm is saved, an Amendment Workspace, similar to the Study Workspace becomes available. Activities available from the Amendment Workspace are required for the user to accomplish the following:

   a. Complete the amendment and the Principal Investigator's Assurance Statement required for amendment submission

      **NOTE:** The system requires the Principal Investigator to complete and electronically “sign” the PI Assurance Statement in order submit the amendment

   b. Respond to requests from reviewers

   c. Track the amendment through the approval process

   d. Access the amendable version of the study protocol (i.e. "view protocol") in order to make changes reflected in the amendment (see below)
e. Complete the PI assurance form and submit the amendment via the Submit Amendment activity on the Amendment Workspace.

**Steps to edit the amended study protocol form are:**

1) Access the study protocol SmartForm via View Protocol button on the Amendment Workspace or the Edit Protocol button on the amendment SmartForm (see above)

2) Edit the amended eProst protocol SmartForm to reflect the modifications described in the amendment.

**NOTE:** The eProst system will not permit the submission of an amendment without a corresponding modification to the study protocol SmartForm.
CHAPTER 9: CREATING A CONTINUING REPORT

Continuing reports must be submitted 60 days prior to a lapse in IRB approval.

Steps to create a continuing report are:

1) Log into eProst (Chapters 1 and 2)

2) Click on Protocol Team from within the Home Workspace page (Chapter 3)

3) Click the Protocols tab to display a list of all of the protocols on which you (the "user") have been included.

4) Click the title of the study for which a continuing report is to be created. This will open the Study Workspace

5) Click New Continuing Report from within the Study Workspace. This will launch the continuing report form.

6) Complete the continuing report form using the principles detailed in Chapter 5.
**NOTE:** Select *Continuing Report* from the drop-down list in question 1.1. Complete the rest of the eProst continuing report form as appropriate.

**NOTE:** Required fields are indicated by a red asterisk (*). If these fields are not completed, the continuing report will not be submitted.

7) Before exiting, be sure to save changes with the **SAVE** link. When the continuing report SmartForm is complete, click on the **FINISH** button or **EXIT** link to be re-directed to the **Study Workspace** (c.f. Figure 7).

**NOTE:** If an amendment is being submitted with the continuing report, the amendment should be created by clicking **Create Related Amendment** in the **Study Workspace**. (c.f. Chapter 8 on Creating Amendments).

8) When the continuing report form is finalized, press **Submit Continuing Report** from the **Study Workspace** to review and attest to the contents of the **Principal Investigator's Assurance Statement**. As appropriate, click "yes" and then **Ok**

**NOTE:** The system will permit only the PI to submit the study.

9) eProst will forward the study to the Principal Investigator's academic department for review and approval. Once approved, eProst will forward the study to appropriate ancillary committees (if applicable) for approval and then to the HSRO for IRB review.

**NOTE:** If reviewers request modifications to the report, these will be communicated to the PI and designees via email, the study will be listed in the **My Inbox** tab and the system will place the continuing report into a state that allows editing.
CHAPTER 10: COMPLETING A "REPORTABLE EVENT" FORM

Steps to completing a "reportable event" form are:

1) Log into eProst (Chapters 1 and 2)

2) Click on Protocol Team from within the Home Workspace page (Chapter 3)

3) Click the Protocols tab to display a list of all of the protocols on which you (the "user") have been included.

4) Click the title of the study in which a "reportable event" has occurred. This will open the Study Workspace

5) Click New Reportable Event from within the Study Workspace. This will launch the reportable event form (c.f. Figure 8)

6) Complete the reportable event form using the principles detailed in Chapter 5.

   NOTE: Select the type of reportable event in question 1.1 and complete the rest of the form as appropriate.

   NOTE: Required fields are indicated by a red asterisk (*). If these fields are not completed, the form will not be submitted

7) Before exiting, be sure to save information with the SAVE link. When the "reportable event" SmartForm is complete, click on the FINISH button or EXIT link to be re-directed to the Study Workspace (c.f. Figure 7).

8) When the reportable event SmartForm is finalized, press Submit Reportable Event from the Study Workspace to review and attest to the contents of the Principal Investigator's Assurance Statement. As appropriate, click "yes" and then Ok

   NOTE: The system will permit only the PI to submit the reportable event form

9) eProst will forward the reportable event form to the HSRO for review. When a determination is made, the PI will be contacted via email.
1. Reportable Event Information

The Reportable Event activity may be used to report the following events to the IRB:

- **Internal Serious Adverse Event** - for Internal serious adverse events (serious adverse events occurring to subjects enrolled at UM/Jackson Health System (JHS) sites or at non-JHS sites under the jurisdiction of the University of Miami IRBs).
- **Protocol Deviation/Study Violations**
- **Study Exception Request** - a temporary change in a protocol or a change that pertains only to one or a few participants.
- **Unanticipated Problem Involving Risks to Participants or Others**
- **Notifications** - for an updated drug/device package insert or investigator brochure, translated consent forms and certificates of translator, external serious adverse events, and other interim reports.

Please do **NOT** use this admitt to report **internal non-serious adverse events**. Internal non-serious adverse events should be reported at the time of continuation/final review, using Form HSR-4A, Internal Non-Serious Adverse Event Log Sheet.

![Figure 11: The "Reportable Event" form](image)

---

**eProst User Guide**  
**Page 29**
**CHAPTER 11: CREATING A FINAL REPORT**

**Steps to create a final report are:**

1) Log into eProst (Chapters 1 and 2)

2) Click on Protocol Team from within the Home Workspace page (Chapter 3)

3) Click the Protocols tab to display a list of all of the protocols on which you (the "user") have been included.

4) Click the title of the study for which a final report is to be created. This will open the Study Workspace

5) Click New Final Report from within the Study Workspace. This will launch the final report form.

6) Complete the final report form using the principles detailed in Chapter 5.

   **NOTE:** Select Final Report from the drop-down list in question 1.1. Complete the rest of the eProst continuing report form as appropriate.

   **NOTE:** Required fields are indicated by a red asterisk (*). If these fields are not completed, the final report will not be submitted

7) Before exiting, be sure to save changes with the SAVE link. When the "final report" SmartForm is complete, click on the FINISH button or EXIT link to be re-directed to the Study Workspace (c.f. Figure 7).

8) When the final report form is concluded, press Submit Final Report from the Study Workspace to review and attest to the contents of the Principal Investigator's Assurance Statement. As appropriate, click "yes" and then Ok

   **NOTE:** eProst will permit only the PI to submit the final report

9) eProst will forward the final report to the Principal Investigator's academic department for review and approval. Once approved, eProst will forward the final report to appropriate ancillary committees (if applicable) for approval and then to the HSRO for IRB review. When a determination is made, the PI will be contacted via eProst notification
CHAPTER 12: GUIDE FOR DEPARTMENTAL APPROVERS AND ANCILLARY COMMITTEE MEMBERS

This chapter describes eProst processes available only to designated Departmental Approvers and Ancillary Committee Members

Steps to reviewing/approving a submission are:

1. You will receive an eProst-generated e-mail notification that there is a study pending your approval.

2. Log into eProst (Chapters 1 and 2)

3. Click on Departmental Approver role or the Ancillary Committee Member role from within the Home Workspace page (Chapter 3), depending on the type of review you will be performing and the permissions allowed to you within eProst.

4. Click on the title of the study you wish to access under the My Inbox tab on the Home Workspace.

5. Click on the View Protocol button on the top left of your screen to view the SmartForm in a multipage format. The user may use the CONTINUE and BACK buttons to navigate within the SmartForm as well as the Jump To: functionality. Alternatively, you may click on the Printer-Friendly Version button if you wish to combine all of the pages within the SmartForm into one continuous web page.

6. Users will be presented with specific activities based on their roles and the permissions assigned to them within the system. These activities include one or more of the following:
   - Issue Departmental Administrative Approval
   - Issue Departmental Scientific Approval
   - Issue Departmental Chair Approval
   - Issue Ancillary Committee Approval
   Additionally, all users with a reviewer role will all have the following two activities available to them:
   - “Changes Requested by Department Reviewer” or “Changes Requested by Ancillary Reviewer”
   - “Issue Department Disapproval” or “Issue Ancillary Disapproval”
7. If the reviewer wishes to request modification(s) to the submission, he/she may do so by clicking the appropriate Changes Requested by… activity. This will automatically unlock the SmartForm for editing by a member of the study team, set the state of the submission to Changes Requested by Originating Department or Changes Requested by Ancillary Reviewer as appropriate, and alert the PI and study contacts via email of the status of the submission.

8. If the reviewer wishes to disapprove the submission, he/she may do so by clicking the Disapprove Study activity. eProst will open a separate window asking the user to confirm their disapproval of the study and provide a comment area to allow the user to provide any further communication they wish to attach to the disapproval.

**NOTE:** The PI will be provided with the ability to appeal any disapprovals.

9. If the reviewer wishes to approve the submission and forward to the next step in the workflow, he/she may do so by clicking the appropriate Issue Approval activity. eProst will open a separate window asking the user to confirm their approval of the study and provide a comment area to allow the user to provide any further communication they wish to attach to the approval.

**NOTE:** If the study is in the Originating Department Review state and the Department Chair or their designees issues the chair approval, eProst will override the requirement for additional departmental review and forward the study to any applicable Ancillary Committees.
CHAPTER 13: IRB MEMBER’S GUIDE TO REVIEWING STUDIES
REQUIRING APPROVAL BY THE FULL IRB

This chapter describes eProst processes available only to members of an Institutional Review Board

Steps to reviewing/approving a submission as a Primary or Secondary Reviewer are:

1. You will receive an eProst-generated e-mail notification that there is a study pending action from you.

2. Log into eProst (Chapters 1 and 2)

3. Click on IRB Member role from within the Home Workspace page (Chapter 3).

4. Click on the title of the study you wish to access under the My Inbox tab on the Home Workspace.

   **NOTE:** The My Inbox tab will only list those submissions to which the user has been assigned as a primary or secondary reviewer for the convened IRB meeting and expedited and exempt studies where the user has been assigned as a reviewer. Full board submissions will be identifiable by a current state of IRB Meeting Assigned. If you wish to read those protocols that will be reviewed at the meeting, please reference the instructions provided in the second part of this chapter.

5. Click on the View Protocol button on the top left of your screen to view the SmartForm in a multipage format. The user may use the CONTINUE and BACK buttons to navigate within the SmartForm as well as the Jump To: functionality as described in Chapter 5. Alternatively, you may click on the Printer-Friendly Version button if you wish to combine all of the pages within the SmartForm into one complete web page.

6. The HSRO staff member who worked with this study prior to assignment to the IRB will record an Internal Communication Log event with any necessary documents, such as guidance documents and checklists included in the event entry. The comments will be visible in the Study Workspace from the History Log and any attached documents will be accessible by clicking on their filenames.

   **NOTE:** The Internal Communication Log is only visible to IRB Members and HSRO staff.
7. Users will be presented with specific activities based on their roles and the permissions assigned to them within the system. These activities include:
   - Edit Consent Form
   - Request External Consultation
   - Study Team Communication Log
   - Internal Communication Log

   **NOTE:** The Edit Consent Form and Request External Consultation activities have been included for the ongoing and future development of the eProst system. This guide will be appropriately updated once these functions are fully tested.

8. If the user, as a reviewer, wishes to communicate with the Principal Investigator and other study contacts, he/she may do so by clicking the Study Team Communication Log activity. This will provide a location for the IRB Member to input any comments they wish and upload any applicable documents into the study workspace as well as alert the PI and study contacts via email that there is a new message available within eProst.

   **NOTE:** Any comments uploaded into the Study Team Communication Log will be viewable by any user who has permission in eProst to access the Study Workspace.

9. If the reviewer wishes to communicate with the HSRO and the other members of the IRB, he/she may do so by clicking the Internal Communication Log activity. This will provide a location for the IRB Member to input any comments they wish and upload any applicable documents into the study workspace. Currently, the HSRO recommends that IRB Members upload any modified study documents (such as the Informed Consent Form) into an Internal Communication event for future review by the convened IRB.

**Steps to view a submission that will be reviewed by the convened IRB are:**

1. Log into eProst (Chapters 1 and 2)

2. Click on the IRB Member role from within the Home Workspace page (Chapter 3).

3. Click on the Upcoming Meetings tab on the Home Workspace. The user will now have access to view all currently available meetings by Date, Start Time, Name and Committee. (c.f. Figure 9)
4. Click on the name of the meeting you wish to view to be taken to the Meeting Workspace. (c.f. Figure 10)

**NOTE:** In addition to allowing the user to access any studies that will be reviewed by the convened IRB at a given meeting, the Meeting Workspace also allows users to **Confirm Attendance** or **Decline Attendance** at the referenced meeting.

5. Click on the ID (eProst number) of the study you wish to access from the list of Electronic Agenda Items available from the Agenda tab of the Meeting Workspace. The user will be taken to the appropriate workspace for the submission. Any communication events will be visible from the History tab. The user may read the submission’s SmartForm by clicking the appropriate link to either View Protocol or view the Printer-Friendly Version. Any documents included with the SmartForm are accessible by clicking their titles from either of these views of the submission SmartForm or by clicking on the Documents tab of the Study Workspace.

![Figure 12: The "Upcoming Meetings" tab of the "Home Workspace"](image-url)
Figure 13: The "Meeting Workspace"
CHAPTER 14: IRB MEMBER’S GUIDE TO REVIEWING EXPEDITED AND EXEMPT STUDIES

This chapter describes eProst processes available only to members of an Institutional Review Board

Steps to reviewing/approving a submission are:

1. You will receive an eProst-generated e-mail notification that there is a study pending action from you.

2. Log into eProst (Chapters 1 and 2)

3. Click on IRB Member role from within the Home Workspace page (Chapter 3).

4. Click on the title of the study you wish to access under the My Inbox tab on the Home Workspace.

   **NOTE:** The My Inbox tab will only list those submissions to which the user has been assigned as a primary or secondary reviewer for the convened IRB meeting and expedited and exempt studies where the user has been assigned as a reviewer. Expedited and exempt submissions will be identifiable by a current state of Expedited Review in Progress or Exempt Review in Progress, as appropriate.

5. Click on the View Protocol button on the top left of your screen to view the SmartForm in a multipage format. The user may use the CONTINUE and BACK buttons to navigate within the SmartForm as well as the Jump To: functionality as described in Chapter 5. Alternatively, you may click on the Printer-Friendly Version button if you wish to combine all of the pages within the SmartForm into one complete web page.

6. The HSRO staff member who worked with this study prior to assignment to the IRB will add an activity titled Forwarded To Expedited Reviewer or Forwarded To Exempt Reviewer (as appropriate) in the study history with any necessary documents, such as guidance documents and checklists included in the event entry. The comments will be visible in the Study Workspace from the History tab and any attached documents will be accessible by clicking on their filenames.
7. Users will be presented with specific activities based on their roles and the permissions assigned to them within the system. These activities include:
   • Edit Consent Form
   • Submit Expedited Review (or Submit Exempt Review)
   • Request External Consultation
   • Study Team Communication Log
   • Internal Communication Log

   **NOTE:** The Edit Consent Form and Request External Consultation have been included for the ongoing and future development of the eProst system. This guide will be appropriately updated once these functions are fully tested.

8. If the user, as a reviewer, wishes to communicate with the Principal Investigator and other study contacts, he/she may do so by clicking the Study Team Communication Log activity. This will provide a location for the IRB Member to input any comments they wish and upload any applicable documents into the study workspace as well as alert the PI and study contacts via email that there is a new message available within eProst.

   **NOTE:** Any comments uploaded into the Study Team Communication Log will be viewable by any user who has permission in eProst to access the Study Workspace.

9. If the reviewer wishes to communicate with the HSRO and the other members of the IRB, he/she may do so by clicking the Internal Communication Log activity. This will provide a location for the IRB Member to input any comments they wish and upload any applicable documents into the study workspace. Currently, the HSRO recommends that IRB Members upload any modified study documents (such as the Informed Consent Form) into an Internal Communication event for future review by the convened IRB.

10. Once the user is prepared to complete their review of the Expedited or Exempt submission, he/she will then click the Submit Expedited Review or Submit Exempt Review activity as appropriate. eProst will then present the user with a form asking their recommendation and additional information such as the approval category, risk determination, and other information as required by federal and state regulations and UM Policies.
CHAPTER 15: FREQUENTLY ASKED QUESTIONS

Western IRB

1. What are the procedures for studies that will be reviewed at WIRB?
   WIRB and the HSRO require that two (2) printed copies of all submissions to be reviewed at WIRB be delivered to the HSRO. When submitting a new study for WIRB review, users must also complete an eProst SmartForm. Once the user indicates that the study will be reviewed at WIRB, eProst will generate “Short Form” which will only ask questions required for UM’s records. Continuing Reports, Final Reports or Reportable Events should be submitted using only the appropriate WIRB form. Amendments will also only require the submission of a WIRB form but the user is asked to update the eProst “Short Form” if necessary.

2. I have a study that is currently being reviewed at WIRB. Will this study now be reviewed by the UM IRB?
   The UM IRB’s are currently in the process of reacquiring some UM studies from WIRB. If your study is being reacquired, PI’s and study contacts will receive an email from a member of the HSRO staff at the time of continuing review letting them know. A Continuing Report should be submitted via eProst. Study teams should contact the HSRO at 305-243-3195 if you have any questions regarding the reacquisition of their studies.

EProst Redeployment

3. What occurred on November 1st, 2006 with the eProst system?
   The full workflow was implemented for the Department of Ophthalmology only. The workflow is a fully electronic process where the study report submission will go through various electronic stages until they are approved: These stages are: a) PI submission; b) department approval c) ancillary committee approval (if applicable); d) review by HSRO; e) review by IRB Board; and f) Approval/Disapproval. These steps ensure that all issues and concerns are adequately addressed. As eProst issues were discovered and corrected, the Department of Ophthalmology beta test was considered successful and other departments have subsequently been included within the eProst workflow. Workshops are being held within each department prior to its going on-line into the eProst system.

4. When will my department be activated on the electronic workflow?
   The HSRO is currently activating all departments on an individual basis. The goal is to have all department on-line by December 31st, 2007. The HSRO may be contacted at 305-243-3195 for specific dates or information.
5. **What are the requirements when submitting a Continuing Report or Amendment?**

When submitting a new Continuing Report or Amendment, the system will verify that the new protocol form has been completed. If this step has not been carried out, the user will receive a message requiring him/her to complete this form. Users should be proactive and complete the new protocol form before a Continuing Report or Amendment is required.

*Please contact the HSRO Help Desk at 305-243-3195 when completing a Final Report to bypass this requirement.*
APPENDIX 1: WORKFLOW DIAGRAM (SIMPLIFIED)

Protocol form is filled out and submitted

Protocol is approved by Originating Department

If needed, protocol is approved by Ancillary Committee(s)

Protocol is reviewed by the Human Subjects Research Office

If needed, protocol is reviewed by an External Consultant

Protocol is reviewed by IRB Board, Chair or Designee

Approved

Disapproved
## APPENDIX 2: TABLE OF FIGURES

Figure 1: the HSRO home page from the website at www.hsro.miami.edu .................. 6
Figure 2: eProst Account Request Form ................................................................. 7
Figure 3: Perhaps this user did not read Chapter 1? ............................................. 8
Figure 4: The "Welcome to eProst" login page ..................................................... 10
Figure 5: The "Home Workspace" page for the user "Test PI" .............................. 12
Figure 6: For advice, call the HSRO 'help' desk at 305-243-3195 or use your discretion if children are available ............................... 13
Figure 7: An example of the "MY INBOX" tab ................................................... 14
Figure 8: The first page of the SmartForm application for a new study ............... 19
Figure 9: The Study Workspace ........................................................................ 22
Figure 10: Perhaps a computer upgrade might help? ....................................... 26
Figure 11: The "Reportable Event" form ............................................................ 29
Figure 12: The "Upcoming Meetings" tab of the "Home Workspace" ................... 35
Figure 13: The "Meeting Workspace" .............................................................. 36