Office for Human Research Integrity (OHRI)
ePIRATE
Users Reference Guide

ePIRATE Home: http://epirate.ecu.edu/app
ePIRATE Assistance: umcirm@ecu.edu

OHRI Website: https://ecu.edu/irb
OHRI Office Phone: (252)744-2914
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Introduction

ePIRATE is a software application that enables researchers to submit human subject research protocols to the University and Medical Center Institutional Review Board online, using a web browser. The ePIRATE Home page address is: https://epirate.ecu.edu/app. Research submitted in ePIRATE is routed, reviewed, and finalized electronically.

This ePIRATE User’s Reference Guide gives you basic information that will familiarize you with using ePIRATE. To use ePIRATE you will need an ePIRATE account.

How to get an ePIRATE Account

Go to the OHRI website, http://ecu.edu/irb and click on this button. This will take you to the ePIRATE login screen.

If you are an ECU faculty, staff or student user and have a pirateID you will log in by clicking on the purple LOGIN icon. You should then expect/take the following actions:

- Enter your pirateID username and password and click sign in.
- The ePIRATE Registration screen will appear where you will be asked to indicate which role(s) you serve in the conduct of human research as well as other basic information. You should complete all required fields on this page and click the “Register” button.
- You will receive a notification that thanks you for registering. The UMCIRB staff will set-up your user account.
Then, you will receive an email notification from umcirb@ecu.edu asking you to create your user profile. A link back to ePIRATE will be provided in this email which will allow you to enter ePIRATE to create your profile.

When you return to ePIRATE and log in you will arrive at the ePIRATE Home Page (example below).

Click on “My Home” which you will see in the purple banner at the top of the screen located next to your name. This will take you to your ePIRATE workspace (example below).
• Click on the “Profile” tab, once you arrive at the next screen click on the link found at about mid-page that says “[Your Name] Profile” which will take you to your profile page where you may edit your profile by clicking on “Edit Researcher Profile” button. Complete all screens in the profile smart form and click the finish button once you’re done.

If you are a non-ECU ePIRATE user you will begin the registration process by clicking on the Non-ECU Registration link at the bottom of the log in page. You should then expect/take the following actions:

• You will arrive at the ePIRATE Registration screen where you will be asked to create your own user name, indicate which role(s) you serve in the conduct of human research as well as other basic information. You should complete all required fields on this page and click the “Register” button.
• You will receive an email notification from umcirb@ecu.edu notifying you that a follow-up email will be generated which will contain your temporary password.
• When you receive the follow-up email it will contain your temporary password and you will be asked to create your profile.
• You may then log in to ePIRATE on the Login page (as seen above) in the area indicated for those who do not have a pirateID. You will be prompted to change your password at this time.
• Once logged in you will arrive at the ePIRATE Home Page (example below).
• Click on “My Home” which you will see in the purple banner at the top of the screen located next to your name. This will take you to your ePIRATE workspace (example below).

• Click on the “Profile” tab, once you arrive at the next screen click on the link found at about mid-page that says “[Your Name] Profile” which will take you to your profile page where you may edit your profile by clicking on “Edit Researcher Profile” button. Complete all screens in the profile smart form and click the finish button once you’re done.
Logging in to ePIRATE After Registering and Creating Your Profile

You will be asked to register and create your profile only once, but you may return to update your IRB CITI module dates or upload your resume or CV. Thereafter, you will log in by taking the following actions:

- Access the ePIRATE Login Page by clicking on the following button located on the OHRI website: [Link] or by logging on at [https://epirate.ecu.edu/app](https://epirate.ecu.edu/app)
- At the ePIRATE Login page, log in according to the type of user (ECU –v- Non-ECU) you are.
- If your login is successful, you will be directed to the ePIRATE Home Page and you should see your name on the right side of the purple banner on the top of the screen.
- If, after several attempts, your login is not successful please contact OHRI at umcirb@ecu.edu or 252-744-2914.

Navigating ePIRATE

The ePIRATE Home Page

The purple and gold ePIRATE banner across the top of the page contains several navigational links. The ePIRATE Home Page displays news and information about ePIRATE and contains links to helpful information found on the OHRI website.
Your Name
The name link, in the top right of the purple banner, displays your registration information. This information is loaded at the time of ePIRATE registration.

My Home
The My Home link, located in the top right of the purple banner, takes you to your ePIRATE workspace. In your workspace you will find your ePIRATE inbox tab, IRB Studies tab and other important information regarding the research in which you are involved. This is your starting location for all interactions with ePIRATE.

Logoff
The Logoff link in the purple banner logs you off of ePIRATE.

Home
The ePIRATE Home link is on the left side of the purple banner. Clicking this link will take you back to the ePIRATE Home page.

IRB Studies
The IRB Studies link in the purple banner gives study team members access to all of their studies and related Amendments, Reportable Events and Continuing Reviews. Studies are divided under tabs which indicate if the study is In Progress, Approved, or Archived.
Exploring Your ePIRATE Personal Workspace

When you log in to ePIRATE then click the “My Home” link next to your name at the right of the purple banner, you are taken to your **personal workspace** (example below). Personal workspaces are designed to help you manage the research in which you are involved.

- “Page for [your name]” is noted at the top of the screen.
- The “My Roles” heading at the left shows the roles assigned to you
- The Inbox tab shows ePIRATE items that are awaiting action by you or another study team member.

To return to your personal workspace at any time, click the My Home link in the purple banner.

**Your Roles in ePIRATE**

If you have more than one role assigned to you in ePIRATE, the information you see in your workspace will depend on the selected role. The selected role shows in the gold bar at the top left side of the screen, and is the role in bold font under the “My Roles” heading.

To view the workspace for a different role, click that role name under the “My Roles” heading.
To view all ePIRATE items awaiting your action, you will need to select each different role you have, and view each Inbox list. You will receive an email notification at your regular email address whenever there is an item in ePIRATE that requires your attention, no matter your role.

Viewing Your Studies

By clicking on the IRB Studies tab in your workspace you will be able to view all the studies to which you have access as a member of the study team (PI, sub-investigator, Study Coordinator, Faculty Mentor, and Other Key Personnel). You may also click the Studies link in the purple banner to find studies to which you have access as a member of the study team.

When you view your studies by clicking on the Studies link in the purple banner you will also be able to view all Amendments, Continuing Reviews and Reportable Events, click those links from the column at the left Studies page.

Your studies may not require action, but you always have access to view them through the Studies link and the IRB Studies tab.

In order to view the details of a particular study you will click on the study title which will open the study’s workspace. Here you will find all of the details of that study. We will explore study workspaces later in this guide.

How to Use the Display Tabs

- The “Inbox” tab displays all studies to which you have access and which require action by a study team member.
- The “IRB Studies” tab displays studies with which you are associated but do not require any action by the study team at the time.
- If you have created copies of any submissions to use as "templates" for future submissions they will be found in the “Templates” tab.
- The “Profile” tab displays your user profile and is the location from which you may edit your profile if needed.

Creating a New Study

Your personal workspace, when in the “IRB Submissions” role, is the location from which you may begin to create a new study. Clicking on the “New Study” button located on the left side of the screen will open a new study “smart form”.

Quick Links

On the lower left side of the screen in your personal workspace you will find live links to the OHRI website where you will continue to have access to our templates for documents such as consents, assents, COI Disclosures and HIPAA Authorizations.
To complete the submission process more quickly, we recommend you create and save documents so they are ready for upload as you move through the application.

**Exploring the Study Workspace**

The *study workspace* is the home page for a study. You see the study workspace when you click on the study name from your home page or the IRB Studies link.

The study workspace gives you information about where the study is in the review process, as well as access to the study application pages and all information associated with the study.

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**Study Header**

The study header includes the rows of information in the top of the workspace that displays identifying information about the study.

The study header always displays:

- **Study** - the short title of the study
- **Protocol ID** - the UMCIRB number (UMCIRB XX-XXXX)
- **Principal Investigator**
- **Study Coordinator**
- **Funding Source(s)**
- Current Expiration Date
- Letter of Approval View – link to approval of new study

**Current State**

The Current State in the gold box at the top of the left side of the screen shows the current status of the study (i.e. Pre-submission, IRB Staff Review, Ancillary Review, Assigned to IRB Meeting, etc)

**My Activities**

The buttons under the “My Activities” heading on the left side of the study workspace screen show the activities that are available to you. Activities include Submit Study, Submit Changes, Agree to Participate, Create New Reportable Event, Create New Amendment, Create New Continuing Review etc. Your role on the study and the study state determine the actions available to you.

**Viewing the Study Smart Form**

**View Study**

To display the study application pages one at a time, click the “View Study” button on the left of the study workspace screen. When the study is in a state where it is editable you may also view the study by clicking the “Edit Study” button which you’ll find in the same location. Your role on the study and the current state of the study determine whether or not the study is editable and which button appears.

- The UMCIRB number shows at the top right of the smart form screen in the purple banner.
- To move through the study pages, click the Continue and Back buttons.
- To view an attached study document, click the name link to open the document.
- To jump to a different smart form page, click the arrow next to the Jump To: drop down box.
- To save the study page, click the Save link in middle of the top light blue banner or click Continue
- To exit the smart form pages and return to the study workspace, click the Exit link in the middle of the top light blue banner.

**Printer Friendly Version**

The “Printer Version” button displays the smart form pages in a format that is more suitable for printing.
• In this view you may scroll through the smart form pages simply by using your scroll bar.
• To view an attached study document, click the name link to open the document.
• To print the smart form, click the Print button at the top of the smart form.
• To close the view and return to the study workspace, click the Close button.

Study Workspace Tabs

History Tab
The History tab in the study workspace shows the review activities. Each activity shows the name of the person who executed the activity, and when. The review activities display in order, with the most recent activities at the top.

Amendments
For approved studies, the Amendments tab shows amendments to the study. To view an amendment and its review information, click the name of the amendment to go to its workspace.

Continuing Reviews
For approved studies, the Continuing Review tab shows Continuing Reviews. To view a continuing review and its review information, click the name of the continuing review to go to its workspace.

Reportable Events
For approved studies, the Reportable Events tab shows Unanticipated Events, Protocol Deviations, DSMB correspondence and other problems/events that require reporting to the UMCIRB. To view a reportable event and its review information, click the name of the reportable event to go to its workspace.

Documents
The Documents tab is a shortcut view to documents attached to the study, such as protocols, research proposals, consent forms, assent forms, letters of support, HIPAA Authorization documents, etc.

Change Log
The Change Log tab shows all changes made to the study by Study Staff after PI signature.

Pre Review Status
The Pre Review Status tab provides the user with a list of all pending and received required Department Approvals and Ancillary Approvals. Please
note, Ancillary Approvers will receive reminder notifications every five
days if they have not taken action on an item that requires their attention.
This tab only appears when a study is in a state prior to the “Approved”
state.

**Agree to Participate**

The Agree to Participate tab provides the user with a list of the study team
members as well as whether or not they have agreed to participate and the
date on which they did so. This tab only appears when a study is in a state
prior to the “Approved” state.

**Exploring the Amendment Workspace**

The *amendment workspace* (example below) is the home page for an amendment.
You see the amendment workspace when you click on an amendment name from
the Amendments tab on a study workspace, or the Amendments link from the IRB
Studies link in the purple banner.

The amendment workspace gives you information about the current state of the
amendment (where the amendment is in the review process) and access to the
modified study smart form. The modified study is a copy of the Original
Approved study. The modified study must contain all of the changes proposed in
the Amendment Request Form. When the amendment is approved by the IRB, the
modified study becomes the Approved study.

The amendment workspace is similar to the study workspace, but has some
unique features.

Amendments include, study revisions, revisions to consent and assent documents,
and investigator revisions.
Amendment Header

The amendment header always displays:

- Amendment: - AMD # - the short title of the approved study plus (Amd#_UMCIRB XX-XXXX) – the amendment sequence number and the Protocol number of the approved study

Amendment Workspace Buttons

View Amendment

Clicking on this button will open the Amendment Smart Form which is the form that describes the proposed changes to the study.

Printer-Friendly Amendment

The Printer-Friendly Amendment button displays the Amendment Smart Form pages in a format that is more suitable for printing.

- In this view you may scroll through the smart form pages simply by using your scroll bar.

View Modified Study

The modified study smart form displays when you click on the View Modified Study button from the amendment workspace. Changes proposed in the amendment smart form must be made to the modified study application smart form.
**Printer-Friendly Study**

The Printer-Friendly Study button displays the modified study application smart form in a format that is more suitable for printing.

- In this view you may scroll through the smart form pages simply by using your scroll bar.

**View Changes**

The View Changes Button will allow the user to view the changes to the modified study. While in the View Changes screen the Change Log tab allows the user to see the differences between the original approved study and the modified study as proposed in the amendment. For a comparison view of the changes click on the text next to the notepad (epad) icon.

**Exploring the Reportable Event Workspace**

The *reportable event workspace* (example below) is the home page for reportable events. You see the reportable event workspace when you click on the Reportable Events tab in a study workspace, or the Reportable Events link from the IRB Studies link in the purple banner. The reportable event workspace gives you information about the current state of the reportable event (where the event is in the review process) and access to the reportable event smart forms.

Reportable Events include:

- Unanticipated Problems
- Protocol Deviation/Violation
- Data Safety Monitoring Report
- Other problems or events requiring reporting to the UMCIRB
Reportable Event Header

The reportable event header always displays:

- Reportable Event Type – Unanticipated Problem, Protocol Deviation/Violation, Data Safety Monitoring Report, Other problems or events requiring reporting to the UMCIRB.
- Event Name
- Event Description
- Protocol ID – the Protocol UMCIRB # XX-XXXX
- Date Event Reported and Occurred
- Principal Investigator
- Study Coordinator

View Reportable Event

This button allows for viewing the Reportable Event smart form which is the form that describes the reportable event.

Printer Version

The Printer Version button displays the Reportable Event smart form in a format that is more suitable for printing.
In this view you may scroll through the smart form pages simply by using your scroll bar.

Exploring the Continuing Review Workspace

The continuing review workspace (example below) is the home page for the continuing review. You see the continuing review workspace when you click on a continuing review name from the Continuing Review tab in a study workspace, or the Continuing Review link from the IRB Studies link in the purple banner. The continuing review workspace gives you information about the current state of the continuing review (where the event is in the review process) and access to the continuing review smart forms.

Continuing Review Header

The continuing review header always displays:

- Continuing Review CR#: Short Title of the study
- Protocol UMCIRB number
- Principal Investigator
- Study Coordinator
- Study Status (i.e., enrolling participants, closed to enrollment, etc)
- Total enrolled for this site since last progress review
• Whether three have been any SAEs since last continuing review.
• Whether the consent requires modification
• Whether significant new findings are being disclosed
• Whether any modifications have been implemented but not received prior to IRB approval.

View Continuing Review
This button allows for viewing the Continuing Review smart form.

Printer-Friendly Version
The Printer-Friendly Version button displays the Continuing Review smart form in a format that is more suitable for printing.

• In this view you may scroll through the smart form pages simply by using your scroll bar.

Using ePIRATE:

Tips for Completing Study Pages

Required Fields
Required fields are preceded by a red asterisk. You can Save, Exit, and Jump To other smart form pages without completing the required fields. However, the Continue button checks for errors on the page, so you must complete the required fields to continue to the next study page. When you submit a study, all the pages are checked for required fields.

Tips for Selecting Study Personnel
If you are attempting to add a person as a study team member to a new study and cannot find them, they might not be registered as an ePIRATE user, or may not have registered for the role for which you would like to request their participation. Please contact that person to determine if either of these is the issue. You may also contact the OHRI if you believe that neither of these is the issue and that it might be some other problem.

Tips for Attaching Documents
Study documents and reviewed documents are attached in a way that is similar to adding attachment to e-mail.

How to View an Attached Document
Click the title link of the attached document
Tips for Naming Attached Documents

In ePIRATE, you can retain multiple versions of the same document. The attachment Title is not the same as the File Name. The Title is a pointer to the attached files, some of which have different file names, e.g. “ICF Adult Ver. 2.doc”, “ICF Adult Ver. 3 tracked.doc”, etc.

When you first attach a document, if you leave the Title field blank, ePIRATE uses the file name, e.g. “ICF Adult Ver. 2.doc” as the Title. However, you might decide to type in a Title instead, such as “Adult Consent”. Then, when you attach different files, revised versions of the same document, you don’t have to revise the Title.

How to Manage Paper Documents

All documents must be attached in ePIRATE in electronic format. This includes investigator brochures, patient diaries, and protocols. Please request electronic documents from sponsors. If you cannot obtain electronic copies, they must be scanned.

We recommend saving scanned documents in PDF format.

Tips for Responding to Reviewer Requests

Reviewers can use tracked changes in Microsoft Word to request specific changes to study documents. Study Staff can use track changes to respond. Each person must make it clear to the other which changes are requested, and/or accepted.

- Submit Clean Documents

When you submit a study for review and after each point in the review where reviewer changes or modifications are necessary, study documents should be submitted clean, without any unaccepted tracked changes.

- Use Track Changes to Show Revisions

When a reviewer requests changes to a document, or the study team requests revisions, all changes should be tracked.

- Use Accept / Reject Tracked Changes to Show Agreement or Disagreement

When you agree with tracked changes, accept all changes and attach a clean copy of the document on the ePIRATE study page. If you are responding to a request with changes, or are changing a document in any way different from the reviewer’s tracked changes, you can reject tracked changes, and/or track your changes and attach the revised document to the study page. Wait until you have agreement on all of the changes before attaching a clean copy of the document for final approval.
Continuing Review Notices

ePIRATE generate continuing review notices at 75 days, 50 days, 25 days and every day for 14 days prior to the expiration date of your study. Once you have submitted the continuing review these notices will end.

ePIRATE Correspondence

You should expect to receive correspondence in your ePIRATE Inbox from study team members, IRB staff and IRB reviewers. There will also be system generated correspondence such as the continuing review notices. Please note that ePIRATE is configured to also route this correspondence to your regular email box so that you are aware of the correspondence without having to be logged into ePIRATE. The correspondence you receive in your email box from ePIRATE will be from umcirb@ecu.edu.

Troubleshooting

Getting Started

If you are unable to view the ePIRATE Home page:

- See if you can access other ECU systems that you would normally access over the web, such as the OHRI web site: http://ecu.edu/irb. If you cannot get to other sites, you are probably having general connectivity problems. Contact your institution’s IT Help Desk.

- If you can go to other sites, but cannot view the ePIRATE Home page, there might be a technical problem with ePIRATE. Contact OHRI at 252-744-2914 or umcirb@ecu.edu.

Getting Help

FAQ

For answers to frequently answered questions, go the ePIRATE page of the OHRI website at http://ecu.edu/irb

ePIRATE Support

If your questions are not answered in this document or by following the link above please contact OHRI at 252-744-2914 or umcirb@ecu.edu.

System Maintenance

Announcement of ePIRATE unavailability for planned maintenance will be made in advance on the ePIRATE Home page. Before the planned maintenance begins, you should make local copies of any study information that you anticipate you will need while the system is unavailable.