How to Create and Submit an Application for ECU to Rely on an External IRB

ePIRATE Training

This tutorial shows you how to create and submit an application for ECU to rely on an external IRB.

You will only be able to create this application if you have completed the ePIRATE registration process and can login to the ePIRATE system. Tutorials on these processes can be found on our "How Do I?" website.

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Hell

» | Dashboard | Home | IRB Studies | Committees | Meetings | Contac

Components | Properties | Pe

Click on Dashboard

- ePIRATE Training
- Institutional Review Board
- Common Rule Changes - Effective 01.21.19
- General Information
- Related Links
- Contact Us
- Application Version Information

Find out more about...

ePIRATE Training

Home

Welcome to ePIRATE, the electronic Portal for Institutional Research at East Carolina University.

This site enables East Carolina University to manage all aspects of Institutional Review Board (IRB) compliance processes.

Click on **Dashboard** in the upper left hand corner of this screen to create a study, create and edit your **Profile**, and perform other actions on existing research studies.

***UPGRADE NOTIFICATION: ePIRATE was upgraded on Wednesday, March 17, 2021.** The biggest change that existing users will notice is with the *look* of the IRB application smartform. The "Jump To" menu has moved to the left side of the screen and several other navigation tools on the application pages have been moved. Please review the following 5 minute tutorial explaining this newest upgrade: ePIRATE Upgrade

***9.11.2020**: Existing research studies that are changing their method of paying

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Hello, UMCIRB UMCIRB

Dashboard | Home | IRB Studies | Issues

IRB Submissions

My Roles

IRB Submissions
Faculty Advisor/Supervisor Approvers
New Registered User

Create

New Study

Click the “New Study” Button

Please note:

To complete this application more quickly, make sure you have all consents, flyers, questionnaires, protocols, etc. prepared and available for upload prior to creating your study. Utilize Quick Links below to find templates and other tools.

Quick Links

Consent Form Templates, COI Disclosure Forms, HIPAA Templates and other tools

Page for UMCIRB UMCIRB

Welcome to your Personal Page, the starting point for all interactions with this site. Note the following:

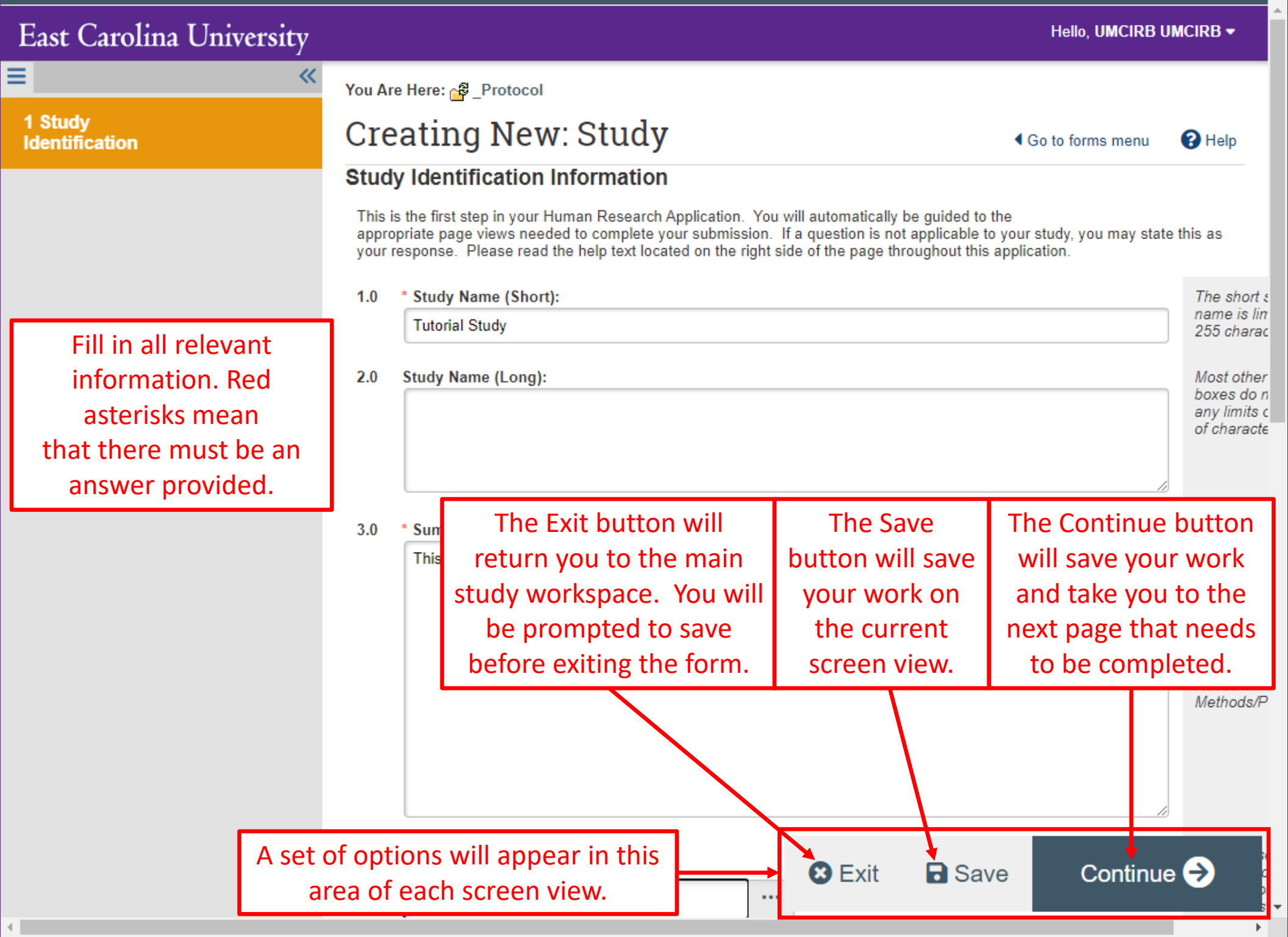
- **Inbox** - Items appearing here may require immediate action by you to speed your submission through the review process. Click on link to process an item.
- **Monitor** the progress of your submissions using the Inbox and IRB tabs.
- Use the **Profile** tab below to create and edit your profile. This is where you will enter the date you completed your IRB training modules which is a requirement for all investigators conducting human subject research.
- **Quick Links** in the lower left corner of this screen provide templates for consents, IRB Conflict of Interest (COI) Disclosure form and other templates and forms you may need to upload during the submission process. To complete the submission process more quickly, design and save documents so they are ready for upload as you move through

Inbox | IRB Studies | Templates | Profile

Displays all items which require action by the study team. Click on links for more information.

Filter by Name | Enter text to search for | + Add Filter | Clear All

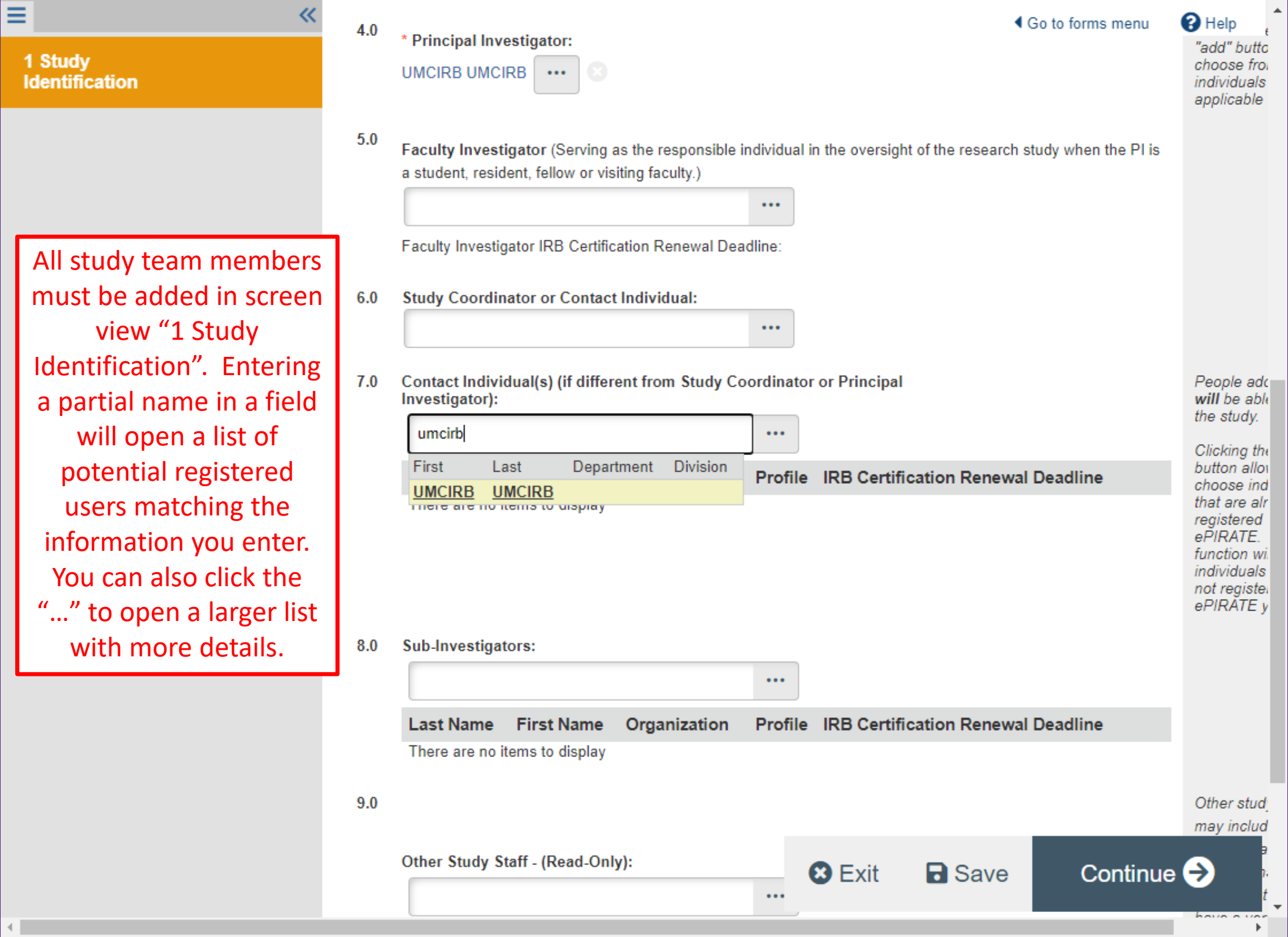
Name	Date Modified	Type	Owner	State	Last State Change
Test Study	3/4/2021 1:44 PM	Study		Pre Submission	7/23/2018 1:21 PM
Neil study	7/6/2020 12:32 PM	Study		Pre Submission	3/19/2014 8:05 PM
2014 Final Report for UMCIRB 13-001979	9/11/2019 6:18 PM	Final Report		Pre Submission	9/11/2019 6:16 PM


East Carolina University
Hello, UMCIRB UMCIRB
1 Study Identification
You Are Here: _Protocol
Creating New: Study
Go to forms menu
Help
Study Identification Information
This is the first step in your Human Research Application. You will automatically be guided to the appropriate page views needed to complete your submission. If a question is not applicable to your study, you may state this as your response. Please read the help text located on the right side of the page throughout this application.
1.0 * Study Name (Short):
Tutorial Study
2.0 Study Name (Long):
3.0 * Sum
This
Fill in all relevant information. Red asterisks mean that there must be an answer provided.
The Exit button will return you to the main study workspace. You will be prompted to save before exiting the form.
The Save button will save your work on the current screen view.
The Continue button will save your work and take you to the next page that needs to be completed.
A set of options will appear in this area of each screen view.
Exit
Save
Continue

ePIRATE uses a logic based branching system to determine which screen views need to be completed for all submission types (including studies where an external IRB will act as the IRB of Record). Clicking the “Continue” button shown in the previous slide will always take you to the next screen view that must be completed based on your responses so far.

Screen views requesting information on members of the study team, roles and responsibilities of those study team members, funding information, potential conflicts of interest and study locations will always be required.

A special “External IRB” screen view will also be required (screen view 1.53).


1 Study Identification
Go to forms menu
Help
4.0
* Principal Investigator:
UMCIRB UMCIRB
5.0
Faculty Investigator (Serving as the responsible individual in the oversight of the research study when the PI is a student, resident, fellow or visiting faculty.)
Faculty Investigator IRB Certification Renewal Deadline:
6.0
Study Coordinator or Contact Individual:
7.0
Contact Individual(s) (if different from Study Coordinator or Principal Investigator):
umcirb
First
Last
Department
Division
UMCIRB
UMCIRB
Profile
IRB Certification Renewal Deadline
There are no items to display
8.0
Sub-Investigators:
Last Name
First Name
Organization
Profile
IRB Certification Renewal Deadline
There are no items to display
9.0
Other Study Staff - (Read-Only):
Exit
Save
Continue
All study team members must be added in screen view “1 Study Identification”. Entering a partial name in a field will open a list of potential registered users matching the information you enter. You can also click the “…” to open a larger list with more details.

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Hello, UMCIRB UMCIRB

Validate | Compare

- 1 - Study Personnel & Funding
  - 1 Study Identification
  - **1.1 Study Staff Roles and Responsibilities**
  - 1.2 IRB Researcher Training Records
  - 1.3 Funding Sources
  - *1.31 Industry Sponsor Information*
  - *1.32 Federal Government Sponsored Studies*
  - *1.33 Non-Profit Sponsored Studies*
  - *1.34 State or Local Government*
  - *1.35 Other University or College*
  - *1.36 Internally Funded (ECU)*
  - 1.4 Conflict of Interest
  - 1.43 Sponsored Programs & Conflict of Interest
  - 1.5 Study Locations
  - *1.51 Multi-Site Coordination*

You Are Here: Tutorial Study

Editing: UMCIRB 21-001255

Go to forms menu | Print | Help

Study Staff Roles and Responsibilities

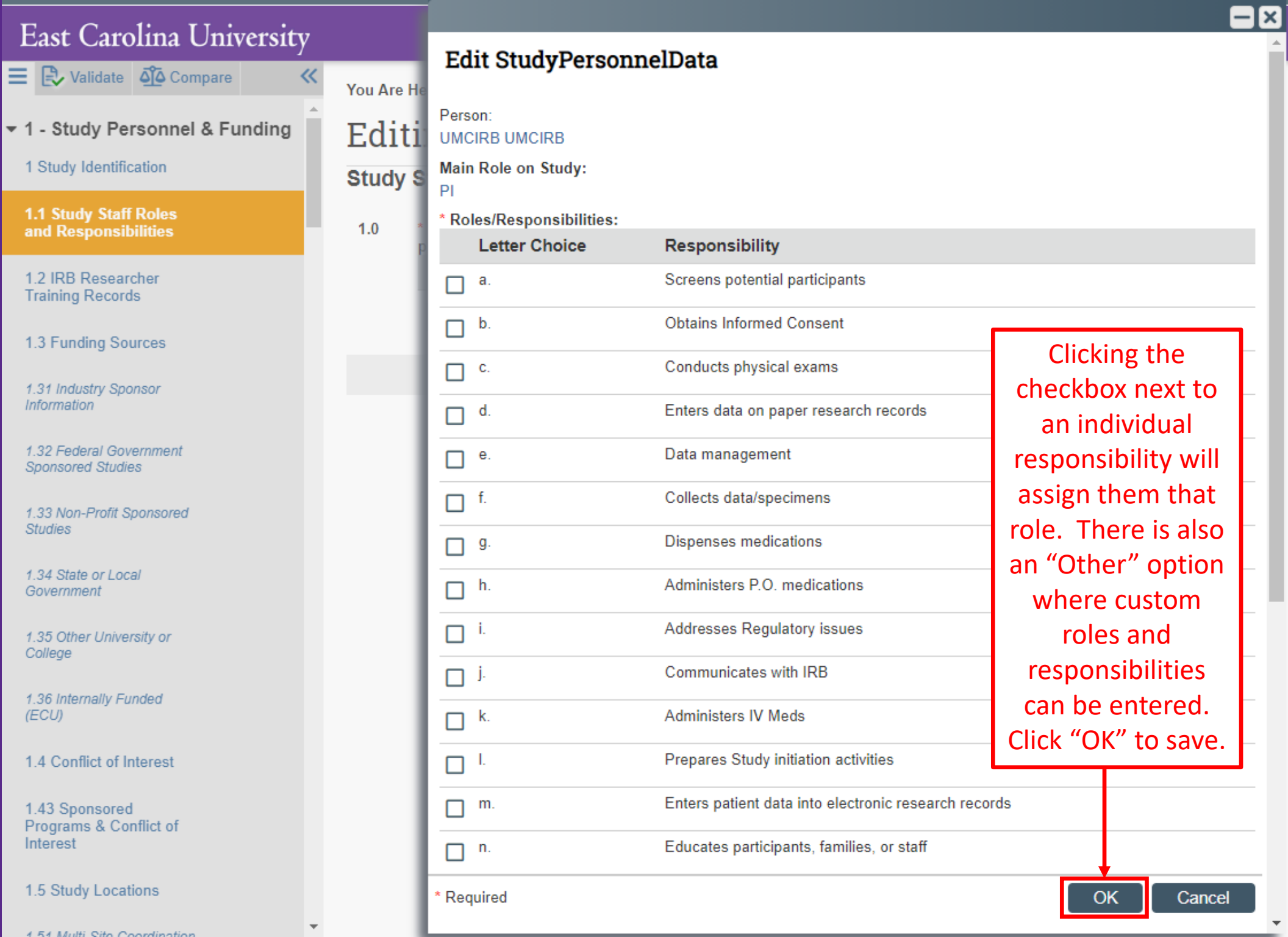
1.0 * Click on the UPDATE button beside each person's name to provide the responsibilities for each study staff member:

	Name	Role	Responsibilities
Update	UMCIRB UMCIRB	Principal Investigator	

This section is mandatory. The Responsibilities of all team members listed should be provided or the application will be returned to you.

Roles and responsibilities must be assigned to all study team members in screen view "1.1 Study Staff Roles and Responsibilities". Clicking the "Update" button next to a study team member's name will open a menu.

Exit | Save | Continue


East Carolina University
Validate
Compare
1 - Study Personnel & Funding
1 Study Identification
1.1 Study Staff Roles and Responsibilities
1.2 IRB Researcher Training Records
1.3 Funding Sources
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1.4 Conflict of Interest
1.43 Sponsored Programs & Conflict of Interest
1.5 Study Locations
Edit StudyPersonnelData
Person:
UMCIRB UMCIRB
Main Role on Study:
PI
* Roles/Responsibilities:
Letter Choice
Responsibility
a. Screens potential participants
b. Obtains Informed Consent
c. Conducts physical exams
d. Enters data on paper research records
e. Data management
f. Collects data/specimens
g. Dispenses medications
h. Administers P.O. medications
i. Addresses Regulatory issues
j. Communicates with IRB
k. Administers IV Meds
l. Prepares Study initiation activities
m. Enters patient data into electronic research records
n. Educates participants, families, or staff
Clicking the checkbox next to an individual responsibility will assign them that role. There is also an "Other" option where custom roles and responsibilities can be entered. Click "OK" to save.
* Required
OK
Cancel

1.35 Other University or College
1.36 Internally Funded (ECU)
1.4 Conflict of Interest
1.43 Sponsored Programs & Conflict of Interest
1.5 Study Locations
1.51 Multi-Site Coordination Center
1.53 External IRB
2 - Study Objectives & Design
2.0 Required Reviews
2.0.1 Study Population
2.0.1.1 Exempt Study Population
2.0.2 Children (Child Participants)
2.0.3 Cognitively Impaired Participants
2.0.4 Employee Participants
2.0.5 Student Participants

director of the facility.

4.0 * **Describe the research setting, listing any safeguards in place for participant safety:**

This study is created to show different functions within ePIRATE.

Research involving military personnel or within the prison system may require additional IRB approval from IRBs related to those entities (i.e., the NC Department of Corrections has an IRB that must grant approval when prisoners will be involved in research; and, depending on the branch of the military, other IRBs will need to review and approve research involving military personnel).

When you get to screen view 1.5 (Study Locations), you will select "Yes" for question 6.0 (Will an external IRB act as the IRB of record for the study?).

5.0 * **Is this a multi-site study being conducted at other sites national or internationally?**
○ Yes ● No Clear

6.0 * **Will an external IRB act as the IRB of record for this study?** ● Yes ○ No Clear

Exit Save Continue

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Validate | Compare

1.32 Federal Government Sponsored Studies

1.33 Non-Profit Sponsored Studies

1.34 State or Local Government

1.35 Other University or College

1.36 Internally Funded (ECU)

1.4 Conflict of Interest

1.43 Sponsored Programs & Conflict of Interest

1.5 Study Locations

1.51 Multi-Site Coordination Center

1.53 External IRB

2 - Study Objectives & Design

2.0 Required Reviews

2.0.1 Study Population

2.0.1.1 Exempt Study Population

2.0.2 Children (Child

You Are Here: Test Study

Editing: UMCIRB 18-001624 Go to fo

External IRB

1.0 * External IRB:

2.0 IRB Authorization Agreement: (if no existing agreement cov

+ Add

Document	Description
There are no items to display	

3.0 Approval letter from external IRB:

[None] Upload

4.0 Approval date by external IRB:

5.0 Expiration date by external IRB:

6.0 Select appropriate Bio-Medical methods and procedures for this study:

Name
☐ Procedures/methods that require Institutional Biosafety Committee (IBC) or Environmental Health and Safety (EH&S) (such as recombinant DNA/RNA, viral vectors, infectious agents, biotoxins, CDC select agents, carcinogens, human cell lines, human blood/serum/tissue manipulated in non-clinical areas, etc.)

7.0 Protocol:

Exit Save Continue

Screen view 1.53 will document the name of the External IRB, collect completed IRB Authorization Agreements and approved study related documents. IAAs must be signed by a representative from the External IRB's institutions and the Institutional Official for research at ECU. The UMCIRB office can assist with getting IAAs signed form ECU. Once this page is complete, "Continue" through the remainder of the External IRB application.

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Validate | Compare

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You Are Here: Test Study

Editing: UMCIRB 18-001624

Go to forms menu | Print | Help

Final Page

If you have completed your application, click "Finish" to finalize and exit the application. **This action does NOT submit the application for review,** it just means you have finished editing the application at this particular time.

For those studies that are being submitted for review and approval by the UMCIRB:

1. All research personnel/team members must login to ePIRATE and click the "Agree to Participate" button ePIRATE will allow a study to be submitted.
2. A submission may only be submitted to the UMCIRE Principal Investigator. To do this, the Principal Inves must login and click the "SUBMIT STUDY" button u Activities for this Study ID:UMCIRB 18-001624.

For those studies that are being submitted for acknowledgr the use of an external IRB:

1. Research personnel/team members are not require "Agree to Participate" before ePIRATE will allow a s be submitted.
2. A submission may be submitted by any listed team member. To do this, the team member must login a the "SUBMIT STUDY" button under My Activities for Study.

You can track the ongoing status of your submission by logging into the study workspace.

Please wait until you receive your final approval/acknowledgemer notice prior to beginning your study and feel free to contact the

Instead of Continue, the Final Page will have a Finish button. This saves your work and returns you to the main study workspace.

Please Note

This does not submit your study for review. It only closes the form and saves your work.

Exit | Save | Finish

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Dashboard | Home | IRB Studies | Issues

Amendments | Continuing Reviews | Final Report | Reportable Events

Help

Current State

Pre Submission

Edit Study

Printer Version

View SmartForm Progress

My Activities

- Submit Study
- Withdraw
- Log Public Comment
- Copy Study
- Edit Email List
- Send Email to Study Team
- Request Participant Agreement
- Agree to Participate

Study:Tutorial Study (UMCIRB 21-001255)

Description: This study has been created to show various functions within the ePIRATE system.

Principal Investigator: UMCIRB UMCIRB **Study Coordinator:**

Funding Type: No Funding **Review Type:** Exempt

Sponsor:

ePIRATE will not allow studies to be submitted for External IRB review unless all required questions in the form have been answered.

History | Attachments | Change Log | Agree to Participate

This area shows instructions and questions and important notifications regarding this Study.

Filter by Activity Enter text to search for + Add Filter × Clear All

Activity	Author	Activity Date
Created Study	UMCIRB, UMCIRB	5/24/2021 1:17 PM

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Dashboard | Home | IRB Studies | Issues

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Current State

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Edit Study

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View SmartForm Progress

My Activities

- PI Submit Study
- SS Withdraw
- Log Public Comment
- PI Copy Study
- SS Edit Email List
- Send Email to Study Team
- Request Participant Agreement
- SS Agree to Participate

Study:Tutorial Study (UMCIRB 21-001255)

Description: This study has been created to show various functions within the ePIRATE system.

Principal Investigator: UMCIRB UMCIRB **Study Coordinator:**

Exempt

Once all required questions have been answered, the "Submit Study" button formally submits the study for review. If there are missing responses in the form or other issues, the system will provide an error message with instructions on what must be completed in order to submit the study.

History | Attachments | Change Log | Agree to Participate

This area shows instructions and questions and important notifications regarding this Study.

Filter by Activity | Enter text to search for | + Add Filter | × Clear All

Activity	Author	Activity Date
Created Study	UMCIRB, UMCIRB	5/24/2021 1:17 PM

Submit Study

Investigator Assurances:

I certify that all information provided in this application represents an accurate description of the intended human research activity.

I agree to follow and abide by all policies and procedures, as well as by all federal, state and local laws concerning the protection of humans in research, including, but not limited to:

- Implementing no changes in the approved research methods or consent form without prior approval of the University & Medical Center Institutional Review Board (UMCIRB);
- Conducting the research using only the qualified personnel listed on the approved protocol;
- Ensuring that all key personnel have completed human research protections training and have attested to follow the research project as approved;
- Submitting a continuing review (if required) at least 30 days prior to the end of the current approval period, as required by federal regulations;
- Notifying the UMCIRB of any unanticipated problems that are serious or more severe than anticipated, related or possibly related to the research, and unexpected, either in severity or frequency, within five (5) working days.
- Reporting all deaths which can be attributed to or possibly attributed to participation in the research within two (2) working days.
- Immediately notifying the UMCIRB upon suspension or termination of the study or the expected departure of the Principal Investigator from this Institution.

I understand that as Principal Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of humans involved in this research.

If this research study is being conducted under the approval of an External IRB, clicking "OK" below indicates that all information provided in this application represents an accurate description of the intended human research activity and that all policies and procedures, as well as all federal, state and local laws concerning the protection of humans in research will be followed, including, but not limited to:

- Conducting the research using only the qualified personnel as listed in the electronic application and ensuring these personnel have completed human research protections training.
- Providing all updated, amended or revised protocols, consent forms, assent forms, surveys/questionnaires and any other documents regarding the approved research methods to the University & Medical Center Institutional Review Board (UMCIRB) via the electronic application.
- Providing study renewal or closure information prior to the end of the current approval period via the electronic application.
- Notifying the UMCIRB of any major protocol deviations or unanticipated problems within five (5) working days via the electronic application.
- Immediately notifying the UMCIRB upon suspension or termination of the study.

Required Department Approvals:
There are no items to display

If you have finished filling out your application and selected the department(s) to review it, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

If you are not ready to submit your application, click ***Cancel****.*

I agree with the above statements * ☐

Click the checkbox to the left and click "OK" to submit the study for review.

OK Cancel

The information contained on the submission screen in the previous slide is extremely important as it lays out the terms an investigator is agreeing to in undertaking the proposed human subjects research.

Where the study routes first following submission will depend on whether a study requires Ancillary Review. If Ancillary Review is required, all Ancillary reviewers will receive an email notification to review the study. Once they have all approved the study, it will arrive in the UMCIRB office queue to validate the use of an External IRB. If no Ancillary Reviews are required, the study will go straight to the UMCIRB office queue for validation.

The study team must wait for email notification from ePIRATE verifying the External IRB application has been validated.