# How to Create and Submit a New Study

**ePIRATE** Training



This tutorial shows you how to create and submit a new study in ePIRATE.

You will only be able to create a new study 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.



Click on Dashboard

## Find out more about...

Properties

ePIRATE Training

Components

## **ePIRATE Training**

# Institutional Review Board

Common Rule Changes - Effective 01.21.19

#### **General Information**

#### Related Links

#### Contact Us

Application Version Information

## Home

Welcome to ePIRATE, the <u>e</u>lectronic <u>P</u>ortal for <u>I</u>nstitutional <u>R</u>esearch <u>at</u> <u>E</u>ast 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





Dashboard

Home

Issues

IRB Submissions

## My Roles

**IRB Submissions** 

Faculty Advisor/Supervisor Approvers New Registered User

## Create



## 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

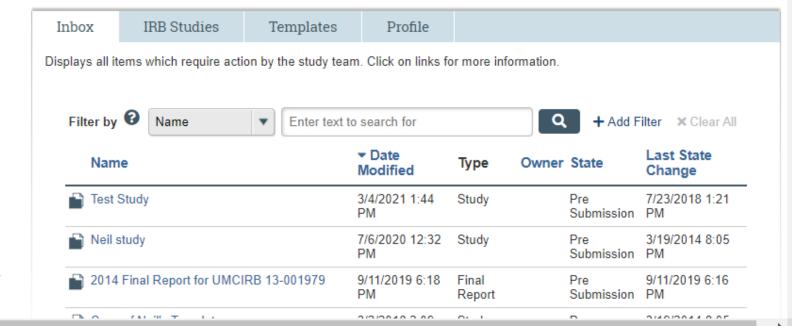
IRB

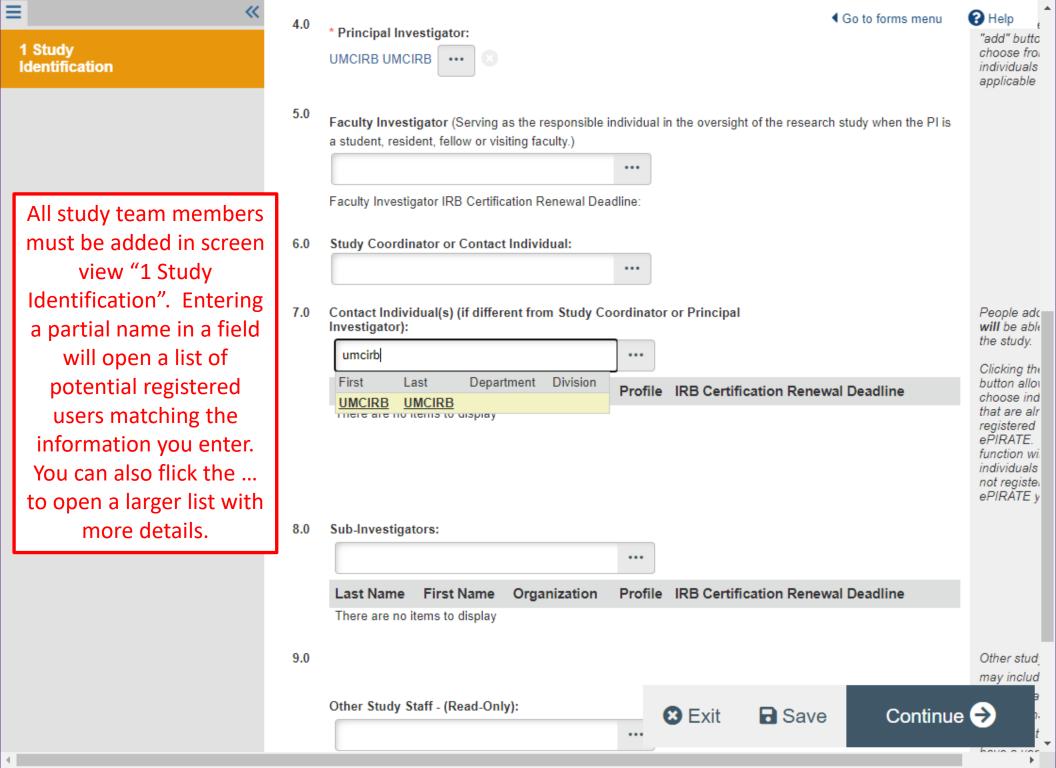
**Studies** 

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

Click the "New Study" Button





R Help

# East Carolina University



1.2 IRB Researcher Training Records

and Responsibilities

- 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

You Are Here: Tutorial Study

# Editing: UMCIRB 21-001255

## Study Staff Roles and Responsibilities

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

provide the res	Name	Role	Responsibilities
	Haine	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.

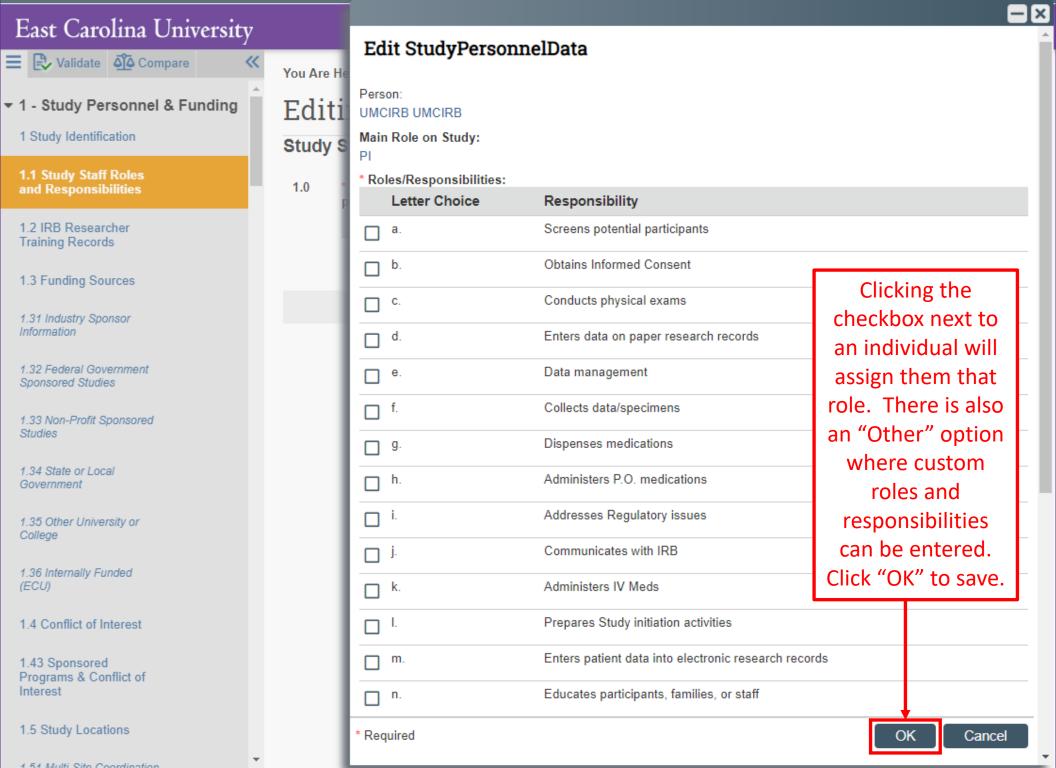
◆ Go to forms menu 
→ Print ▼

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.









# 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
- 1.31 Industry Sponsor Information
- 1.32 Federal Government Sponsored Studies
- 1.33 Non-Profit Sponsored Studies
- 1.34 State or Local Government
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- 1.43 Sponsored Programs & Conflict of Interest
- 1.5 Study Locations

# 1.51 Multi-Site Coordination

You Are Here: Test Study

# Editing: UMCIRB 18-001624

◆ Go to forms menu 
→ Print ▼



R 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.
- 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 ur Activities for this Study ID:UMCIRB 18-001624.

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

- Research personnel/team members are not required "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 at the "SUBMIT STUDY" button under My Activities for Study.

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.

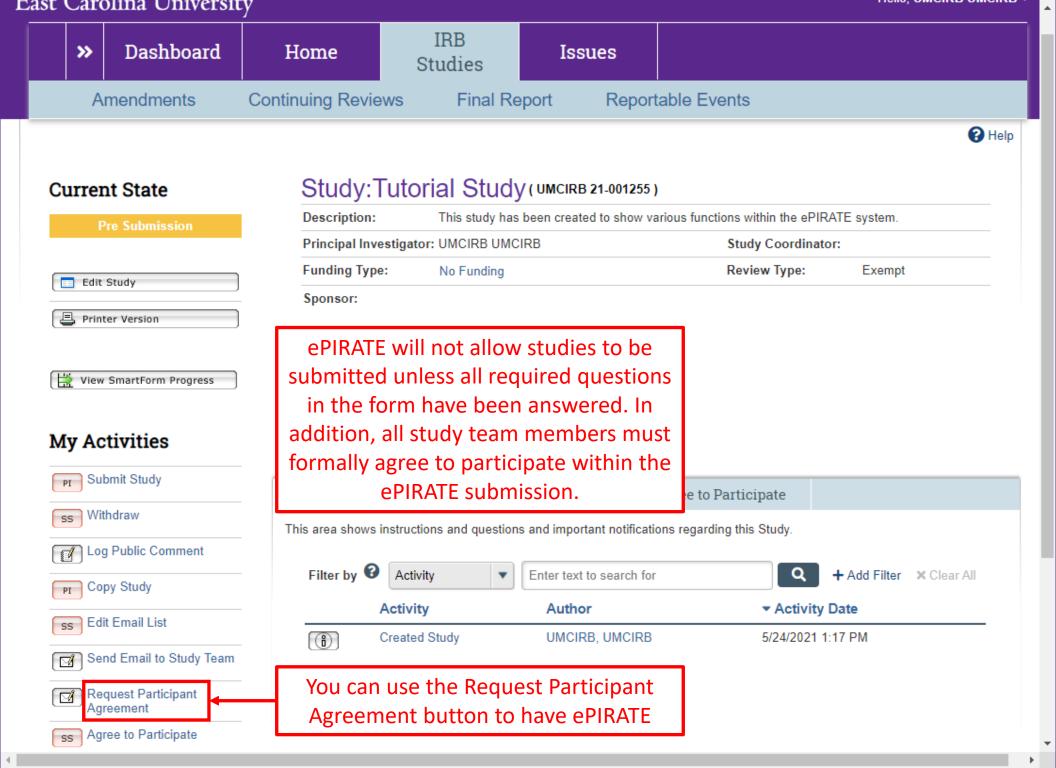
You can track the ongoing status of your submission by logging into the study workspace.

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





Finish



### Request Participant Agreement

Select research team members that will need to Agree to Participate in this research study:

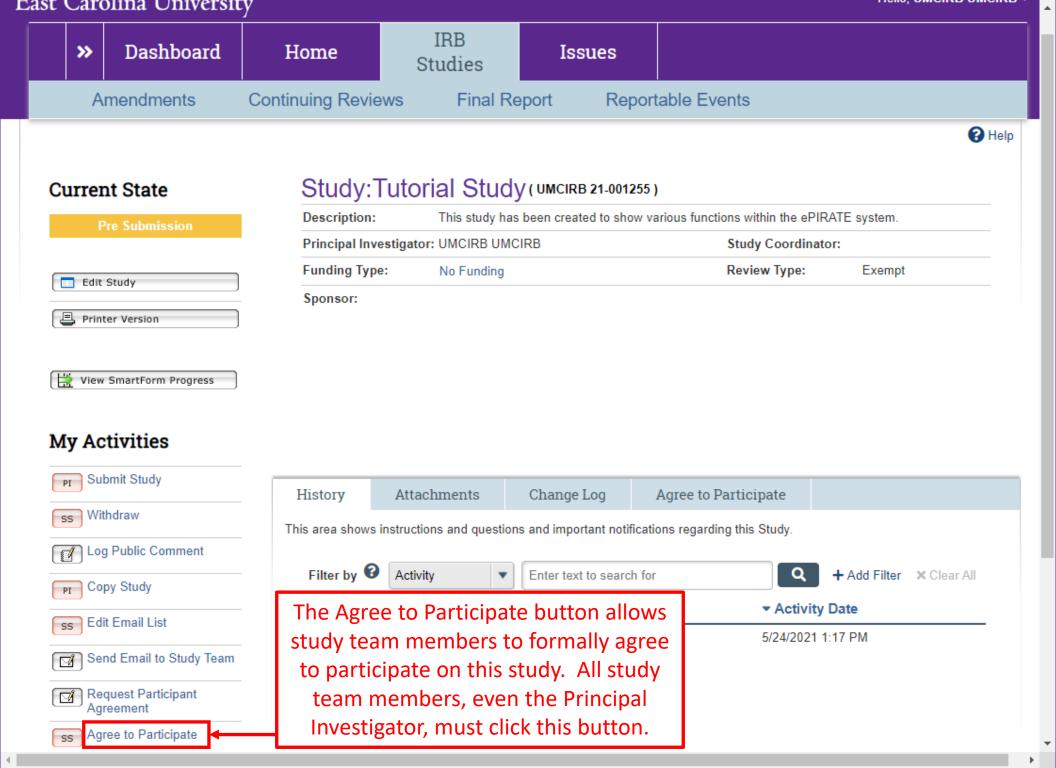
Request Agreement	Person	Role on Study	Agreement Date
✓	UMCIRB UMCIRB	Principal Investigator	

These team members will receive an email notification requesting them to agree to participate in this study.

A pop-up window will open with a list of all study team members. Click the check box under "Request Agreement" for any study team members that need to agree to participate. Once you click "OK", ePIRATE will send an email to anyone with a check next to their name. Those that have already formally agreed to participate will have a date under the "Agreement Date" column above.

OK

Cancel



#### Agree to Participate

#### Key Personnel Attestation

I certify that I have received sufficient training to fulfill my responsibilities in this research.

I also certify that I have read the proposed research and either have a copy for my records or know where I can obtain one, should I have questions. I agree to follow and abide by all ECU University & Medical Center Institutional Review Board (UMCIRB) policies and procedures, as well as by all federal state and local laws concerning the protection of human participants in research including, but not limited to:

- Implementing no changes in the approved protocol or consent document without prior review and approval of the UMCIRB;
- Respecting the privacy of each participant and the confidentiality of the information gathered about participants;
- Notifying the Principal Investigator 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;
- · Notifying the Principal Investigator of all deaths immediately; and
- Reporting to the UMCIRB, any conflict of interest or perceived non-compliance.

I understand that as Key Personnel in this research, I have responsibility for the protection of the rights and welfare of the human participants involved.

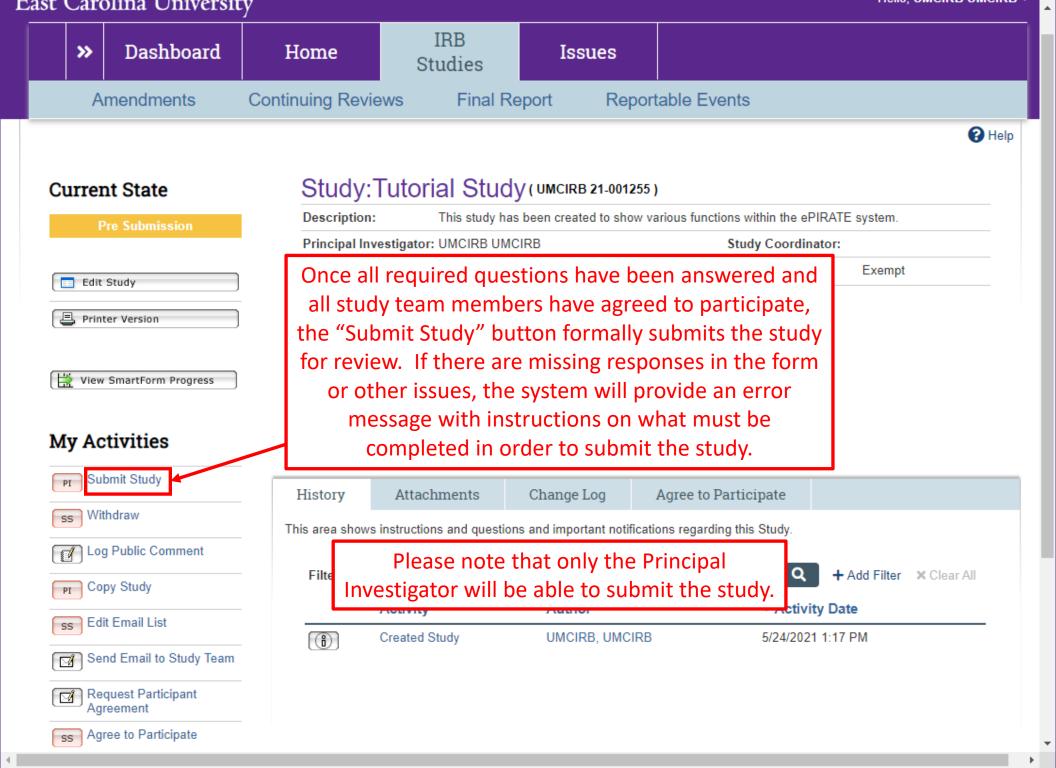
If you have finished completing this form, click "OK" below. The proposal cannot go forward without your response. If you have questions for the Principal Investigator about your role in this research, click "Cancel".

I agree with the above statements.

Click "OK" to complete the agree to participate process

OK

Cancel



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.

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 the institutional affiliation of the Principal Investigator and whether a study will be under the oversight of the UMCIRB or an external IRB.

Studies under the oversight of the UMCIRB with ECU affiliated Principal Investigators first route to Departmental Review.

Studies under the oversight of an external IRB with ECU affiliated Principal Investigators first route to either Ancillary Review or to the UMCIRB office (if no Ancillary Reviews are required). Studies with non-ECU affiliated Principal Investigators route this way as well.

