

# 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.

[Dashboard](#)[Home](#)[IRB  
Studies](#)[Committees](#)[Meetings](#)[Contact](#)[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

IRB Submissions

# 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

## My Roles

- IRB Submissions
- Faculty Advisor/Supervisor Approvers
- New Registered User

## Create

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

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

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

The short name is limited to 255 characters.

2.0 Study Name (Long):

Most other boxes do not have any limits on the number of characters.

3.0 \* Summary:

This

Methods/P

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 ➔

# 1 Study Identification

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):



First	Last	Department	Division	Profile	IRB Certification Renewal Deadline
UMCIRB	UMCIRB				

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 flick the ... to open a larger list with more details.

[Go to forms menu](#)

[Help](#)

"add" button choose from individuals applicable

People added will be able to choose individuals for the study.

Clicking the button allows you to choose individuals that are already registered in ePIRATE. The function will not register individuals not registered in ePIRATE.

Other study staff may include...

Validate Compare



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
UMCIRB UMCIRB	Principal Investigator	

 Update

*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

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

Edit

Study S

1.0

### Edit StudyPersonnelData

Person:  
UMCIRB UMCIRB

Main Role on Study:  
PI

\* Roles/Responsibilities:

Letter Choice	Responsibility
<input type="checkbox"/> a.	Screens potential participants
<input type="checkbox"/> b.	Obtains Informed Consent
<input type="checkbox"/> c.	Conducts physical exams
<input type="checkbox"/> d.	Enters data on paper research records
<input type="checkbox"/> e.	Data management
<input type="checkbox"/> f.	Collects data/specimens
<input type="checkbox"/> g.	Dispenses medications
<input type="checkbox"/> h.	Administers P.O. medications
<input type="checkbox"/> i.	Addresses Regulatory issues
<input type="checkbox"/> j.	Communicates with IRB
<input type="checkbox"/> k.	Administers IV Meds
<input type="checkbox"/> l.	Prepares Study initiation activities
<input type="checkbox"/> m.	Enters patient data into electronic research records
<input type="checkbox"/> n.	Educates participants, families, or staff

Clicking the checkbox next to an individual 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



## Editing: UMCIRB 18-001624

## 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 UMCIRB Principal Investigator. To do this, the Principal Investigator must login and click the "SUBMIT STUDY" button under My Activities for this Study ID:UMCIRB 18-001624.

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

1. Research personnel/team members are not required to click "Agree to Participate" before ePIRATE will allow a submission to 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 this Study.

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

Please wait until you receive your final approval/acknowledgement 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.**

## 1 - Study Personnel &amp; 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 &amp; Conflict of Interest

## 1.5 Study Locations

## 1.51 Multi-Site Coordination Center

### 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 unless all required questions in the form have been answered. In addition, all study team members must formally agree to participate within the ePIRATE submission.

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

Filter by Activity  + Add Filter ✕ Clear All

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

You can use the Request Participant Agreement button to have ePIRATE

## 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
<input checked="" type="checkbox"/>	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



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:

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

x Clear All

▼ Activity Date

5/24/2021 1:17 PM

The Agree to Participate button allows study team members to formally agree to participate on this study. All study team members, even the Principal Investigator, must click this button.

**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

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: Exempt

Once all required questions have been answered and all study team members have agreed to participate, 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.

Please note that only the Principal Investigator will be able to submit the study.

Filter [Search] + Add Filter x Clear All

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

**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.

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.