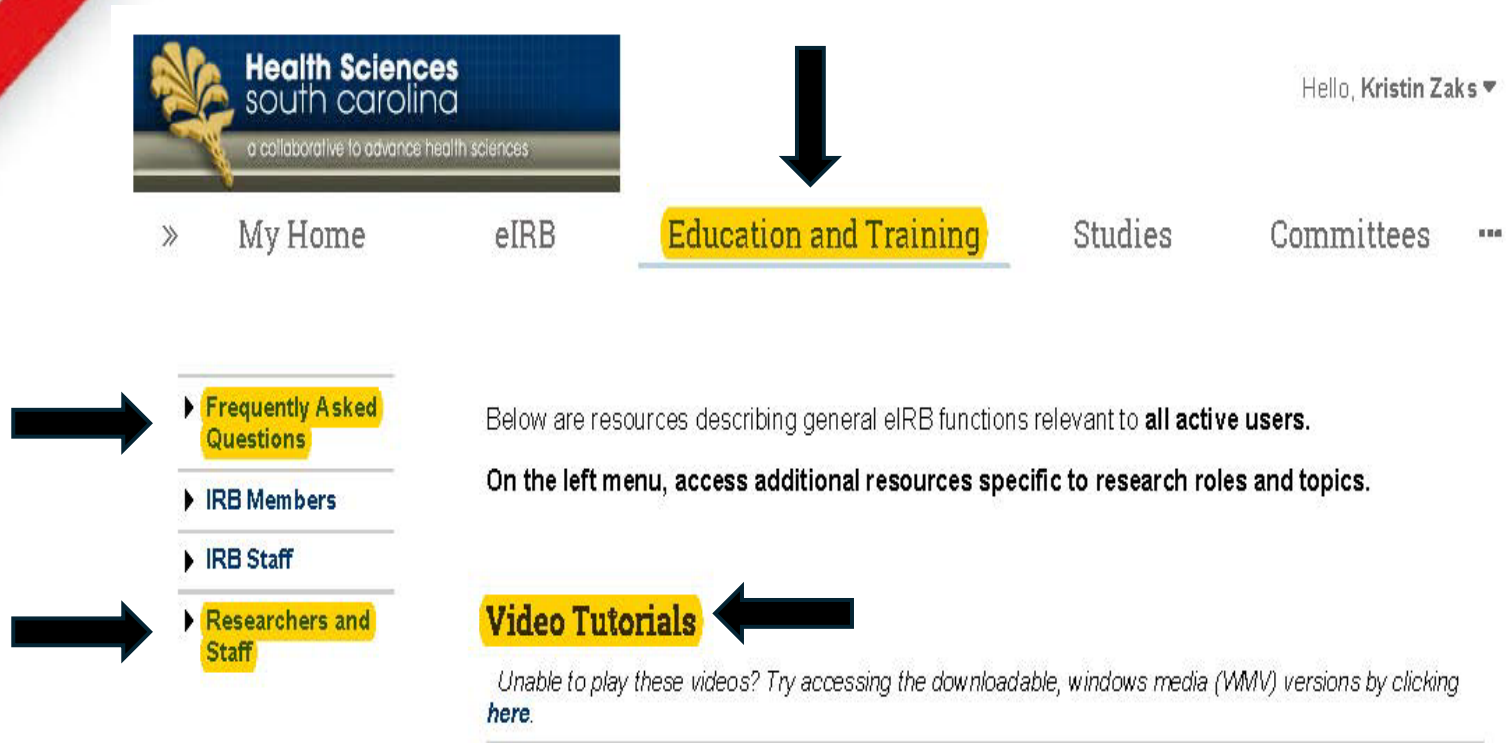
Common Problems: Helpful Tips and Tricks from the IRB!

Medical University of South Carolina

Problem 1: Navigating the eIRB system

Take advantage of the online training resources available in eIRB



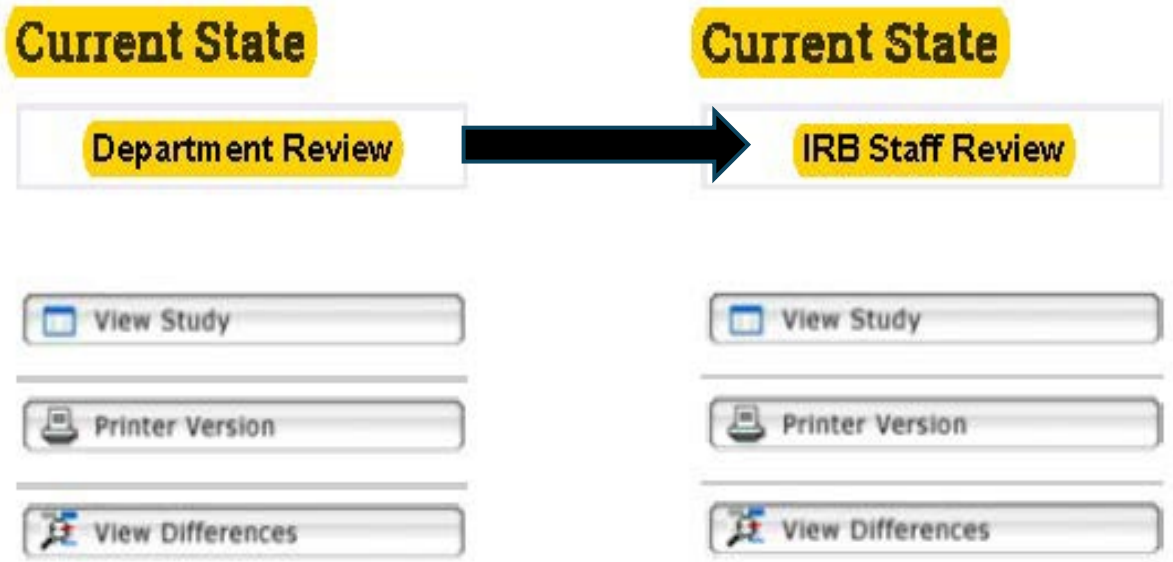
Problem 2: Personnel not available in eIRB

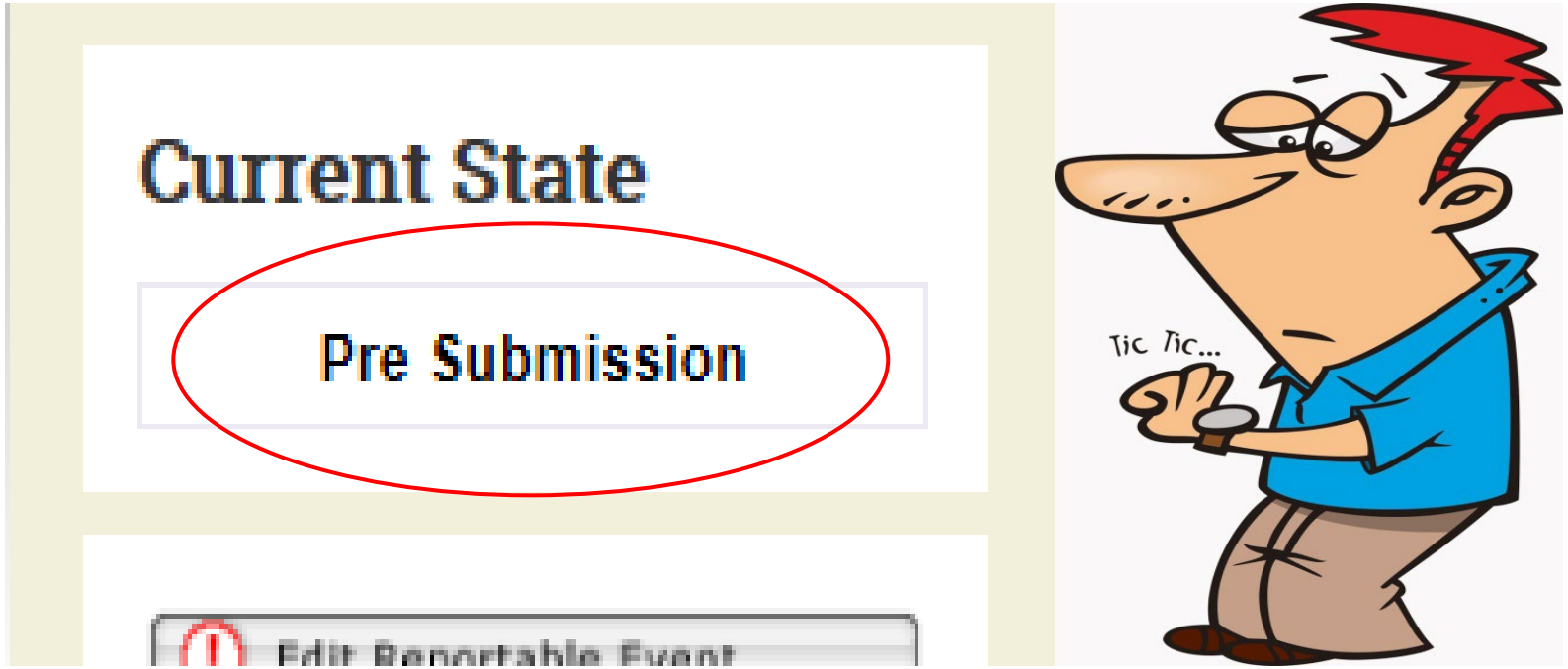
Questions to ask before reaching out to the IRB:

1. Have they completed MUSC CITI training?
2. Have they registered in eIRB?
3. Were they assigned the correct role in eIRB at registration? (Check registration confirmation email)
4. Do names and primary email match in both CITI and eIRB databases?

Problem 3: Department and Ancillary Review Delays

Follow the state of your study!

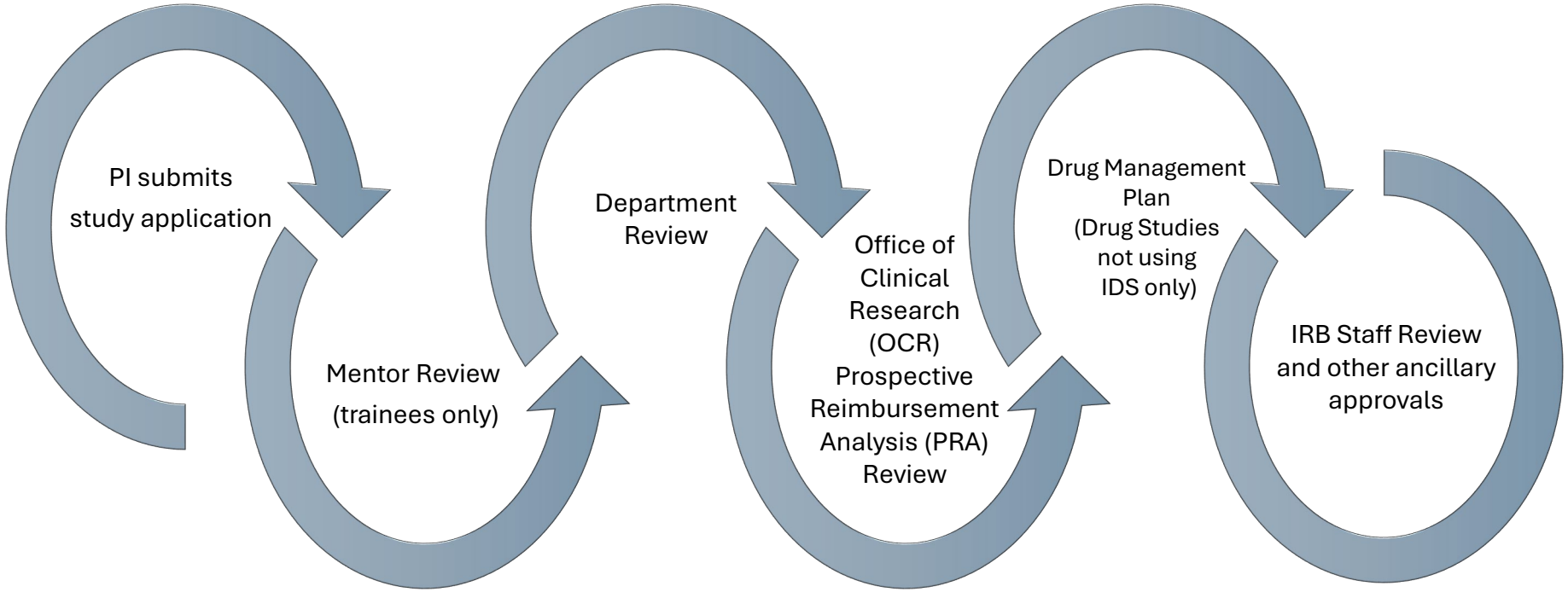




State of the Study

Check the current “State” of the study under the study’s main page.
The IRB does not have the study until the “State” is “**IRB Staff Review**”.

Other common states are:
In Review
Assigned to IRB Meeting
Changes Required per IRB Staff
Changes Required per IRB Reviewer
Awaiting Correspondence



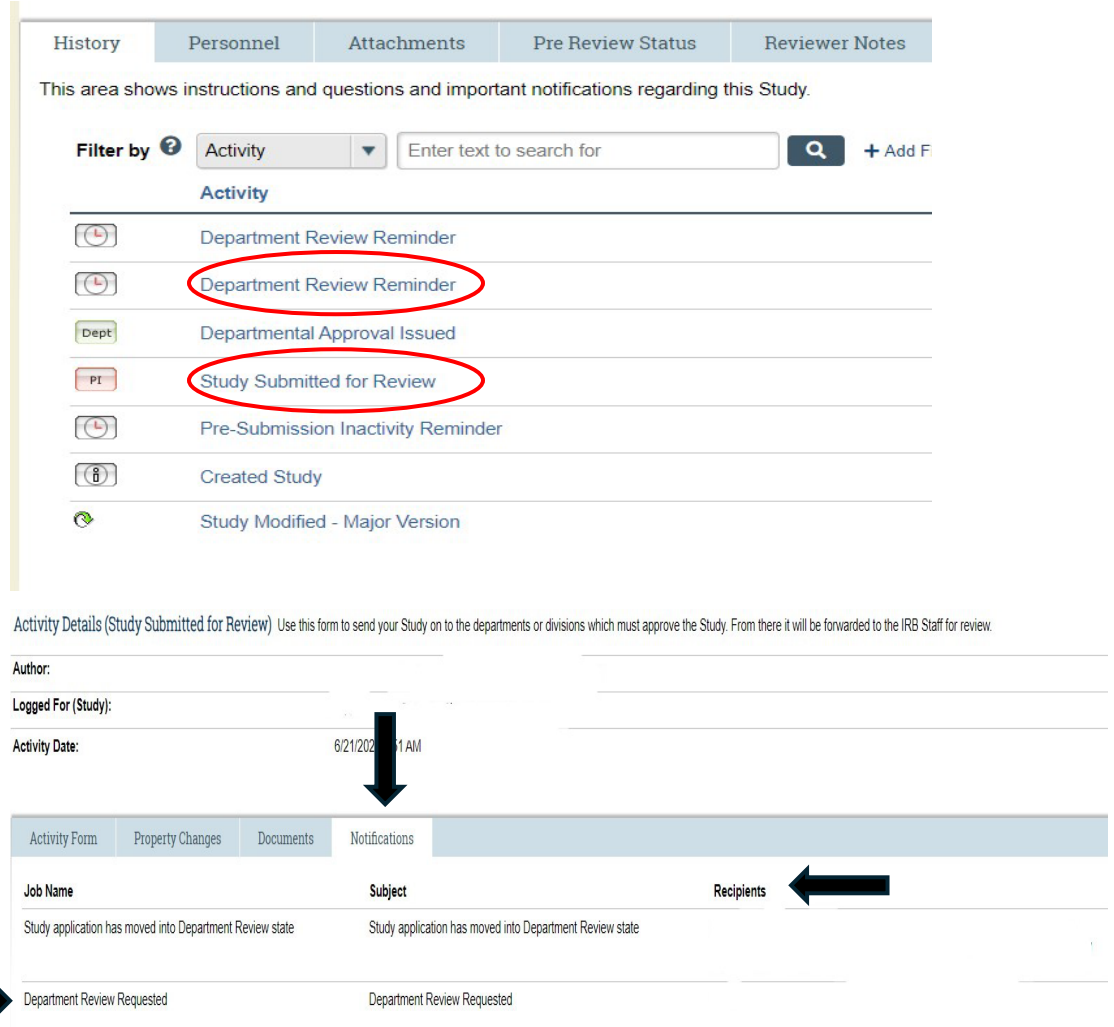
Study Routing

Before a study is received by the IRB, departmental and/or other approvals must be obtained.

How to Check Where the Study is in Department Review

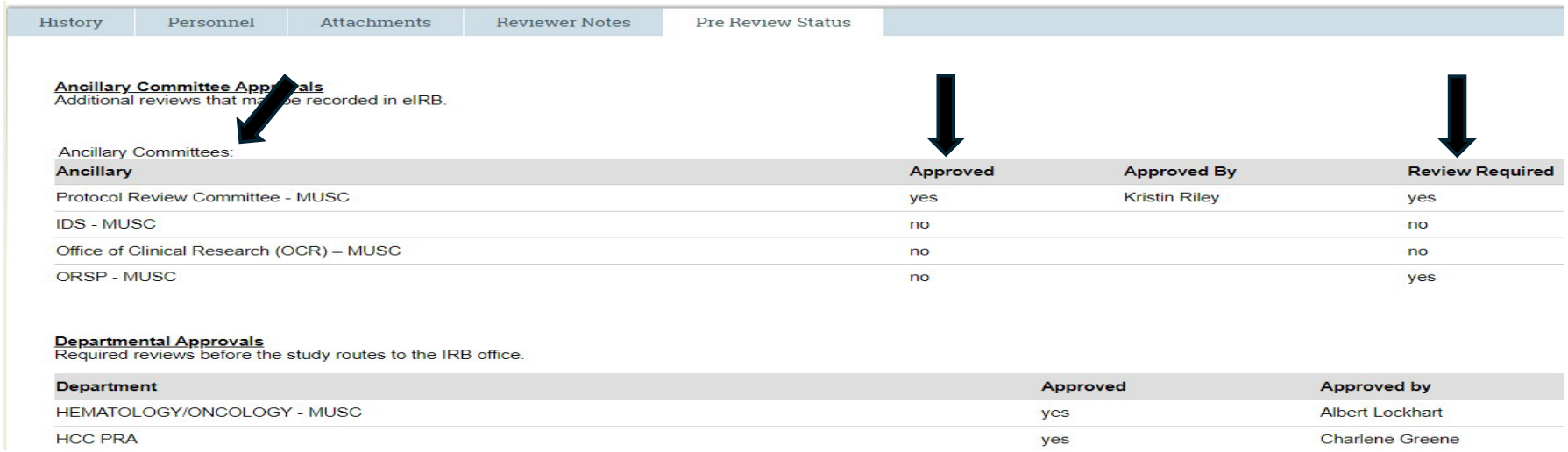
When a study is in Department Review, check who the department reviewers are by going to the History Tab on the Main study page →“Study Submitted for Review” or “Department Review Reminder”.

Then, a new page will pop up. Click on the “Notifications” Tab and a list of department reviewer recipients will be displayed.



Keeping Track of Ancillary Reviews

On the main page of the study, you will see a tab called "Pre-Review Status". This tab tells you which Ancillary Reviews are required and if they have been completed.



History | Personnel | Attachments | Reviewer Notes | Pre Review Status

Ancillary Committee Approvals
Additional reviews that may be recorded in eIRB.

Ancillary Committees:

Ancillary	Approved	Approved By	Review Required
Protocol Review Committee - MUSC	yes	Kristin Riley	yes
IDS - MUSC	no		no
Office of Clinical Research (OCR) – MUSC	no		no
ORSP - MUSC	no		yes

Departmental Approvals
Required reviews before the study routes to the IRB office.

Department	Approved	Approved by
HEMATOLOGY/ONCOLOGY - MUSC	yes	Albert Lockhart
HCC PRA	yes	Charlene Greene

Problem 4:
Lack of Consistency
Incomplete/Incorrect attachments

1. Have the protocol and applicable study documents carefully reviewed and finalized before beginning your eIRB application.
   - SUCCESS Center – Attend a free consultation! (https://research.musc.edu/resources/sctr/about/success)
2. Read questions carefully and be careful when you cut/paste from study documents.
   - The word "you" should not be seen throughout the eIRB application.
3. Know what forms need to be included with your application.
   - Scientific Protocols are not required for Exempt Study Applications
   - What documents need the MUSC watermark?

Problem 5:
Coded vs. De-identified Data

Coded data has identifying information, such as name or medical record number, by which the study team can readily ascertain the identity of the subject. If you are collecting identifiers (PHI), the data cannot be de-identified.

- There must be a separate linking document to your data set that includes a uniquely assigned code for each subject and their identifying data.
- The linking document with the identifiers and the unique code must be stored separately from your research data.
- Examples of a unique code on the linking document are: Subject 001, Subject 002, Subject 003, and so on.

De-identified data contains no identifiers or codes, so there is no way to link the data back to the subject.

- Data can become de-identified once the linking document is destroyed.

Final Thoughts!

- Be sure to check over your application before submitting to the IRB.
- Make sure the correct, proofed, clean copy documents are uploaded in the correct smartforms.
- Always get IRB approval before starting the study or implementing any changes.