GUIDANCE: Changing a Study PI

1. Open a Site Modification on the parent study with 'Other Parts of the Study' selected at its scope.
2. Use the ‘Summarize the modifications’ section of the RUTH SmartForm to explain the nature of the change. Clearly state which investigator is relinquishing and which investigator is adopting the PI role designation.
3. Use the ‘Basic Site Information – 1. Local Principal Investigator’ section of the RUTH SmartForm to remove the outgoing PI and list the incoming PI of the study.
4. Attach a letter signed by both the outgoing PI and the incoming PI to the “Local Site Documents - 3. Other Attachments” section of the SmartForm.
    a. The body of the letter should include an acknowledgment by the outgoing PI that they are relinquishing their responsibilities with respect to the research, as well as an acknowledgment from the incoming PI that they are taking over these responsibilities. If the outgoing PI has left the institution, the Department Chair will be required to sign on the behalf of the department.
5. Notify the Financial Administration of Clinical Trials Services (FACTS) office and the Grants and Contract Office (GCO) of the change if there is a contract in place, as both offices then need to be involved
6. Where appropriate, update any documents that list the outgoing PI’s name and contact information so that they list only the incoming PI’s information consent forms, HRP-503, protocol, etc) keeping in mind that if the project is closed to enrollment, updating the consent form should not be necessary. Use good judgment when deciding which documents need to be updated.
7. If the incoming PI is not already a member of the local study team, add the incoming PI to the Triggering Event (TE) form in eDMS. The incoming PI also needs to submit their financial disclosures, and complete all required CITI training courses.
8. Determine whether the study team needs to provide information regarding the PI change to enrolled subjects. Notify the IRB as to how the study team will provide the information to the enrolled subjects.
9. If the study is approved by an external IRB, attach the external IRB approval letter under Site Related Documents >> Other Attachments.
10. Ancillary Reviews

    A. FCOIR: Assign FCOIR for all PI changes.

    B. IDS: Assign IDS if IDS was assigned as an Ancillary Review during the initial review of the study.

C. RSC: Assign RSC if RSC assigned as an Ancillary Review on the initial review of the study AND there is an Authorized User (regardless of who the Authorized User is).

11. Submit the modification for PI change in RUTH using the “Submit” button located to the left-hand side of the parent study’s main workflow page once all of the above steps are complete.