

TC IRB Departing PI Checklist

Purpose: This checklist guides Primary Investigators (PIs) who are leaving Teachers College (TC), including graduating or leaving for another institution, and have open or active studies involving students, ensuring proper transfer and closure of these studies.

Contac	t the IRB Office
	Notification : Email the TC IRB Office at <u>irb@tc.edu</u> about your departure and discuss any open studies.
	Consultation: Schedule a meeting to review each study's status and determine necessary
	actions (closure, transfer, etc.). Please use this link: <u>TC IRB Office Hours</u> to schedule office hours.
Review	and Action on Active Studies at TC
	Review List of Active Studies: Use the IRB management system (Mentor) to identify all
	studies under your oversight, focusing on those involving students.
	Decide on Study Continuation or Closure:
	 ☐ If all research activities are complete, close the study with the IRB by submitting a closure request in Mentor. Please refer to How to Terminate an IRB Protocol. ☐ Transfer ongoing studies to a new PI. Identify an appropriately qualified faculty member at TC to take over. Ensure they are briefed and can access all necessary study materials and data. Please refer to How to Submit an IRB Modification, Continuing Review, Protocol Deviation, and Adverse Event.
Transfe	You must arrange for IRB approval if you are still doing research at your new institution. (For most federally-funded studies, a reliance agreement will be required rather than separate IRB approval from your new institution's IRB.) er Study to New Institution
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	If you are transferring the study to your new institution, you must close out the study with the IRB by submitting a closure request in Mentor.
	Obtain necessary IRB approval from the new institution to continue the study there.
	Contact TC's Research Compliance Director, General Counsel, and the Office of the Provost to arrange the transfer of documents, data, and materials.
	Set up a data transfer agreement to comply with all regulatory and institutional policies.
Transfe	er Responsibilities
	Notification of Sponsors : If the study has a sponsor, notify them of the change in PI and secure their approval.
	Modification Submission : Submit a Modification in Mentor to change the PI officially. Include details of the new PI who will be taking over the study.
	Transfer of Documents and Data : Ensure all relevant study documents and data are transferred to the new PI. Review subject status and ongoing needs with the new PI.

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Additional Requirements for Student-Related Studies ☐ **Student Graduation Contingency**: Specifically address studies led by graduating students. Arrange for faculty sponsors to take over these studies to ensure continuity and compliance. Unresponsive PI Protocol: Establish a protocol for handling studies where the PI becomes unresponsive, mainly due to them leaving TC. This may include transferring responsibilities to a department chair until a new PI is designated. Final Steps ☐ **Inform Key TC Departments**: Communicate with relevant departments about the status of each study, especially if there are special considerations like investigational drugs or significant equipment involved. **Document Storage**: Ensure that all physical and electronic study documents are stored in a manner accessible for audits or future research needs. Refer to Applicable Regulations and Guidelines ☐ Ensure compliance with relevant federal regulations and guidelines, including checking specific requirements for studies involving human subjects or controlled substances.

Resources

Investigator Responsibilities FAOs

21 CFR 312.60;

21 CFR 312.62;

21 CFR 312.68;

21CFR812.140

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