Northwestern | OFFICE FOR RESEARCH

Principal Investigator (PI) Transitions: Setting Up Studies for Success

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Today's Agenda

- Case Study
- Study Support Resources
- Office for Research Resources
- PI Transfer Checklist
- Q&A

Poll Question

- Have you been on a study during a PI transition or have helped investigators onboard/off board?
  - Yes
  - No
  - Not sure

Why PI Transfers and Why Now?

- Numerous cases of Non-Compliance over the last year where root causes include:
  - New faculty continuing research from their past institution(s) without consulting with the IRB to setup the appropriate agreements
  - Faculty leaving Northwestern transferring their studies to a new Northwestern PI without knowing and disclosing the state of the studies to the new PI(s)
  - Faculty leaving Northwestern and taking their identifiable data with them without the appropriate agreements

Who can be a PI?

STATUS/TITLE	IRB			SPONSORED RESEARCH			IACUC		
	Eligible	Case by Case	Not Eligible	Eligible	Case by Case	Not Eligible	Eligible	Case by Case	Not Eligible
Curators	x			x				x	
Instructors	x			x				x	
Librarians	x			x				x	
Non-tenure-track research and/or clinical faculty (full, associate, and assistant professors)	x			x			x		
Tenure-track faculty (full, associate, and assistant professors)	x			x			x		
Senior research investigators (Faculty with emeritus status or who are tenured and retired but wish to continue as PI)	x			x			x		
Adjunct Faculty		x		x				x	
Lecturers		x			x			x	
Contributed Services Faculty		x			x			x	
Health System Clinicians		x			x			x	
Visiting Faculty		x			x			x	
Visiting Scholars		x			x			x	
Postdoctoral fellows		x			x				x
Research Assistants and Graduate Students			x		x				x
Research Associates			x			x			x
Undergraduate students			x			x			x

- Northwestern researchers can utilize this chart to pre-determine whether they are eligible to serve in the role of Principal Investigator (PI) on an IRB protocol, IACUC protocol or a Sponsored Research proposal/award
- If based on your University status/title you fall into the “case-by-case” category, please consult the website of the respective office for detailed instructions on how to submit a formal request for consideration of PI status

Case Study – Why is this relevant?

- Dr. Blue is the PI for more studies than he has time to effectively manage
- Dr. Blue decides to transfer PI-ship for some to Dr. Red
- After becoming the PI, Dr. Red is randomly selected by the IRB compliance team to undergo post-approval monitoring
- During the routine post-approval monitoring visit the compliance analyst identifies various compliance issues such as ineligible participants enrolled, delayed safety reporting, inadequate consent process, and a lack of study visit documentation
- Dr. Red was unaware of these issues when she became the PI and informs the compliance team that the study was managed by a different PI at the time when the non-compliance occurred

Case Study – Poll Question

Is Dr. Red responsible for the non-compliance that occurred before she became the PI?

- Yes
- No
- Not Sure

Case Study – Why is this relevant?

- Answer: YES
- When Dr. Red assumed the role of PI, she also assumed responsibility for the study
- Before you assume the roles and responsibility of PI, ensure you know the state of the study that you are inheriting
- If you are transferring your study to a new PI, ensure you know the state of your study and give your colleague a frank and accurate accounting of what they are accepting

PI Transfers

- If a Principal Investigator (PI) would like to or is required to relinquish PI responsibility for a research project, a new PI must be identified and accept responsibility for the study in its entirety
- When transferring PI responsibility to a new PI, the following is required:
  - A formal statement of transfer from the current PI and a statement of acceptance from the new PI
  - Revisions to the current study documents to update the PI name and contact information
  - A Modification submission in eIRB+ to change the PI
- The new PI must also have access to all current and previous regulatory documentation and participant file documentation (if applicable)

PI Transfers

- HRP-1408 Principal Investigator (PI) Transfer of Responsibilities Checklist provides a comprehensive list of study record considerations and can be completed when transitioning a study to a new PI. This document **does not** have to be submitted to the IRB but can be retained in the regulatory binder/research record

If a study will be closed rather than transferred to a new PI:

- If a PI wishes to close a study rather than transfer responsibility to a new PI, the following should be considered:
  - All data and records, including regulatory documentation and participant files, should be retained per the University's retention policy
  - The study should be closed in eIRB+ through a Continuing Review application

Study Support Resources

The IRB Office created Study Support Resources for investigators that comply with university policies and the federal regulations.

- These tools should be used throughout the research lifecycle to organize paper based or electronically maintained regulatory documentation and research data.
- Researchers are encouraged to maintain a real-time accounting of all study related documents and data. Investigators should have all regulatory and participant-related information properly documented, as it plays a crucial role in validating research results throughout the life of the study.
- The tools are located on the IRB website under the Compliance tab

PI Transfers – Best Practices

- We recommend all studies use the Study Support Resources located on the IRB website under the Compliance tab to organize their research records
- We created a new PI Transfer of Responsibilities Checklist to assist outgoing investigators preparing their records for transition, and to assist new investigators in knowing what questions to ask and what to expect when they assume the responsibilities of PI

Incoming PIs with Ongoing Research

- Email IRBReliance@Northwestern.edu to discuss your ongoing research, determine whether the research requires formal review by the Northwestern IRB, and determine whether IRB agreements between Northwestern and another entity are required
- Contact MTA@Northwestern.edu if you may be bringing data or specimens with you to Northwestern to establish the appropriate agreements

Outgoing PIs

- When either the research is complete or you will no longer take part in ongoing research, either:
- Close your research by submitting a continuing review(s) to the IRB; or
- Identify a colleague at Northwestern who is willing to take over the study as PI and submit a modification request(s) with the following:
  - A formal statement of transfer from the current PI and a statement of acceptance from the new PI
  - Track change copies of current study documents to update the PI name and contact information
  - If contact with participants is ongoing, a plan to notify participants of the PI change or a statement about why notifying participants isn't required.
- Contact MTA@Northwestern.edu if you plan bringing data or specimens with you to Northwestern to establish the appropriate agreements.

Outgoing PIs

- If you are leaving and plan to continue to participate in the research:
  - Submit the modification request to transfer the ongoing research to a new Northwestern PI
  - When you have left the institution, the new PI may submit a modification request to add you back to the study in your new role if you will be engaged in Human Research, including access to identifiable research data.
- Contact MTA@Northwestern.edu before you leave if you plan to access research data or specimens after you leave Northwestern to establish the appropriate agreements

Investigators with Multiple Appointments

- Investigators who maintain more than one faculty appointment are encouraged to contact the IRB to discuss when and if their research activities engage more than one institution
- When in doubt, submit a request to the IRB for a formal determination
  - If your research engages Northwestern without obtaining IRB approval from Northwestern before you start your research, it cannot be subsequently reviewed and approved by the Northwestern IRB

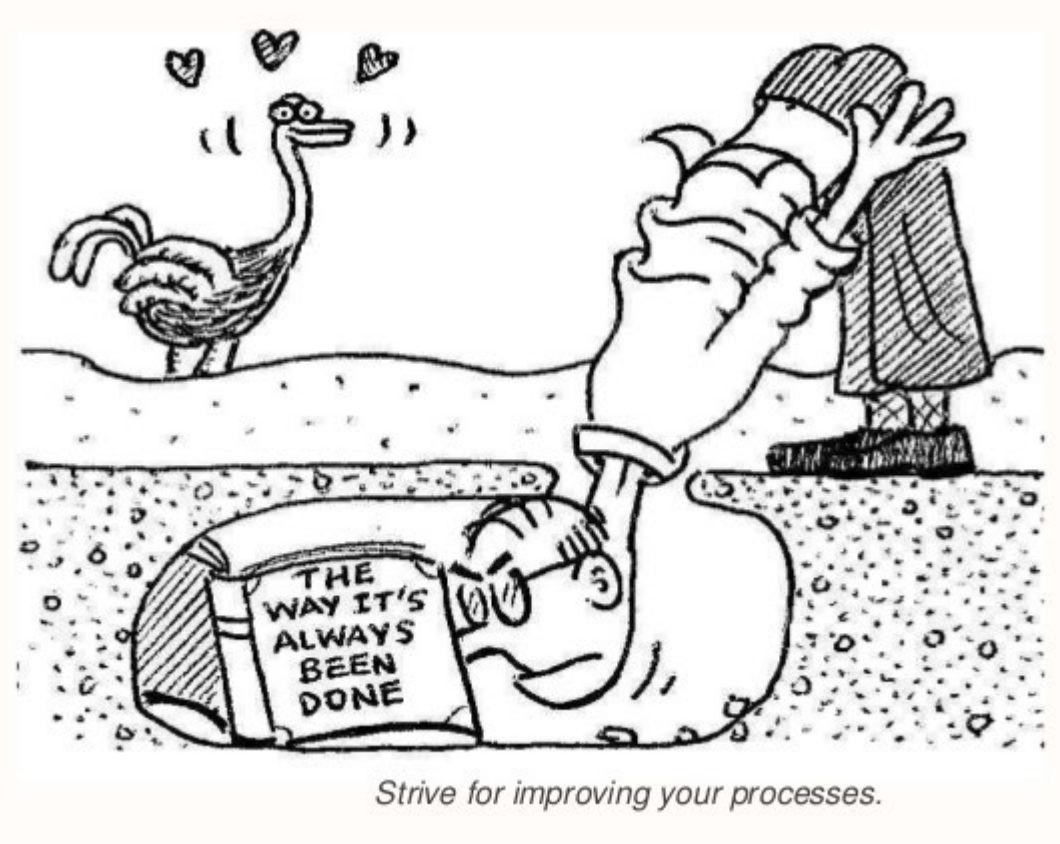
Office for Research Resources

- PI Onboarding Procedure Checklist and PI Check-out Procedure Checklist

Sponsored Research	Institutional Review Board
Clinical Trials	Institutional Animal Care and Use Committee
Project Finances	Laboratory (Research Safety)
Effort Reporting	Research Records (Data Retention)
Project Equipment	Innovations and New Ventures

- HRP-1408 Principal Investigator (PI) Transfer of Responsibilities Checklist
  - The IRB PI Transfer checklist
  - Study record considerations
  - This document **does not** have to be submitted to the IRB but can be retained in the regulatory binder/research record

How to Set Up Studies for Success

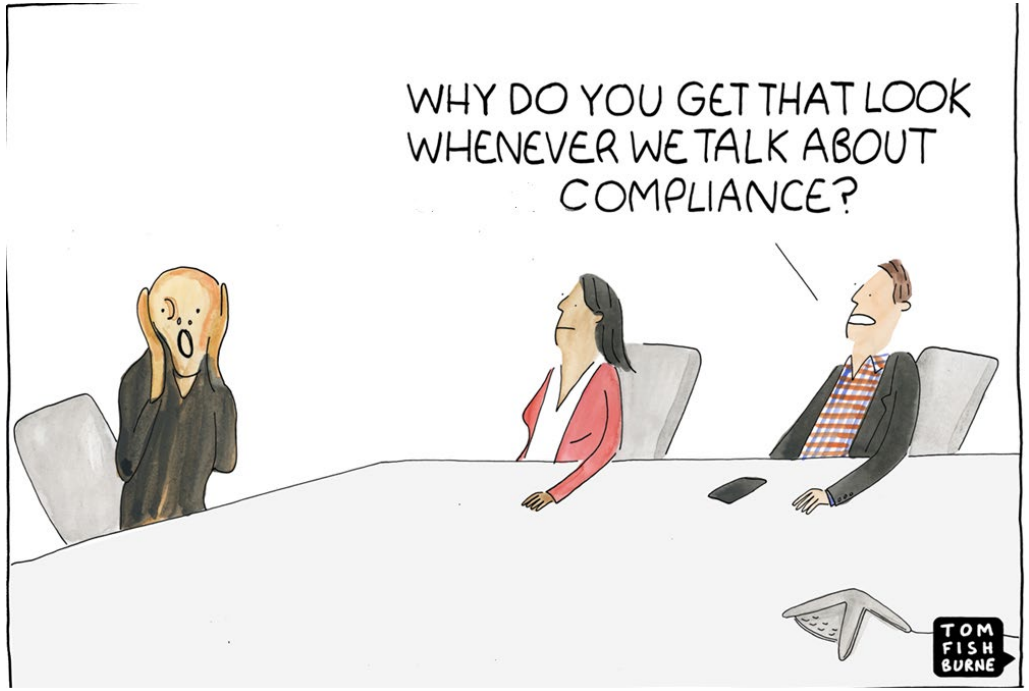


Strive for improving your processes.

- **DOCUMENTATION, DOCUMENTATION, DOCUMENTATION!**
- Don't wait until the study is already in progress or over – prepare before the study starts
- Become familiar with the requirements, policies, and regulations
- The research record/regulatory binder can be in paper form, electronic, or a mixture of both
  - Note: eIRB+ is **not** a valid source to serve as a research record/regulatory binder
- Update records in real time

How to Set Up Studies for Success

- Utilize resources that already exist – no need to reinvent the wheel
- Be consistent across your research portfolio
- If errors/discrepancies are noted, report them to the IRB if needed and correct as soon as possible
- Ask the IRB – we are here as a resource



Contact Information and Resources

- IRB Compliance: irbcompliance@northwestern.edu
- IRB Reliance: irbreliance@northwestern.edu
- IRB Website: https://irb.northwestern.edu/
- Data Use Agreements and Material Transfer Agreements: mta@northwestern.edu
- Office for Sponsored Research: https://osr.northwestern.edu/agreements/
- Office for Research Website: https://www.research.northwestern.edu/


QUESTIONS
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