



SOP: Principal Investigator (PI) Permissions

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1 PURPOSE

- 1.1 This policy establishes the process by which the IRB Office receives, verifies, and tracks PI permissions granted by the Associate Vice President for Research (AVP).
- 1.2 The process begins when the IRB Office receives an email from the AVP granting permission to serve as PI.
- 1.3 The process ends when the IRB Analyst verifies the PI permission status for a specific study.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/20/2020.

3 POLICY

- 3.1 In this procedure, PI permissions are received via email to the IRB Office Compliance inbox.
- 3.2 Specific PI permissions, which are granted on a study-by-study basis for individual studies, are required as detailed in the PI Eligibility Requirements found at:
<https://www.research.northwestern.edu/pi-eligibility-for-irb-protocols-iacuc-protocols-and-sponsored-research-proposalsawards/>

4 RESPONSIBILITIES

- 4.1 PI permissions are only granted by the Associate Vice President for Research.
 - 4.1.1 Depending on the area in which the research is conducted, the AVP may consult with the appropriate associate vice president who has oversight within that area.
- 4.2 The IRB Office is responsible for verifying PI eligibility on each study reviewed.
- 4.3 The IRB Office Compliance team tracks PI permissions received from the AVP in the Compliance inbox. The name of the individual, date of approval, STU number, and affiliation are documented.

5 PROCEDURE

Initial request:

- 5.1 Individuals will follow the instructions found here to request permission to serve as PI:
<https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>
- 5.2 If the AVP approves the request, the AVP will copy the Compliance team's email address on the approval notification to the proposed PI.
 - 5.2.1 The email must contain the following documentation:
 - 5.2.1.1 The PI's CV
 - 5.2.1.2 IRB protocol
 - 5.2.1.3 Letter of support from the individual's department chair, division chief, school dean, unit director, or hospital system supervisor.
- 5.3 The Compliance team will input all relevant information into the tracking sheet and save a PDF copy of the email with associated attachments.
- 5.4 When a new project is submitted, the investigator is responsible for uploading a copy of the AVP approval into the study application.
- 5.5 The IRB analyst assigned to review the submission will verify that AVP approval is submitted within the application.
 - 5.5.1 If AVP approval is needed but is not present in the study application, the IRB analyst will request clarification to obtain the documentation.
- 5.6 Once verified, the study will undergo IRB review.



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Change in faculty appointment:

- 5.7 If a PI's faculty appointment changes from a status that confers automatic approval to serve as PI to that requiring approval from the AVP, the investigator must obtain permission to continue to serve as the study's PI following the steps outlined on the IRB Office website.
- 5.8 If the AVP approves the request, the AVP will copy the Compliance team's email address on the approval notification to the investigator.
 - 5.8.1 The email must contain the following documentation:
 - 5.8.1.1 The PI's CV
 - 5.8.1.2 Copy of the IRB-approved protocol
 - 5.8.1.3 A letter of support from the PI's department chair, division chief, school dean, unit director, or hospital supervisor.
 - 5.8.1.4 A supplemental document that explains the PI's plan to manage their study, provide oversight, communicate with study team members and participants, and adhere to other compliance obligations.
- 5.9 The Compliance team will input all relevant information into the tracking sheet and save a PDF copy of the email with associated attachments.
- 5.10 The PI will submit a modification application to inform the IRB of their status change.
 - 5.10.1 The investigator is responsible for uploading a copy of the AVP approval into the study application.
 - 5.10.2 The investigator is also responsible for including a plan to institute appropriate management, communication, oversight, and adherence to other compliance responsibilities and obligations.
- 5.11 The IRB analyst assigned to the submission will verify that AVP approval is submitted within the application.
 - 5.11.1 If AVP approval or the investigator's plan are absent from the study application, the IRB analyst will request clarification from the investigator to obtain the documentation.
- 5.12 Once verified, the submission will undergo IRB review.

Post approval:

- 5.13 An individual's status as PI may be withdrawn for just cause. Such a decision may be appealed to the Vice President for Research.
 - 5.13.1 The Compliance Team will document these determinations into the tracking sheet and save a PDF copy of the email with associated attachments.
- 5.14 Outside collaborators (non-Northwestern personnel or personnel employed by Northwestern's affiliates) may not be listed as PIs or co-PIs on Northwestern or its affiliate's Human Research. An outside collaborator is not a Northwestern faculty member and does not "automatically" have PI status or an ongoing contractual relationship with the institution.

6 MATERIALS

- 6.1 WORKSHEET: Pre-Review (HRP-308)
- 6.2 WORKSHEET: Permission to Serve as Principal Investigator (PI) (HRP-1302)
- 6.3 [PI Eligibility for IRB Protocols Flowchart](#)

7 REFERENCES

- 7.1 Policy: Investigator Manual (HRP-103)
- 7.2 Website: <https://www.research.northwestern.edu/pi-eligibility-for-irb-protocols-iacuc-protocols-and-sponsored-research-proposalsawards/>

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7.3 Website: <https://irb.northwestern.edu/submitted-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>