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# Yale University Human Research Protection Program

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## 730 PR.1 Procedure for Departing Investigators

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### Overview

This procedure describes the process for departing investigators on Yale human research protocols to fulfill their responsibilities to either arrange for the transfer of active protocols to another Yale investigator, remain on the protocol at Yale under conditions described below, to close the protocol at Yale, or, as may be required, arrange for review and approval of their participation on the protocol from their new institution.

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### Responsibilities of the Principal Investigator

Principal Investigators (PIs) who are leaving the University are responsible for ensuring that their research-related duties are appropriately transitioned or completed before officially exiting their positions (see <http://www.yale.edu/hrpp/responsibility/roles.html>). Failure to do so may adversely affect research participants, and may result in study suspension or closure by the Institutional Review Board (IRB) (Human Investigation Committee (HIC)/Human Subjects Committee (HSC)).

The PI must notify the Yale Institutional Review Board (IRB) and revise each protocol under his/her purview so that it conforms to one of the following statuses **prior to leaving his/her position at the University**:

- **Designate a new Principal Investigator.** The study (or studies) may continue at the University with an amendment to the protocol(s) initiating the proper transfer of duties to a newly designated Principal Investigator. Under these circumstances, PIs should identify a qualified successor and facilitate a smooth transfer of principal investigator responsibilities. Depending on the IRB that was originally charged with the protocol oversight (HIC or HSC), this can be accomplished in the following ways:
  - The departing PI may submit the Request for Approval of Amendment to Change Principal Investigator for a Biomedical Protocol (100 FR12, found at <http://www.yale.edu/hrpp/forms-templates/biomedical.html>) or
  - The departing PI may submit the HSC Amendment Request Form (found at <http://www.yale.edu/hrpp/forms-templates/behavioral.html>),

in which he or she can identify a successor as Principal Investigator on the study (or studies), as well as make any requisite changes in (light of this transfer) to the protocol, including identifying the new PI and his/her contact information on informed consent and Health Insurance Portability and Accountability Act (HIPAA) Research Authorization Form (RAF) or Compound Authorization documents.

OR

- **Remain on the protocol with IRB approval from new institution, if required.** The study (or studies) may continue at Yale under the oversight of an appropriate, newly designated Principal Investigator at Yale (following the procedures described above), and the departing investigator may remain on the protocol in a different capacity (typically as a non-Yale Co-Investigator or consultant) with documentation of approval from the IRB at his/her new institution if required. If the departing investigator wishes to remain on the protocol and is no longer affiliated with an institution, she/he may request permission to serve as a collaborating investigator. (See HRPP Policy 910 for further information on when IRB approval from a collaborating investigator is needed).

OR

- **Remain on the protocol as Principal Investigator by retaining a Yale faculty appointment.** In general, continuing as principal investigator is not encouraged, although exceptions may be made, depending on the

appointment and permission from the appropriate Yale department and IRB. In this case, the PI should consult with the appropriate Yale IRB for further direction on how to proceed.

**OR**

- **Close the protocol(s).** Provided all study-related interventions with participants and data analysis have ended, the study (or studies) may be closed by the Principal Investigator prior to his/her departure from the University. Depending on the IRB that was originally charged with the protocol oversight (HIC or HSC), this can be accomplished in the following ways:
  - The departing PI may submit the Request to Close a Research Study form (100 FR5C, found at <http://www.yale.edu/hrpp/forms-templates/biomedical.html>)
  - The departing PI may submit the HSC Request for Renewal or Closure form (found at <http://www.yale.edu/hrpp/forms-templates/behavioral.html>)

**Note: both forms should be submitted well in advance of the departure date, preferably at least 2 weeks before the date of departure, to allow for communication with the IRB on any matters needing clarification.**

**OR**

- **Close the protocol and transfer the research to his/her destined institution.** Requirements for transferring University human research records are found in HRPP Policy 730: Human Research Record and Biological Specimen Retention and Transfer (see <http://www.yale.edu/hrpp/policies/index.html#PostApproval>). Note that there is draft OHRP and FDA Guidance on Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution that describes possible actions to consider in transferring research projects (see <http://www.hhs.gov/ohrp/newsroom/rfc/transferdraftdoc.html>).

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## Responsibility of the Co- or Sub-Investigator

A departing Co- or Sub-Investigator on at least one active protocol also should notify the IRB of his or her upcoming departure as soon as possible. When informed of an investigator's expected departure, the IRB will contact the applicable Principal Investigators for studies on which departing Co- or Sub-Investigators are listed to request that the requisite Personnel Amendment be submitted to ensure that the protocol has an up-to-date list of personnel.

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## Responsibility of the Faculty Advisor

A departing Faculty Advisor should identify a suitable replacement and inform his/her advisee to notify the IRB via a personnel amendment to the protocol. The advisee cannot be left to independently serve as principal investigator.

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## Protocols for which a new PI has not been designated

If the PI has left the University and a new PI has not been designated, all activity on the protocol must cease and the IRB will not act on any protocol submission unless such request includes the requisite request to change the Principal Investigator. The protocol will be administratively closed by the IRB if the protocol's approval has expired, notification(s) to the PI by the IRB are not responded to and the appointment of a new PI has not been made. (See **700 PR.4 Suspension and Termination of Human Research.**)

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## Responsibilities of the IRB

### Identification of Active Protocols

When the IRB is alerted to the upcoming departure of a Yale investigator, the IRB will check its records for any active protocols on which the investigator is listed as Principal Investigator or Co- or Sub-Investigator. Essential protocol information—including the IRB number, study title, name of investigator, and approval and expiration dates—is recorded by IRB staff on a spreadsheet for tracking purposes.

The list of protocols is then sent via email by the IRB office to the departing investigator and any applicable Correspondents listed on each protocol. Specific language within the email differs depending on whether the investigator leaving the University is a Principal Investigator or a Co- or Sub-Investigator on the protocol in question.

### **Monitoring Status of Affected Protocols**

Once the IRB has notified the investigator of affected protocols, the IRB will monitor any responses submitted by or on behalf of the departing investigator, and will provide follow-up communication where applicable.

In situations where a protocol retains a status of “Active” without an adequate succession plan for the departing investigator, the IRB may be required to suspend the research and initiate a follow-up procedure by the HRPP Compliance Manager with the Department Chair or Dean and Business Manager of the department of the departing investigator. Alternatively, the IRB may administratively close a protocol that has been left open after the PI has departed. In such a case, the IRB will notify the Grants and Contracts Administration (GCA), Department Chair or Dean and Business Manager of the closure and obtain confirmation of such notification. In no case shall any human research activities continue, nor shall federal funds be spent on an administratively closed protocol.

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### **Related Information**

The Office of Research Administration website offers an Exiting Faculty Checklist to help ensure that the more common issues and concerns related to leaving the University are addressed in advance. See the Items of Interest “Exiting Faculty Checklist” on the OHRP website: <http://researchadministration.yale.edu/>