



## GUIDELINE FOR INVESTIGATORS LEAVING THE INSTITUTION

OHSP Policy 901 Investigator Responsibilities indicates Investigators are responsible for notifying the RSRB when they plan to leave the institution, either temporarily or permanently. The information below provides guidance on the things to be considered and addressed in advance of the Investigator's departure.

### 1. Grants and Other Sponsored Research

The Investigator should communicate with the Office of Research Projects and Administration (ORPA) regarding contracts and sub-contracts for government and industry sponsored research agreements, as applicable. The Investigator will need to determine whether a grant will remain held by the University or transferred to the Investigator's new institution. Also, consultation with the sponsor may be necessary to review the terms of an agreement. In either case, ORPA will assist to establish the activities required prior to the Investigator's departure (refer to the [ORPA Guidance for Principal Investigators Leaving the University](#)).

### 2. Active Research

- a) If research activities are continuing at the University:
  - i. Transfer the research protocol to another University eligible Principal Investigator (PI)
  - ii. Notify ORPA of the change in Investigator and process appropriate paperwork to enact the change.
  - iii. Submit an amendment to the RSRB to process the staff change.
  - iv. If any active research is registered on ClinicalTrials.gov, contact [Regulatory Support for ClinicalTrials.gov](#) or the [Research Help Desk](#) in the CTSI.
- b) If research activities will not continue at the University, but will be transferred:
  - i. Notify ORPA and begin the process to transfer the project as necessary.
  - ii. Determine if information will need to be shared with the new institution. If so, determine what the PI will need access to and how the data sharing will be managed. See 3a below or contact the Privacy Office to determine under what conditions research data or specimens may be shared with an outside institution.
  - iii. Close the active study with the RSRB by completing a final progress report.

Note: If research activities will not be transferred to the PI's new institution and will be discontinued at the University, a final progress report must be submitted to the RSRB to close the study.

### 3. Research Data and Study Documentation

- a) The PI should consider what types of research data need to be managed in advance of his or her departure, including consent forms, source documentation (e.g., questionnaires,

assessments), Word files or Excel spreadsheets, lab notebooks, and biological specimens. Note: financial records, supporting documents, and all other study related records pertinent to a federally funded award shall be retained by the University.

- b) Data may be shared with the new institution under the applicable guidelines of the Health Insurance Portability and Accountability Act (HIPAA) rules. Options for data sharing include:
1. Obtain a HIPAA Authorization from subjects indicating agreement to release information to the new institution,
  2. A Limited Data Set is shared with the new institution in conjunction with a Data Use Agreement between the UR and the new institution, or
  3. A de-identified data set is shared with the new institution.

Further information regarding data sharing mechanisms is available in the [HIPAA Policy & Training Manual](#), procedure 0P-25 regarding “Uses & Disclosures of PHI for Research Activities”.

#### **4. Research Materials (Data, Samples, Equipment)**

Research material (RM) developed or used at the University (e.g., tissue samples, blood samples, data) may be transferred to the new institution under a Material Transfer Agreement (MTA). If the researcher used materials at the UR received under an MTA, a new MTA must be negotiated for the material to be used at the new institution.

#### **5. Intellectual Property**

The Investigator should communicate with UR Ventures to ensure there are no pending issues in regard to patents, copyrights, etc. In particular if the Investigator may have intention to use any intellectual property following his or her departure from the University. The following information should be noted:

- a) The inventor receives a percentage of royalties, even if he or she is no longer at the University.
- b) If an inventor leaves, the individual (and new employer as applicable) needs to ensure that the appropriate rights to use the patent exist.
- c) For pending patents (in process, but not yet issued), the University needs to ensure the inventor will remain available during continued prosecution of the pending patent.