

Guidance for Investigators Related to their Research upon Leaving Johns Hopkins University

This document is designed to help investigators who are leaving the University make appropriate arrangements for the orderly transition of research activity and resources. It is recommended that you begin the applicable procedures listed below at least two months prior to your departure date. The process can be complex, and you are urged to contact your department administrator and the cognizant research affairs office with any questions.

Fiscal and Contractual Matters

- The department administrator should work with the departing investigator to schedule payroll, faculty and medical staff appointment changes, final expenditures, effort certification, data system access, return of badge and P-cards, and parking permit termination.
- The departing principal investigator (PI) may request that JHU relinquish active grants and contracts to the new institution subject to a satisfactory plan for continuing collaborators and students and sponsor prior approval. Permission of the academic Department or Division Director is required for the relinquishment of any grants, or the transfer of any data, equipment or materials. (http://www.hopkinsmedicine.org/research/resources/offices-policies/ora/handbook/handbook_V_g.html, https://research.jhu.edu/jhura/wp-content/uploads/sites/2/2016/12/JHURA_GUIDETORESEARCHADMINISTRATION_VERSION3.pdf) When an investigator is departing following or during an investigation related to safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions), the relevant research office will note that on the relinquishment notice as required by sponsor terms and conditions. Once approval is granted, the PI or department research administrator should contact the cognizant research office (Office of Research Administration (ORA), or Johns Hopkins University Research Administration (JHURA)) to complete necessary paperwork, including but not limited to required final progress and invention reports.
- Johns Hopkins Technology Ventures (JHTV) will assist with any needed Material Transfer Agreements (MTAs) to transfer research materials. ORA or JHURA will assist with Data Use Agreements (DUA) to transfer University research data. No University research materials or data may be taken to a new institution without an approved MTA or DUA in place. For outgoing MTAs, use this form: <https://ventures.jhu.edu/faculty-inventors/forms-policies/material-transfer-agreement-request-form-for-outbound-material/>
- If active awards proposed for transfer involve collaborator(s) from external entities under sub-agreements, the departing investigator should work closely with ORA or JHURA to enter a close-out process with a selected end date to stop expenses and allow for administrative time to complete. The sub-agreement close out process must be completed before JHU can complete the prime award relinquishment.

Intellectual Property and Rights in Data

- Departing investigators with invention disclosures, or patent applications in process, or those receiving proceeds from licensing of intellectual property, should provide their new contact information to JHTV's Technology Transfer Office (<https://ventures.jhu.edu/licensing-commercialization/>).
- The University retains ownership of research data generated by University faculty. Data access, retention and transfer is addressed in the JHU Policy on Access and Retention of Research Data and Materials. (http://dms.data.jhu.edu/files/2016/08/JHURDataRetentionPolicy2008_WithAppendices.pdf). Original research data must be retained by the responsible department for the periods outlined in the JHU Records Retention Policy (https://policies.jhu.edu/?event=render&mid=769&pid=32357&fid=policy_32357.pdf&_id=0.768382547383).
- If faculty request copies of research data, the department research administrator should obtain Department or Division Director approval and then contact ORA, or JHURA to obtain a data use agreement to govern the use of the data at the new institution. Data Trust approval is necessary for transfer of any Johns Hopkins Health System patient data, and IRB approval may be necessary for transfer of human subject research data.

Laboratories and Equipment

- Laboratory space must be inspected by Health Safety and Environment (HSE) staff before vacating. (https://hpo.johnshopkins.edu/hse/policies/156/11009/policy_11009.pdf?_=0.714544886484)
- Countertops, chemical fume hoods, biological safety cabinets and any other potentially contaminated surfaces in the vacated laboratory must be cleaned. All waste must be properly discarded. (https://hpo.johnshopkins.edu/hse/policies/156/11005/policy_11005.pdf?_=0.199381120857)

Biological safety cabinets (BSC) must be decontaminated by a qualified vendor prior to being moved or closing the lab. Laboratory personnel are NOT permitted to perform or certify decontamination of a biological safety cabinet that is being moved.

- A formal decommissioning plan must be developed with HSE prior to vacating a BSL-3 laboratory.

Transfer of Laboratory Equipment

- The ability to move laboratory equipment to your new institution depends on factors such as the funds used to purchase the equipment and whether it is needed for ongoing research at JHU. Normally only equipment purchased from active grants that are also being transferred may be moved. Exceptions may be granted if the equipment is not needed at JHU and there is adequate compensation to JHU for the value of the equipment. Investigators should submit a list of equipment they wish to be relocated to their Department or Division Director, who will make a recommendation to the cognizant Research Dean. The Research Dean will consider the recommendation of the Department Director in reviewing proposed exceptions. Refer to the ORA Handbook for further guidance. (http://www.hopkinsmedicine.org/research/resources/offices-policies/ora/handbook/handbook_V_g.html#a6)
- Equipment that will be disposed of or transferred must be cleaned and inspected prior to disposal or transfer, per HSE's Laboratory Equipment Clearance Policy. (https://hpo.johnshopkins.edu/hse/policies/156/11010/policy_11010.pdf)

Transfer of Chemical and Biological Substances

- Develop an inventory of remaining chemical and biological substances.
- Dispose of all unwanted chemicals through the HSE's Management of Hazardous Chemicals. (https://hpo.johnshopkins.edu/hse/policies/156/10996/policy_10996.pdf?_=0.151853849755, <https://hpo.johnshopkins.edu/hse/?event=section§ionid=1006>)
- Prior to transferring any usable chemicals to JHU colleagues, forward the comprehensive chemical inventory to HSE for review and approval.
- Highly toxic materials and chemicals which are on the Department of Homeland Security's Chemicals of Interest list should not be transferred. (<https://www.dhs.gov/appendix-a-chemicals-interest-list>)
- HSE must be contacted for the disposal of large volumes of chemicals before the investigator leaves JHU. The Department will be billed for chemical disposal. (https://hpo.johnshopkins.edu/hse/policies/156/10996/policy_10996.pdf?_=0.135574940877)
- Remove regulators from all compressed gas cylinders, replace the protective cap, and ensure proper labeling of each cylinder. Contact the gas distributor to have the gas cylinders removed.
- In general, it is not permissible to transfer Drug Enforcement Administration (DEA) controlled substances to another investigator. HSE should be contacted for information regarding disposal of controlled substances through a reverse distributor or another acceptable method. (<http://web.jhu.edu/animalcare/policies/DrugRecords-Storage-Disposal2015.pdf>)

Studies Using Animal Subjects

- All Animal Care and Use Committee (ACUC) protocols for which the departing investigator is designated the Principal Investigator (PI) must be terminated, or an alternate PI may be designated via an amendment form. (<http://web.jhu.edu/animalcare/forms.html>)
- If the animal is a proprietary model obtained under a Material Transfer Agreement (MTA) or purchased under an agreement with a commercial supplier, contact JHTV to determine whether the animals can be transferred to a third party.

- To export rodents to another institution, the PI must download and complete a Request for Health Certificate – Export Form. For more information, contact Research Animal Resources. (http://www.hopkinsmedicine.org/animalresources/Protected_Pages/Imports_exports/How_to_ship_rodents.html)
- If any departing personnel hold a special Access Card to gain entry to secure animal housing facilities (Homewood campus, Rangos Building), the card may not be transferred to another investigator; it must be returned to issuing unit. (http://web.jhu.edu/animalcare/faqs/buildings_central.html, <http://www.hopkinsmedicine.org/animalresources/Forms/index.html>)

Studies Involving Human Subjects

- If the departing investigator is designated as the PI on one or more Institutional Review Board (IRB) applications, he/she is responsible for notifying the IRB well in advance of their departure to close the study (via a Termination Report) or name another appropriately qualified individual currently at the institution to serve as the PI. Departing faculty should refer to the JHM IRB Research Faculty Resignation Questionnaire for further guidance. (http://www.hopkinsmedicine.org/institutional_review_board/forms/research_faculty_resignation_checklist.docx)
- If the departing investigator is designated as a study team member, a change in research application must be submitted for each study to remove him/her from the study team, or arrangements must be made with the departing investigator's new institution to permit reliance by the new institution on the JHM IRB. See Office of Human Subject Research – Institutional Review Board Guidelines and Policies: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/changes_research.html. Investigators with protocols active at the JHSPH IRB should submit an amendment via <https://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/amendments/>, and investigators with protocols active at the Homewood IRB should submit an amendment via <http://homewoodyrb.jhu.edu/ehirb-documents/>.
- If the departing investigator is the PI, Record Owner, or otherwise named on any record registered under a Johns Hopkins entity on ClinicalTrials.gov, the departing investigator must contact the Johns Hopkins ClinicalTrial.gov program at registerclinicaltrials@jhmi.edu to arrange for any necessary record transfer.
- Outbound Human Biospecimen Transfer must be requested under this policy: https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_af=0.25523869118.
- Research drug supplies should be disposed of or transferred as indicated in the study agreement with the sponsor. If no such agreement exists, the investigator should contact the Pharmacy and Investigational Drug Service at The Johns Hopkins Hospital. (http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/pharm_jhh.html)

Studies Conducted Under a University-based, Sponsor-Investigator Investigational New Drug (IND) or Investigational Device Exemption (IDE) Application

- If the departing investigator is currently the sponsor of an IND or IDE application, the application should be withdrawn (if clinical studies being conducted under the application have been Closed to Accrual or Terminated) or transferred to another University investigator if clinical studies will continue. If the IND or IDE will be transferred to the departing investigator's new institution and clinical studies being conducted under the IND/IDE will continue at JHU alternative arrangements may be made to maintain a site at JHU.

Studies Using Recombinant DNA

- All protocols approved by the Institution Biosafety Committee (IBC) for which the departing investigator is designated as the PI must be terminated, or an alternate PI must be designated via a protocol modification form. Consult the IBC Office. (<http://www.hopkinsmedicine.org/hse/ibc/>)

- Radiation-Producing Devices and Materials** ○ If any radiation-emitting equipment (e.g., x-ray device) will be removed, relocated, or discarded, the JHMI Radiation Control Unit (RCU) must be notified. (http://www.hopkinsmedicine.org/hse/radiation_safety/)

- If any radioactive material is stored in the laboratory, contact the RCU to coordinate its removal, transfer, or disposal. (https://hpo.johnshopkins.edu/hse/policies/156/11018/policy_11018.pdf?_=0.463682095158)
- If any departing personnel hold Access Cards to secured areas containing radiation-emitting devices (e.g., gamma irradiators, gamma knife) the RCU must be informed of the individual's departure. Access Cards held by departing personnel may not be transferred to another investigator; they must be returned to the RCU.

Checklist for Investigators Leaving JHU

to be used with Procedure for Investigators Leaving Johns Hopkins University

- MTA
- DUA
- NDA
- Discussed with Director
- Salary, Appointments, parking, JH systems access and identity cards
- Prior approval from sponsor on transfer-obtain through ORA/JHURA
- Provided new Point of Contact
- Alternate PI designated
- HSE contacted
- Equipment Cleaned
- Equipment Inspected
- Equipment Transfer Authorized
- Lab Space Inspected
- All surfaces cleaned
- Waste disposed
- BSC decontaminated
- Decommissioning plan
- Chemical and biological substances inventory
- Unwanted Chemicals Disposed
- Transferred usable chemicals
- Regulators Removed
- Disposed DEA controlled substances
- Animals euthanized, transferred, or exported
- IRB notified
- Biospecimen Transfer Form
- Research drugs disposed
- IND/IDE application withdrawn/transferred
- Notified JHMI Radiation Control Unit
- Access Cards returned