

Icahn School of Medicine at Mount Sinai (ISMMS)

PI Exit Document

April 2023

This is a standard document that must be completed by Principal Investigators (PIs) who end their employment with the School, whether through resignation, retirement, or termination. The document provides the steps the PI and department will need to complete in order for the PI to officially exit from the School. This document includes important Human Resources information, departmental logistics, and procedures for PIs involved with active research projects. Following the steps outlined in the document will facilitate the transition of the PI from active employment to her/his eventual departure date. This process is intended to assist the School and Departments to be in compliance with state and federal guidelines, providing an efficient and effective means to close out projects and resources associated with sponsored research.

Item	Action	Responsible.	Item Perform. Initial/Date	Item Verified Initial/Date
1.0	Notification (ISMMS Administration)			
	<i>Formal written notification is required at least 6-weeks prior to intended departure date. The notification should include: Date of departure, Name and Contact (Grants Officer) of new institution (if applicable), Grants expected to transfer (by GCO #), and Names, Life Numbers and Termination Dates of other ISMMS Employees.</i>	PI		
1.1	Division Chair & Admin. – Resignation Letter	PI		
1.2	Dean's Office – PSM 100	Administrator		
1.3	Finance (SPA) – Copy of Resignation Letter	Administrator		
1.4	GCO – Copy of Resignation Letter (GCO will work with the Investigator and department to determine whether to transfer, request change of PI or terminate awards early as appropriate)	Administrator		
2.0	CCMS / IACUC			
2.1	CCMS – Copy of Resignation Letter -- Animal users MUST develop a transition plan with CCMS to ensure that all protocols, animal colonies and charges are adequately addressed.	Administrator		
2.2	IACUC – Copy of Resignation Letter -- Animal users MUST develop a transition plan with IACUC to ensure that all protocols, animal colonies and charges are adequately addressed.	Administrator	09/28/21 CBL	
3.0	IRB			
3.1	Projects to be transferred from and closed at ISMMS	PI		
3.1.1	Assess transferability of research to new institution (e.g., geographic proximity for human subjects, etc.) (done by PI or Proxy)	PI		
3.1.2	Submit application through new institution's IRB. (done by PI or Proxy)	PI		
3.1.3	Submit final report to ISMMS IRB through RUTH. (done by PI or Proxy) Keeping in mind the project may be managed by an external IRB. Both IRB offices must be alerted to the closure of the study.	PI		
3.1.4	Include a management plan for any currently enrolled	PI		

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	research subjects (e.g., withdrawing subject from research that do not wish to be transfer to the new institution, notifying subjects of the change, etc.) in the Final Report. (done by PI or Proxy)			
3.1.5	Consult with the IRB and MSIP regarding any transfer of research data including the management of any HIPPA issues. (done by PI or Proxy)	PI		
3.1.6	Consult with GCO and/or FACTS if an external Sponsor/or grant is involved related to transferring the project.	PI		
3.1.7	Manage the PI's Investigational New Drug or Device registration with FDA to transfer the application. Contact ORS (Research 411) and/or Research Compliance (Vivian Mitropoulou) first for assistance. This must be managed before the PI departs.	PI		
3.2	Projects to be retained at ISMMS	PI		
3.2.1	Either transfer the project to a co-I currently involved in the project or apply for Voluntary or Adjunct Faculty Appointment through Chair (may be done via Resignation Letter,) and/or work with Department to identify new PI.	PI		
3.2.2	If a new PI will take on the project: submit a modification to other parts of the study via RUTH	PI		
3.2.3	Follow the change in PI guidance on the PPHS website here . (done by PI or Proxy) Note: Special considerations for Industry Sponsored Research – Industry sponsor has final approval over change of PI and/or institution, and will modify any clinical trial agreement	'Exiting' PI and 'New' PI		
3.2.4	Manage the PI's Investigational New Drug or Device registration with FDA. Contact ORS (Research 411) and/or Research Compliance (Vivian Mitropoulou) first for assistance. This must be managed before the PI departs.	PI		
3.3	Projects to be Terminated/Closed	PI		
3.3.1	Submit Final Report regardless of the IRB of Record. If the project uses an external IRB, both IRB offices must be notified.	PI		
3.3.2	Manage the PI's Investigational New Drug or Device registration with FDA. Contact ORS (Research 411) and/or Research Compliance (Vivian Mitropoulou) first for assistance. This must be managed before the PI departs.	PI		
	Note: Special considerations for Industry Sponsored Research – Industry sponsor has final approval over change of PI and/or Institution, and will modify any Clinical Trial agreement.			
4.0	ClinicalTrials.gov PIs must contact ORS at ClinicalTrials.gov Assistance - Research 411 Portal - Jira Service Management (atlassian.net) to transfer or complete the study record on ClinicalTrials.gov prior to leaving MSHS.	PI		
5.0	Equipment			

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	Transfers – All equipment sent to another facility must be decontaminated. Contact the Chemical, Biological, or Radiation Safety Officer, as appropriate. Complete the Certificate of Decontamination form, as necessary: https://icahn.mssm.edu/files/ISMMS/Assets/Research/Bio safety-001-Certificate-of-Decontamination.pdf	PI / Administrator		
5.1	Prepare a list of equipment. (Include: Description of Equipment, ISMMS Tag #, Purchase Order #, and Funding Source.)	PI / Administrator		
5.2	Approve list; send to Finance.	Chair / Administrator		
5.2.1	Compare the list of items for transfer to the Capital Asset Ledger. Account for the absence of any capital items indicated as 'purchased with Grant funds,' but not on the PI's itemized list. Equipment purchased with Institutional or donated funds cannot be transferred without Dean's or CFO's approval.	SPF / Administrator / PI		
5.3	Negotiate Fair Market Value.	Chair / PI / Administrator		
5.4	Prepare Property Pass.	SPF		
5.5	Approve transaction; sign Property Pass.	Dean's Office		
6.0	Subcontracts			
6.1	Notify collaborating institutions in writing that grants may/will be transferring.	PI		
6.2	Copy SPF so SPF can prepare Amendment to terminate the subcontract	PI / Administrator		
6.3	Prepare 'Change Orders' to terminate ISMMS subcontracts.	Administrator		

Laboratory Close-Out

Because laboratories often contain hazardous materials and equipment and other supplies obtained through several sources, coordination and care must be taken when either closing a lab completely or transferring some or all of the contents to another institution. To fully comply with health, safety and ownership requirements, the following actions may be required. All items listed below should be completed PRIOR to departing the School.

7.0	Laboratory Close-out			
7.1	Notify <u>Facilities Management</u> , and make arrangements for disposal of unwanted items (furniture, equipment, etc.) All unwanted items MUST be decontaminated! Contact the Chemical, Bio-, or Radiation Safety Officer, as appropriate. Complete Form BSO-2 – Certificate of Decontamination, as necessary.	Administrator		
7.2	Notify <u>Biological Safety Program</u> (biosafety-program@mssm.edu), and make arrangements for disposal of biological hazards, including clinical specimens, and “sharps” items.	PI / Administrator		
7.3	Notify <u>Environmental Health & Safety</u> , and make arrangements for disposal of chemicals and unknown/unidentified containers.	PI / Administrator		
7.4	Notify <u>Radiation Safety</u> , and make arrangements for the removal or disposal of all radioisotopes, and related samples/specimens.	PI / Administrator		
7.5	Biological Select Agents & Toxins: The Federal Select Agents Program governs the possession and use of biological select agents and toxins. The PI must develop a plan for the final disposition of biological select agents and toxins with the Responsible Official. Please contact the Responsible Official biosafety-program@mssm.edu .	PI / Administrator		
8.0	Personnel Actions			
	<i>Online HRTS Transactions are required for all terminating staff employees, well in advance of the termination dates.</i>			
8.1	Process HRTS Termination Transactions	Administrator		
8.2	Process Terminations.	SPF		
8.3	Review Time & Effort Reports; Obtain employee signatures; Return to Finance.	Administrator		
8.4	File Time & Effort Reports.	SPF		
9.0	Shared Research Facilities & Other Allocations			
9.1	Verify that all Grant-related re-charges have been properly allocated to the fund. Charges include, but are not limited to: Shared Research Facilities Print Shop Library Etc. Notify Admin of missing/expected re-charges.	PI / Administrator		

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9.2	Contact appropriate service provider and/or SPF to investigate/process appropriate re-charges.	Administrator		
9.3	Process re-charges.	SPF		
10.0	Third Party Obligations and Miscellaneous			
10.1	Confirm all final reports from closed applications are filed	PI/SPF/MSIP		
10.2	Terminate all open data transfer use agreements	PI/MSIP/GCO		
10.3	Update IND filing as appropriate	PI/ORS		
10.4	Re-Assign Access to ELN and any data repositories for work done at Sinai	PI		
10.5	Provide emergency contact information to departmental administrator in case of outstanding items, such as questions on final reports	PI/Administrator		
11	Relinquishing Statement			