Researcher Separation



Manual



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The Researcher Separation Manual outlines steps for finalizing research activities at the University of North Carolina at Chapel Hill ("University," "UNC-Chapel Hill"), address administrative and financial matters, and facilitate the transfer of responsibilities in an efficient and organized manner when researchers are leaving employment with the University. Moreover, it serves as a communication tool, fostering collaboration and coordination among parties engaged in the departure process. Arranged by subject, the Manual aims to streamline navigation for users.

The Manual serves as an additional resource and does not negate the need for close coordination with local Human Resources (HR) Representatives, as listed in the <u>HR Directory</u>.

Message to Departing Researcher:

Your dedication to ensuring a seamless transition of your research activities upon your departure from the University of North Carolina at Chapel Hill is deeply appreciated. Whether you are retiring, resigning, or leaving for any other reason, such transitions require meticulous planning and coordination to comply with University policies and regulations and ensure continuity of research.

To support you through this change, UNC Research has developed the Researcher Separation Manual. This manual is designed to streamline your transition, offering a clear roadmap of essential tasks and responsibilities to be addressed promptly before your ONYEN expires.

Thank you for your cooperation in ensuring a smooth transition.

01 Sponsored Research

OFFICE OF SPONSORED PROGRAMS (OSP)

Email: SponsoredPrograms@unc.edu, OSPcontracting@unc.edu, OSPSubs@unc.edu

Phone: 919-966-3411

- Obtain documented approval for award transfer(s) from your department chair before communicating with OSP. **Note:** The institution and department are granted the awards, and sponsored external awards can only be transferred with approval from the department chair and higher institutional authorities.
- Work with Departmental Effort Coordinator to review and certify their final effort statement.
- Ensure all reports (financial and technical) and other deliverables have been submitted to sponsors. **Important:** Failure to submit the final Progress Report may result in the Investigator and Institution not being able to receive future funding.
- If you anticipate a Data Use Agreement (DUA), refer to the Office of Sponsored Programs (OSP) <u>Data use</u> <u>Agreement Guidance</u> and the <u>Contracting Agreements webpage</u> for detailed information about DUA requirements. If you need assistance, contact the OSP Contracting team at OSPContracting@unc.edu.

All Sponsored Projects

Please email <u>SponsoredPrograms@unc.edu</u> a list of active sponsored projects in which you are listed as a Principal Investigator (PI), Co-PI, key personnel, or collaborator. For each project where you serve as are the PI, provide the following details:

- Indicate whether the project(s) will be transferred to the new Institution or to a new PI at UNC-Chapel Hill.
- Specify if you have committed (cost share) and/or actual effort on a sponsored project.
- Indicate if the project(s) include subawards.
- Note if there are pending proposals that are likely to be funded and/or agreements pending execution.
- Specify if there are any active contractual agreements associated with the project(s) (e.g., Federal/State funded grants, cooperative agreements/contracts, subcontracts).
- State if the project(s) have ended, but final technical reports are still outstanding with the sponsor.

Industry Sponsored Projects

Please email <u>OSPContracting@unc.edu</u> a list of active industry-sponsored projects, including both clinical and non-clinical studies. For each project, detail the following:

- Indicate whether the project(s) will be transferred to the new Institution or to a new PI at UNC-Chapel Hill.
- Provide a contact person from the PI's Department.
- Include contact information for the new institution.
- Specify if the sponsor has been notified of the departure.

Investigator Initiated Projects with Industry Funding

Please email <u>OSPContracting@unc.edu</u> a list of projects that are PI-initiated and Industry-funded, including both clinical and non-clinical studies. For each project, detail the following:

- Indicate whether the Clinical Trial Agreement (CTA) will be transferred to the new Institution.
- Include contact information for an interim PI (if the project will transfer) or a new PI (if UNC-Chapel Hill will remain a site for the project).
- Confirm whether the funding source has been notified (including those who only provide the drug and/or device).
- Include contact information for the new Institution, if applicable.
- Specify any anticipated DUA related to incoming and outgoing project data.

If you have	That Will	You will need to
Active External	Transfer to	Determine if subaward back to UNC-Chapel Hill is needed (i.e., to
Awards	new	continue support of students/fellows).
	institution	• Submit a <u>prior approval request</u> to OSP to transfer the award; agency
		relinquishing statement.
		Email OSPSubs@unc.edu to terminate subawards.
		Submit a <u>prior approval request</u> to OSP to transfer equipment to new
		institution (See University Policy/Procedure <u>603.6</u>).
		Submit any outstanding reports and deliverables to the sponsor.
		Work with OSP to close out the award.
	Relinquish	Email OSPSubs@unc.edu to terminate subawards.
	prior to	Submit any outstanding reports and deliverables to the sponsor.
	separation	Submit a final invention statement, if applicable.
		Work with OSP to close out the award.
	Remain at	Identify new PI of record.
	this	Submit a <u>prior approval request</u> to OSP to change PI on project.
	institution	
Expired external		Submit any outstanding reports and deliverables to sponsor.
awards		

02 Animal Research

OFFICE OF ANIMAL CARE AND USE (OACU)/INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

Email: iacuc@med.unc.edu Phone: 919-966-5569

Contact the Office of Animal Care and Use (OACU), the IACUC Support Office, to provide the anticipated end date for animal-related work.

If the protocol is transitioning to another Principal Investigator (PI) at UNC-Chapel Hill, please submit an amendment in ACAP (Application to Use Live Vertebrate Animals Office of Animal Care and Use).

If animals are no longer involved and work at UNC-Chapel Hill has concluded, request termination of the protocol in ACAP.

DIVISION OF COMPARATIVE MEDICINE (DCM)

Email: bakerts@ad.unc.edu Phone: 919-962-5335

Contact the DCM to indicate whether animals will be transferred to the new institution or to explore other disposition options.

If required, change the chart field in ACAP (Application to Use Live Vertebrate Animals Office of Animal Care and Use) for billing purposes.

Note: Access to buildings will be terminated.

03 Non-animal Laboratory Research

ENVIRONMENT, HEALTH AND SAFETY (EHS)

Website: ehs.unc.edu Phone: 919-962-5507

Please inform EHS of your departure via labsafety@unc.edu at least 30 days before the laboratory closeout date.

Review EHS Closeout Instructions.

Complete the Laboratory Closeout Checklist and submit to EHS when completely moved out of lab space.

Complete the EHS Waste Disposal Request for any unwanted hazardous materials prior to closeout. **Note:** Any hazardous material left behind **may result in charges** to Principal Investigator (PI)/Department for proper disposal.

For research proposals that <u>require medical surveillance</u> closeout evaluation, contact the University Employee Occupational Health Clinic (UEOHC) at 919-966-9119 to schedule an appointment.

04 Clinical Research

OFFICE OF HUMAN RESEARCH ETHICS (OHRE)

Email: irb questions@unc.edu Phone: 919-966-3113

Provide OHRE with the <u>Principal Investigator Separation Request Form</u> at least 45 days before departure or retirement through a Help Desk ticket in IRBIS.

Review all studies and their study status and determine requested action for each study.

For all studies that will continue at UNC-Chapel Hill under a new Principal Investigator (PI), promptly submit a modification in IRBIS to add the new PI and remove the existing PI from the study team.

For all studies in which the role is one other than the PI on the study, submit a modification in IRBIS to remove the departing researcher from the study team.

For studies that will be transferred to a new institution without any ongoing involvement at UNC-Chapel Hill:

- 1. Contact the IRB team at the new institution to obtain IRB approval at the new institution.
- 2. Contact the OHRE reliance team to discuss whether a reliance agreement is needed to cover IRB oversight of the study during the transition to the new institution.
- 3. If UNC-Chapel Hill is the IRB of record for other sites, contact the OHRE reliance team and the IRB at the new site to determine if the new site is willing to serve as the IRB of record. UNC-Chapel Hill IRB will not continue as the IRB of record if the study is no longer conducted at UNC-Chapel Hill.

Initiating the transfer process promptly is crucial, as it requires a considerable amount of time to complete.

Note: UNC-Chapel Hill Adjunct Faculty who hold primary appointments at other institutions or organizations may not continue to serve as the PI at UNC-Chapel Hill. Emeritus faculty (retirees) may continue to serve as PI on studies that are in data analysis only.

For studies in which the data or specimens will be transferred to the new institution:

- 1. Contact OSP to ensure this transfer is permitted per the grant or contract.
- 2. Contact the IRB at the new institution to determine next steps, as an IRB approved study will be required at the new institution for the storage and/or analysis of identifiable data or specimens.
- 3. Submit a modification to the UNC-Chapel Hill IRB to request data or specimen transfer approval.

Department Responsibility for the transfer of data or specimens:

1. Ensure the IRB approved consent form states that data may be shared outside UNC-Chapel Hill.

- 2. If the study is closed, verify the storage of data and/or specimens is approved for storage beyond study closure.
- 3. Contact OSP to request a data and/or materials transfer agreement.

For studies where all study activities have concluded or will not continue at UNC-Chapel Hill after the PI's departure or transfer to another institution, submit a closure submission for the studies in IRBIS.

CLINICAL RESEARCH COMPLIANCE OFFICE (CRCO) Email: ClinResComp@unc.edu						
ClinicalTrials.gov Records						
LCCC	Email:	CRCO Email:				
Oncology Studies	Melahat Canter@med.u	Non-oncology studies <u>m_coudurier@unc.edu</u>				
	nc.edu					
ClinicalTrials.gov records for which UNC-Chapel Hill or a UNC-Chapel Hill Principal Investigator (PI) (i.e.,						
	, , , , , , , , , , , , , , , , , , , ,	must be updated to reflect the current study status.				
		investigator or a new institution.				
If you have	That Will	You will need to				
a ClinicalTrials.gov record	Remain at the institution	Ensure that the record is up to date.				
with a <u>study status</u> of any		Assign a new UNC-Chapel Hill PI to be the				
of the following:		Responsible Party at this institution.				
Study not yet		Contact the CRCO or LCCC. ClinicalTrials.gov				
recruiting		Administrator to update the ClinicalTrials.gov				
Recruiting		record with the new PI.				
Enrolling by	Transfer to PI's new	Ensure that the record is up to date.				
invitation	institution	Contact the CRCO or LCCC. ClinicalTrials.gov				
Active, not		Administrator for record transfer assistance.				
recruiting						
 Suspended 		IMPORTANT: Records associated with an award can				
		only be transferred if the award has officially been				
		transferred.				
a ClinicalTrials.gov	Remain at the	Ensure that the record is up to date.				
record with a <u>study</u>	institution	Assign a new UNC-Chapel Hill PI to be the				
status of any of the		Responsible Party at this institution.				
following:		Ensure new PI has access to study data &				
 Completed 		materials.				
Terminated		Contact the CRCO or LCCC. ClinicalTrials.gov				
 Withdrawn 		Administrator to disable the departing PI's user				
		account.				
IND/IDE Records						
LCCC Email:	LCCC IND@unc.edu	CRCO Email: ClinResComp@unc.edu				
Oncology Studies Non-oncology studies Email: Commescomp@dric.ed						
INDs or IDEs held by you, or	the University must be upo	dated to reflect the status. They can be transferred to a				

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new institution or completed/withdrawn if the study will be closed.

If you have	That Will	You will need to
	Transfer to Principal Investigator's (PI's) the new institution	 Contact the LCCC or CRCO IND/IDE program, as applicable, about transfer procedures. Provide confirmation to the LCCC or CRCO IND/IDE program once the transfer is complete.
An IND/IDE held by you	Transfer with you to the new institution, but the study will still be conducted at UNC-Chapel Hill	 Identify new PI of record for this institution. Have the new PI submit a 1572 to you as the sponsor (must be submitted to FDA within 30 days of new investigator being added). Contact the LCCC or CRCO IND/IDE program, as applicable, about transfer procedures. Provide confirmation to the LCCC or CRCO IND/IDE program once the transfer is complete.
An IND/IDE held by the University	And will remain at this institution	 Contact your Department Chair (non-oncology) or LCCC Director (oncology) to request permission to transfer the IND/IDE to you or the new institution and send the approval to the CRCO and LCCC IND/IDE program, respectively. Contact the new institution to determine their process to transfer the IND/IDE and provide this information to the CRCO and LCCC IND/IDE program, respectively. Contact the LCCC or CRCO IND/IDE program, as applicable, about transfer procedures. Provide confirmation to the LCCC or CRCO IND/IDE program once the transfer is complete. Identify a new PI of record (must be submitted to FDA within 30 days of new investigator being added)
	tins institution	 Contact the LCCC or CRCO IND/IDE program, as applicable, about transfer procedures
An IND/IDE held either by you or the University	Be closed prior to the sponsor- investigator transferring to the new institution	 Submit a closure report to FDA and provide a copy to the CRCO and LCCC IND/IDE program, respectively. Provide a copy of the FDA response (if applicable) to the CRCO and LCCC IND/IDE program, respectively.

INSTITUTIONAL PRIVACY OFFICE (IPO)

Email: privacy@unc.edu Phone: 919-962-6332

If you plan to bring UNC-Chapel Hill research data with you:

- 1. Provide IPO with written IRB approval of request to transfer research data, including the IRB study number, data elements to be disclosed, recipient institution's name, and how the data will be transferred and stored.
- 2. Additionally, if the study is closed with the IRB, you must also provide the IPO with written documentation of IRB approval of storage of data beyond study closure.

Important: Ensure Department approval has been obtained for the use and transfer of the data, if needed (such approval may be indicated a Data Use Agreement (DUA) or through other OSP Contracting processes). Review OSP and OHRE section for additional guidance and procedures pertaining to data transfer.

Data Use Agreement (DUA):

If you anticipate a DUA, refer to the Office of Sponsored Programs (OSP) <u>Data use Agreement Guidance</u> and the <u>Contracting Agreements webpage</u> for detailed information about DUA requirements. If you need assistance, please contact the OSP Contracting team at OSPContracting@unc.edu.

For the Department: If the researcher has already left the University (including retirees), immediately contact the IPO as a separate analysis will be required.

05 All Research

OFFICE OF UNIVERSITY COUNSEL (OUC)

Email: Sarah.Goldin@unc.edu Phone: 919-843-8979

If you are on a legal hold notice, contact OUC using the provided contact information. If you are contacting OUC on behalf of the departing researcher, be prepared to identify them during the communication. If a response is not received, please call OUC's general line at 919-962-1219.

CONFLICT OF INTEREST (COI)					
Email: coi@unc.edu Phone: 919-843-9953					
Email the COI Program with the date of your departure and the name of the new institution.					
Ensure that any outstanding COI disclosures are completed in AIR.					
If you have	That Will	You will need to			
An IRB study	Stay at UNC- Chapel Hill	 Remove or modify the position and contact information on the IRB application to avoid receiving UNC COI disclosures. Remove or modify the COI disclosure language in the informed consent form as applicable. Note: A reliance agreement with the new may be necessary. 			
A Sponsored Project	Stay at UNC- Chapel Hill	Update the position and contact details on the IPF or account in RAMSeS to ensure appropriate linkage with COI disclosures. Note: If the project continues at a new institution, the Department may need to initiate a subcontract.			
A Monitoring Committee for a COI	Stop upon departure	Email the COI Office at coi@unc.edu to arrange a "close-out" meeting with COI Office and Chair before departing.			

EXPORT CONTROLS OFFICE

Email: exportcontrol@unc.edu

If you have participated in any type of export-controlled research or project, notify the Export Control Office of your departure.

If you are a foreign national returning to your home country and you have participated in any type of export-controlled research or project, collaborate with the Export Control Office to determine which data, if any, can be brought back to their home country. Controlled data may not be transferred out of the country without review and approval from the Export Control Office. You will also be required to sign an export attestation prior to transferring any permitted controlled data outside of the United States.

If you intend to transfer export-controlled equipment, materials, biologics, and/or data to another institution/entity, coordinate with the Export Control Office to ensure that all documentation and export controls requirements are met. The Export Control Office will also liaise with the receiving institution/entity to ensure compliance with transfer requirements.

If you are retiring and wishes to personally retain export-controlled data, complete an Export Control Office attestation prior to termination.

ASSET MANAGEMENT

Email: Assets Team@unc.edu

If you are the custodian of any assets, review the following procedures on asset management to ensure smooth transition of assets:

- 1. Managing Assets & Capital Asset Information
- 2. 603.5 Procedure for Transfer or Sale of Capital Equipment Between University Departments
- 3. 603.6 Procedure for Transfer of Capital Equipment to Other Institutions

For additional information regarding asset management, please visit the <u>Asset Management</u> webpage or contact the <u>Asset Management Team</u>.

OFFICE OF TECHNOLOGY COMMERCIALIZATION (OTC)

Email: otc@unc.edu Phone: 919-966-3929

Provide the name of the new employer and a forwarding address.

Provide information on materials that will be transferred to the new location (cell lines, clinical samples, etc.)

Note: Contact the Office of Sponsored Research (OSR) to transfer research equipment.

Confirm material received from external parties has been returned/destroyed **OR** permission has been obtained to transfer the material to the new Institution.

Provide a final update on previously disclosed inventions.