



# CLASP Module

## Administrative Considerations for PI Movements to or from Peer Institutions





# Objectives

- Enhance awareness of various aspects involved with a PI moves to or from a peer institution, and the potential scope of managing a PI movement successfully





# General Principles

- Awards are made to an institution, not to an individual investigator.
- When a PI moves between institutions, sponsored projects may or may not transfer with them.



# Background - PI Movement to a Peer Institution



- The investigator discusses the requested project transfer with the Department Chair and the Dean's Office.
- If the project transfer is approved, the department administrator obtains a copy of the resignation letter and notifies ORPA and ORACS.
- PI must provide the following information:
  - Firm departure date
  - Contact information at the new institution
  - Plan for current projects





# PI Movement to a Peer Institution

## Possible Offices to Contact

- ORPA/ORACS
- Property Office
- Personnel/Human Resources
- Environmental Health and Safety Office
- University Committee on Animal Resources
- Office for Human Subject Protection
- ORPA/MTA
- UR Ventures



# ORPA/ORACS



- Transfer procedures for projects vary by sponsor.
- Date of relinquishment needs to be determined.
- If a project is a NIH Multiple PI project, all PIs must agree to the relinquishment.





# ORPA/ORACS

When a project transfers to new institution;

- PI notifies Program Officer/sponsor of intent to transfer the project.
- Department and ORACS work on relinquishment statement.
- Determine if a portion will be subcontracted back to UR
- If there are subawards, work with ORPA to notify those third parties
  - Amendment with new end date
  - Need for final invoice and final invention report



# ORPA/ORACS



- Ensure account is reconciled, encumbrances are identified and final invoices are obtained for any subagreements.
- Prior to termination, ensure all closeout costs have been processed, all cost sharing commitments have been completed and documented, and all program income has been deposited and recorded.
- Terminate on-line purchasing privileges, blanket orders and PCard access.
- PI must be current on all required reports (e.g., progress reports, final reports).
- If the PI has pending proposals within a fundable score, notify the potential sponsors and their seek guidance.







# ORPA/ORACS

When a project remains at UR:

- Determine if PI will maintain an appointment at UR
  - If so, will it be a paid or unpaid appointment
  - If not, a new PI must be identified and a justification statement will need to be signed by PI and ORPA and sent to sponsor for approval. The new PI's Biosketch will also be sent.



# Property Office



- Create a list of each item's cost, acquisition date and tag number.
- The original source of support for each piece of equipment to be transferred needs to be determined.
- Share the list with Chair to ensure the transfer of the equipment has been approved.
- If UR does not have title, sponsor approval will be needed.



# Property Office



- NIH reserves the right to transfer title of equipment to the new institution.
- Update equipment inventory
- Transferred equipment purchased with sponsored funds must be listed on the relinquishment form for any sponsor.
- Corporate Purchasing will need to be consulted if the receiving institution must purchase the equipment.





# Personnel/Human Resources

- If no portion of project will remain at UR, identify future work assignments for project team members.
- A list of personnel supported by the PI should be developed, including timelines, and (as appropriate) plans for any layoffs, termination letters and payouts.
- Certain staff might leave with the PI.
- Any persons leaving UR must certify their final effort/payroll allocation on the respective termination PAF.
- Immigration issues (e.g. visas) need to be addressed, as applicable.



# Environmental Health and Safety (EH&S)



- Contact EH&S if a laboratory needs to be closed or lab material is to be transferred.
- Prepare for decommission of laboratory, which can be expensive (e.g., disposal of chemicals, radioactive material, gas cylinders, select agents).
- If bio-hazardous materials are involved, contact Institutional Biosafety Committee to ensure proper disposal of materials.
- Ensure costs are paid by PI's sources prior to departure.



# University Committee on Animal Resources (UCAR)



- If animals are involved, contact UCAR to close out the protocol.
- Develop a termination plan (e.g., colonies, animal models, on-going care), which could involve substantial expense.



# Office of Human Subject Protection (OHSP)



- If PI is planning to transfer research data involving human subjects, PI needs to contact the OHSP and check the Guideline for Investigators Leaving the Institution.



# Office for Human Subject Protection (OHSP)



Depending upon HIPAA Authorization, data can be shared with the new institution under either:

1. New authorization (subject acknowledges new institution)
2. Limited Data Set with Data Use Agreement for sharing data with new institution
3. De-identification (data stripped of all HIPAA identifiers)





# ORPA/



## Material Transfer Agreement (MTA) Office

- If any research materials (e.g., tissue samples, animal models, datasets, stored data, files, etc.) will be transferred to the new institution, contact the ORPA/MTA Office.
- Need a MTA to move the materials to the new institution.
- If a researcher was working with material received under a MTA, the new institution will need to negotiate a new MTA for the material.



# UR Ventures Considerations

- If any inventions have resulted from PI's projects, contact UR Ventures.
- The University owns Intellectual Property.
- If an inventor leaves, they need to request the right to use the patent. The PI's new institution will need to obtain a license prior to use.
- For patents in process, the inventor needs to be available to cooperate in continued prosecution.



# Other Considerations



- Research data must be retained or easily available at the UR, regardless of whether the project will continue at the UR. This includes source documents, Excel spreadsheets, lab notebooks, etc.
- PI should be familiar with the *UR's Access to and Retention of Research Data policy*, which includes a section for PIs leaving the UR.
- If PI is moving out of the country, export rules and regulations will need to be considered for transfer of data and projects.



# Other Considerations



- The Embryonic Stem Cell Research Oversight Committee must be notified of the departure of a PI with an approved protocol.
- If the PI is the sponsor of an IND or IDE application, the application should be withdrawn if the clinical studies under the IND or IDE have been completed, or are to be transferred to another institution if the studies are to continue at the other institution.
- Research drug supplies should be disposed of as indicated by the study sponsor.



# Other Considerations



- Update eRA Commons registration
- ID Card Access to secured space must be disabled for all departing personnel.
- University ID cards for all departing personnel need to be collected and destroyed.
- Notify other PIs who collaborate with the departing PI of the PI's departure.
- Ensure PCs and portable electronics to be taken from UR are wiped clean prior to departure.





# PI Movement to the UR

## Possible Offices to be Contact

- ORPA /ORACS
- Property Office
- Personnel/Human Resources
- Environmental Health and Safety Office
- University Committee on Animal Resources
- Office for Human Subject Protection
- ORPA/MTA
- UR Ventures





# ORPA/ORACS

- Obtain a copy of the notification the other institution provided to sponsors regarding the project transfer.
- Obtain a copy of the final relinquishing statements from the other institution.
- When award notice is received, account set up in COEUS and URFinancials will be identical to the process for any new award.





# ORPA/ORACS

- Provide documents that will be needed by the sponsors for the transfers of the projects:
  - Scope of Work
  - Budget
  - Biographical sketches
  - “Other Support”
  - Resources
- Create subaward documents, if applicable







# ORPA/ORACS

- If F&A rate of previous institution is higher than UR's rate, use the UR's rate and re-budget the residual budget to be utilized for expenses to fulfill the project's aims (with scientific justification from the PI).
- If F&A rate of prior institution is lower than UR's rate, use the lower rate for the remainder of the budget period, but request sponsor to provide UR's negotiated F&A rate for the next budget period.





# Property Office

- Obtain list of equipment being transferred to UR.
- Compare the list to the physical assets that are received.
- Inform Property Office, obtain property tags, tag the equipment.
- Update equipment inventory.





# Personnel/Human Resources

- Obtain expected salary, start date and sources of funding.
- If other individuals are coming with the PI, request same information as for the PI.
- Request space, IT equipment, email accounts, telecommunications equipment.
- Immigration issues (e.g. visas) need to be addressed, as applicable.



# Environmental Health and Safety (EH&S)



- If any chemicals are being brought to the UR, determine if any of the chemicals are select agents and, if so, notify EH&S.
- If bio-hazardous materials are to be used, contact Institutional Biosafety Committee.
- PI must complete required training modules.



# University Committee on Animal Resources (UCAR)



- If animals are to be used in the PI's research, obtain the protocols for the respective studies.
- PI must complete required training modules.





# Office for Human Subject Protection (OHSP)

- If the PI is to engage in human subject research, the PI must successfully complete basic human subjects training through CITI, as needed.
- All incoming personnel associated with the PI must complete the training, as needed, if they will participate in the human subject research.
- Protocols and consents for human subject research studies transferring to the UR must be submitted for IRB review and approval.



# ORPA/



## Material Transfer Agreement (MTA) Office

- If any research materials (e.g., tissue samples, animal models, datasets, stored data, files, etc.) will be transferred to the UR, contact the ORPA/MTA Office.
- A Material Transfer Agreement (MTA) will be needed between UR and the prior institution.
- If a researcher was working with material received under a MTA, UR will need to negotiate a new MTA for the material.





# UR Ventures

- Intellectual Property Agreement (IPA) must be completed, as is UR policy for anyone who participates in sponsored research at the UR.
- The completed form is to be submitted to ORPA prior the PI's start date.







# Other Considerations

- PI must complete a conflict of interest disclosure.
- If PI has PHS/NIH funding, PI must complete the UR 60-minute on-line Conflict of Interest training.
- Verify that the PI (and any other staff coming with the PI) are not currently debarred or suspended.
- Determine if any work could potentially involve foreign entities and/or be deemed an export.





# Other Considerations

- Update eRA Commons registration.
- The Embryonic Stem Cell Research Oversight Committee must be notified if the a study involves stem cells.
- If the PI is the sponsor of an IND or IDE application, the application needs to be transferred to UR if the studies are to continue at UR.





# Useful Resources

- ORPA Website
  - “UR Access to and Retention of Research Data”
  - “IP Issues When a PI Leaves” PowerPoint presentation
  - MTA checklists
  - Export Control Policies and Guidelines
- OHSP Website
  - Guideline for Investigators Leaving the Institution
- EH&S and UCAR websites

