Are you "Bidding Adieu to SLU"?

At any moment in the academic year, we may have an opportunity to offer a fond farewell to friends and colleagues who are following their own career paths into retirement, private practice, or new academic or corporate endeavors. For the convenience of members of the SLU research community heading into their next chapter, we have compiled a list of items to consider for a compliant transition forward.

This list benefited from collaborative efforts from the Office of General Counsel, Research Integrity and Safety Group, Research Innovation and Commercialization, Grant Operations (GO) Center, the Clinical Trials Office, and the Compliance Office, and is intended for SLU professionals engaged in the design, conduct or reporting of research. This list should not be considered an all-inclusive checklist but may be used to accompany other off-boarding guidance provided elsewhere.

It is essential to provide advanced notice to each of the research oversight offices listed on the attached table. For example, one must notify <u>ehs@slu.edu</u> of any planned departures and the need to allow *several weeks* for decommissioning of the departing faculty member's laboratory; to be scheduled *and* completed prior to the faculty member's departure.

The Principal Investigator (PI) has four options available to them when leaving the University:

- 1. Close their human study at SLU and submit a Final Report Form in eIRB (if human subjects were involved); and/or submit an amendment in eIBC to close their biosafety protocol (if applicable); or
- 2. Transfer the IRB (and/or IBC) protocol to another SLU Investigator via a formal Protocol Amendment; or
- 3. Retain the research at SLU by receiving an Adjunct Faculty appointment from the department; or
- Request a transfer of research outside of SLU in accordance with the <u>Policy on Research Records</u> and <u>Biological Specimens: Ownership, Retention, Transfer, and Destruction</u>. Industry-sponsored clinical trials typically will not be allowed to transfer outside of SLU unless it is proven to be in the patients' best interests.

While the PI is responsible for making the notifications, the Department Chair, Business Manager, and Dean's office are also responsible for verifying that the appropriate notifications have been made well in advance of the faculty member's departure.

<u>No Research Records or Materials are to be removed from Saint Louis University</u> premises or shared with other investigators without appropriate approval and compliance with federal and University regulations. "Research Records" are defined in the policy link above and include both original and copied content.

Step 1: Approval for the transfer has been granted by the funding agency or sponsor. Recommend notifying the sponsor at least 30 days prior to the departure or in accordance with contract terms.	Contact: Funding agency/ sponsor's representative
Step 2: An Amendment &/or Final Report Form to the <i>human subjects research protocol</i> detailing the change (e.g., transfer of research records, change in PI, etc.) and justification has been submitted and approved by the SLU IRB.	Contact: SLU IRB 314-977-7744 irb@slu.edu
 Step 3: If the PI is requesting the transfer of research records to his/her new institution, a human subjects research protocol must be approved by the IRB of the receiving institution to guarantee appropriate use and storage of the records and/or data. If the PI is requesting to remain on the SLU human subjects research protocol, an IRB Authorization Agreement between SLU and the new institution is required. The IRB Office can help facilitate this agreement. 	Contact: SLU IRB 314-977-7744 irb@slu.edu
 Step 4: If the PI is involved in <i>clinical trials</i>, notify the CTO to revise the study's fund, modify the Clinical Trials Management System (CTMS) and adjust the billing system. ClinicalTrials.gov postings may be subject to transfer or require posting information to be updated. Contact the CTO if you are involved in a Ct.gov posting to discuss the requirements. 	Contact: Clinical Trials Office 314-977-6335 <u>Clinical-Trials-Office@health.slu.edu</u>
 Step 5: SLU IRB must be consulted for transfer of human subject Research Records and will determine whether a transfer of these materials or copies thereof is appropriate and allowable. For human subjects Research Records, the IRB will determine whether Research Participants must be notified of the transfer, and whether they must give additional consent and/or HIPAA authorization for the transfer of their Research Records. In the case of anonymous data or specimens, the IRB will determine if the transfer is consistent with the consent provided by the subjects and the sponsor protocol/grant, if applicable. In addition, the PI must ensure that there is no conceivable way to identify the source of the data or specimens. In the case of clinical trials, the PI must ensure continuation of patient care. 	Contact: SLU IRB 314-977-7744 irb@slu.edu
Step 6: If the PI has an <i>IBC Protocol,</i> whether to close the protocol or transfer the protocol to another SLU PI, submit a protocol amendment in eIBC.	Contact: Environmental Health & Safety IBC Manager 314-977-6797 patricia.osmack@slu.edu
Step 7: <i>If you have developed intellectual property,</i> steps must be taken to ensure that intellectual property rights of the University and research team are protected.	Contact: Research Innovation & Commercialization 314-977-1672 <u>Anne.Miller@slu.edu</u> OTM@slu.edu

Step 8: Any <i>use or disclosure of Protected Health Information</i> must be in accordance with HIPAA and the authorization provided by the subjects.	Contact: SSM Health-SLU <i>Care</i> Physician Group Privacy Program Manager 314- 989-3158 Ron.Rawson@ssmhealth.com
Step 9: Any PI with <i>hazardous materials</i> (e.g., chemicals, radioactive materials, biohazards, or select agents) must contact Environmental Health & Safety (EHS) for guidance and assistance with disposal and laboratory decommissioning.	Contact: EHS 314-977-6884 <u>Renee.Knoll@slu.edu</u> <u>EHS@slu.edu</u>
Step 10: <i>If you use live vertebrate animals,</i> Notify the Institutional Animal Care and Use Committee (IACUC) of your intentions to close out the animal use protocol (AUP) or export the animals to the new institution. Laboratory Animal Exports must be approved and coordinated by Comparative Medicine. In addition, all outstanding business accounts must be settled.	Contacts: IACUC 314-977-2569 <u>Steve.Tinge@slu.edu</u> Comparative Medicine 314-977-8345
Step 11: <i>If you are transferring any data or tangible materials</i> from SLU, a Materials Transfer Agreement (MTA), Data Transfer Agreement (DTA), Memorandum of Agreement (MOA), or Memorandum of Understanding (MOU), or other documentation as appropriate, must be signed and approved by the VP for Research or his/her designee. Email contracts@slu.edu for assistance in getting these agreements generated and signed.	Contact: OVPR Contracts <u>contracts@slu.edu</u>
Step 12: <i>If you are taking lab equipment,</i> Notify the controller's office of changes to the information previously provided on the Equipment Information Form. Also, review the original source of the equipment's funding as federally purchased items may require notification to the original sponsor.	Contact: Business & Finance 314-977-3727 <u>Karen.Wamhoff@slu.edu</u>
Step 13: <i>If you are the named PI of an externally funded research project</i> that you are either (I) transferring to another SLU investigator or to another institution; or (II) terminating early prior to completing the full scope of work/protocol, notify the Research Contracts Office of your intended plans and reference the name of the research project or other internal identifier (such as an eRS #, Workday #, IRB #, or Agiloft #).	Contact: OVPR Contracts <u>contracts@slu.edu</u>