GA-109 – Departing Investigators

1. **PURPOSE:**
   To integrate research responsibilities into the regular departmental off-boarding process by ensuring the proper transfer or closure of all active research studies conducted by a Principal Investigator employed by UTRGV, including any affiliate, or otherwise approved by the UTRGV Institutional Review Board (IRB).

2. **SCOPE:**
   All research protocols either conducted at UTRGV or any facility affiliated with UTRGV (Research Site) or approved by the UTRGV IRB

3. **RESPONSIBLE INDIVIDUALS:**
   This SOP applies to all Principal Investigators (PI) and Department Administrators.

4. **RELATED TERMS AND DEFINITIONS:**
   Please reference the Standard Operating Procedure Glossary of Terms for complete definitions of terms in this SOP.

5. **POLICY STATEMENT:**
   The PI is responsible for the proper transfer or closure of the research study prior to departure from UTRGV.

6. **PROCEDURES:**
   - 6.1 Notify the Office of Clinical Research (OCR) that the PI is leaving.
   - 6.2 The IRB will provide the point person with a list of studies that require action.
   - 6.3 The PI will communicate departure and collaborate with the OCR to define an acceptable action plan for each open study:
     - 6.3.1 close study completely;
     - 6.3.2 transfer study to a new PI at UTRGV and do not open at new institution;
     - 6.3.3 close study at UTRGV and open at another institution;
     - 6.3.4 transfer study to new PI at UTRGV and open at new institution.
   - 6.4 The point person will notify all parties.
   - 6.5 The PI is ultimately responsible for completing all of the items applicable to each study.

6.6 Data & Materials

All study data or study materials (including all samples), in any format are the property of UTRGV. No study data, materials, or samples may be transferred outside of UTRGV without the following:

- Permission from the department chair
- Completion of study closure or transfer responsibilities as listed in this SOP
- Outstanding account balances have been reconciled
- A contract, approved by UTRGV, is in place for the transfer that has been approved by appropriate leadership.

6.7 Equipment & Funds

If any equipment has been purchased with grant funds and is required to be transferred for the sole purpose of completing the study, approval is required from Institutional research leadership and the director of grants management. If any funds remain in the account and are required to be transferred for the sole purpose of completing the study, approval is required from the department chair and the director of grants management. No funds will be transferred until all outstanding payments have been made. If a study has already been completed, no funds or equipment should be transferred.

6.8 Subject Notification

In order to determine if subject notification is required, the PI must contact the IRB of record for a determination of appropriate timelines for subject notification and requirements for obtaining (re)consent from study subjects, if applicable. IRB approval will be needed of any new or revised forms, documents, or communication tools prior to their use.

7. REFERENCES

- ICH-GCP E6(R2)
- UTRGV GA-106
- UTRGV RA-201

8. FORMS OR ATTACHMENTS

None