GA-106 – Transfer of Sponsor-Investigator Initiated FDA Regulated Studies

1. **PURPOSE:**
   To outline the process for when a Sponsor-Investigator leaves UTRGV and how to properly close or transfer the sponsorship of investigator-initiated research and related applications (IRAs) regulated by U.S. Food and Drug Administration (FDA): Investigational New Drug Applications (INDs), Investigational Device Exemptions (IDEs), Master Files (MFs), Emergency Use Authorizations (EUAs) and corresponding clinical investigations.

2. **SCOPE:**
   This policy applies to Sponsors who are:
   2.1 transferring institutions and maintaining their sponsorship of the IRAs
   2.2 transferring the sponsorship to another individual within their institution
   2.3 transferring the sponsorship to another individual outside of the originally approved research site
   2.4 discontinuing or closing the IRAs

3. **RESPONSIBLE INDIVIDUALS:**
   The Sponsor-Investigator is responsible for ensuring that this SOP is followed.

4. **RELATED TERMS AND DEFINITIONS:**

   Emergency Use Authorization (EAU)
   Discontinue - for the purposes of this document means that the IND, IDE, MF, or EUA has a "final" action, i.e., cancelled, closed, exempted, terminated, voided, or withdrawn with the FDA and closed with the IRB
   Florence eBinders™
   Investigational Device Exemption (IDE)
   Investigational New Drug (IND)
   Institutional Review Board (IRB)
   Master File (MF)
   Sponsor – For purposes of this document includes IND or IDE Sponsor-Investigator

   Please reference the Standard Operating Procedure Glossary of Terms for complete definitions of terms in this SOP.

5. POLICY STATEMENT

A Sponsor-Investigator who leaves UTRGV must properly discontinue or transfer the sponsorship of the investigator-initiated research regulated by the FDA.

6. PROCEDURES

6.1 Notification of IRA Transfer

The Sponsor-Investigator should first confirm the details of their departure and then immediately notify the Department Chair and Administrator of their pending employment transfer. The Sponsor-Investigator should also initiate the FDA Administrative Action Checklist and submit to the Office of Clinical Research (OCR). The OCR will schedule a meeting with the Sponsor-Investigator, the newly intended Sponsor-Investigator (if it will remain open at UTRGV), their research team, and any applicable department or research personnel to discuss any pertinent information pertaining to the study.

6.2 FDA Protocol Status Review

OCR will conduct a review of the FDA regulated protocol to ensure all regulatory, compliance, and financial matters with the FDA and local institution are up to date prior to making changes. The attendees of the review meeting will vary based on the findings of the review, which will include:

6.2.1 Regulatory Review

- Original approval letter
- Most recent annual report and approval letter
- Upcoming tasks that would need to take place prior to the study transfer

6.2.2 Monitoring Status Review

- Monitoring findings
- Complete resolution of monitoring findings

6.2.3 Data Analysis/Database Review

- Data collection
- How the data is being collected
- Where the data is being stored
- Has the data been queried during the study life cycle. If so, are all queries resolved

6.2.4 Data Safety Monitoring Board or Independent Safety Monitor

- DSMB Charter and DSMB meeting schedule
- DSMB meeting minutes
- DSMB members and affiliated institutions
- DSMB compensation for membership
- Programs, reports, etc.

6.2.5 Grants Accounting Review

- Confirmation of all paid invoices

6.2.6 Stock/Supply review and reconciliation

6.2.7 Drug/Device stock reconciliation

6.3 Notification of pending transfer to all appropriate parties

6.3.1 The Sponsor-Investigator will ensure that all appropriate parties, including OCR, are notified of the pending study transfer within ten (10) business days of the transfer

- FDA (formal written letter)
- Existing IRB and transfer IRB (formal amendment)
- Appropriate department personnel at both current and transfer site (email)
- PI (if not the Sponsor), Co-Investigators listed on the FDA/IRB approved protocol at current site and PI (if not the Sponsor) at transfer site (formal written letter/email)
- Device Sponsor (if applicable – formal written letter/email)
- Drug Sponsor, meaning manufacturer or funding agency (if applicable - formal written letter/email)
- Data Safety Monitoring Board or Independent Safety Monitor (formal written letter/email)

6.3.2 The above referenced notification to all the applicable parties, should include all of the following that applies:

- Notice of transfer
- Reason for transfer
- Exact date of transfer
- New transfer location for IRA
- Sponsor-Investigator's new contact information
- Notify subjects by certified mail that the study will be ending at the current site. Include a plan for their research going forward and

contact information for the new PI. This should include a time frame where subject can expect to hear from the new PI for next steps.

6.3.3 This section applies to Sponsor-Investigators who are transferring institutions and maintaining sponsorship of the IRA and Sponsor-Investigators who are transferring the sponsorship to another individual outside of the originally approved research site.

6.4 Document/Data Transfer

6.4.1 Regulatory documentation required for compliance with applicable law at the new institution and associated with FDA trial(s) is subject to be copied and taken to the new institution by the Sponsor. The documentation should not include any Protected Health Information (PHI), work conducted preparatory to research or any confidential information of UTRGV. A data use agreement or other form of contract must also be executed and documented prior to the transfer of study materials. The contract should include a list of documents sent.

6.4.2 The document copying and packing process must be overseen and approved by a current UTRGV employee within the department. Shipment of all materials must be completed by a third party, independent, professional shipment company (i.e., cannot be transported by the Sponsor-Investigator or a member of the current/new research team) to the new site of the Sponsor-Investigator at the new site's expense. Documents should be shipped in a way that allows for verification of receipt (e.g., certified mail, return receipt requested).

6.4.3 All paper/physical copies of regulatory documentation must be stored in a secure, double locked location (i.e., locked cabinet, locked office) within the department prior to the transfer of the study.

6.4.4 Regulatory documentation stored in Florence eBinders™ must be downloaded from the system by authorized personnel. After the successful download and transfer, the study will be archived in Florence. The downloaded material can be transferred by:

- Being password protected in an electronic file and sent securely via email to an authorized person at the new institution, copying the Office of Clinical Research.
- Transferred to a disc or other device, password protected and then overseen and shipped in accordance with 6.4.2.
- Printed onto paper, stored in accordance with 6.4.3 and overseen and shipped in accordance with 6.4.2.

6.5 IRB Notification of Closure and/or Amendment Submission

6.5.1 If the IRA is being transferred to another institution, and will not continue at UTRGV, the IRB of record must be updated.

6.5.2 If the IRA is being transferred to another investigator at a different institution, but the conduct of research procedures will still take place at UTRGV under the direction of a different PI, the IRB application will need to be amended appropriately to reflect institutional and personnel changes. All submissions to the IRB are to be completed prior to the departure of the investigator in order to ensure proper sign-off of the changes.

6.5.3 If the IRA is to remain open at UTRGV, but transferring to a new PI, the IRB application will need to be amended appropriately to reflect personnel changes.

6.5.4 If the IRA is being closed completely, a closure will need to be submitted to the IRB of record.

6.6 Final FDA Administrative Action Checklist

6.6.1 The final FDA Administrative Action Checklist should be completed by the Sponsor within 30 days of the final transfer or closure. The OCR should be notified of any existing contracts to conduct services, otherwise the PI and regulatory coordinator are responsible for completing the checklist.

7. REFERENCES

8. FORMS OR ATTACHMENTS

FDA Administrative Action Checklist