GA-101 – Development and Maintenance of Standard Operating Procedures

1. **PURPOSE:**
   This Standard Operating Procedure (SOP) describes the standard format and method the UTRGV Clinical Research Standard Operating Procedure Oversight Committee will use in writing and maintaining the Clinical Research SOPs, policies, and Investigator Manual for IRB submissions for UTRGV research. This SOP describes how the research community may use these SOPs as guidelines and examples in developing their own SOPs.

2. **SCOPE:**
   This SOP will provide instruction and promote consistency across UTRGV and UT Health RGV for those involved in the conduct of research and the development of clinical research SOPs.

3. **RESPONSIBLE INDIVIDUALS:**
   3.1 The UTRGV Clinical Research SOP Oversight Committee is responsible for:
   - 3.1.1 Preparing, revising, and implementing the SOPs to serve as a reference or guide for the research community on appropriate research practices,
   - 3.1.2 Obtaining input and feedback from investigators.

   3.2 The UTRGV Office of Clinical Research is responsible for:
   - 3.2.1 Monitoring compliance with research SOPs
   - 3.2.2 Maintaining current SOPs on the UTRGV website
   - 3.2.3 Ensuring timely review of SOPs,
   - 3.2.4 Providing training to research team members on implementing research SOPs in their area.

   3.3 The Investigator is responsible for:
   - 3.3.1 Developing specific SOPs, as necessary but not conflicting with institutional policies, local, state, and federal laws and regulations,
   - 3.3.2 Ensuring compliance with site specific SOPs
   - 3.3.3 Training research team members on implementing site-specific SOPs in their particular research area.

4. **RELATED TERMS AND DEFINITIONS:**
   Standard Operating Procedure (SOP)

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

POLICY STATEMENT:

This SOP must be used as a guide to write, format, implement, and maintain research SOPs for UTRGV. SOPs are not intended to supersede existing institutional policies, or local, state, and federal laws and regulations.

5. PROCEDURES:

5.1 Identifying the Need for SOPs

5.1.1 Institutional Level

The UTRGV Research SOP Committee will determine the priority of the SOPs to be completed, revised, and formally implemented at UTRGV. The priorities will be based on input from each Committee member representing their department or investigators.

5.1.2 Department/Investigator Level

Priorities should be based on the needs of the department or investigator.

5.2 Writing the SOP

5.2.1 Institutional Level

The UTRGV Clinical Research SOP Oversight Committee determines the level of detail for the SOP. After the first draft of the SOP is complete, each SOP is reviewed by the members of the Committee for accuracy and clarity. This should include tools designed to be used with the SOP such as forms, templates, checklists, etc., if applicable.

5.2.2 Department/Investigator Level

5.2.2.1 Depending on the nature of the SOP, the appropriate individuals should determine the level of detail for the SOP. After the first draft of the SOP is completed, each SOP must be reviewed for accuracy and clarity. Include tools designed to be used with the SOP such as forms, templates, checklists, if applicable.

5.2.2.2 Each research area ensures that site procedures and activities detailed in the SOP accurately reflect how the tasks are performed within each research area. The Department Chair, Principal Investigator, or other designee must ensure that any revisions are made to the SOP and implemented within the research area. These changes should be documented in a site specific or protocol specific SOP, as needed.

5.3 Format

SOP GA-101 may be used as a template in formatting new and revised SOPs with regards to spacing, margins, indentation, numbering structure, etc., and include the following items and sections:

TITLE of SOP: Descriptive statement that represents the document's purpose. The wording should be descriptive, but concise.

1. **PURPOSE**: Qualifies and describes the intent of the SOP.

2. **SCOPE**: Statement that describes the personnel and situations to which the SOP applies.

3. **RESPONSIBLE INDIVIDUALS**: Documents the parties involved and specific performance standards or requirements for the procedure.

4. **RELATED TERMS AND DEFINITIONS**: A brief listing of key words, acronyms, or phrases within the SOP. A hyperlink to the full glossary in this area is recommended.

5. **POLICY STATEMENT**: The governing statement of standards for a specific activity.

6. **PROCEDURES:** A description of the tasks or step-by-step procedures necessary for completion of the activity. Include definitions as necessary.

7. **REFERENCES**: A list of regulations, policies and guidelines applicable to or referenced in the SOP. The citation in the SOP will also identify documents to review for additional information regarding a specific activity.

8. **FORMS OR ATTACHMENTS:** A list of reference materials such as appendices, forms, checklists, or other additional information that may be utilized in the implementation of the SOP.

9. **REVISION HISTORY:** Use this table to document revisions throughout the life of the SOP. This section and table are not required to be included until an SOP has undergone a revision.

SOP Number	Date revised	Author	Summary of Revisions

5.4 Implementation

5.4.1 Signature

5.4.1.1 Institutional Level

The draft SOP will undergo formal review and approval by the Clinical Research SOP committee and sign off by the AVP, Clinical and Translational Research.

5.4.2 Formal Notice and Training

5.4.2.1 Institutional Level

After the SOP is finalized, the SOP will be posted on the UTGV Clinical Research website and notification will be distributed throughout the research community through the clinical research distribution list.

When a new SOP is approved or when there are significant revisions to an existing SOP, the Office of Clinical Research will organize education within a 60-day period for the research community. This will help ensure an understanding of the requirements and activities necessary for adherence to the SOPs. Appropriate individuals should participate in the training pertaining to the announced SOP. This includes investigators, research staff, and any individuals whose scope of practice or research assignment is related to the SOP. The training will be made available in person and virtually.

Documentation of this training will be maintained in Learning Management System or Florence eBinders™ if completed online, by the department if the education was provided at the department level, or by UTRGV Office of Clinical Research, if provided in a live session.

5.4.2.2 Department/Investigator Level

After the SOP is final, the Department Chair or other designee, as appropriate, should ensure that all appropriate individuals are trained. Documentation of this training should be maintained.

5.5 SOP Revisions and Retention

5.5.1 Institutional Level

SOPs are reviewed every three years for possible revisions needed due to updates or changes in regulations, local policies, or procedures, and to maintain compliance with applicable regulations, policies, or laws. The revised SOP will be included in the SOP Manual posted on the website. Research Education will maintain all versions of the institutional SOPs for monitoring or audit purposes.

5.5.1.1 Retraining will occur as described above in Formal Notice and Training.

5.5.2 Department/Investigator Level

5.5.2.1 Each research area ensures that the site procedures, and activities detailed in the SOP accurately reflect how the tasks are performed within their research area. If revisions are required, the Department Chair, Principal Investigator, or other designee must ensure these revisions are made to the SOP and implemented within the research area. Documentation of retraining must be maintained. For monitoring or audit purposes, all versions of the SOP must be maintained and are the responsibility of the Department Chair, Principal Investigator, or other designee.

5.5.3 In the event of a regulatory audit, the regulatory agency may audit a study against the SOP that was in effect at the time of study conduct, and thus, appropriate documentation must be maintained.

6. REFERENCES

- Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812, and 814)
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
- Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D)
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines https://www.fda.gov/media/93884/download
- UTRGV Clinical Research Policies and Procedures

7. FORMS OR ATTACHMENTS

SOP Template – Contact UTRGV Office of Clinical Research for a copy.