GA-105 – Investigator Responsibility for Study Team Training and Documentation

1. **PURPOSE:**
   To describe the Good Clinical Practice based guidelines for training and documenting training of study staff involved in the conduct of clinical research at UTRGV.

2. **SCOPE:**
   This SOP applies to all individuals participating in the conduct of clinical research at UTRGV. All individuals assigned one or more research tasks by an investigator, whether or not they are a UTRGV employee, are required to follow this SOP.

3. **RESPONSIBLE INDIVIDUALS:**
   The Principal Investigator (PI) is responsible for ensuring that all persons assisting with research are adequately trained and that the training is documented for each person. The training topics must include, but are not limited to, the following:

   3.1 the protocol
   3.2 the investigational product(s)
   3.3 research-related duties and functions for each role on the study
   3.4 UTRGV institutional requirements for conducting research

   The PI is also responsible for ensuring that study staff are only delegated tasks to which they are qualified by education, training, experience, or licensure.

   NOTE: It is necessary to complete a Delegation Log for each study to document the study staff to whom the PI has delegated protocol specific tasks.

   Study team personnel are responsible for following the procedure described in this policy.

4. **RELATED TERMS AND DEFINITIONS:**
   CITI – Collaborative Institutional Training Initiative
   Delegation Log
   Florence eBinders™
   GCP – Good Clinical Practice

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

5. **POLICY STATEMENT**

UTRGV requires documentation of completion of all applicable CITI modules for all individuals listed as study personnel on any research protocol regardless of funding.

6. **PROCEDURES**

6.1 Initial Training for non-UTRGV research staff

6.1.1.1 Complete UTRGV Research Credentialing

6.2 Initial Training for all (UTRGV research employees and non-UTRGV research staff)

6.2.1 UTRGV specific clinical research training is provided by the Office of Clinical Research. The required training will vary depending upon the role, department and staff responsibilities. For questions, please contact the Office of Clinical Research at clincalresearch@utrgv.edu.

6.2.2 Completion of required CITI training modules. The CITI completion report (not the certificate) is to be filed in the regulatory binder and a copy included with IRB submissions. Required modules are:

- Good Clinical Practice
- Basic Human Subjects
- Responsible Conduct of Research

6.2.3 Protocol-specific training and documentation for all studies to which the individual is assigned.

6.2.4 UTRGV clinical research education curriculum. This includes, but is not limited to:

- UTRGV Clinical Research SOPs
- UTRGV IRB Policies
- Study Coordinator training (if applicable)

6.2.5 Training on how to access and operate all clinical research software and applications. Including, but not limited to, Florence, Tick@Lab, and ARGO.

See section 6.5 of this SOP regarding procedures for study specific initial training.

6.3 Ongoing Training for all (UTRGV research employees and non-UTRGV research staff)

6.3.1 CITI Refresher courses

6.3.2 Training and documentation for all applicable study staff in the event of:

- IRB approved protocols are amended
- IRB approved consent form changes
- Protocol deviations occur and if applicable, corrective and preventive action plans (CAPA) are implemented
- New information about a study or study product becomes available (e.g., Investigator Brochure, action letter, etc.)

See section 6.6 of this SOP regarding procedures for study specific ongoing training.

6.3.3 UTRGV Clinical Research SOP Training

6.3.3.1 Retraining with significant changes to existing SOPs

6.3.3.2 When new SOPs are approved.

6.4 Documentation of training

6.4.1 Document training in a training log, or other format, and include (at minimum):

- Trainee name (clearly written)
- Date of training
- Title and brief description of training (if training syllabus is available, attach to training log)
- Trainer name
- Trainee(s) signature and date
- Trainer signature and date

6.4.2 Training records will be retained as per UTRGV, sponsor (if applicable), and study guidelines. They are subject to inspection by authorized regulatory agencies and internal review committee.

6.5 Initial Protocol Specific Training for Clinical Research within Florence eBinders™

6.5.1 Initial training should take place during the site initiation visit (SIV) for each study.

6.5.2 The regulatory coordinator or designated site staff will create a training log and delegation log within Florence eBinders™ (Florence).

6.5.3 The regulatory coordinator or designated site staff will create an announcement in Florence for those who were unable to attend the SIV. The announcement will contain a link to the training slides and/or pertinent protocol information.

6.5.4 The regulatory coordinator or designated site staff will create a task in Florence for all staff receiving the announcement to complete and sign the training and delegation logs. The task will have a due date of one week.

6.5.5 Task reminders will be sent each week until staff have completed training and sign the training and delegation logs. Any staff who have not completed training after four (4) weeks will be removed from the list of potential site staff for the study in question and the PI will be notified via email.

6.5.6 The PI will sign off on the training and delegation logs in Florence.

6.5.7 If the study is not using the Florence system, the communication will be done via email. The training documents will be attached within the email. The training and delegation logs will be paper, and the signatures will be wet ink.

6.6 Amendment Training for Clinical Research within Florence eBinders™

6.6.1 The regulatory coordinator or designated staff will create an announcement in Florence. The announcement will contain a link to the summary of changes and/or pertinent documents and information.

6.6.2 The regulatory coordinator or designated staff will create a task within Florence to for all staff receiving the announcement to complete training and sign the training log. The task will have a due date of one week.

6.6.3 Task reminders will be sent each week until staff have completed training and signed the training log. Any staff who have not completed training after four (4) weeks will be removed from the delegation log for the study in question and the PI will be notified via email.

6.6.4 The PI will sign off on the training and delegation logs in Florence.

6.6.5 If for any reason the study is not using the Florence system, the communication will be done via email. The training documents will be attached within the email. The training logs will be paper, and the signatures will be wet ink.

7. REFERENCES

- Guidance for Industry, E6(R2) Good Clinical Practice: Consolidated Guidance

- Guidance for Industry – Investigator Responsibilities – Protecting Rights, Safety, and Welfare of Study Subjects
- UTRGV Clinical Research SOPs
    - GA-101 Development and Maintenance of Standard Operating Procedures
    - GA-104 Scope of Practice
    - RA-201 Regulatory Documentation
- Investigator Manual for IRB Submissions

8. **ATTACHMENTS (studies using Florence must use the logs available within Florence)**
    - Drug Study Delegation Log
    - Non-Drug Delegation Log
    - UTRGV Research Training Log