RA-206 – Florence End User Training

1. **PURPOSE:**
   The purpose of this SOP is to outline the procedures to train research employees at UTRGV on Florence eBinders™/eISF. Florence eBinders™ is the software used by clinical research for electronic regulatory and storage of study records and will be referred to throughout the rest of the document as "Florence".

2. **SCOPE:**
   This SOP applies to all research personnel using Florence for electronic regulatory and/or study records. It also applies to the Office of Clinical Research, which is responsible for granting user access to the system.

3. **RESPONSIBLE INDIVIDUALS:**
   UTRGV Office of Clinical Research is responsible for designating System Administrators.
   System Administrators are responsible for ensuring this SOP is followed before allowing users access to Florence.
   All members of a study team, including the Principal Investigator (PI), are responsible for following the training steps in order to gain access to Florence.
   Monitors, Auditors, Internal Quality Assurance, Post Approval Monitoring, Information Technology personnel, or any other person needing access to Florence is responsible for following this SOP.

4. **RELATED TERMS AND DEFINITIONS:**

   Florence
   Electronic Investigator Site File (eISF)
   System Administrator

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

5. **POLICY STATEMENT:**
   UTRGV requires all persons who require access to Florence to follow the training procedures outlined in this SOP.

6. PROCEDURES:

6.1 The research staff member requesting access or designee will contact the Office of Clinical Research (OCR) at clinicalresearch@utrgv.edu. The following information must be provided in the communication with OCR:

- Full name of staff member needing access
- Email address of staff member needing access
- Department of staff member needing access
- Role within the department
- How many studies does the staff member need to access? List the following for EACH study:
    - Study PI
    - Full Study Title
    - Short Study Title/Study Number (if applicable)
    - Role on Study

6.2 A representative from OCR will respond within seven (7) business days of receipt of the email request.

6.3 Once OCR has all the information needed, an OCR representative will send training links to the research staff member needing access. The links will be appropriate to the role of the staff member. Any of the following may be sent:

- Link to Florence Academy with an explanation on which modules to complete.
- A Link to the Florence Course Catalog with an explanation on which modules to complete.
- The Production Team Training Document with an explanation on which link applies to the staff member requesting access.

6.4 OCR will send an invitation for the research staff member to join the Florence training environment. The invitation will come via email. The research staff member requesting access will follow the instructions in the email to create their account for the training environment.

6.5 OCR will create a signature request on an Attestation Form within the Florence training environment.

6.6 After completing the appropriate training, the research staff member requesting access must send their training certificate to clinicalresearch@utrgv.edu **and** sign the attestation within Florence.

6.7 Once they've completed both steps in 6.6, the OCR will send them an invitation to join the production environment (real Florence). The invitation will come via email. The research staff member will follow the instructions in the email to create their account for the production

environment.

6.8 OCR will create a folder within the appropriate departmental credentialing binder that contains the training certificate(s) and signed attestation. The folder will be labeled with the research staff member's name. The folder will be used from that point forward to file any credentialing documents pertaining to that staff member.

6.9 It is important to note that while the training environment and production environment look similar, they are a different URL. Therefore, it is important to encourage all research staff to save and label the production environment URL after they've gained access to it.

6.10 Study staff may contact clinicalresearch@utrgv.edu at any point for questions regarding the use of, and access to, Florence.

6.11 Study staff may also contact the Florence helpdesk for technical assistance at 1-888-829-0896 or support@florencehc.com.

7. REFERENCES:

- UTRGV PM-304
- UTRGV RA-205

8. FORMS OR ATTACHMENTS:

Production Team Training Links
Florence Training Attestation Form