Clinical Research
STANDARD OPERATING PROCEDURE

DM-505–Certified Copies of Research Regulatory Documents

1. **PURPOSE:**
   This standard operating procedure (SOP) outlines the process for the creation of certified copies of research documents at UTRGV.

2. **SCOPE:**
   This SOP is applicable to all research regulatory documents within each clinical study or trial at UTRGV. This applies to both paper/physical regulatory documents and regulatory documents stored and created within Florence. This SOP does not apply to patient charts or health records.

3. **RESPONSIBLE INDIVIDUALS:**
   Principal Investigators (PI) and all members of any research team involved in conducting and regulating research at UTRGV.

4. **RELATED TERMS AND DEFINITIONS:**

   Certified Copy
   Florence
   Regulatory/Essential Documents

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

5. **POLICY STATEMENT**
   For a certified copy of research regulatory documents from a study at UTRGV or its affiliates to be considered verified it must have the appropriate attestation (including the signature and date of both the responsible party and witness) attached to document the process. Certified copies include CDs, DVDs, and zip drives with study information transferred to them, as well as paper/physical copies of original documents or previously certified documents.

6. **PROCEDURES:**
   6.1 When creating a certified copy of documents, the PI or designee should have the procedure observed by an impartial witness.

6.2 PI or designee must verify that any copy (electronic or physical) created from an original document includes the same context, content, attributes, information and structure as the original.

6.3 After the copies have been made, both the witness and the responsible party should complete the certified copy attestation or electronic certified copy attestation.

6.4 The documents copied should be listed on the attestation. If the full study record was copied, “Full Study Record” should be written.

6.5 For physical copies, the attestation should be attached to the end of any copied documents.

6.6 For electronic documents, the signed document should be inserted as the last page of the PDF. For copies that involve multiple electronic files, the signed attestation should be its own, clearly labeled, pdf file.

REFERENCES:

- FDA Guidance for Industry Computerized Systems Used in Clinical Investigations
- ICH GCP E6(R2) 1.63, 8.1
- UTRGV DM-502
- UTRGV RA-205

7. FORMS OR ATTACHMENTS

Certified Copy Attestation

Electronic Certified Copy Attestation