1. PURPOSE

To ensure that all required study-related correspondence is securely maintained and available for long-term review.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is required to prepare and maintain adequate records of all general correspondence to and from the investigative site.

4. BACKGROUND

Correspondence pertinent to the conduct of the study, such as communication between the site, sponsor, and the Institutional Review Board (IRB), must be maintained on file at the clinical site. The purpose of the correspondence file is to document communications between the sponsor/contract research organization (CRO), PI, FDA, and Study Participants (SPs) concerning clinical research investigations.

All records should be maintained in an area accessible to the FDA if requested during an inspection [21 CFR 312.62, 812.140 (a)(3)].

5. PROCEDURE

5.1. The PI will be responsible for all communications concerning the investigation. He/she may delegate the duty of correspondence maintenance to appropriate clinical research site personnel as acceptable to the sponsor and/or IRB. Relevant communications/ correspondence include:

- 5.1.1. Notes of telephone calls pertinent to the conduct of the study:
  - 5.1.1.1. Telephone notes will be placed in the Investigator regulatory documents binder and/or the source document if referring to an SP.
- 5.1.2. Newsletters and fax communications
- 5.1.3. Letters and email to and from sponsor/CRO representatives
- 5.1.4. Letters and email to and from SPs
- 5.1.5. Letters and email to and from colleagues regarding the study
- 5.1.6. Other pertinent general communications and meeting notes

5.2. The Investigator or other designee will receive study-specific correspondence and forward such correspondence to the appropriate study personnel. Following dissemination and follow-up, the SC, Regulatory Document Specialist (RDS), or other designee will ensure the original is filed in the SP binder and/or Investigator regulatory documents binder. If the original correspondence is electronic mail, then a printout of the email should be filed and the electronic copy maintained through the data retention period specified on the clinical study agreement, if applicable.

5.3. The SC, RDS, or other designee will review the Investigator regulatory documents binder on a regular basis to ensure that all correspondence is filed in chronological order (most recent on top).

5.4. The SC, RDS, or other designee will review the Investigator regulatory documents binder on an ongoing basis to ensure that outstanding issues are addressed and all required documents are current.

5.5. The SC, RDS, or other designee will review the Investigator regulatory documents binder on a regular basis to ensure that financial correspondence is maintained separately. Financial records are not part of the auditable regulatory files.

6. TERMS & ABBREVIATIONS

CRF Case Report Form
CRO Contract Research Organization
FDA Food and Drug Administration
IRB Institutional Review Board
PI Principal Investigator
RDS Regulatory Document Specialist
SC Study Coordinator
SP Study Participant

7. REFERENCES

7.1. 21 CFR 312.64 - Investigator Reports
7.2. 21 CFR 812.140 - Records
7.3. 21 CFR 812.150 - Reports
7.4. ICH GCP Consolidated Guideline - Part 4. Investigator
7.5. ICH GCP Consolidated Guideline - Part 8. Essential Documents for the Conduct of a Clinical Trial

7.6. Clinical Research Site SOP 10.00 - Documenting Delegation of Authority

8. ATTACHMENTS

None