


<b>Standard Operating Procedures for Clinical Research at USF Health CRC</b>			
	<b>COMMUNICATION PRACTICES</b>		
<b>SOP#: 304</b>	<b>Effective Date:06/01/2016</b>	<b>Version: 1.0</b>	<b>Page 1 of 4</b>

**PURPOSE:** This SOP describes the communication documents at the CRC between key research personnel and sponsor/ Clinical Research Organization (CRO), including telephone and written interactions, during the course of a clinical research study at the CRC.

**SCOPE:** This SOP applies to communications between CRC personnel involved in the conduct of clinical research and sponsors/CROs.

**RESPONSIBILITY:** All key research personnel will ensure proper documentation of communication conforming to the principle of ALCOA

**Principal Investigator (PI):** Responsible for review and sign-off of completed documents (e.g.: test results, subject records) with date and assigns responsibilities for data collection and recording

**Research Coordinator:** Ensures proper documentation of all communications and maintains documents in secure and retrievable locations and formats

**DEFINITIONS:**

**ALCOA:** Acronym applied to source documentation in order to achieve quality data. Source documentation should always be:


- **Attributable-** It should be obvious who wrote or did what
- **Legible-** Print names if signatures are illegible
- **Contemporaneous-** The notation, signature, and date need to be completed at the same time and should be within one month of the event
- **Original-** Meaning the first recording of the information, creation of a copy that is certified, or direct entry into an electronic data tracking system
- **Accurate-** Content should precisely reflect the event being recorded

**Adverse Event (AE):** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

**Case Report Form (CRF):** A paper or electronic questionnaire specifically used in clinical trial research. The Case Report Form is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

**Contract Research Organization (CRO):** A person or an organization contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

**Regulatory Binder:** Method used to organize/store essential study documents. The regulatory binder is often the first document reviewed during audits and inspections.

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**Sponsor:** An individual, company, institution, or organization that takes responsibility for and initiates a clinical research trial.


**PROCEDURE:**

**1. General Communications:**

- 1.1. Provide the sponsor/CRO a contact list of CRC personnel involved in study start up, along with each individual's role (e.g., Research Coordinator will be responsible for site visits; Regulatory Coordinator will handle IRB submissions, etc.)
- 1.2. Communicate regularly, courteously and in accordance with CRC standards with the sponsor/CRO about all study-related issues.
- 1.3. Be familiar with the sponsor's SOPs pertaining to communications, including reporting timelines and preferred communication mode.
- 1.4. Keep originals or photocopies of all study-related communications, including faxes with corresponding confirmations, e-mails, and written summaries of phone conversations. File all communication documents in the appropriate section of the regulatory binder.
- 1.5. Retain all sponsor-generated communications regarding conduct of the study (e.g., teleconference announcement) in the correspondence section of the regulatory binder. Budget, payment, financial disclosure forms, and other contractual or financial communications should be filed separately from the regulatory binder.
- 1.6. Ensure information is communicated to the Principal Investigator (PI) and other key research personnel as applicable.

**2. Pre-Study Communications:**

- 2.1. The research team in collaboration with the Office of Clinical Research (OCR) will facilitate pre-study communications by the following:
  - Send the Confidentiality Agreement to the Sponsor/CRO once reviewed and signed by Research Administration
  - Notify the Sponsor/CRO of the PI's decision to conduct the research study at CRC
  - Send the signed protocol signature page (if appropriate) to the Sponsor/CRO
  - Submit all pre-study regulatory documents to the IRB
  - Send updated/revised documents as required by the IRB
  - Review the protocol and submit any questions concerning interpretation of the protocol or conduct of the study to the sponsor/CRO in writing and file the reply in the regulatory binder

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**PROCEDURE (cont.):**


**3. Ongoing Study Communications:**

The study coordinator will perform the following ongoing study communications:

- 3.1. Submit study status logs (SSLs) to the OCR by the first of every month to facilitate sponsor invoicing.
- 3.2. Notify sponsor/CRO about adverse events (AEs) per the sponsor's definitions and timelines, as defined in the protocol or Sponsor Operations Manual.
- 3.3. Communicate protocol deviations, as they occur, according to the sponsor's requirements.
- 3.4. Submit completed CRFs (paper-based or electronic data capture) to the sponsor/CRO in accordance with the clinical trial agreement.
- 3.5. Respond promptly to data queries as requested via fax, e-mail, and/or direct electronic data capture resolution, per the sponsor's requirements.
- 3.6. Communicate significant regulatory changes per the sponsor's requirements (e.g., IRB acknowledgement of an AE or protocol deviation, IRB approval of a revised consent document, etc.).
- 3.7. Submit sponsor-generated protocol amendments to the IRB and in-service to pertinent research personnel or involved clinical staff regarding the changes prior to implementation.
- 3.8. Forward safety reports received from the sponsor to the PI who will review the event and determine whether or not the event meets criteria to report to the IRB and report if applicable. Notification of other key research personnel and/or enrolled subjects may be necessary (e.g., new risk identified related to investigational treatment).

**4. Study Close- Out Communications**

- 4.1. Provide the sponsor/CRO with any required regulatory correspondence related to study close-out (e.g., IRB Final Report/Closure letter).
- 4.2. Ensure all close-out activities are performed (e.g., monitor close-out visit) and any sponsor/CRO requirements are met. File all close-out communications in the appropriate section of the regulatory binder (e.g., documents related to return or disposal of test article or lab supplies).
- 4.3. Inform sponsor/CRO and Research Administration promptly if notified by an external regulatory body, such as the FDA, of an impending inspection. Provide Research Administration with a copy of any report generated as a result of the external regulatory inspection (e.g. Form FDA 483).

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<b>REFERENCES:</b>	ICH-GCP (E6 1.20); 21 CFR 312.32-33; 21 CFR 50, 56; FDA Information Sheet, October 1998: Sponsor-Investigator-IRB Interrelationship; May 1997 International Conference on Harmonization (ICH) Good Clinical Practices	
<b>RELATED POLICIES:</b>	SOP 102: Training Clinical Research Staff ; SOP 104: Clinical Study Conduct SOP 201: Regulatory Documentation; SOP 204: Adverse Event Reporting SOP 302:Site Qualification Visit; SOP 303: Site Initiation Visit SOP 602: Audits	
<b>APPENDICES:</b>	None	
<b>REVISION HISTORY:</b> Keep a running history of all revision dates.		
<b>Approval Date</b>	<b>Effective Date</b>	<b>Review/Revision Date</b>
<b>01/01/2015</b>	<b>06/01/2016</b>	