1 PURPOSE
This procedure describes the process for documenting all clinical study communications that are required during the conduct of human subject research.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
a) The Investigator is responsible for ensuring that all key study personnel understand required communications and the documentation of those communications.

b) The Investigator is responsible for maintaining all original documentation or where appropriate, copies of documentation of communications among all affected parties. These communications are to be filed and maintained according to SOP 503, Documentation and Records Retention.

c) The Investigator is responsible for communicating to the IRB of record, all appropriate and known information necessary to permit an informed decision-making process by the IRB during its review and approval(s) of applicable clinical studies.

d) The Investigator is responsible for ensuring that written and dated IRB approval is obtained for: the protocol, subject informed consent form, any materials used to recruit subjects, and any changes to these documents prior to implementing changes to an ongoing study.

3 SPECIFIC PROCEDURES
3.1 General Communications
a) All communications should be appropriately summarized and documented on the appropriate forms or other records, and distributed/filed as required by applicable standard operating procedures (SOP) and/or regulations.
Investigator Standard Operating Procedures

b) Participating Investigators and their study staff will be trained on communication requirements during the initiation visit.

c) The Investigator is expected to communicate regularly with the IRB, sponsor (if applicable), and appropriate government regulatory agencies about significant study-related issues.

d) The frequency of communications depends on the complexity of the study, subject matter and context, but should be regular enough that parties are thoroughly apprised of current study status.

e) All pertinent written, verbal, and electronic communications should be documented in sufficient detail, signed and dated by the person documenting the communication, and filed in the appropriate section of the Investigator’s Regulatory Master File.

3.2 Investigator’s Communications with the IRB

a) The Investigator must communicate regularly and appropriately with their IRB(s) of record about all study-related issues, particularly those involving human subject safety and protocol adherence.

b) With respect to federally funded research that requires an approved Federal Wide Assurance (FWA) from the Office of Human Research Protections, the Investigator will consult with the IRB to confirm the requirements for obtaining such an assurance.

c) The Investigator will ensure that the study is properly submitted to the IRB of record.

d) Prior to study initiation the Investigator will assure that he/she will:
   - Complete the initial IRB submission packet.
   - Include all attachments as directed by the reviewing IRB of record, e.g. the protocol, protocol summary, Investigator Brochure, informed consent form/assents, advertisements, etc.
   - Obtain documentation of full IRB approval for the protocol and informed consent form prior to study start.
   - File all relevant IRB communications in the appropriate section of the Regulatory Master File and/or study file.

e) During the time while the study is ongoing, the Investigator or designee will:
   - Notify the IRB of any changes to the protocol and/or informed consent/assent, and of any new information on any investigational product, obtained directly or from another participating investigator.
   - Obtain IRB approval of amendments and revisions to study-related documents, such as advertisements, and document that approval prior to implementation except to eliminate hazards to study subjects.
   - Notify the IRB as per its policies of any study personnel changes affecting the oversight, management, or conduct of the investigation.
   - When applicable, provide the IRB with documentation of human subject protections training of study personnel as required.
   - Submit a periodic report for renewal of the study prior to the expiration of the current approval period, at intervals required by the IRB.
Investigator Standard Operating Procedures

- Promptly notify the IRB and applicable government agencies, if applicable, of any serious, unexpected, or unanticipated events involving risks to subjects or others during the approval period for the ongoing study either those observed by the Investigator or reported by another participating Investigator.
- Report any patterns of expected adverse events occurring at higher frequency than expected to the IRB and any applicable government agencies (FDA) as part of the periodic or annual reporting requirements.
- Inform the IRB and OHR, and the Sponsor if applicable, promptly when notified by FDA or another external authority of an impending inspection or audit.
- Provide final inspection or audit reports (if conducted by external regulatory authority) to OHR, and upon request, to the IRB.

f) When the study is completed, the Investigator or designee will submit a final study report to the IRB and any applicable government agencies within the specified time following study completion.

3.3 Investigator Communication Records

a) All pertinent verbal communications between the Investigator, his/her designees, and other applicable parties will be documented as a summary via email, or by other appropriate memorandum to file. This record will be kept to follow and document the content and frequency of verbal communications, as well as assess the effectiveness of those communications. Each communication must be signed and dated by the party documenting the communication.

b) The Investigator and all other parties will keep originals or photocopies of all relevant communications records, including facsimile confirmations and printed copies of e-mail, in the appropriate section of the Regulatory Master File. Routine emails from sponsors will be kept electronically.

c) The Investigator will keep copies of all FDA documentation (Form FDA 483, Warning Letters) and resulting follow-up correspondence generated from the inspection of the Investigator and the IRB in the appropriate sections of the Regulatory Master File.

d) The Investigator will provide copies of relevant communications to OHR and other appropriate institutional officials.

e) The Investigator will notify sponsors promptly of information pertaining to inspections in accordance with contractual agreements.

4 REFERENCES TO OTHER APPLICABLE SOPS

- 201 Contacts and Submissions for FDA
- 202 Reporting Requirements for FDA
- 402 Initiation Visit and Site Training
- 503 Documentation and Records Retention
- 504 Routine Monitoring Visits
- 505 Study Closeout Visits
5 ATTACHMENTS
None

6 APPLICABLE REGULATIONS AND GUIDELINES
- Responsibilities of Sponsors and Investigators (21 CFR 312 Subpart D)
- Responsibilities of Sponsors (21 CFR 812 Subpart C)
- Responsibilities of Investigators (21 CFR Subpart E)
- The Principles of ICH GCP (ICH E6, Section 2.0)
- Compliance with Protocol (ICH E6, Section 4.5)
- Medical Expertise (ICH E6, Section 5.3)
- Trial Management, Data Handling and Record Keeping (ICH E6, Section 5.5)
- Allocation of Responsibilities (ICH E6, Section 5.7)
- Compensation to Subjects and Investigators (ICH E6 Section 5.7)
- Record Access (ICH E6, Section 5.15)
- Multi center Trials (ICH E6, Section 5.23)
- Essential Documents for the Conduct of a Clinical Trial (EHH E6, Section 8.0)