SECTION: Research and Compliance				NUMBER: CLN-41.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/19/2009	REV. B: 8/27/2010	REV. C:
TITLE: Handling IRB Communication			Page 1 of 2	

1. PURPOSE

To provide guidance regarding necessary communication between the clinical investigational site and the Institutional Review Board (IRB) concerning clinical research investigations.

2. SCOPE

Applies to 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 correspondence to and from the IRB. All records should be readily accessible to the Food and Drug Administration (FDA), IRB, Research and Compliance, and/or sponsor representative(s), if requested during an audit or inspection.

4. BACKGROUND

Before initiating a trial, the PI must have written IRB approval for the research protocol, Informed Consent Form (ICF), and any other written information to be provided to subjects. All documents subject to review must be submitted to the IRB on behalf of the responsible PI. IRB communication files contain copies of all such relevant communications and serve as an audit trail for a trial.

5. PROCEDURE

5.1. The PI will be responsible for all communication with the IRB concerning the investigation. The PI may assign clinical site research personnel (i.e. Regulatory Document Specialist (RDS)) the duty of communicating with the IRB and maintaining documentation of such communication.

5.2. IRB communication should include, but not be limited to:

- 5.2.1. Request for protocol, ICF, HIPAA Authorization, or HIPAA Waiver approval
- 5.2.2. IRB approval notification
- 5.2.3. Request for approval of protocol modifications (e.g., amendments, addenda, revisions, etc.)
- 5.2.4. ICF: original stamped approved version(s)
- 5.2.5. Request for approval of ICF revisions
- 5.2.6. Progress reports
- 5.2.7. Notification of unanticipated problems, including adverse events, from site and sponsor and communication about any change in risk/benefit ratio

5.2.8. Request for approval of advertising materials, recruitment materials, participant information, etc.
5.2.9. IRB approval of advertising materials, recruitment materials, participant information, etc.
5.2.10. Correspondence and/or status reports regarding memos, notes to file, amendments, etc.
5.2.11. General correspondence to and from IRB
5.2.12. Notification of study closure/PI's final report

5.3. The RDS or delegated staff will place communications in the Investigator regulatory files and submit copies to the trial sponsor. The RDS will disseminate all communication from the IRB as appropriate.

5.4. Original documents of communication returned from the IRB will remain in the local regulatory binder.

6. TERMS & ABBREVIATIONS

FDA Food and Drug Administration
ICF Informed Consent Form
IRB Institutional Review Board
PI Principal Investigator
RDS Regulatory Document Specialist

7. REFERENCES

7.1. Title 21 CFR 312.66 - Assurance of IRB Review
7.2. Title 21 CFR 56.115 - IRB Records
7.3. Title 21 CFR 812.140 - Records
7.4. Title 21 CFR 812.150 - Reports
7.5. Title 45 CFR 46.115 - IRB Records (if applicable)
7.6. ICH GCP Consolidated Guideline - Part 4.4 Communication with IRB/IEC
7.7. Creighton University Institutional Review Board Policies and Procedures

8. ATTACHMENTS

None