SECTION: Research and Compliance				NUMBER: CLN-1.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/21/2009	REV. B: 8/25/2010	REV. C:
TITLE: Standard Operating Procedure (SOP) Use and Maintenance			Page 1 of 2	

1. PURPOSE

To document the purpose, creation, revision, and evaluation of Standard Operating Procedures (SOPs) as applicable to clinical research.

2. SCOPE

All clinical research groups in which clinical research involving human subjects is conducted.

3. RESPONSIBILITIES

3.1. Compliance with the SOPs of the clinical research unit is a condition of staff employment.
3.2. All job descriptions make reference to knowledge of and compliance with all SOPs.
3.3. Overall unit compliance with SOPs is formally evaluated and forwarded to the Principal Investigator (PI) for any appropriate corrective action.
3.4. Violations of SOPs are documented and reviewed for purpose of quality assurance.

4. BACKGROUND

The object of Standard Operating Procedures (SOPs) is to ensure a uniform standard of work by all staff in the conduct of clinical trials involving human Study Participants (SPs). These SOPs ensure that clinical trials are conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidance and applicable regulatory requirements. It should be noted that the SOPs are under constant thought, formal review, and revision when required.

Exceptions to the SOPs affecting human subjects may be considered as long as the procedures have been approved by the Institutional Review Boards (IRBs) and are documented in the protocol, the application, or separate documentation. See IRB Policies and Procedures.

Other exceptions must be in accordance with University policies.

5. PROCEDURE

5.1. **Review and Revision-** An ongoing recording and reporting system is available for the staff to note SOPs that: 1) should be included (added), or 2) are in need of revision.
5.1.1. Formal review of SOPs is coordinated at least annually by the Office of Research and Compliance.
5.1.2. SOPs may be revised and rewritten as needed.

5.1.3. At least one copy of each expired SOP is retained indefinitely for later accessibility and reference if required.

5.2. **Distribution**

5.2.1. SOPs will be kept on the Research and Compliance web site

5.2.2. All staff, including the PI, will be required to document in their file that they have read, understand, and will comply with these SOPs.

5.2.3. Unit-specific SOPs will be submitted and posted on the Research and Compliance web site.

5.3. **SOP Deviation**

5.3.1. Deviation from the SOPs is acceptable only under special, atypical situations and must be immediately documented.

5.3.2. The PI or his/her designee must approve all deviations from SOPs if they are known and contemplated in advance.

5.3.3. Documentation of approval to deviate from SOPs must be written and then filed in the regulatory binder or study file.

6. TERMS & ABBREVIATIONS

GCP Good Clinical Practice
ICH International Conference on Harmonisation
IRB Institutional Review Board
PI Principal Investigator
SOP Standard Operating Procedures
SP Study Participant (Normal Healthy Volunteer, Patient Volunteer, Study Control, etc.)
QA Quality Assurance

7. REFERENCES

7.1. 21 CFR 312.60

8. ATTACHMENTS

None