

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-42.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/19/2009	REV. B: 8/31/2010	REV. C:
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1. PURPOSE

To outline the process of handling study protocol modifications at the clinical research site so that change(s) in the protocol can be implemented.

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 modifications to the study protocol and/or Informed Consent Forms (ICFs), and must maintain documentation of Institutional Review Board (IRB) approval of the modifications.

4. BACKGROUND

Protocol modifications by the study sponsor (for externally sponsored projects) or the Investigator (for Investigator-initiated projects) change or revise a study protocol. There may be multiple modifications to a protocol throughout the duration of a trial. However, some protocols may not have any modifications.

The Investigator should not implement any deviation from or changes to the protocol without agreement by the sponsor and prior review and documented approval from the IRB of a modification, except where necessary to eliminate immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change in telephone number(s)) [ICH GCP 4.5.2].

5. PROCEDURE

- 5.1. Upon notification of a protocol modification, the PI shall review the proposed change(s) and sign the signature page if indicated, according to sponsor policy.
- 5.2. The PI or designee will submit a copy of the protocol modification to the IRB, according to Creighton University IRB Policy 122, "Modification of Approved Research." No changes will be implemented without the approval of the reviewing IRB, except to eliminate an apparent immediate hazard to study subjects. These sorts of modifications must be reported to the IRB within five (5) working days.
- 5.3. The IRB will review and approve or disapprove the protocol modification according to their written procedures and communicate approval or disapproval in writing to the

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Investigator. Upon receipt of written approval (or disapproval), the PI or designee will submit a copy of the IRB letter and the signed protocol signature page to the sponsor.

- 5.4. All study documents containing information affected by the protocol modification will be revised and submitted to the IRB for approval, along with the modification application form, if required, by the PI or designee.
- 5.5. The PI or designee will inform all study subjects currently enrolled in the trial of any change or new information that may impact their decision to continue participation in the study.

6. TERMS & ABBREVIATIONS

GCP	Good Clinical Practice
ICH	The International Conference on Harmonisation
IRB	Institutional Review Board
PI	Principal Investigator
SC	Study Coordinator

7. REFERENCES

- 7.1. Title 21 CFR 56.103 - Circumstances in which IRB review is required
- 7.2. Title 21 CFR 56.109 - IRB Review of Research
- 7.3. Title 21 CFR 56.111 - Criteria for IRB Approval of Research
- 7.4. Title 21 CFR 312.30 - Protocol Amendments
- 7.5. Title 21 CFR 812.64 - IRB's Continuing Review Title 45 CFR 46.109 - IRB Review of Research
- 7.6. ICH GCP Consolidated Guideline - Part 4.4 Communication with IRB/IEC
- 7.7. ICH GCP Consolidated Guideline - Part 4.5.2 Compliance with Protocol
- 7.8. Creighton University Institutional Review Policy 122, "Modification of Approved Research"

8. ATTACHMENTS

None