SECTION: Research and Compliance				NUMBER: CLN-13.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/14/2009	REV. B: 8/26/2010	REV. C:
TITLE: Maintaining Subject Confidentiality			Page 1 of 2	

1. PURPOSE

To establish guidelines for ensuring the confidentiality of Study Participants (SPs) who participate in studies.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigator(s), Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for all aspects of a clinical study, including maintaining confidentiality and ensuring that the SP is comfortable knowing that her/his confidentiality will be maintained.

4. BACKGROUND

Both the Department of Health and Human Services and Food and Drug Administration regulations require confidentiality statements to be included in Informed Consent Form (ICF).

Federal health privacy regulations, known as the Health Insurance Portability and Accountability Act (HIPAA), came into effect in April 2003. The privacy regulations require that health care providers, physicians, and institutions obtain patient authorization to use or disclose individually identifiable health information, with certain broad exceptions.

Study participants must receive written notice of their privacy rights and the organization's privacy practices.

5. PROCEDURE

5.1. The informed consent process should describe the measures that are taken to protect the confidentiality of records identifying the SP.

5.2. On study-related material, with the exception of the ICF and demographic information form, SPs are identified by non-identifiable SP numbers and/or initials.

5.3. An Investigator must obtain a separate valid written HIPAA research authorization, approved by the IRB, from a research subject or his/her legal representative in order to

obtain, use, or disclose the subject's individually identifiable protected health information (PHI).

5.3.1. The HIPAA authorization is a legal document that cannot be altered after the SP has signed it. Changes to the HIPAA authorization require the SP to sign a new document.

5.4. Publications from the study must not identify any SPs in any way.

5.5. SP names are not to be discussed outside of the context of the study. The identity of the SP must, at all times, be kept strictly confidential.

5.6. In studies requiring HIV testing, it is especially important to keep the patient's HIV status confidential. Nebraska state law requires a separate consent for HIV testing. Researchers shall use the clinical HIV testing consent. To request a copy of this form, contact Creighton Medical Laboratories. This form does not require IRB approval.

6. TERMS & ABBREVIATIONS

FDA Food and Drug Administration
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act
ICF Informed Consent Form
IRB Institutional Review Board
PI Principal Investigator
PHI Protected Health Information
SP Study Participant

7. REFERENCES

7.1. HIPAA Directive
7.2. HIPAA Authorization for Research
7.3. FDA 21 CFR Part 56
7.4. DHHS 45 CFR Part 46

8. ATTACHMENTS

None