Name of SOP: Obtaining Informed Consent
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Approval Signature: _____

Purpose: The Informed Consent process is an essential component of any Clinical Trial. Ethically and by ICH cGCP requirements a Subject must be informed of certain elements of research and how this may affect them personally. The purpose of this SOP is to define the elements of Obtaining Informed Consent.

Introduction: Informed consent implies the full disclosure of information to a potential Clinical Trial Subject. It is essential that the potential subject understands the possible risks and benefits of the study and it is the responsibility of the investigator to ensure that this relevant information is available to the subject in a timely fashion. There are two types of obtaining informed consent;

1. Obtaining personal written informed consent.
2. Obtaining informed consent for patients unable to give personal consent.

Procedures:

Informed consent for persons able to give their own consent:

1. The informed consent must be obtained prior to any study specific procedure being conducted on the patient.
2. Obtaining personal written informed consent:
    a. The information is to be given to the subject in written format, the Informed Consent Form (ICF).
        i. Verify that the ICF given to the potential subject is the most recent IRB approved version of the consent for that clinical trial.
        ii. The ICF can be first presented to the patient by the Study Coordinator or other qualified personnel.
    b. The potential subject must be given ample time to read and understand the ICF.
    c. Study staff will then return and discuss the ICF with the potential patient, making sure to highlight important areas of the consent such as:
        1. The purpose of the study.
        2. That the test article to be given to the subject is an investigational product and not yet licensed for sale.
        3. Explain that the subject may receive placebo, if applicable, and what chances the subject has of receiving the real test article.
        4. Explain how many subjects will be involved.
        5. Discuss the duration of the study.

6. Explain how many visits the subject will make.
7. Discuss procedures; labs, blood tests, urine samples.
8. Responsibilities of investigator and subject.
9. Any compensation to the subject.
10. Notification of any other treatment available for the condition.
11. That the subject has the right to withdraw.
12. Confidentiality vs. what information will be reviewed by the Sponsor.

ii. Promote the exchange of information with the subject and encourage any questions.

d. The Principal Investigator (or Sub-Investigator) should then join the potential subject and the subject then given an additional opportunity to ask questions.

3. The ICF will then be signed by the subject, study staff presenting the ICF and the Principal Investigator/Sub-Investigator.
   a. The original ICF will be kept with the subject's source documentation (clinic chart).
   b. A copy of the ICF will be given to the subject.
   c. A copy of the ICF will be kept in the Regulatory Binder.

Obtaining informed consent for patients unable to give personal consent:

1. Legal incompetence is defined specifically by different national legislations. Once incompetence has been established informed consent should be obtained from the subject's legal guardian. Usually the guardian is a close relative of the subject that may act on behalf of the Subject. Examples of such cases may include but are not limited to:
   a. Mental incapacity.
   b. Illiteracy.
   c. Specified medical conditions.
2. In the case of a minor child who is capable of reading and writing and of understanding consent, the assent of the child as well as the consent of parent or legal guardian must be obtained.
   a. This usually applies to a minor of the age of approximately 7 to 17 years old.
3. In the case of a child that is too young to read and write or understand the consent process the ICF must be signed by the parent or legal guardian only.
4. In the event of any of the above situations the consenting process remains unchanged from that described for a person capable of giving their own consent with the exception that the person signing the ICF for the subject must be present and an active participant in the consenting process.

References:

21 CFR 50.25	Elements of informed consent
21 CFR 56.109	IRB review of research
21 CFR 56.111	Criteria for IRB approval of research
21 CFR 312.54	Emergency research under §50.24 of this chapter
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
45 CFR 46.116	General requirements for informed consent
	FDA Internal Compliance Program Guidance Manual, 1994; 7348.811: Clinical Investigators
FDA Information Sheets, October, 1995	Frequently Asked Questions, A Guide to Informed Consent Documents, Informed Consent and the Clinical Investigator, The Belmont Report and Declaration of Helsinki
May 9, 1997	International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

Relevant Government Acts:

USA:	Health Insurance Portability and Accountability Act (HIPAA) of 1996 located at the United States Department of Health & Human Services Website: http://aspe.hhs.gov/admnsimp/pl104191.htm
State:	Local laws vary, consult State Authorities.
Canada:	Privacy Act (PIPEDA) an unofficial version located at the Department of Justice Canada Website: http://laws.justice.gc.ca/en/P-21/94401.html
Provincial:	Local laws vary, consult Provincial Authorities.

References to Other Applicable SOPs:

03-03-001	Essential Documents for a Clinical Trial
03-03-007	Informed Consent Development Process
03-03-004	Regulatory Binder Requirements
03-02-009	Source Documentation
03-02-011	Sponsor Monitoring Visits
03-02-017	Audits
03-04-004	Long-term-Storage of Study documents