***Data Collection***

1. **PURPOSE**

This Standard Operating Procedure (SOP) describes the processes and procedures for methodical collection of clinical trial subject data to ensure its integrity and quality.

(**MANDATORY LANGUAGE**)

1. **SCOPE**

This Standard Operating Procedure applies to all members of the research team involved with the collection of clinical trial subject data including the identification, creation and maintenance of source documents. It describes the responsibilities, processes, and procedures pertaining to the collection, transcription, and secure storage of clinical trial subject data. The collection and archival of clinical trial study documentation are not within the scope of this Standard Operating Procedure.

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 *[Optional: Insert any additional details necessary to further define the scope of this SOP]*

1. **POLICY**

This Standard Operating Procedure supports the Good Clinical Practices guidelines established by the International Conference on Harmonization (ICH):

Section E6: 2.10 *All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification*.

Section E6: 2.11 *The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s)*.

Section E6: 4.9.1 *The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports*.

Section E6: 4.9.2 *Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.*

Section E6. 4.9.3 *Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e., an audit trail should be maintained); this applies to both written and electronic changes or corrections. (see 5.18.4 (n)). Sponsors should provide guidance to investigators and/or the investigators’ designated representatives on making such corrections. Sponsors should have written procedures to assure that changes or corrections in CRFs made by sponsor’s designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.*

Section E6. 4.9.7 *Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.*

FDA Regulation ☐ N/A

*[If this SOP is not intended for FDA regulated clinical trials, check the N/A box]*

Per CFR part 312 INVESTIGATIONAL NEW DRUG APPLICATION:

Sec. 312.62 Investigator recordkeeping and record retention.

*(b) Case histories. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.*

Per CFR Part 812 -- INVESTIGATIONAL DEVICE EXEMPTIONS:

Sec. 812.140 Records.

*(a) Investigator records. A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:*

*(3) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes.*

University of Michigan Health System (UMHS) Policies

01-04-002 Confidentiality of Patient Information:

It shall be the policy of the University of Michigan Health System (UMHS) that all information regarding care of the individual patient be maintained in a confidential and secure fashion in accordance with UMHS policies and state and federal law.

01-04-360 Use of Protected Health Information (PHI) in Research:

It shall be the policy of the University of Michigan Health System (UMHS) to obtain a patient's written authorization or satisfy an exception to the authorization requirement before using or disclosing the patient's PHI for research purposes.

**Additional Regulations or Policies ☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply]*

1. **DEFINITIONS**

CASE REPORT FORM (CRF):A printed, optical, or electronic (eCRF) document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

INVESTIGATIONAL DEVICE EXEMPTION (IDE): An investigational device is a device, including a transitional device, that is the object of an investigation. Approval by FDA for investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully across state and international boundaries for the purpose of conducting investigations of that device.

INVESTIGATIONAL NEW DRUG APPLICATION (IND): A request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application.

PROTECTED HEALTH INFORMATION (PHI): Individually identifiable health information held or maintained by covered entities, or by business associates acting for the covered entity. PHI is subject to HIPAA Privacy Rule protections. HIPAA Privacy Rule permits researchers to access and use PHI when necessary to conduct research, with certain restrictions.

SOURCE DATA: All information in original records and certified copies of original records or clinical findings, observations, of other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

SOURCE DOCUMENT:Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

“Many of the definitions above were obtained from the IRBMed Glossary.  These definitions were current as of 12-Jun-2015 and are subject to change.  Please see the [IRBMed Glossary](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/glossary) for the most current definitions and additional guidance.”

 **(MANDATORY LANGUAGE)**

 *[Optional: Insert any additional definitions for technical or special terms used within the Standard Operating Procedure that may not be familiar to the lay reader]*

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

An individual filling the role of Principal Investigator (PI) is accountable for the collection of clinical trial subject data. The Principal Investigator or Designee shall be responsible for the following activities:

* Ensures accurate, timely, complete, and secure collection of clinical trial subject data
* Stores clinical trial subject data securely in accordance with applicable regulations
* Ensures secure transfer of clinical trial subject data
* Shares clinical trial subject data based on local, state, federal and/or sponsor requirements
* Retains clinical trial subject data appropriately based on applicable local, state, federal and/or sponsor requirements
* Ensures clinical trial subject data are documented and traceable back to the source
* Conducts all data collection activities in a manner that adheres to state, federal and/or University regulations on Protected Health Information (PHI)

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator/Designee*]

**Study Coordinator/Designee**

An individual filling the role of Study Coordinator is responsible for the collection of clinical trial subject data. The Study Coordinator or Designee shall be responsible for the following activities:

* Performs accurate, timely and complete tracking, collection and recording of subject data including source documentation and Case Report Forms (CRFs) in accordance with applicable regulations and sponsor requirements
* Creates modifications and corrections to the clinical trial subject data
* Stores clinical trial subject data in a manner designed to maintain data security and patient privacy requirements
* Conducts data collection activities in a manner that adheres to state, federal and/or University regulations on Protected Health Information (PHI)

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator/Designee*]

**Additional Roles and Responsibilities**  **☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SOP]*

1. **PROCEDURE**

**Collection of Clinical Trial Subject Data**

*[Describe the process used to collect clinical trial subject data through the use of Case Report Forms or source documentation (paper and/or electronic). For example, EKG, lab data, etc. Include processes to ensure the data are accurate, legible, and timely.]*

**Tracking of Clinical Trial Subject Data**

*[Describe the process used to track clinical trial subject data including Case Report Forms and source documentation (paper and/or electronic). For example, EKG, lab data, etc.]*

**Transcription of Clinical Trial Subject Data**

*[Describe the process used to transcribe clinical trial subject data collected from source documents to Case Report Forms (paper and/or electronic) based on protocol defined CRF-specific timepoints. Include any processes to ensure the data are accurate, legible, and timely.]*

*[Describe the process used for source document verification. Include internal quality control measures that ensure data are valid, e.g. data verified by a second party]*

*[Describe the process used for data entry including any methods utilized to ensure data accuracy. For example, double data entry, verification by another staff member, etc.]*

**Storage of Clinical Trial Subject Data**

*[Describe the process used to securely manage and store clinical trial subject data including Protected Health Information (PHI).]*

**Additional Procedures** **☐ N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

Good Clinical Practice Guidance Document:

<http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf>

Guidance for Industry. Part 11, Electronic Records; Electronic Signatures - Scope and Application:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

University of Michigan Health System (UMHS) Policies - 01-04-002 Confidentiality of Patient Information:

<http://www.med.umich.edu/i/policies/umh/01-04-002.html>

University of Michigan Health System (UMHS) Policies - Compliance -HIPAA Privacy and Security:

<http://www.med.umich.edu/i/policies/umh/toc.html#HIPAA>

University of Michigan IRBMed Protected Health Information (PHI):

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/privacy-board/protected-health-information-phi>

University of Michigan IRBMed Record Keeping Guidance:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/record-keeping-guidelines/>

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

**Appendix A:** Document Tracking Log **☐** **N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP appendices]*