DM-501 STANDARD OPERATING PROCEDURE FOR DATA MANAGEMENT

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at this investigative site for the collection of clinical research data, transcription of the data to case report forms (CRFs), and the management of the data, including procedures for:

- Quality control
- Data query resolution
- Record retention and archiving

2. SCOPE

This SOP applies to data management for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.56	Review of ongoing investigations
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR 312.70	Disqualification of a clinical investigator

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
PM-302	Site-Sponsor/CRO Communications
PM-303	Regulatory Files and Subject Records
QA-601	Audits

5. ATTACHMENTS

A. Source Documentation Requirements

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in data collection, transcription to CRFs, and the management of the data.

This includes the following:

- Principal investigator
- Sub-investigator
- Research Director/Manager
- Research coordinator
- Support staff

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline, apply to this SOP.

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Documentation: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or 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 Documents: 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 and complete, 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).

8. PROCESS OVERVIEW

A. Collection of clinical research data
B. Transcription of the data to case report forms (CRFs), including remote data entry
C. Management of the data, including procedures for:
   - Quality control
   - Data query resolution
   - Record retention and archiving

9. PROCEDURES

A. COLLECTION OF CLINICAL RESEARCH DATA

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Ensure that copies of the most recent IRB-approved consent form are available for subject enrollment. Based upon the protocol and case report forms, develop study-specific source documentation, checklists and logs if not provided by sponsor. (Attachment A).

B. TRANSCRIPTION OF THE DATA TO CASE REPORT FORMS (CRFS), INCLUDING REMOTE DATA ENTRY

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator Support staff	Record all documentation in black ball point pen. Complete all fields in the CRFs according to sponsor specifications. Correct errors by striking through the error, dating and initialing it, and making the correction. Ensure the original entry is not obliterated. If necessary, note an explanation in the right margin. Ensure that data for the CRFs are transcribed promptly from the source documentation (3-4 working days.)
Research coordinator Support staff	If the sponsor requires remote data entry, ensure that data are entered by computer according to sponsor specifications promptly from the source documentation.

C. MANAGEMENT OF THE DATA

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Support Staff Research coordinator	Ensure that the first sets of completed CRFs are reviewed for completeness and accuracy by another member of the research team or by another designated individual.

Research coordinator	Request a copy of the sponsor's SOPs for making changes or corrections to the CRFs. Collect any discrepancies noted at the sponsor's monitoring visit on a data clarification form to ensure a trail of clarifications and corrections. If a sponsor-specific form is not available, ensure that any discrepancies are noted on a generic data clarification form (Attachment C, Data clarification Form). Ensure that the data clarification forms are kept with the other study records in the regulatory files for this study. Correct errors to the CRFs noted at the monitoring visit by using the procedures described above.
Research coordinator Support staff	At the conclusion of the study, ensure that data are retained according to regulatory and sponsor requirements. Inform the sponsor of the study in writing and obtain approval prior to destroying any study-related data.

Attachment A

SOURCE DOCUMENTATION REQUIREMENTS

For each study, source documentation to support case report form data should include the following:

1. Date of entry into the study, sponsor's protocol number, and subject number.

2. Note that written informed consent was obtained; consent form dated and signed by subject (or subject's representative).

3. Record any current medications and medications discontinued within the last month (or longer, as specified by the protocol).

4. Record subject's diagnosis and status prior to treatment, including documentation of medical history, particularly that relevant for the disease or condition being treated.

5. Record names of possible study drugs along with the dose and start dates.

6. Document the dates and the results evaluations and procedures required by the study; note any deviations from the protocol and provide an explanation.

7. Record any reported complaints or adverse events that occurred during the treatment period and for a period specified by the sponsor following the last dose of study drug. Record any treatment administered and/or recommended.

8. Record subject's condition during and/or after treatment.

9. Document final disposition of the subject and subject status at time of study termination.