

101.1 PREPARATION, REVIEW, REVISION, AND MAINTENANCE OF STANDARD OPERATING PROCEDURES

I. PURPOSE

To establish a consistent procedure for the preparation, review, revision, and maintenance of Standard Operating Procedures (SOPs) written and implemented by The University of Tennessee Graduate School of Medicine's (GSM).

II. SCOPE

Details the management of SOPs implemented by GSM relating to site and business operations for the conduct of clinical trials.

III. BACKGROUND

An SOP is an established procedure to be followed in a given situation. SOPs establish consistent methods to be utilized by personnel to achieve uniformity in the performance of procedures when conducting clinical research. SOPs provide information necessary to perform a job properly, consistently, and to ensure compliance with regulations. SOPs are the foundation of training, compliance, and quality assurance.

IV. ROLES/PROCEDURES

1. Best Practice

- a. SOPs are written in a clear and concise manner utilizing the GSM standard format as outlined in this SOP.

2. First Page Header

- a. SOP number
- b. Title
- c. Version
- d. Date revised

3. Structure

- a. The structure of all SOPs will be identical and shall include:
 1. Purpose
 2. Scope
 3. Background, if applicable
 4. Regulations and guidelines, if applicable
 5. Definitions, if applicable
 6. Roles/Procedures
 7. Attachments, if applicable

SOP Number: 101.1

Version 1 Date: August 17, 2021

The University of Tennessee Knoxville Graduate School of Medicine

4. Approval of New or Revised SOPs May Only be Performed by:

- a. GSM Dean
- b. GSM Director of Research
- c. GSM Assistant Director of Research

5. Revision and Review

The GSM Dean, Director of Research, and/or the Assistant Director of Research will be responsible for ensuring that all SOPs are reviewed and maintained in accordance with current processes, guidelines, and regulations. Every two years SOP's will be reviewed for any required updates.

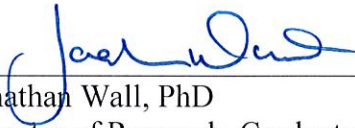
6. Distribution

An email notification of new/revised SOPs concerning site operations will be sent to GSM faculty, principal investigators, and study personnel conducting clinical trials within GSM. SOP's will be posted on the appropriate GSM Research Website page.

7. Training

At a minimum, GSM personnel involved with clinical research will read all relevant SOPs dependent on job function.

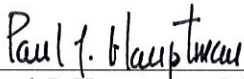
APPROVED:



Jonathan Wall, PhD
Director of Research, Graduate School of Medicine

9/23/2021

Date



Paul J. Hauptman, MD
Dean, Graduate School of Medicine

09/23/2021

Date