Ministry of Health

Republic of ……

Central/National Public Health Reference Laboratory

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Section: General

Procedure of creation, review and approval of standard Operating Procedures (SOP of SOPs)

SOP Number: GLB-S-101

Version: GLB-S-101.0

Date last Revised: Original

Review and Approval Signatures

Written By: _____Date: __/___/___
(Technical Staff)

Reviewed by: _____Date: ___/___/___
(Technical Staff)

Approved By_____ Date: ___/___/___
(Laboratory Director/Manager or Designee)

Effective Date: ___/___/___

Withdrawn By:_____ Date: ___/___/___

Introduction

1. Purpose/Applicability:

1.1. This SOP describes the preparation, implementation and maintenance of all SOPs in the **(Facility name)** laboratory

1.1.1. These standards are to ensure compliance with GCLP requirements as appropriate for all investigational trials conducted at this site.

1.1.2. This SOP also describes procedures for SOP training and documentation of training.

1.2. The SOP applies to the designated Quality Assurance unit personnel, Laboratory personnel and the laboratory director or designee.

1.3. Training on SOPs/policies will be conducted upon entry into any position within **(Facility name)** laboratories and annually for all personnel to which the SOP applies.

1.4. This SOP is also applicable to all temporary duty personnel, students and volunteers visiting and/or attached to the laboratory.

2. Responsibilities:

2.1. It is the responsibility of the laboratory director or designee to review and approve all SOPs.

2.2. It is the responsibility of all staff to follow the SOPs that impact the research and clinical activities they perform.

2.3. Technical staff is responsible for the preparation, review and updating all SOPs relative to their daily operations.

2.4. The lab director and/or designees are responsible for ensuring that all SOPs are updated annually to meet the standards outlined within this SOP.

2.5. Laboratory director/designee is responsible for reviewing, signing and dating all procedural standards and other policies.

2.6. Laboratory Director or designee is responsible for changes made on this and all other laboratory SOPs/policies

3. Materials and Equipment: NA

4. PROCEDURES:

4.1. **All laboratory SOPs/policies will meet the following standards**:

4.1.1. Serve as a tool for staff either as reference material or procedural standards.

4.1.2. Be easily understood by all personnel who may be responsible for the execution of the procedures.

4.1.3. Be easily understood for training of new personnel, to ensure that the new personnel are capable of following the instructions.

4.1.4. Be maintained within the applicable sections.

4.1.5. Have an assigned SOP number in accordance with numbering system applicable in the lab section

Example given SOP ***GLB-S-101.0***

GLB - general SOP i.e applicable in all sections of the laboratory
S – Procedure (replaced by F for forms related to that SOP)
101 – SOP number as per the facility numbering system
101.0 – version number; this is the original version of the SOP (version 1; 101.1)

4.1.6. All SOPs will have the following information included:

4.1.6.1. Purpose/Applicability - preparation, implementation and maintenance

4.1.6.2. Responsibility – describe reviewing and signing of SOP

4.1.6.3. Materials, Reagents and equipment

4.1.6.4. Procedure – methodology and process

4.1.6.5. Explanation of Terms and abbreviations
4.1.6.6. References
4.1.6.7. Appendices
4.1.6.8. Version table- Retired and Current SOP Titles, numbers and dates, number of pages
4.1.6.9. Review and updating table
4.1.6.10. Training Signature log

4.2. **Preparing new SOPs/Policies**:

4.2.1. If a new SOP is required:

4.2.1.1. A member of the technical staff for that section will prepare a draft SOP and submit it to the quality assurance unit personnel for review and formatting.

4.2.1.2. The draft will be reviewed by the laboratory Quality Assurance officer for accuracy and completeness and returned to the quality assurance personnel to finalize. Quality Assurance officer will produce a final SOP/policy document.

4.2.1.3. The SOP will be signed by the authore, Quality Assurance officer and approved by the laboratory Director/Manager/Incharge and entered into a control log that designates the SOP number, title, applicable section(s), version, effective date and annual review due date.

4.2.2. All laboratory or applicable section staff will be trained on the new SOP, and the training documented. Individual SOP signature sheets are dated, initialized and signed by all applicable laboratory personnel on initial training/ and/or reading of the SOP (appendix 7.1). (Initials or names can be used with the signature) will be signed for annual SOP training/ and/or reading on subsequent annual reviews and filed in the laboratory continuing education folder or attached to the SOP.

4.2.3. All locations of copies of the SOP will be documented within the SOP copy control log.

4.2.4. The SOPs will be maintained in the applicable laboratory section(s), copy by the QA office and with the director/Manager/Incharge. Electronic copies shall also be maintained.

4.3. **Updating existing SOPs/Policies**:

4.3.1. As SOPs/policies are annually reviewed, they shall meet the standards outlined in this SOP. All SOPs/policies will meet this standard no later than one year from this SOP's effective date plus or minus two months. Alternatively, the annual SOP/policy reviews can be staggered to enable the lab director/Manager/Incharge to efficiently review the entire laboratory SOPs/policies.

4.3.2. A review and updating log will be maintained with all original copies of the SOP, appendix 7.2.

4.3.3. Any changes made in SOPs must go through the same approval procedure as a new SOP.

4.3.4. Minor changes to an SOP can be documented in the SOP changes table (Appendix 7.2) then signed as required. This will be maintained in the SOP without changing the version until the next SOP annual review, when the new version is printed and approved as necessary.

4.3.5. When the author is not available during the SOP/Policy annual review and no revisions changes have been made to the document, another technologist/technician can sign and date for the author.

4.3.6. Where the author has left the facility and the document has to be revised, the original authors' name may be retained while the technologist/technician making the changes will have a row inserted to include his/her name, signature and date.

4.3.7. The laboratory director/Manager/Incharge is required to perform an annual review of the SOP/policy and it will be documented along with the SOP/policy. The documentation will include the reviewer's signature and date the review was conducted. The laboratory directors'

designee may perform the annual review of the SOPs/policies where possible and this shall to be authorized by the director.

4.4. **Criteria for changing SOPs/Policies version**

4.4.1. Change in testing methodology, equipment
4.4.2. Change in the content of an SOP that significantly influences the performance of a process or assay or safety
4.4.3. Change to fulfill regulatory or compliance requirements
4.4.4. Change of the SOP author
4.4.5. Change of SOP format, numbering system
4.4.6. Modification of laboratory charts/forms

4.5. **Retiring of discontinued SOPs/Policies**:

4.5.1. All previous versions of the SOP will be maintained for at **least two years** past the discontinuation of the procedure or the use of equipment or in accordance with the study protocol requirements.
4.5.2. The retired SOPs will be kept in a separate folder out from the laboratory working area

4.6. **Returning to use discontinued SOP/Policy or Test Method**:

4.6.1. Revise the document where necessary and have it approved
4.6.2. Produce as a new version to supersede the retired document
4.6.3. Conduct training and have staff read, understand and sign

4.7. **Test Method**

4.7.1. When a test/Method is to be put back into production, the following requirements must be met:
4.7.1.1. Proficiency testing or alternative assessment is performed before restarting patient testing
4.7.1.2. Method performance specifications verified, as applicable, before restarting patient testing
4.7.1.3. Competency assessed to staff is done prior to restarting patient testing

4.8. **SOP/Policy Training Requirements**

4.8.1. Initial training is required for all new personnel on all safety and general policies and applicable section SOPs for the individual's duty functions. The training documentation will be initialized and dated by the trainee and trainer as applicable.
4.8.2. A copy of the training documentation is maintained with all original copies of the SOP and also be filed in the laboratory continuing education training folder where necessary.
4.8.3. All policy/SOPs trainings must be undertaken prior to the employee starting to perform his/her duties. For current employees the training log will be completed upon the completion of required training/reading.
4.8.4. Employees must date and sign for having read and understood the policy/SOPs within one month before OR one month after the SOP approval and effective dates (appendix 7.1)
4.8.5. Training on general and applicable section SOPs will be conducted annually along with the annual review.
4.8.6. Copies of all specimen collection SOPs will be distributed to all areas outside laboratory that participate in specimen collection for testing in the **(facility Name)** laboratory.

5. Explanation of Terms and Abbreviations:

5.1. SOP- Standard Operating Procedure.
5.2. NA-Not applicable
5.3. GCLP-Good Clinical Laboratory Practice

5.1. CLIA- Clinical Laboratory Improvement Amendments

6. References:

Reference Number or Authors	Document Title
6.1.	CLIA '88 Homepage – http://www.cms.hhs.gov/clia/
6.2	

7. Forms and Appendices:

Form or Appendix Number	Title
7.1.	Laboratory staff training documentation
7.2.	SOP Copy Control and Updating Log

8. Version Table:

Version	Dated:	SOP No.:	No. Pages:
Original (0): Procedure of creation, review and approval of standard Operating Procedures (SOP of SOPs)		**GLB-S-104.0**	

Appendix 7.1: LABORATORY STAFF TRAINING DOCUMENTATION

TITLE OF CLASS:
INSTRUCTOR/TRAINER:
CLASS DATE:
Audience:

I acknowledge that I have been trained and read, understood and agree to follow this SOP.

No	PRINTED NAME	SIGNATURE	Date

Lab. Director/ Manager or Designee Approval _____ Date _____

Appendix 7.2: SOP Copy Control and Updating Log

DOCUMENT COPY CONTROL

DATE PRINTED: October 2011		NUMBER OF COPIES**: 2**	
SOP DISTRIBUTION			
COPY 1 OF 2 **LAB**	COPY 2 OF 2 **NAS**		

By Initialing and dating below I understand and approve of the changes to the attached SOP.

SOP CHANGES		Changes Approval Initials/Date	
Date/Initials	Nature of Change	QA	Approving Authority