INTEGRATED BIOREPOSITORY OF H3AFRICA UGANDA

MAKERERE UNIVERSITY
COLLEGE OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

TITLE: **DOCUMENT CONTROL**		**PAGE 1 of 7**
SOP #: **IBRH$_3$AU-SOP-BSP-015.4**	Effective Date: **01/09/2018**	Next Rev: **SEPT 2021**
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VALIDATION AND RETIREMENT

	NAME	DATE
Validated by:		
Retired by:		

ACKNOWLEDGEMENT OF READING AND UNDERSTANDING

I have received and understood the training on this SOP. If I have not understood the training I have asked the trainer to retrain me to ensure that I completely understand all the requirements.

	NAME	SIGNATURE	DATE
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1 SCOPE

This document applies to the preparation of a Standard Operating Procedure (SOP), and how forms, attachments and other documentation are established, modified and managed. Uniformity ensures standardization, clarity and readability of documents within the Immunology laboratory.

2 OBJECTIVE

This key objective of this standard document is to describe the "how" an SOP is written within the Integrated Biorepository of H3Africa Uganda (IBRH3AU).

It also illustrates the format design and guidelines for the preparation of all Laboratory SOPs including but not limited to the Quality Manual.

3 ABBREVIATION, DEFINITIONS AND TERMS

SOPs - Standard Operating Procedures

IBRH3AU - Integrated Biorepository of H3Africa Uganda

4 TASKS AND RESPONSIBILITIES

4.1 *Author:*

Follow this procedure to write SOPs.

Submit a draft for review and approval.

Cite reviewers and distribution list.

4.2 *Reviewer(s):*

Check and confirm that SOPs conform to standard format.

Provide feedback and (if) necessary corrections.

4.3 *Approval:*

The SOP requires approval from the Laboratory Director

5 SAFETY AND ENVIRONMENT

Not applicable

6 PROCEDURE DESCRIPTION:

6.1 This procedure –The Standard Operating Procedure of Standard Operating Procedures (SOP of SOPs) - provides a rule to format and structure all current and future SOPs for the IBRH3AU, to establish a consistent approach for the SOP writing process.

6.2 IBRH3AU documents shall be typed in a "Times New Romans, and font 12 with a 1.5 spacing between lines and 18 space between paragraphs"

6.3 Each main step shall be numbered and subsequent steps below which shall be indented with sub-step numbering example if x.o is the main step, then x.1 becomes its sub-step and x.1.1 becomes the subsequent sub-step etc.

6.4 All SOPs must contain the following:

6.4.1 Header/Footer: The standard format is a:

Header with the SOP's title, number, and version ID.

The Footer contains the page number.

6.4.2 Scope: The scope is to whom and what the document applies. Example: This document applies to SOPs writing.

6.4.3 Objective: The SOP aims to harmonize the procedures carried out.

Example: This SOP sets formatting standards.

6.4.4 Procedure: The SOP describes the steps to perform the procedure. Where necessary will refer to supplementary documentation (i.e. when there are a large number of steps).

6.4.5 Materials: The SOP describes the materials used.

6.4.6 Equipment: The SOP describes equipment, its function and operational steps.

6.4.7 Documentation: The SOP brings up all supplementary documents, and cross-references with other SOPs, as well as their location both electronically and hardcopy.

6.4.8 Safety: The SOP addresses all safety issues regarding the task. Example: The SOP describes any necessary steps to perform a safe work (i.e. wear a mask) as well as the location of the Materials Safety Data Sheets (MSDS).

6.4.9 Records: The SOP states where to annotate and keep records (electronic and hardcopy).

6.4.10 Responsibilities: The SOP assigns responsibility for the procedure. Name and dated signatures are mandatory for SOP author, reviewer, and approval.

6.4.11 Signatures: Authors, Reviewers, and Authorizing signatures should be attached at the front page of the document, with date of approval.

7 PROCESS

7.1 Designing an SOP

7.1.1 The need for a SOP in a specific procedure is identified.

7.1.2 The laboratory manager then shall provide a name to that SOP.

7.1.3 The Quality officer (QO) subsequently allocates a number to the SOP.

7.1.4 The SOP name with respective code is forwarded to the laboratory Manager or technical designee, who shall write or delegate to the respective staff to write the SOP as per the identified test or procedure.

7.1.5 When the author finalizes writing the SOP, the author gives the SOP to the laboratory Manager or technical designee who shall review the SOP and makes sure it conforms to the laboratory SOP writing format.

7.1.6 The QO then arranges a meeting to discuss the draft SOP with the rest of the laboratory.

8 REVIEWING

8.1.1 When the SOP is written, it's typed and whoever was delegated to write shall be asked to check for consistency, typographical and/or grammatical errors.

8.1.2 Review and Discuss the content of the SOP in a Quality meeting:

8.1.2.1 *To agree on the content*

8.1.2.2 *To clarify any obscurities*

8.1.2.3 *To guarantee that the whole work procedure is covered*

8.1.2.4 *To assure that the handling procedure is written in the correct order*

8.1.2.5 *To agree on the number of photocopies and where these photocopies should be placed (despite of the paper version in the quality archive)*

8.1.3 The author will adjust the SOP according to meetings discussion and agreements.

8.1.4 The authoring staff and QO or a member of the quality team shall review the SOP before finally passing for authorization by the laboratory manager.

9 APPROVAL AND IMPLEMENTATION

9.1.1 Set a date for discussing the final approved SOP in a biweekly biorepository meeting.

9.1.2 Put the new / revised SOP on the agenda.

9.1.3 Agree on that everybody has read the SOP.

9.1.4 Discuss the content of the SOP to ensure that all the staff have read and understood the SOP

9.1.5 Explain that the SOP is binding and that everybody needs to work according to the SOP to gain good quality performance.

9.1.6 The lab manager should stress that it is compulsory to work according the agreed procedure.

9.1.7 The QO gives the final version of the SOP an x.0 number.

9.1.8 Agree on a date when the SOPs will be approved, so that the effective date can be filled in and the SOP can be printed. The effective date in the header of the SOP should be the same date as the date of signing by the authorizer.

9.1.9 The author and reviewers sign the final version on the front page.

9.1.10 Approval is done by the authorized person, most of the time the lab manager.

9.1.11 The authorizer approves the SOP, by dating and signing the first page, and putting initials on every following page to indicate that this is the original approved version of the SOP.

10 CHANGES

10.1.1 As soon as any modifications on the current version is needed, the QO changes the current valid version to x.1, distributes it to the author, so that the SOP can be revised.

10.1.2 The SOP will be discussed in a meeting, so that any other alterations can be included when revising the SOP and to emphasize the need of the change and to update all the staff of the modification in the work procedure.

10.1.3 Requested modifications need to be approved by the authorizer, before they can be documented in a new version of the SOP. When agreed on and approved by authorizer, the SOP can be changed by the author.

10.1.4 After discussing the SOP in a meeting, the author applies the agreed comment in the SOP, which is now version number 1.2.

10.1.5 If a next meeting/discussion is needed, more modifications will be made, which lead to version 1.3 etc.

10.1.6 The QO gives the final version of the SOP an x.0 number.

10.1.7 Approval is done by the authorized person, most of the time the PI or any other delegated person. Agree on a date when the SOPs will be approved, so that the effective date can be filled in and the SOP can be printed.

10.1.8 The authorizer approves the SOP, by dating and signing the first page, and putting initials on every following page to indicate that this is the original approved version of the SOP.

Note: Until the new version of the SOP is implemented, alterations in SOPs should be written on the front page under "Approved modifications", signed and dated for approval by the authorized person; when a staff member did not attend the meeting, this person will be updated by the alteration in the front page of the SOP.7

11 REVISING SOPS

11.1.1 Every year a SOP needs to be reviewed by the reviewers. The QO changes the current valid version to x.1, distributes it to the author and reviewers, so that the SOP can be reviewed.

11.1.2 Agree on a date for a Q-meeting to review the SOP.

11.1.3 Discuss the suggestions for modification in a quality meeting with the author, reviewers and authorizer.

11.1.4 See for changes "7.4 Changes"

12 DOCUMENT CONTROL

12.1.1 Place the signed original SOP in the Master SOP file.

12.1.2 Place a photocopy of the original copy with a signature of the authorizer (authenticating the copy) on the front page in the bench SOP file. The photocopied initials on every page indicate that the copy is photocopy of the original document. ONLY the original SOP may be photocopied.

12.1.3 Update the document control log

13 REVISED VERSIONS:

1.1.1. When a new version is valid, the old version of an SOP cannot be valid. Only one version of an SOP can be valid. As soon as the new version is valid, it needs to replace the old version at the workstations: the old versions will be removed and immediately made unavailable to prevent different versions at the workstation. The old version the SOP in the quality archive will NOT be destroyed! On the front page of the retired SOP the date of retirement will be written and the SOP will be archived for an agreed period of time.

13.1.1 Paper archive:

13.1.1.1 *The paper archive contains:*

All original valid copies signed by the reviewers and authorized person (blue or black pen).

Previous versions, also the original copies, indicating when this version was retired.

Accessibility: Archived SOPs should be made unavailable

A copy of Products' leaflets available in commercial *in-vitro* diagnostic products.

Note: Another copy of the leaflet will be incorporated into the archive only if the manufacturer includes new changes in the leaflet.

13.2 Electronic archive

13.2.1 The final valid versions need to be read-only documents (PDF), to prevent unauthorized modifications.

13.2.2 After every modification a backup will be made.

13.2.3 The previous versions in the electronic archive system will NOT be destroyed! On the front page of the retired SOP the date of retirement will be written and the SOP will be archived for an agreed period of time.

13.2.4 When a version is retired, the QO types the date of retirement on the front page (same as paper copy).

13.2.5 The QO, lab manager and lab director will have access to the retired SOPs which will also be password protected.

13.2.5.1.1 The electronic archive contains:

13.2.5.1.1.1 All draft versions until they are valid versions
13.2.5.1.1.2 All valid copies, read only.
13.2.5.1.1.3 Previous versions, indicating when this version was withdrawn.

14 DOCUMENT CONTROL LOG

14.1.1 The copies should be listed in a document control log, to track all the documents and replace them when needed.

14.1.2 Three sheets are used:

14.1.2.1 *SOP overview contains a table with:*

14.1.2.1.1 SOP code,

14.1.2.1.2 title,

14.1.2.1.3 current version,

14.1.2.1.4 effective date,

14.1.2.1.5 review date,

14.1.2.1.6 distributed copies,

14.1.2.1.7 author,

14.1.2.1.8 reviewer,

14.1.2.1.9 and authorization,

14.1.2.1.10 and previous version,

14.1.2.1.11 valid till,

14.1.2.1.12 Copies removed from.

14.1.2.1.13 This file is used, to have a complete overview of new SOPs. In a meeting a deadline is agreed as well as the deadline for the review. Once an SOP has a code, it will stick to that code!

14.1.2.2 Code SOP: Unique number of SOP,

14.1.2.3 Review date: the date the SOP should be reviewed (periodically)

14.1.2.4 Distributed copies: always one in the archive (locked) and at least one at the workstation. The copy at the workstation may be a photocopy of the original

one, but it needs to be signed on the front page (blue pen). In the document log the place of all the copies should be mentioned.

14.1.2.5 Author and reviewers should be appointed by the authorizer of the SOP

14.1.2.6 Reviewer: this should be the Quality officer (for checking with the ISO 15189 standard) and one of the authorized technical staff who does the analysis frequently.

14.1.2.7 Authorization is done by the PI

14.1.2.8 Requested changes contain a table with: SOP code, SOP version, date requested, approved by, date approved, who will change, deadline change implemented, date new version implemented.

14.1.2.9 Nr of requested change (record number)

14.1.2.10 SOP code of the SOP in which a change should be made

14.1.2.11 Date when the change was requested

14.1.2.12 The version of the SOP in which the change should be made

14.1.2.13 Authorized person who approved the requested change

14.1.2.14 Date when the change was approved by the authorized person

14.1.2.15 Person who is going to change the SOP

14.1.2.16 Deadline when the change should be implemented

14.1.2.17 Date of the implementation of the new SOP

14.1.2.18 Author's overview of new SOPs contains a table with: SOP code, title of SOP, name of the author. This file is used to have a complete overview of new SOPs. The author needs to be appointed by the authorized person.

14.1.2.19 Unique number for SOP

14.1.2.20 Title of SOP, in this case an analysis SOP

14.1.2.21 The author

14.1.2.22 When should the first draft be ready so that the SOP can be discussed during a meeting

14.1.2.23 When should the final draft be ready and been reviewed

15 FORMAT:

15.1.1 The SOP should be divided in sections (where appropriate):

15.1.1.1 *Header/Footer*

15.1.1.2 *Scope*

15.1.1.3 *Objective*

15.1.1.4 *Materials*

15.1.1.5 *Equipment*

15.1.1.6 *Documentation*

15.1.1.7 *Safety if applicable*

15.1.1.8 *Records-records about the procedure*

15.1.1.9 *Description(Procedure)*

15.1.1.10 *Related forms/documents/Appendices*

15.1.1.11 *References*

15.2 Document formatting:

15.2.1 Header/Footer

15.2.2 Maintain style and consistency across documents to assist in their readability.

15.2.3 State scope and objective at the beginning.

15.2.4 Give a descriptive title. Provide a tentative ID.

15.2.5 Illustrate the procedure by dividing it in small steps, described in one sentence.

15.2.6 Emphasize topics where mistakes are more likely to occur.

16 REVISION HISTORY

Revision No	Effective Date	Description of Changes Made from Preceding Revision	Approved by/ Date

ANNEX 1: DOCUMENTATION OF SUGGESTED CHANGES TO THIS SOP

CLAUSE	SUGGESTION	BY	DATE