Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat Intestinal Dysbiosis in Acutely Ill Severely Malnourished Children

Study Specific Procedure	SSP No:DM02 Version No: 1.0 Supersedes: None Effective Date: 21st October 2021

Title: Electronic Filing			
	NAME	SIGNATURE	DATE
PREPARER	Narshion Matai Ngao		29th September 2021
Q.A. AUTHORITY	Aisha Bwika		16th October 2021
APPROVING AUTHORITY	Robert Bandsma		20th October2021

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1.0 PURPOSE / INTRODUCTION:

The following describes the protocol by which electronic documents are to be saved and stored at Co-ordination centre in Nairobi, the University of Washington in Seattle and Hospital for Sick kids in Toronto. Files will be shared between the two sites using a program called OneDrive. All users will need to register for an individual Dropbox account in order to obtain access to the files. This will allow for restricted access where necessary.

2.0 SCOPE / RESPONSIBILITY:

This procedure is applicable to all CHAIN staff both in the coordination teams (Nairobi, Seattle, Toronto) as well as those at sites. This is a File Management SOP. All members, including temporary staff, will be appropriately trained before executing this procedure independently.

Responsibilities

Study PIs/ Co-ordination team: Responsible for adhering to the naming procedure detailed below.

Gate keeper: Responsible for the implementation of the electronic filing system. All final versions of a file will be sent to the gate keeper. The gate keeper will ensure the document has been named appropriately. If not, he/she will return it to the author for appropriate naming based on guidelines below. The gate keeper will then update the index of 'Current Forms/Files' (discussed below) and sync using the OneDrive program. They will also upload a latest version to the website/TGHN site and announce its immediate availability via email.

A member of co-ordination team from data management will be appointed as Gate keeper.

3.0 DEFINITIONS /ABBREVIATIONS:

 3.1 File – An electronic document that can be shared.

4.0 MATERIALS

5.0 METHODOLOGY:

 5.1 FILE STORAGE AND STRUCTURE

   5.1.1   All files will be stored into a standardized file directory, organized by functional group on OneDrive.

   5.1.2   OneDrive is used to share documents between the study leadership, coordination and site teams. There are several main folders on the Dropbox for sharing documents between these teams: -

     5.1.2.1 Amendments – contains protocol submissions and amendments

     5.1.2.2 Consent Forms – Contains Informed Consent Forms

5.1.2.3 CRFs

5.1.2.4 CVs

5.1.2.5 Database

5.1.2.6 Designs

5.1.2.7 DSMB

5.1.2.8 Ethical Boards

5.1.2.9 Ethics Certificates and GCP

5.1.2.10   Organization

5.1.2.11   Pharmacy Board Requirements

5.1.2.12   Regulatory Bodies

5.1.2.13   SAP

5.1.2.14   Sites

5.1.2.15   SOPs

5.1.2.16   Supporting literature

5.1.2.17   Training

5.1.2.18   TSC

5.2 File Naming

5.2.1   File names will all follow a standard format. All files names will contain these elements separated by underscores (_) or hyphens (-):

5.2.1.1 Study initials – no more than 8 characters that will be consistent throughout the study Examples: PB-SAM

5.2.1.2 Document type/title Example: Enrollment CRF, Follow-up CRF, Stool collection form

5.2.1.3 Version Number

o   This will allow easier identification of most recent versions.   Version number format is "v1.0".

o   Therefore, an example for the study enrollment form is named as:

o   "PB-SAM_Enrolment_v1.65".

5.2.2   File names will be indicated on the bottom left of the document. Version number will be duplicated on the bottom right of the document.

5.3 Consent Forms:

5.3.1   A word version will reflect what was submitted for approval. This version will not be printed or edited without the PIs approval. Once approved, consent forms will be scanned into PDF format and saved with an additional file extension "_stamped" at the end of the file name. This version will be available to study staff to print. This will help prevent printing incorrect versions.

5.4   INDEXING

5.4.1   **ALL FILES**

- Each study folder contains an 'Index' subfolder. As listed above in the personnel section, the gate keeper will be responsible to keep all indexes up to date. As current versions of a file become available, these will be reflected in an index document for the study.

   Current example:

Form Name	Version date	Comments

- In the future, even if similar forms are used in separate studies, they will have individual names to reduce confusion.

5.5 IRB RELATED FILES

- For tracking and indexing of the Institutional Review Board (IRB), a spreadsheet will be used to track approvals, modifications, and amendments of the IRB. This file will be stored in the 'Index' sub-folder and will be called, "studyabbreviation_IRB_vdate.xls"
   - An example of headers in this file is listed below

   "Study IRB Tracking Document"

Study	Institution/ Department	Document	Description	Submission Date	Disposition Date	Disposition	Notes	Renewal Deadline

6.0 APPENDICES:
None
7.0 REFERENCES:
None
8.0 DOCUMENT CHANGE HISTORY

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Version Table:

Version 1.0: Title: **Electronic Filing**	Dated: **21st October 2021**	SSP No.: **DM02**	No. Pages: **6**
Version 2.0: Title:	Dated:	SSP No.:	No. Pages:
Version 3.0: Title:	Dated:	SSP No.:	No. Pages:
This document is effective from the date of training/last approval signature and will be reviewed in two years.			

SSP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW AND CHANGES MADE

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SSP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfillment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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