SOP title	CHAIN Analysis Workflow SOP
Version	1.0
Date issued	02-06-2021
Next Review	02-06-2022

1. Purpose

The CHAIN Network aims to make maximum use of its data to benefit child health and to support training and career progression among investigators. Because the CHAIN dataset is very broad and international there are many opportunities for analysis and there is a need to ensure harmonisation between analyses and clarity over which people and groups are answering which questions, avoiding overlap.

2. Scope

This SOP describes the procedure for the approval of new analysis activities within the CHAIN Network. Therefore, it applies to all concepts, proposals and studies that will utilize CHAIN data and other resources such as data management and statistical support.

3. Abbreviations/Definitions

- CHAIN – Childhood Acute Illness and Nutrition Network
- SAP – Statistical Analysis Plan

4. Procedure

1. The process starts at the concept stage. Concepts need not include the very final questions to be answered as these often need development but should describe a health problem and the broad question that the analysis aims to inform. It is important to start with a health problem and question then looking to see what CHAIN data can contribute. An aim at this stage is to help identify appropriate support for early career to develop the precise questions and a statistical analysis plan (SAP).
2. Formation of Proposal Interest Group - Concepts will be reviewed to ensure the broad questions are clear, whether technical support is needed, and to link investigators with existing groups for concepts that relate to existing CHAIN sub-studies and analyses.
3. The aim of the SAP is to describe the data required and detailed methods to be used for answering the questions. This step is important in ensuring quality in CHAIN analyses and ensuring that investigators have the resources and support that they need. SAPs also help avoid 'mission creep' and unforeseen overlap with over analyses. In creating the SAP, investigators may seek help from the CHAIN data team and statisticians for advice on things like how to accommodate the fact that enrolment was stratified or other issues. For many domains, like overall illness severity or general household mortality risks, classification and

scoring has already been done and these existing scores should be used where possible. However, some questions may involve examining data domains in more depth.

4. During the analysis stage, providing regular updates will help the coordination teams ensure analyses are on track and whether additional help is needed.
5. Updates to CHAIN co-PIs – This will ensure scientific guidance and help is provided as well as help keep the analysis on track and whether additional help is needed.
6. Manuscript and Publication Updates – This stage will inform members of co-ordination teams and CHAIN co-PIs on the results of the analysis and final details for publication.

5. Responsibility

The following is the responsibility matrix for this procedure.

Role	Responsibility
Investigator	Anyone that has come up with a concept note or proposal that needs to go through the workflow.
Co-ordination Data Manager	A member of the CHAIN Co-ordination data team that will be responsible for logging and distribution of the concept to the CHAIN Co-ordination team.
Co-ordination Administrator	A member of the co-ordination team that will be responsible for:- • Allocating a time slot for the investigator to discuss their proposal in the analysis co-ordination meeting • Circulate proposal to CHAIN co-PIs and allocating time for the investigator to make presentations and updates to the team. • Take note of and circulate action points to those assigned during meetings/update sessions.
CHAIN PIs	Attend co-ordination meetings and the all CHAIN Co-PIs meetings and they are mandated to: - • Give guidance and allocate support to the investigator • Give votes for approval/disapproval of the concepts/proposals/updates of analysis. • Help shape the analysis in the right direction by providing input to the SAP.
Proposal Interest Group	This group will be formed for each proposal/concept and will constitute members of the CHAIN team and external collaborators that will have a part to play in the analysis.

6. References

7. Document history

Version 1	Author	Approved by	Dated	SOP No:
1.0	Narshion Ngao	James Berkley	02-06-2021	

8. Site training record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**
1.01	KDT	Example row	1st Jan 2016	DM

9. SOP AWARENESS LOG

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

Number	Name	Signature	Date (dd/mmm/yyyy)
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10.Appendix A

Detailed Workflow Diagram