CURRICULUM: SMART4TB Early Stage Investigator Training and Mentorship Program

Phase 1: Core Training

Objectives:

1. Obtain certification in foundational clinical research areas including basic concepts of clinical research, development of a valid research question, and principles of good clinical practice in the research setting.
2. Demonstrate an understanding of the responsibilities of a Principal Investigator in a research study.
3. Demonstrate ability to do a literature search and to write a good research question.
4. Demonstrate an understanding of the role of community engagement in research.
5. Demonstrate an understanding of the qualities of a good research proposal.

Phase 1 Goal: Submit a research proposal concept sheet.

Materials:

Global Health Network eCourses:

Introduction to Clinical Research:
https://globalhealthtrainingcentre.tghn.org/introduction-clinical-research/

The Research Question
https://globalhealthtrainingcentre.tghn.org/research-question/

Good Clinical Practice (GCP)
(Prior certification e.g., *CITI (Collaborative Institutional Training Initiative) GCP* acceptable)
https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/

SMART4TB TA6, webinar series on the following topics:

Overview of the SMART4TB Research Agenda

Overview of the SMART4TB Training and Mentorship Program

Introduction to Responsibilities of a Principal Investigator

How to do a Good Literature Search

Developing a Research Question

CURRICULUM: SMART4TB Early Stage Investigator Training and Mentorship Program

Community Engagement as a Good Participatory Practice

Developing a Research Proposal

Activities:

1. **Assessment:** complete for each webinar.
2. **Develop and submit a research proposal concept sheet to the Training Mentorship Committee** – required for Phase 2 application.

Timeline: 3-6 months

Phase 2: Research Proposal Development

Objectives:

1. Demonstrate an understanding of the key components of a research proposal.
2. Design a research study, including data analysis methodology.
3. Incorporate community engagement in your research study.
4. Develop a budget, regulatory plan, and data management strategy for your research design.

Phase 2 Goal: Submit a research proposal

Materials:

SMART4TB TA6, webinar series on the following topics:

Responsibilities of a Principal Investigator

Study design

Data Analysis in Research: Types & Methods

Community Engagement - Role of Community Advisory Board (CAB)

Data Management

Biostatistics

IRB (Institutional Review Board) - Approvals and other regulatory Issues

Creating a Budget

CURRICULUM: SMART4TB Early Stage Investigator Training and Mentorship Program

Mentee-Mentorship Training

AS NEEDED DEVELOPMENT – SMART4TB TA6, courses/webinars added based on Early Stage Investigator (ESI) need. ESI will also be able to request technical consultations from consortium experts (e.g., biostatistical support, research ethics, community engagement, laboratory issues, etc.) specific to their proposal to support the development of their proposal, as needed.

Activities:

1. **Assessment:** for each webinar
2. **Attend** intensive writing workshop with mentors and consortium faculty.
3. **Participate** in Monthly TB Journal Club.
4. **Participate** in monthly proposal progress meetings with mentors.
5. **Present** quarterly to their ESI cohort colleagues and their mentors.
6. **Develop, finalize, and submit a research proposal** – – approval and funding of their final research proposal is required for Phase 3 application.
7. **Request** Consultations as needed, related to your research proposal

Timeline: 6 – 9 months

Phase 3: Study Implementation

Objectives:

1. Demonstrate skills of Good Clinical Practice (gained from Phase 1 coursework).
2. Perform research study monitoring and data collection.
3. Adhere to and apply IRB approved practices.
4. Demonstrate community engagement in the implementation phase of their research study.
5. Design a community engagement and results sharing plan.

Phase 3 Goal: Implement your research study

Materials:

SMART4TB TA6, webinar series on the following topics:

Data Collection Form Development

Questionnaire Development

Study Monitoring

CURRICULUM: SMART4TB Early Stage Investigator Training and Mentorship Program

AS NEEDED DEVELOPMENT – SMART4TB TA6, courses/webinars added based on ESI need. ESI will also be able to request technical consultations from consortium experts (e.g., data management, protocol/CRF/SOP development, research ethics, community engagement, study monitoring, etc.) specific to their research study to optimize the implementation of their study as needed.

Activities:

1. **Implement your research study**
2. **Participate** in Monthly study implementation progress updates with mentors.
3. **Participate** in Quarterly study implementation progress updates with your ESI cohort and their mentors.
3. **Participate** in Monthly TB Journal Club.
4. **Request** Consultations, as needed, related to your research study.

Timeline: 12-15 months (Dependent on the study design)

Phase 4: Analysis, Publication, and Results Sharing

Objectives:

1. Perform data analysis of your research study.
2. Draft at least one first-authored scientific paper based on your research study results.
3. Implement a community engagement and results sharing plan.

Phase 4 Goal: Publish your research study and share results of your study with the NTP and other local programmatic and community SMART4TB stakeholders.

Materials:

SMART4TB TA6, webinar and writing workshop series on the following topics:

Data Analyses and Data Visualization

Community Engagement and Results Sharing

How to Write and Publish a Research Study

AS NEEDED DEVELOPMENT – SMART4TB TA6, courses/webinars added based on ESI need

Activities:

1. **Submit and have accepted a first or last authored paper by a PubMed journal.**

2. **Monthly virtual progress updates and presentations** on analysis/publication drafts with mentors
3. **Quarterly progress updates and presentations** on analysis/publication drafts with ESI cohort
4. **Participate** in Monthly TB Journal Club
5. **Request** Consultations, as needed, related to analysis and publication of your research study.

Timeline: 6-12 months