

East Africa

leDEE

**INTERNATIONAL EPIDEMIOLOGY
DATABASES TO EVALUATE AIDS**



East Africa leDEA

**Concept Proposal Development, Submission and Review Process
Standard Operating Procedure (SOP)**

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PURPOSE

This document provides the requirements for the development, submission, review, and approval of concept proposals.

SCOPE

The procedures outlined in this SOP apply to East Africa leDEA concept proposals. Procedures for authorship, publication, and presentation are outlined in a separate SOP.

DEFINITIONS

Concept Proposal: Description of a research study or an analysis (e.g. data visualization) utilizing the East Africa leDEA data and/or research infrastructure. This includes studies that use data from the East Africa leDEA Regional Database and/or the multi-regional leDEA site surveys that include East Africa leDEA sites.

- Retrospective concept proposals: Those studies utilizing existing patient-level and site-level data that do not require collecting new data except for minimal site-level information.
- Prospective concept proposals: Those studies that require collecting primary data at the patient-level or extensive site-level data collection.

Cores: Groups of East Africa leDEA investigators and/or staff with similar duties, interests, and responsibilities.

The Consortium is organized into three Cores:

The **EA-leDEA Administrative Core** consists of the Regional PIs, the IU Senior (Sr.) Data Manager, -U.S. Assistant Director of EA-leDEA, Program Manager, Contract and Grants Specialist, and Country Coordinators (Kenya, Tanzania, and Uganda). The core is responsible for overall grant administration, concept coordination, conference calls, meeting management (regional and multiregional), budgets, regulatory approvals, communication, liaising with external entities (e.g., government representatives, NIH, normative bodies), website management (www.iEDEA-ea.org), training and Hub administration.

The **EA-leDEA Biostatistics and Analysis Core** includes statisticians and modelers in North America and East Africa. Core members participate in study design, assist in data request development, and review analysis plans. The Core is distributed between Indiana University in the United States, the AMPATH Data Center at Moi University in Eldoret, Kenya, and the Infectious Diseases Institute (IDI) in Kampala, Uganda. This core includes **doctoral-level faculty and senior analysts** at the three institutions, **MS-level biostatisticians, and FIMP Trainees**.

The **EA-leDEA Data Science Core** includes data managers and IT experts who curate, process, harmonize, and distribute data for EA leDEA. Core staff are located in the EA-leDEA Regional Data Centers (RDCs) at IU (Indianapolis, USA), Moi (Eldoret, Kenya) and IDI (Kampala, Uganda). Each leDEA site is responsible for maintaining and

transferring their clinical data on an annual basis. The Core is responsible for building and maintaining the EA-IeDEA data infrastructure, including the **Clinic Cohort Database**, Multi-regional site assessment surveys, Sentinel Research Network (SRN) Cohort, and other prospective study databases.

Investigators:

Regional Multiple Principal Investigators (MPIs): The Investigators responsible to NIH for the performance of East Africa IeDEA (Drs. Semeere, Yiannoutsos, and Wools-Kaloustian)

Site Principal Investigator (PI): Investigator in charge of one of the Programs/Sites within EA-IeDEA (e.g. AMPATH, MUST, IDI, Kisesa, etc).

Project Lead or Project PI: Individual(s) who leads a project within EA-IeDEA (AYANI, MANGO, Telederm, etc.)

Project Team: The investigators and staff that support a project within EA-IeDEA (AYANI, MANGO, Telederm, etc.)

Concept Leader(s): Individual(s) who develop(s) and lead(s) a concept

Concept Team/Writing Group: individuals working on designated concepts.

Junior Investigator/ Early-Stage Investigator (ESI): Individuals who are in an active training/educational program or who completed their terminal research degree or post-graduate clinical training, whichever date is later, within the past 10 years.

Global IeDEA: Includes the 7 regions for IeDEA, West Africa, East Africa, Central Africa, Southern Africa, NA-ACCORD, CCASAnet, and Asia Pacific. For more information regarding Global IeDEA please go the website [<https://www.iedea.org/>]. All multiregional concepts, manuscripts and abstracts must adhere to the processes outlined in the Global IeDEA SOPs and will need to be approved by the relevant Global IeDEA working groups and Executive committee.

PROCEDURES

Concept Proposal Development and Review Steps

A diagram of the concept development process is outlined in **Appendix II**. Concepts that involve the collaboration of more than two of IeDEA's seven regions (i.e., three or more regions) should utilize the multiregional process referred to above.

- A.** Concepts should be developed using the current version of the EA IeDEA concept proposal template, which can be found by clicking [here](#). Investigators will need to work with the Data Science Core during the concept drafting stage to understand and ensure variable availability within each cohort.
- B.** Investigators will contact members of the Administrative Core to coordinate a meeting between the investigator and the Biostatistics and Analysis Core to develop

- a detailed plan for analysis. If an external analyst is used, a detailed plan for analyses should be embedded in concept.
- a. Concepts associated with specific project teams (e.g., AYANI, MANGO, SRN, Telederm) **should be reviewed by the project team with written (email) approval from the project team lead prior to submission to the Executive Committee (EC).**
 - b. Concept leads are responsible for:
 - the overall scientific robustness, completeness, and linguistic clarity of the proposal
 - reviewing the availability of patient-level variables to assess the feasibility of the research question (develop concise and answerable questions that are consistent with the research objectives of the East Africa leDEA consortium)
 - Identify concept team/writing group members.
 - Circulate to appropriate Project Team for comment.
- B. When ready for EC review, the concept should be uploaded to the EA leDEA Hub by clicking [here](#) using the *Create EC request* button. Additional information about the concept is requested via the Hub “survey” tool that will be used when soliciting subsequent feedback from the EC.
 - C. The EA-leDEA Administrative Core will screen the submission for completeness and clarity. The concept may be returned to the submitting investigator for interim revision(s).
 - D. Once cleared, the proposed concept will be distributed for EC review through the EA Hub, with supporting details provided via the Hub submission process. The EC will provide feedback, engage in discussion, and determine if the proposal is appropriate. **A targeted end date for review, comment, and voting will be set for approximately 10 business days after initial EC distribution.**
 - E. Site PIs will vote on their site’s participation via the leDEA-EA Hub within 10 business days of receipt and provide contact information for a writing team member from their site. Please consider nominating early-stage investigators for the writing team.
 - F. Concepts will require a response from the EC, no assumption of approval will be made.
 - G. If objections are noted, the concept proposal will be discussed at the next EC meeting and the concept lead will be asked to join to discuss the concerns.
 - H. Site PIs are expected to engage with the submitting investigators through the Hub regarding substantial site or individual concerns about the concept prevent approval.
 - I. If approved, the Hub will send automatic notifications to the lead concept investigator and the EA leDEA Senior Data Manager. The lead investigator will submit the final version of the approved concept to the Hub. The EA leDEA Senior Data Manager will assign a tracking number and move it to the Concept list where progress to conclusion or publication will be tracked.
 - J. If the EC determines that minor modifications are needed (e.g., refinement of objectives, clarification of analytical methods), the approval process may take longer than 10 working days .
 - K. Concepts requiring major modifications (substantial amended or revisions to reflect additions or changes in scientific aims or to how data will be used for that project, will require additional review , which will vary by concept (e.g., review by a project team, regional MPIs, or full EC) and will be determined by the and Administrative Core. Review deadlines will be adjusted, as appropriate.

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- L.** The EC has the discretion to shorten the concept review timeline for amended/revised concepts if changes are minor.
- M.** If plans for more than one manuscript develop from an approved concept, each subsequent manuscript will require a separate concept, which will need to go through each of the concept review steps outlined above *prior* to the distribution/publication of these secondary analyses.
- N.** If the concept proposal is deemed “not feasible” by the Administrative Core, then it will be abandoned at this point.

*For **Early-Stage Investigators**: If a senior investigator has not already been identified as a mentor for the project, the Administrative Core will assign mentors to the project that will assist the Early-Stage Investigator in completing the EA leDEA Concept Proposal Form.

Prioritization of Concepts

- Decisions about the priority of a concept will be made based on a combination of scientific merit, deadlines for presentation/submission, level of complexity for dataset development and additional resources needed for the planned analysis.

**APPENDIX I
EA-IeDEA Contacts**

EA – IeDEA Assistant Director: Adrian Norris, adrnorri@iu.edu
EA – IeDEA Regional Program Manager: Marion Achieng, machieng@idi.co.ug
EA – IeDEA Program Manager: Versie Barnes, barnesv@iu.edu
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MPI Signatures of Approval

X *Kara Wools-Kaloustian*

Kara Wools-Kaloustian

X *Constantin Yiannoutsos*

Constantin Yiannoutsos

X *Aggrey Semeere*

Aggrey Semeere

12th October 2024

Appendix II

CP: Concept Proposal EC: Executive Committee PI: Regional Principal Investigators
SOP: Standard Operating Procedures WG: Working Group

East Africa Concept Proposals

