

**East Africa IeDEA**

**Concept Proposal Development, Submission and Review Process**

**Standard Operating Procedure (SOP)**

**Version 2: October 9, 2020**

|  |
| --- |
| **East Africa IeDEA****Standard Operating Procedure** |
| **Title:** Concept Proposal Development, Submission and Review Process | **Effective:** 2020 |
| **Version:** 2 | **Last Reviewed:** Oct 2020 |

1. **PURPOSE**

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

1. **SCOPE**

The procedures outlined in this SOP apply to East Africa IeDEA and investigator-initiated proposal for new East Africa IeDEA research studies. Procedures for authorship, publication and presentation are outlined in a separate SOP.

1. **DEFINITIONS**

**Concept Proposal:** Description of research study or any form of analysis (e.g.data visualization) developed by investigators utilizing the East Africa IeDEA research and data infrastructure including studies which use data from the East Africa IeDEA Regional Database and/or the international IeDEA site surveys.

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

**Program Managers:**

* Yee Yee Kuhn ykuhn@iu.edu
	+ - * Marion Achieng machieng@idi.co.ug

**Cores:** Groups of IeDEA investigators and/or staff who have similar duties, interests and responsibilities.

The Consortium is being reorganized into three main Cores:

* *The Scientific Core:*

A group of investigators who drive the scientific agenda of the Consortium. The group will include all EC members plus interested investigators from IeDEA sites

* *The Data Analytics Core:*

This group includes all quantitative analysis personnel within this consortium including but not limited to analysts at Moi University, Infectious Disease Institute, Indiana University and UCSF. This group is tasked with the primary responsibility of undertaking all statistical design and analyses of IeDEA studies and the performance of methodological research.

* *The Data Science Core:*

This Core will include the data managers from the RDC (at Indianapolis, Eldoret, and Kampala) and the data managers working in San Francisco and Switzerland. As knowledge and experience grows, senior site data managers may also join this core. The Data Science Core shall perform all data-related functions as well as participating in the design of the data structures for each Concept Proposal.

1. **PROCEDURES**
	1. **Retrospective Concept Proposals**

These concept proposals utilize pre-existing patient-level and site-level data within the IeDEA consortium. Some additional site-level data collection can be undertaken if needed by specific proposals.

* + 1. **Development and Submission**

We anticipate that concepts will be submitted by junior investigators with little experience in concept development (Category A) and by senior investigators with extensive experience in concept development (Category B).

 **Category A: Concepts submitted by junior investigators**

* Investigator Procedures:
	+ On the East Africa IeDEA Concept Proposal form (Appendix 1) complete the following sections:
		- Requested By
		- E-mail Contact
		- Project Title
		- Writing Team Members (if those have been identified)
		- Background and Significance (brief)
		- Research Questions, Aims and Hypotheses- for this section try to clearly define your research question. The Scientific core mentor assigned to this project will assist you in developing aims and hypothesis
		- Targeted Cohort(patient population)
		- From which sites should cohort be drawn
		- The Scientific, Data and Analytics Core Mentors assigned to the project will assist you in completing the Variables Required and Research Method’s sections
	+ Send proposal form to the US and EA Program managers
* Project Coordinator Procedures:
	+ Disseminate Project to the Leaders of the Scientific, Data Science and Analytics Cores.
	+ Organize Conference calls as needed
* Leaders of Scientific, Data Science, and Analytics Cores Procedures:
	+ Assign mentors from each core for concept proposal
* Mentors from Scientific, Data Science, and Analytics Cores Procedures:
	+ Mentors will become formal members of the writing team for this concept proposal
	+ The primary mentor from the Scientific Core will in conjunction with the Project Coordinator organize a conference call with the assigned mentors and the investigator to discuss concept proposal, develop time lines, and assign responsibilities. If the concept proposal is deemed “not feasible” by the mentor panel then it will be dropped at this point.
* Mentors plus Investigator:
	+ Revision of the concept proposal will be undertaken as outlined during the conference call.
	+ It is anticipated that multiple revisions of the concept proposal will be needed prior to the mentor panel feeling comfortable with the product. Subsequent discussion about the proposal will be via e-mail or conference call whichever is deemed appropriate.
	+ Once the mentors have deemed the project proposal complete they will submit the final product to the Program Managers

**Category B: Concepts submitted by senior investigators**

* Investigator Procedures:
	+ Complete all sections of the East Africa Concept Proposal Form (Appendix 1) or the International Epidemiology Databases to Evaluate AIDS (IeDEA) Concept sheet for multi-regional projects (Appendix 2)
	+ Send the Concept Proposal form to the U.S. and East Africa Program Managers
* Program Manager Procedures:
	+ Disseminate Project to the leaders of the Scientific, Data Science and Data Analytics Cores.
* Leaders of Scientific, Data Science, and Analytics Cores:
	+ Assign reviewers from each core for concept proposal
* Reviewers from Scientific, Data Science, and Analytics Cores Procedures:
	+ Review for scientific merit, address completeness of patient and site level variables, and review appropriateness of the analysis plan
	+ Provide suggestions for revisions via e-mail
	+ Once the mentors have deemed the project proposal finalized, they notify the investigator.
* Investigator Procedures:
	+ Edit the concept proposal as recommended by the reviewers
	+ Once the Concept Proposal is finalized, send a copy to the U.S. and East Africa Program managers
		1. **Executive Committee Approval Process**
* Program Manager Procedures:
	+ Add project to the project tracking sheet
	+ Disseminate to the EC
		- Finalized concept sheet
		- Site Participation Form
	+ Receive EC comments and Site Participation Forms
	+ Forward EC comments to the investigator and cc Regional PIs
	+ Track site participation in the Concept Reviews sheet
* EC member procedures:
	+ Review concept proposals within 10 working days of dissemination and relay comments, approvals or objections to the Program Managers
	+ If no objections from the EC are received within 10 working days of dissemination, then the assumption of approval by the site will be made. If objections are noted then the concept sheet will be discussed at the next EC meeting and the investigator will be asked to join to discuss his/her concerns. A vote of the EC members present on the call will be taken as to whether or not to proceed with the concept sheet and a simple majority vote decide the issue.
	+ Complete and return the Site Participation Form to the Program Managers within 10 working days of receipt. If this is not possible (i.e. the data sharing committee will not be meeting at your site within the window period) then notify the program managers about when they can expect the completed Site Participation Form.
		1. **Prioritization of Concepts**
* The leaders of the three cores will meet on a regular basis to prioritize 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 particular analysis.
	1. **Prospective Concept Proposals**

At the core of these proposals is the primary collection of data. These proposals may be developed in response to IeDEA supplements or other funding opportunities. These proposals will not require the approval of the EC but the EC should be notified early in the process of proposal development.

* Investigator Procedures:
	+ Notify the EA IeDEA Regional PIs of the intention to submit a prospective proposal as soon as possible in the process
	+ Circulate the first draft specific aims to the Regional PIs and the EC as soon as they are available
	+ Involved the sites identified for participation in the project as early in the course of project development as possible
	+ Develop a budget with involvement from the Regional and Site PIs
		- * If being routed through IU, you must use the IU budget template: **DO NOT ALTER FORMULAS OR HARDWIRE NUMBERS UNLESS GIVEN PERMISSION BY THE IU BUSINESS MANAGER.**
	+ Ensure that the Regional PIs receive a final or near final draft of the proposal at least 2 **full working days** (based on East Standard Time in the U.S.) prior to the deadline for submission (this is to include the budget and budget justification).
	+ If being routed through IU, routing now requires 7 working days. There are no exceptions to this rule so **if the protocol is received less than 7 working days prior to the deadline (NIH, CDC etc) the PIs cannot guarantee that it will be approved and submitted to the funding organization.**
* East Africa IeDEA Regional PI procedures:
	+ Provide scientific input as requested
	+ Provide budgetary input
	+ If the project is received by deadlines outlined above the Regional PIs will ensure that the project is shepherded through IU Administration and is receive at the funding organization by the grant deadline.
1. **RESPONSIBILITIES**
	1. **Investigators**

The main responsibility of all IeDEA investigators is to develop research -questions that can be answered within the scope of East Africa IeDEA or the International IeDEA Consortium. Different tasks are required according to the type of research study proposed. These include:

Retrospective Studies:

* + Review the availability of patient-level variables to assess the feasibility of research question
	+ Review the availability of site-level variables collected through the international site survey to assess the feasibility of the research question (<https://rocket.app.vumc.org/index.php?doc_id=14602>).
	+ Develop concise and answerable questions that are consistent with the research objectives of the East Africa IeDEA consortium.
	+ Use the updated East Africa IeDEA Concept Proposal Form for any regional concepts and the International IeDEA concept proposal form for projects involving multi-regional collaborations
	+ Submit the proposal to the US and the East Africa Program managers

Prospective Studies:

As prospective studies involve the collection of new data, there is a pre-requisite that a funding stream must be identified. The following is required from IeDEA investigators in the development process of prospective studies:

* + Contact the IeDEA Regional PIs as soon as a prospective study is being considered.
	+ Circulate the initial draft of the Specific Aims to the EC as soon as it is available. This draft must include a plan addressing the costs of the collection of the new data (e.g., a grant or supplement application, etc.)
	+ Engage participating sites early in the protocol development process and, if a grant application is considered, the grant application process (e.g., for the receipt approval of the study, obtaining regulatory clearance, letters of support, etc.).
	+ Circulate the submitted protocol to the EC.

Grant applications:

To obtain funds for undertaking prospective studies or to perform research which is not supported with funds available to the Consortium, investigators will find it necessary to apply for supplemental funds. These funds will be procured through grant or supplement applications. The following are the responsibilities of all investigators submitting grant or supplement applications, for projects which, if approved, will use the East Africa IeDEA data and research infrastructure:

* + Investigators must obtain permission in writing from the Regional PIs and the sites that will be involved in the project, in order to use the East Africa IeDEA Consortium infrastructure.
	+ To do so, the investigators must submit the abstract of their grant application for approval to the EC.
	+ The Regional PIs and site PIs must review and approve the project. This may be done through e-mail or through a bespoke conference call.
	+ The timeline to finalize decisions will be grant and grant timeline dependent but the principal investigator should provide EA-IeDEA with sufficient time to assess the application (no less than 7 days).

* 1. **US and East Africa Program managers** (responsibilities may be delegated to country coordinators as needed) leaders
* Forward retrospective concept sheets to the leaders of the Scientific, Data Science and Analytics Cores
* Once Retrospective Concept has been fully developed, circulate the concept to the EC for comment and final approval.
* Circulate site participation forms.
* Track site participation responses in the Concept Reviews table.
	1. **Leaders of the Scientific Core**
* Assign a primary and secondary reviewer/mentor to each retrospective protocol
	1. **Leaders of the Data Science Core**
* Assign a data manager to each retrospective project
	1. **Leaders of the Data Analytics Core**
* Assign an analyst to each retrospective project
	1. **East Africa IeDEA EC**
* Review all retrospective and prospective concept proposals
* Review and approve all grant applications using East Africa IeDEA data and research infrastructure (involved sites only)
	1. **Site PIs**
* Complete the site participation form for each project within 10 working days of the date when the form was e-mailed.
* Review and approve all grant applications using East Africa IeDEA data and research infrastructure at the site