Principles and procedures for IeDEA multiregional research collaborations

Concepts, abstracts, reports, manuscripts, and authorship

Version 2 October 2019

Administrative core and communications
Aimee Freeman
Johns Hopkins University
NA-ACCORD
afreeman@jhu.edu

Concept sheet management and output tracking
Morna Cornell and Kathleen Kehoe, University of Cape Town
IeDEA Southern Africa
morna.cornell@uct.ac.za; leenikehoe@gmail.com

Global EC Chair
Annette Sohn
TREAT Asia/amfAR
IeDEA Asia-Pacific
annette.sohn@treatasia.org

These procedures outline the processes for proposing, engaging in, and disseminating results from research collaborations that involve the use of data from more than one IeDEA region. *When proposed data use falls outside of these stated parameters, investigators are requested to contact the administrative contacts on page 1 for further clarification.*

Table of Contents

A. Background

The **International Epidemiology Databases to Evaluate AIDS (IeDEA)** is a global cohort consortium established in 2006 to develop seven regional data centers to gather, harmonize, and analyze data to address clinical and programmatic research questions in HIV/AIDS treatment and care (see www.iedea.org). This initiative is funded through 10 institutes, centers, and programs of the US National Institutes of Health (NIH): the National Institute of Allergy and Infectious Diseases (NIAID), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the Fogarty International Center (FIC), and the National Library of Medicine (NLM). The seven participating IeDEA regions (**Appendix 1**) are in Asia-Pacific (IeDEA Asia-Pacific), the Caribbean, Central and South America (CCASAnet), North America (NA-ACCORD), and sub-Saharan Africa (Central Africa IeDEA; East Africa IeDEA; IeDEA Southern Africa, IeDEA West Africa). In collaboration with participating sites, each regional data center is responsible for the development of a regional research agenda, the establishment of mechanisms for receiving and combining data from sites, verifying the quality of these data, harmonizing definitions of variables captured, as well as for the implementation of methods for analyzing cohort data and training on data collection, processing and cleaning.

Multiregional research activities are an integral part of IeDEA. These include the identification of research questions to be addressed with combined data sets from multiple regions and other potential external research collaborators, the definition of key information to be obtained across regions, the development of protocols for hypothesis testing, data collection, coding, merging, harmonization, and data analyses. Multiregional research is primarily conducted through the development, execution, and completion of multiregional research concepts.

B. Roles and Responsibilities Within IeDEA Global for Managing Multiregional Research Activities

Coordination and improvement of concept management standards is guided by the **Concept Sheet Management and Output Tracking team** at the University of Cape Town (Leads: morna.cornell@uct.ac.za; leenikehoe@gmail.com), the Data Harmonization Working Group (co-Chairs: Beverly Musick, bsmusick@iu.edu; Stephany Duda, stephany.duda@vanderbilt.edu), the Harmonist project (Lead: stephany.duda@vanderbilt.edu), and the EC Administrative Core team (Lead: Aimee Freeman, afreeman@jhu.edu), in collaboration with the below groups (**Figure 1**).

B.1 Regional data centers and sites

The IeDEA regional data centers (RDCs) are responsible for coordinating their region's participation in multiregional research collaborations through concept sheets or special projects (e.g., supplemental research). Proposals for multiregional research in the form of analysis concept sheets or other documents are discussed in the context of relevant working groups, when appropriate, and formally submitted to the IeDEA Executive Committee (EC; see Section C.2) for consideration. Approval is at the EC level. The sites, according to regional procedures, will make their own decisions regarding participation in a given concept.

Once a concept sheet or other research proposal is approved by the IeDEA EC and regional investigators, the RDCs' responsibilities include, but are not limited to, the following:

- Confirming which site(s) within their region will contribute data to individual research activities;
- Ensuring that sites contributing data to the analysis/study have complied with associated regulatory and ethics requirements of their institution(s) and the NIH, and locally maintaining copies of regulatory approval documents on file;
- Circulating scientific products (e.g., abstracts, presentations, manuscripts) to their affiliated and data-contributing sites, according to regional policies and practices, for the purposes of review and approval.
- Supplying the requested data elements, associated reviews, and approvals in a timely manner.

B.2 IeDEA Executive Committee

The IeDEA EC is composed of the Principal Investigators (PI) of the seven IeDEA RDCs and representatives of the NIH funding institutes and centers (ICs). The EC oversees the multiregional agenda of the consortium, including multiregional projects and administrative coordination between both internal and external partners/collaborators. In addition to coordination, the EC has the responsibility to:

- Review and approve multiregional concepts and other proposals, and associated scientific products;
- Track progress of multiregional research activities;
- Moderate disagreements related to multiregional research activities between investigators

The EC elects a Chair who serves in this capacity for a minimum of two years, who is supported by a core team from multiple regions (e.g., administration and communications at NA-ACCORD, concept and website management at IeDEA Southern Africa, investigator meetings at East Africa IeDEA). The EC meets by conference call on a monthly basis, and at an annual in-person meeting. Meetings are coordinated by the Chair with support from the core team and NIH representatives.

B.3 IeDEA Working Groups

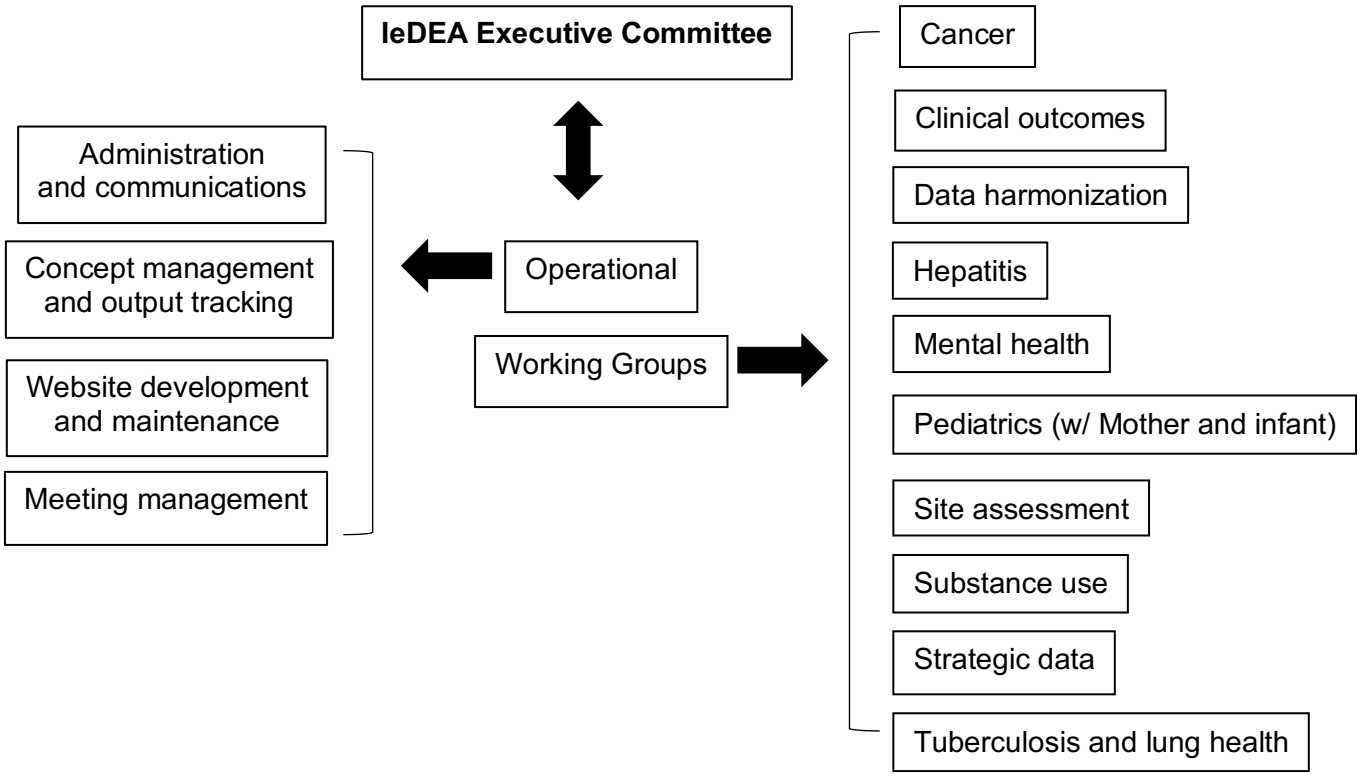
There are multiple core Working Groups within the IeDEA consortium. They include:

- Cancer
- Clinical Outcomes (sub-group: Renal)
- Data Harmonization
- Hepatitis
- Mental Health
- Pediatrics (sub-group: Mother and Infant)
- Site Assessment
- Substance Use
- Strategic Data
- Tuberculosis and Lung Health

Each Working Group is chaired by IeDEA investigators who coordinate regular Working Group conference calls, annual in-person meetings, and develop IeDEA's scientific agenda around these topic areas. Multiregional research concepts may be generated from within the Working Groups, or the EC or Working Group Chairs may ask one or more Working Groups to review a

concept or scientific product of an analysis that includes their focus population (e.g., children, adolescents) or addresses their thematic area of interest (e.g., cancers). The Working Group review is intended to help assess feasibility and provide feedback for optimal design and implementation of the analysis (see Section C.2). Additional ad-hoc Working Groups may be formed on a temporary basis for specific projects (e.g., Sentinel Research Network).

Figure 1. IeDEA organizational chart



C. Management of multiregional research projects

When proposed data use and research activities fall outside of the below parameters, investigators are requested to contact the administrative contacts on page 1 for further clarification.

C.1 Management principles

A. Ownership of the regional cohort data remains with the sites, as represented by the RDCs, led by the regional Principal Investigators (PIs).
B. Multiregional research projects must be reviewed and approved by the IeDEA EC in advance of any request for data.
    a. Additional *Working Group* reviews and approvals may be required, as appropriate (see below).
C. The review process seeks to ensure that proposed concepts are a) scientifically sound; b) methodologically viable; c) feasible within the limits of IeDEA Global resources; and d)

not duplicative of ongoing efforts.

D. All RDCs will have one vote each on concept proposal submitted to the EC for approval, regardless of whether or not they were invited to contribute data.
E. An RDC can choose whether or not to contribute data (by individual sites or the entire region) to a multiregional research project to which they were proposed to join.
F. Data transferred from one RDC to another data center or external partner for analysis of specific research concepts may only be used for that specific concept's analyses. Additional permissions from the EC and the participating RDCs are required for the use of the same dataset for a different concept.
G. Concepts initially approved for limited use (e.g., reporting to WHO, UNAIDS), must be revised and resubmitted for EC review should the concept leads want to proceed to develop a more complex analysis or a manuscript for publication.
H. Only one manuscript may be produced for one multiregional research concept sheet ("one concept, one paper"). The development of additional manuscripts originating from a primary concept requires submission to the EC of a revised or new secondary concept for review and approval.
I. Scientific products from multiregional concept analyses and other relevant research activities (i.e., abstracts, reports, manuscripts) require review and approval from the IeDEA EC before conference/workshop submission, external distribution, or publication.
    a. Posters and slide sets for oral presentations associated with previously approved abstracts should be reviewed by the EC and co-authors prior to presentation.
    b. The need for additional reviews of these products and presentations by relevant Working Groups will be determined by the concept leads.

C.2 Concept development and review steps

The process for concept development is outlined in **Figure 2**. Where there are questions about the concept management process, the narrative SOPs (this document) take precedence.

A. Concepts should be developed using the standard and current version of the IeDEA concept sheet template, available at https://www.iedea.org/resources/ (**Appendix 3**). Investigators are encouraged to work with regional data managers and the Data Harmonization Working Group during the concept drafting stage to facilitate the selection of variables that match with available multi-cohort data, application of the IeDEA Data Exchange Standard definitions, and to improve the efficiency of future data requests and transfer processes.
    a. Concepts related to active Working Group projects ***should be reviewed in their respective working groups prior to submission to the EC***.
B. When ready for EC review, the concept should be uploaded to the *IeDEA EC Review Hub* at https://bit.ly/iedearequest. Additional information about the concept is requested via the Hub "survey" tool that will be used when soliciting subsequent feedback.
C. The Hub administrators will review the submission for completeness and clarity. Once cleared, the proposed concept will be distributed for EC review through the Hub, along 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 two calendar weeks after initial EC distribution***. The concept would preferably be presented on the next scheduled monthly EC conference call to allow for additional questions, clarifications, and discussion.
D. If approved, the Hub will send automatic notifications to the lead concept investigators and the *IeDEA Concept Management Core* at IeDEA Southern Africa (University of

Cape Town IeDEA Project Manager [UCT PM in Figure 2]; Morna Cornell, morna.cornell@uct.ac.za), and Kathleen Kehoe, leenikehoe@gmail.com). The lead investigators will submit the final version of the approved concept on the Hub. The Concept Management Core will assign a tracking number, upload the final version to the Hub, and track the progress from concept approval to conclusion or publication.

E. Following or simultaneous to the EC review process, the regional PIs will distribute the concept to regional investigators for local decisions regarding participation, according to internal regional policies and practices. Each regional cohort will decide through its own established procedures whether they will contribute data to the research and recommend cohort representative(s) to be part of the Writing Group for that concept. This should be done within ***four weeks*** of concept approval by the EC.
    a. Specifically, the regional PIs are responsible to communicate to the lead concept investigators any additional details regarding regional approval and site/cohort participation that are needed for proceeding with the concept within ***four weeks*** of concept approval by the EC.
F. In the case of submission of concepts determined by the EC to require additional modifications before they can move forward (e.g., overlapping objectives, unclear analytical methods), these processes may take longer, pending additional discussions and communications.
G. Concepts that need to be substantially amended or revised to reflect major additions or changes in scientific aims or how data will be used for that project should go through additional review processes, which may vary by concept (e.g., review by a working group, regional PIs, or full EC) and will be determined by the Chair and Administrative Core. Review deadlines will be adjusted, as appropriate.
    a. The EC has the discretion to shorten the concept review timeline for amended/revised concepts if changes are minor.
H. **If plans for more than one manuscript develop from an approved concept, each subsequent manuscript will require a <u>separate concept</u>, which will need to go through each of the concept review steps *prior* to the initiation of these secondary analyses.**
I. Collaborations that involve more than one region but are not open to all regions may be developed for the purposes of supplemental projects (e.g., hepatitis screening) or to answer limited research questions (e.g., focusing on outcomes in the Americas or across Africa).
    a. It is preferred that such projects go through the standard review process as multiregional concepts. However, if the scope and depth of the project is such that a broad review is deemed unnecessary by the Chair and the Administrative Core, they may be shared with the EC but managed outside of the internal approval processes.
    b. A key aim for all IeDEA-related multiregional work is to facilitate regional engagement and tracking, and avoid future confusion and overlap, or duplication of effort.

<u>C.3 Data requests</u>

Following EC +/- Working Group and regional-level cohort approvals, the concept leads will develop formal data transfer requests using standard tools and templates in accordance with the IeDEA Data Exchange Standard.

A. If the data analysis is taking place ***outside of IeDEA***, additional steps may be required before transfer can occur (see Section D, Collaboration with external partners).

B. Concept leads are required to work with the Data Harmonization Working Group on the data specifications for their concepts.
C. *Requests for non-patient data.* IeDEA collects information about participating sites, clinical management practices, national guidelines, and other operational information. Use of such data would need to be requested and specified in a standard multiregional concept sheet. Once approved by the EC and data-contributing regions, these data can be requested through the EC operational core, which will forward them to the appropriate working group (e.g., Data Harmonization, Site Assessment, Strategic Data), as appropriate.
D. *Concepts not involving site- or patient-level data.* IeDEA working groups or investigators may work through the cohort consortium to develop concepts that do not require data per se (e.g., related to statistical methodology, the Data Exchange Standard). Such concepts may involve different types of internal approvals (e.g., by working groups and the EC, but not necessarily at the regional level) and authorship guidelines (e.g., authors outside of IeDEA and variable regional representation). It is advised that such concepts go through the standard review process to facilitate regional engagement and tracking, and avoid future confusion and overlap or duplication of effort.

C.4 Concept Writing Groups

A writing group will be assembled for each approved concept. Concept leads are encouraged to identify core members of their writing group soon after approval in order to engage them earlier in the analysis and research product development processes (e.g., abstracts, reports, manuscripts) and facilitate the receipt of regional-level feedback.

A. The concept lead investigators who submitted the approved concept will be the point people for that group, unless otherwise specified. The group will generally include at least one investigator from each participating region.
B. Additional Writing Group members may be recommended by the lead investigators, the regional PIs and external collaborating cohorts, if appropriate.
C. The concept lead investigators have primary responsibility for completion of the analyses and preparation of related scientific products, as well as regular communications with the Concept Management Core and the relevant Working Group and EC Chairs, as appropriate.
D. The concept lead investigators are responsible for providing regular progress updates to other members of the Writing Group, relevant Working Group(s), the EC, and the Concept Management Core, and may be asked to provide updates directly to the EC.

C.5 Concept fast-track requests

In the event of a request for multiregional data or analysis outputs that may be used to inform assumptions in models or for summary information for the purpose of national or global reporting (e.g., by WHO, UNAIDS, national government partners), a fast-track process may be followed. The following criteria apply:

A. The request can be fulfilled through the use of an existing dataset that was created for a previously approved multiregional concept.
B. The regional data center responsible for the existing dataset is willing to provide the requested information.
    a. Potential considerations for the data center may include additional time required to manipulate data or conduct new analytical work.
C. The request is for aggregated information, not individual-level data.

D. The IeDEA data or analysis outputs are not the primary focus of the model, report, or study, nor require IeDEA data or analysis outputs in order to be completed.
E. IeDEA will be acknowledged in an appropriate way for its contribution(s) (see below).

Requests meeting these criteria may be submitted by email to the IeDEA Administration Core point person who will be responsible to process the request (see below). Requests may be submitted through IeDEA multiregional concept leads, an IeDEA region, an IeDEA Working Group, or by individual IeDEA or external investigators. Requests should be provided in the IeDEA Fast-track Request template available at https://www.iedea.org/resources/ (Appendix 4) and include the following:

1) The title of the project
2) The names of the investigators involved in the project and their affiliations
3) A brief description of the aims and purpose of the project (1 paragraph)
4) A description of the summary data or analysis outputs that are requested
5) An explanation of how these data will be used in the project
6) Expected future outputs (e.g., journal publication, policy document, model structure)
7) Confirmation that the above fast-track criteria have been met

The request will be screened by the IeDEA EC Chair prior to circulation to the IeDEA EC for review on the Hub. The IeDEA EC will be given **one week** (inclusive of holidays, weekends) during which to raise any concerns. In particular, if the responsible data center(s) or the IeDEA regional Principal Investigators feel that the fast-track criteria are not met, they may recommend that a full concept sheet is submitted for further consideration.

It is anticipated that IeDEA would be acknowledged in some way for information provided through this fast-track process in a manner deemed appropriate by the data center(s) involved. If publication is anticipated, the data center(s) involved should have the ability to review any potential publications before these are published, and co-authorship may be explored.

Approved fast-track requests will be given tracking numbers by the Concept Management Core that are linked to the primary concept (e.g., “MR090-F1”)

C.6 Concept revisions

In the event that an approved concept needs to be modified in a way that does not require a separate fast-track request nor an additional separate concept, it may be submitted for EC review as a revision. The procedures for managing revisions will be similar to those outlined in C.2, except that proposed revisions should be submitted in tracked changes in the previously approved concept file.

Approved revision requests will be given tracking numbers by the Concept Management Core that are linked to the primary concept (e.g., “MR116-R1”).

C.6 Authorship

Authorship allocations by region and decisions about group authorship should be made prior to requests for review, even if a minority of individual co-authors are still to be named.

A. Authorship slots are generally distributed between the concept’s lead region and data-contributing regions. To the extent possible, the lead region should seek balanced representation across the participating regions. This may be based on levels of

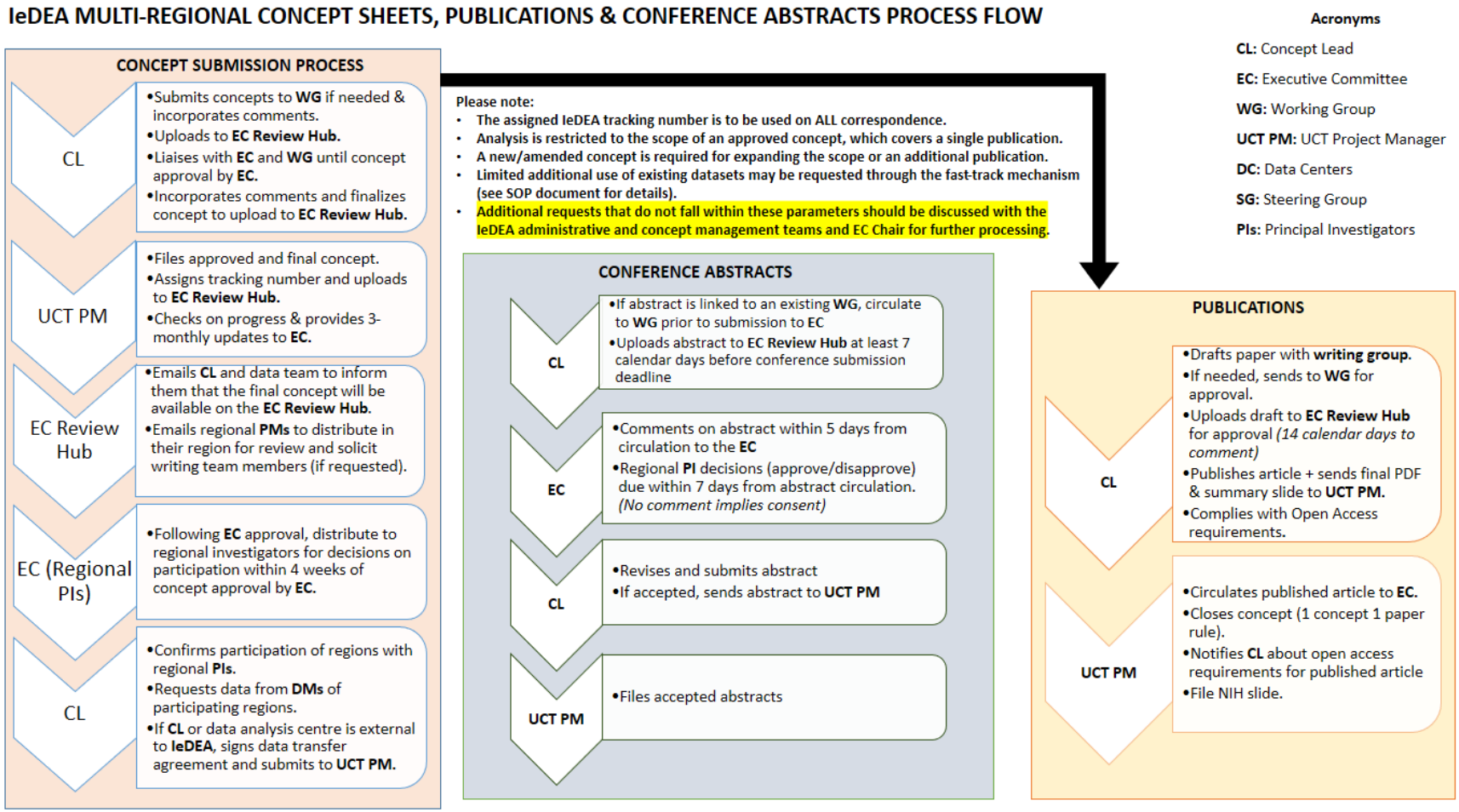
contribution to the analysis and abstract, the numbers of patients contributed to the analysis, and other factors.

B. For abstracts or manuscripts that have a restriction on the number of masthead authors, the priority authorship from within the Writing Group would be (1) investigators on the Writing Group working directly on the analysis and drafting the manuscript; (2) investigators on the Writing Group from among regions that contribute data; (3) other IeDEA representatives.
C. If the authorship restriction is less than what the Writing Group deems a reasonably representative number of co-authors, the masthead may include the concept lead(s) and state "on behalf of IeDEA," with the concept leads responsible for final selection of authorship.
D. The inclusion of co-authors should be determined in line with the Uniform Requirements issued by the International Committee of Medical Journal Editors (see http://www.icmje.org/).
E. If the manuscript is published under group authorship, the Writing Group should be listed in the appendix of the manuscript and include all individuals who have made substantial contributions.
F. All multiregional abstracts, manuscripts, and reports should have one authorship slot for the consortium, such as "…on behalf of IeDEA."

C.7 Acknowledgement of regional investigators and funding

A. ***All IeDEA funding grants for all data-contributing regions must be acknowledged and listed in submitted and final published manuscripts.*** The most up to date version of IeDEA global and regional acknowledgements are available at https://www.iedea.org/resources/.
B. Depending on the manuscript and the scope of the collaboration (e.g., within or beyond IeDEA), investigator lists (e.g., steering or project committees) characterizing the leadership of the individual participating regions should be included in the acknowledgements or an appendix (see Appendix).

Figure 2


IeDEA MULTI-REGIONAL CONCEPT SHEETS, PUBLICATIONS & CONFERENCE ABSTRACTS PROCESS FLOW
CONCEPT SUBMISSION PROCESS
CL
•Submits concepts to WG if needed & incorporates comments.
•Uploads to EC Review Hub.
•Liaises with EC and WG until concept approval by EC.
•Incorporates comments and finalizes concept to upload to EC Review Hub.
UCT PM
•Files approved and final concept.
•Assigns tracking number and uploads to EC Review Hub.
•Checks on progress & provides 3-monthly updates to EC.
EC Review Hub
•Emails CL and data team to inform them that the final concept will be available on the EC Review Hub.
•Emails regional PMs to distribute in their region for review and solicit writing team members (if requested).
EC (Regional PIs)
•Following EC approval, distribute to regional investigators for decisions on participation within 4 weeks of concept approval by EC.
CL
•Confirms participation of regions with regional PIs.
•Requests data from DMs of participating regions.
•If CL or data analysis centre is external to IeDEA, signs data transfer agreement and submits to UCT PM.
Please note:
The assigned IeDEA tracking number is to be used on ALL correspondence.
Analysis is restricted to the scope of an approved concept, which covers a single publication.
A new/amended concept is required for expanding the scope or an additional publication.
Limited additional use of existing datasets may be requested through the fast-track mechanism (see SOP document for details).
Additional requests that do not fall within these parameters should be discussed with the IeDEA administrative and concept management teams and EC Chair for further processing.
CONFERENCE ABSTRACTS
CL
•If abstract is linked to an existing WG, circulate to WG prior to submission to EC
•Uploads abstract to EC Review Hub at least 7 calendar days before conference submission deadline
EC
•Comments on abstract within 5 days from circulation to the EC
•Regional PI decisions (approve/disapprove) due within 7 days from abstract circulation. (No comment implies consent)
CL
•Revises and submits abstract
•If accepted, sends abstract to UCT PM
UCT PM
•Files accepted abstracts
PUBLICATIONS
CL
•Drafts paper with writing group.
•If needed, sends to WG for approval.
•Uploads draft to EC Review Hub for approval (14 calendar days to comment)
•Publishes article + sends final PDF & summary slide to UCT PM.
•Complies with Open Access requirements.
UCT PM
•Circulates published article to EC.
•Closes concept (1 concept 1 paper rule).
•Notifies CL about open access requirements for published article
•File NIH slide.
Acronyms
CL: Concept Lead
EC: Executive Committee
WG: Working Group
UCT PM: UCT Project Manager
DC: Data Centers
SG: Steering Group
PIs: Principal Investigators

D. Collaboration with External Partners

IeDEA regions or Working Groups may be asked by external partner groups (e.g., WHO, UNAIDS) or individuals to contribute data or pre-analyzed results to an analysis, a report, or a manuscript that is outside the context of an existing multiregional research concept.

While individual RDCs will independently manage requests that are limited to their region, when estimates or data from more than one IeDEA region are involved, the proposed data project must be presented in advance to the IeDEA EC for their approval and to determine if a multiregional research concept should be developed. The IeDEA Strategic Data Working Group will review all of these requests prior or simultaneous to review by the EC.

Data transfers for analysis by partners outside of the seven IeDEA regions will require a data transfer agreement between each participating region and the external partner. Where data are provided for inclusion in a report, and the lead author/s subsequently wish to publish these results, a separate concept sheet must be submitted and the usual approval process followed. As with internal analyses, any subsequent use of data contributed to an external collaboration must be separately authorized by the EC and the regions that contributed data.

E. IeDEA EC Review Processes for Scientific Products – Abstracts, Reports, Manuscripts

E.1 Overview

The EC reviews scientific products from concept analyses (e.g., abstracts, reports, manuscripts) and other multiregional IeDEA-related work (**Figure 3**). The review process is coordinated by the EC Chair and the Administrative Core. The concept lead investigators act as the overall scientific leaders and manage the flow of the work from concept to publication. This includes providing regular updates to the Writing Group, the relevant Working Groups, the IeDEA core teams, and the EC, as appropriate. The process is tracked by the Concept Management Core.

The concept lead investigators usually act as the first or senior author, and corresponding author on abstracts, reports, and manuscripts. They determine authorship order and distribution across participating regions, ensure that accepted abstracts are presented at conferences and workshops, share draft documents and presentations for review, and adhere to internal IeDEA policies and practices.

Figure 3. Pre-Submission/Pre-Presentation Review Requirements

Item	Co-Authors	Working Group	Executive Committee	Executive Committee	Format of Approval
	Time period for review			Formal Voting	
Concept Sheet	Required	If applicable	Required	Required	Unanimous vote
Conference Abstract	Required	If applicable	Required	Required	Unanimous vote
Journal Manuscript	Required	If applicable	Required	If applicable	No concerns after comment period*
Report	Required	If applicable	Required	If applicable	No concerns after comment period
Conference Poster	Required	If applicable	Required	None	No concerns after comment period
Presentation Slides	Required	If applicable	Required	None	No concerns after comment period

*Concerns to be addressed in revisions or explained to EC if authors defer. Regions that do not approve the revised manuscript will work with the concept leads in order to resolve the situation.

E.2 Abstracts

All abstracts for international, regional, and national meetings related to approved, multiregional IeDEA concepts require formal approval by the IeDEA EC prior to submission. Questions about these procedures can be discussed with the Administrative Core and EC Chair.

A. Abstract files should be submitted to the Hub for EC review. Abstract submission deadlines for EC distribution are based on US Eastern Standard Time (i.e., 5pm US EST).
B. In order to have adequate time for each region and regional investigators to review, concept leads are responsible to submit proposed abstracts to the IeDEA EC ***at least 7 calendar days prior to the conference abstract deadline. Individual conference-specific deadlines will be set by the Administrative Core and may take weekends or holidays into consideration***.
C. ***Substantive comments and concerns are due back to the concept lead investigators within 5 days and regional PI decisions (approve/disapprove/abstain) are due within 7 days after abstract circulation***.
D. Prior to submission, revisions requested by the EC should be incorporated or the concept leads should explain why they were not incorporated. Concept leads should upload final submitted versions of abstracts to the EC Hub.
E. Abstract submitters are encouraged to notify the Administrative Core in advance if they plan to submit an abstract to a given conference. This will improve communications around the process, help the regions to anticipate the reviews, and ***may impact whether or not the abstract is eligible for review*** (e.g., for workshops like IWHOD that have a per cohort abstract limit).
F. Working Group reviews: Abstracts arising from concepts developed through Working Groups should be reviewed and approved by the Working Group ***prior to EC review***. If this is not feasible, it is up to the relevant Working Group Chair(s) to determine whether simultaneous review by the Working Group(s) and the EC is appropriate.

G. Author reviews: ***Prior*** to submission on the Hub for EC review, draft abstracts must be reviewed by the Writing Group. Co-author lists and discussions about group authorship should be clarified as much as possible ***prior*** to circulation of the abstract. Specifically, abstracts will only be circulated for EC review if there is confirmed approval by at least one co-author (named or as part of group authorship) from every participating region. Even if additional named regional co-authors are still to be confirmed at the time of EC circulation, all named co-authors and participating regions must approve the abstract prior to the EC review deadline. Additional criteria for EC review may be specified in advance for individual conferences/meetings (e.g., IWHOD for per cohort submission limits). Failure to confirm required authorship by EC-specified deadlines may result in either non-circulation of the abstract or withdrawal following circulation (see E.2.H).
    a. Authorship slots are generally distributed between the concept's lead region and data-contributing regions. To the extent possible, the lead region should seek balanced representation across the participating regions. This may be based on levels of contribution to the analysis and abstract, the numbers of patients contributed to the analysis, or other factors.
    b. All multiregional abstracts should have one authorship slot for the consortium, such as "…on behalf of IeDEA."
H. Abstract rejections by the EC. Abstracts may be rejected in the following situations: Late submission of the abstract for review, failure to respond to substantive feedback, inability to achieve consensus on the authorship list, or if there is unresolvable disagreement among regional PIs about the abstract. The EC Chair will be responsible for managing discussions around abstract rejections.
    a. If only one region rejects the abstract, the concept leads have the option to reanalyze the data without that region's data and request re-review by the EC. However, this option will be discussed by the EC on a case-by-case basis and is subject to review timelines specified by the EC Chair. Abstracts that are rejected by two or more regions will not be submissible.
I. Accepted abstracts: Concept leads are responsible for sending the accepted abstract to the Administrative Core and the Concept Management Core for tracking.

E.3 Manuscripts and reports

IeDEA investigators seeking to submit multiregional manuscripts to peer-reviewed journals or reports to external partner agencies require formal approval by the IeDEA EC ***prior*** to submission. Manuscripts must have ***already been reviewed and approved by the co-authors and appropriate Working Group(s)*** and have incorporated their feedback in advance of EC review. Simultaneous review by the associated Working Group may be considered with the approval of the Working Group Chair(s) and EC Chair. Questions about these procedures can be discussed with the Administrative Core and EC Chair.

A. Following other appropriate reviews and approvals, the lead investigator should send the manuscript or report files for EC review through the IeDEA Review Hub (see Section C.2 and Appendix 3 for more information about the Review Hub).
B. The EC will review and comment on the manuscript and associated files within ***14 calendar days,*** which may include further distribution at the regional level, as deemed necessary by each region. Concept leads also have the option of circulating "early drafts" of their work for EC feedback. Submission of "final draft" files for formal review will still be required at a later date.
C. Request for revision: The EC may request that a revised manuscript or report be re-circulated for further review, prior to providing approval for formal submission to a journal

or an external group/organization. Revisions requested by the EC should be incorporated or the concept lead should explain why they were not incorporated.

D. Revisions made during the process of a journal editorial review are at the discretion of the concept leads, Writing Group, and co-authors. Substantial changes to previously approved manuscripts may require additional Working Group and/or EC review.
E. Concept leads and the primary regional cohort are responsible for ensuring full compliance with the US NIH's Public Access Policy. This includes ensuring that all grant support is added to submitted manuscripts/reports, and that any publishing or copyright agreements are consistent with funder requirements to submit publications to PubMed Central (consult http://publicaccess.nih.gov/submit_process_journals.htm for detailed instructions).
F. Concept leads are responsible for sending a copy of the published article and a single slide summarizing the publication to the Concept Management Core.

F. Appendices

1. IeDEA Global Regions and Principal Investigators

Asia-Pacific Annette Sohn amfAR TREAT Asia Bangkok, Thailand Matthew Law Kirby Institute University of New South Wales Sydney, Australia www.amfar.org/treatasia	Australia Cambodia China and Hong Kong SAR India Indonesia Japan Malaysia New Zealand Philippines Singapore South Korea Taiwan Thailand Vietnam
Caribbean, Central and South America (CCASAnet) Catherine McGowan Vanderbilt University School of Medicine Nashville, Tennessee Pedro Cahn Fundación Huésped Buenos Aires, Argentina www.ccasanet.org	Argentina Brazil Chile Haiti Honduras Mexico Peru
The North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) Richard Moore and Keri Althoff Johns Hopkins University School of Medicine Baltimore, Maryland www.naaccord.org	Canada United States of America
Central Africa Kathryn Anastos Montefiore Medical Center Albert Einstein College of Medicine Bronx, New York Denis Nash	Burundi Cameroon Rwanda Republic of the Congo Democratic Republic of the Congo

City University of New York Graduate School of Public Health and Health Policy New York, New York Marcel Yotebieng Albert Einstein College of Medicine Bronx, New York www.ca-iedea.org	
East Africa Kara Wools-Kaloustian Indiana University School of Medicine Indianapolis, Indiana Constantin Yiannoutsos Indiana University Richard M. Fairbanks School of Public Health Indianapolis, Indiana www.iedea-ea.org	Kenya Tanzania Uganda
Southern Africa Matthias Egger University of Bern Bern, Switzerland Mary-Ann Davies University of Cape Town Cape Town, South Africa www.iedea-sa.org	Lesotho Malawi Mozambique South Africa Zambia Zimbabwe
West Africa François Dabis Institute of Public Health, Epidemiology and Development (ISPED) Bordeaux, France www.mereva.net/iedea	Benin Burkina Faso Cote d'Ivoire Ghana Mali Senegal Togo

2. Funding acknowledgements

For complete regional acknowledgements, please see:
https://www.iedea.org/resources/administrative-resources/

For multiregional abstract posters and presentations

IeDEA global funding acknowledgements – core grants only

The International Epidemiology Databases to Evaluate AIDS (IeDEA) is supported by the U.S. National Institutes of Health's National Institute of Allergy and Infectious Diseases, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the National Cancer Institute, the National Institute of Mental Health, the National Institute on Drug Abuse, the National Heart, Lung, and Blood Institute, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Diabetes and Digestive and Kidney Diseases, the Fogarty International Center, and the National Library of Medicine: ***Asia-Pacific***, U01AI069907; ***CCASAnet***, U01AI069923; ***Central Africa***, U01AI096299; ***East Africa***, U01AI069911; ***NA-ACCORD***, U01AI069918; ***Southern Africa***, U01AI069924; ***West Africa***, U01AI069919. Informatics resources are supported by the Harmonist project, R24AI124872. This work is solely the responsibility of the authors and does not necessarily represent the official views of any of the institutions mentioned above.

3. Current concept sheet template, version 7 May 2018; file available at https://www.iedea.org/resources/administrative-resources/

CONCEPT SHEET: MULTIREGIONAL ANALYSIS

Date of EC approval:	*(to be added by UCT data centre)*
Tracking number:	*(to be added by UCT data centre after EC approval)*
Title:	
Concept Lead (email):	
Collaborators:	
IeDEA Correspondent (email):	
Data Manager (email):	
Lead Statistician (email):	
Where will data be merged?	
Where will statistical analyses be done?	
Abstract: (±200 words)	Background and objectives Methods
Project outline: (±1000 words)	Background Objectives and hypotheses Study design Eligibility criteria Key variables and definitions Outcomes Data collection and statistical methods Sample size considerations References
Ethics:	☐ This concept uses only the IeDEA standard dataset and is covered by the core IeDEA ethics approvals. ☐ This concept requires additional collection of health-related data, measurements or tests, or sampling of biological material not included

	in the IeDEA standard dataset. Additional ethics approval is required. ☐ This concept does not fall into either ethics category above. *Describe*:
Dataset:	☐ This concept requires new patient-level datasets. ☐ This concept uses existing patient-level datasets submitted for a previous concept: *Concept title:* *Concept number*: MR_____ ☐ This concept uses IeDEA Site Assessment or other IeDEA survey data. ☐ This concept does not use any IeDEA data (e.g., viewpoint paper).
Target journal(s):	
Milestones:	Circulation of concept sheet: <date> Circulation of draft paper: <date> Submission to target journal: <date>

Next Steps

Thank you for preparing a concept proposal for an IeDEA Multiregional Analysis. All IeDEA Concept Sheets are reviewed by the IeDEA Executive Committee (EC). Here are the steps for submitting your concept:

1. Before submitting the concept sheet, please **ensure all sections have been completed** or marked not applicable, the document is clean (all edits and comments are removed), and references have been added. If you are participating in an IeDEA region, ensure your Regional Principal Investigator has reviewed and approved the concept prior to submission.
2. Concepts that are developed within or have relevance to one or more IeDEA Working Groups (see list of Working Groups here) may be required to **obtain approval from the relevant IeDEA Working Groups** before submission to the EC. Please contact Aimee Freeman (afreeman@jhu.edu) with questions on this requirement and to circulate the document to the appropriate Working Group.
3. Once the document is ready for circulation to the IeDEA Executive Committee, you can **upload it to the IeDEA Hub for EC review** at the following link:

http://bit.ly/iedeasubmit

The concept will be reviewed by IeDEA Administrators prior to circulation to the Executive Committee. If you have questions about the form content, contact Aimee Freeman. For questions about the IeDEA Hub upload process, contact the Harmonist team at harmonist@vumc.org.

4. Fast-track concept sheet template – version 21 May 2018; file available at https://www.iedea.org/resources/administrative-resources/

Multiregional Fast-Track Request

Date of EC approval	*(to be added by UCT data centre)*
Tracking number	*(to be added by UCT data centre after EC approval)*
Project title	
Multiregional concept or other dataset to which the request is linked (e.g., MR number and title, dataset description)	
Primary contact, affiliations, email	
Collaborators and affiliations	
Brief description of the aims and purpose of the project (one paragraph)	
Description of the summary data or analysis outputs that are requested	
Explanation of how these data or analysis outputs would be used in the project	
Expected future outputs (e.g., journal publication, policy document, model structure)	
Confirmation that the IeDEA global fast-track criteria have been met	☐ The request can be fulfilled through the use of an existing dataset that was created for a previously approved multiregional concept. ☐ The regional data center responsible for the existing dataset is willing to provide the requested information. ☐ The request is for aggregated information, not individual-level data. ☐ The IeDEA data or analysis outputs are not the primary focus of the model, report, or study, nor require

	IeDEA data or analysis outputs in order to be completed. ☐ The regional data center responsible for the existing dataset agrees that IeDEA will be acknowledged in an appropriate way for its contribution(s).