

**East Africa IeDEA**

**Authorship, Publication and Presentation**

**Standard Operating Procedure (SOP)**

**Version 6: October 9, 2020**

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| **East Africa IeDEA**  **Standard Operating Procedure** | |
| **Title:** Authorship, Publication and Presentation | **Effective:** 2020 |
| **Version:** 6 | **Last Reviewed:** October 2020 |

1. **PURPOSE**
   1. To protect the integrity of the data, privacy of patients and safeguard the ownership of the collected data by the Consortium sites.
   2. To appropriately recognize the contribution and commitment of the contributing investigators, collaborators and collaborating institutions
   3. To ensure that investigators involved in the East Africa IeDEA Consortium obtain formal approval and clearance from co-authors, local and national authorities, participating site and clinical program directors and other stakeholders to publish Newspaper Articles, Abstracts, Program Descriptions or Research Papers.
   4. To ensure that investigators and collaborators have the opportunity to participate in the development and authorship of publications generated by the consortium.
   5. To ensure that all publications and presentations developed under the auspices of East Africa IeDEA consortium are documented in the East Africa IeDEA Bibliography.
2. **SCOPE**

### These guidelines apply equivalently to all public scientific presentations, reports, posters, abstracts, journal articles, data visualization dashboards, newspaper or interview presentations or any other public dissemination of data or results that are based on prospective or retrospective projects undertaken under the auspices of the East Africa IeDEA Consortium.

1. **DEFINITIONS**

Publications: journal articles, newspaper reports, data visualization dashboards or any other public dissemination of printed or electronic materials.

Presentations: abstracts, posters, platform presentations at meetings, invited lectures, radio or TV interviews.

Retrospective: These publications/presentations are derived from concept proposals which utilize pre-existing patient-level and site-level data within the IeDEA Consortium.

Prospective: These publications/presentations are derived from concept proposals that involve the primary collection of new, not previously or routinely collected data. These proposals are often developed with additional funding obtained from IeDEA supplements or other funding opportunities. These concept proposals may also utilize retrospective data.

Site: a health clinic (e.g., Mbarara ISS clinic).

Clinical program: aggregate group of many clinical sites (e.g., AMPATH).

Primary Investigator: Primary author of publication or presentation

Co-authors: All other named authors on the publication

Executive Committee (EC): Leadership group of the Consortium, constituted of the Regional co-Principal Investigators (co-PIs) and the site PI from each of the sites/programs within the Consortium.

1. **RESPONSIBILITIES**

Primary Investigator:

* Proposes the analysis and drafts the concept sheet
* Establishes the writing group – please note that when a concept is circulated to the EA\_IeDEA EC a participation query is also circulated. The Primary investigator should review the participation query log to identify additional members of the writing group who may not have been involved with drafting the initial concept sheet.
* Assumes the primary responsibility for development of the manuscript/abstract/or other scientific output from concept sheet in a timely manner.
* Ensures that co-authors have the opportunity to review, comment on and approve publications/presentations.
* Forwards publications to the Program Managers for dissemination to the EC in a timely fashion.

Co-Authors:

* Contribute to the development of a presentation/publication as outlined in Appendix 1: Criteria for Authorship

Project Coordinators (U.S. and East African):

* For retrospective concept proposals, develop a list of interested co-authors (based on Appendix 2: Site Participation Form) and forward it to the Primary Investigator of the concept sheet.
* Receive and circulate to the EC all publications, abstracts and presentations.
* Review all submitted publications/presentations to ensure that the Site Participation Query has been submitted for all sites/programs whose data are being used in the publication and that all sites/programs have agreed to participate in the project and have regulatory approval (as documented in the Site Participation Query).
* Notify the Primary Investigator and EA IeDEA PIs if a publication/presentation does not have documented approval from all sites/programs.
* Track the development of all publications/presentations and ensure that they are included in the East Africa IeDEA Bibliography.

Executive Committee:

* Review all research publications/presentations (including but not limited to manuscripts, abstracts, presentations, reports, etc.).
* Adjudicate all complaints related to publications including but not limited to authorship disputes, concerns about the content of articles, rigor of data analysis, soundness of scientific methodology and interpretation of findings.
* In the process of assessing the quality of the publications, the EC may form ad hoc review groups of non-members made up from relevant experts (e.g., statisticians, economists, oncologists, etc.) to ensure appropriate review of the publication under consideration.

1. **PROCEDURES**

Primary Investigator:

* **Establishes the writing group** where necessary (all papers and abstracts) and ensures that the group:
  + **Includes individuals involved with development of the concept proposal** or the project team (See Concept Proposal Development, Submission and Review Process SOP)
  + **Includes a data manager (DM) and a statistical analyst (SA)**
    - Category A –junior investigators- DM and SAs will be assigned by the Head of the Data Management Core and the Head of the Statistical Analysis core.
    - Category B –senior investigators – these individuals may identify their own DM and SA or may request assignment of these individuals (see Category A)
  + **Includes site representatives in the writing group (for retrospective papers)**
    - Identifying site representatives - these individuals will be selected from the list of potential co-authors provided by the sites on their site participation queries. The EA-IeDEA Program Managers maintain a list of which sites have had co-authors on prior papers. They will assist the Primary investigator in determining what sites should take priority for representation on a writing group.
    - Notifying interested individuals who were not selected for participation in the working group about the reason they were not selected. Reasons for non-selection include: journal limitations on the number of authors, site non-participation in the concept, failure of a nominated author to respond in a timely manner to the Primary Investigator.
* **Establishes an E-mail distribution list for the writing group**
  + With assistance from the Project Managers, e-mail distribution lists will be established in order to facilitate communication within the writing group. Any changes to the list that occur during the project should be sent by the Primary Investigator to the Project Manager.
* **Maintains communication with the writing group** 
  + The Primary Investigator should maintain regular communication and should receive regular input from the writing group. We are advocating the following schedule.
    - Immediately after EC approval
      * Establish a timeline and milestones for the project
    - Three months after EC approval
      * Follow-up on data set and confirm date of dataset delivery
    - Monthly calls after dataset delivery to analyst
      * Follow-up on the analysis, identify challenges and problem solve
    - Monthly calls after analysis delivery to PI
      * Follow-up on manuscript development process, identify challenges and solve problems
* **Develops the abstract/presentation/publication**
  + Manuscripts should be completed within 6 months of receiving the analysis dataset and within 3 months of receiving the analysis results. If these deadlines are not met a grace period may be granted or alterations in authorship may be needed to complete the work.
* **Establishes authorship order using the following guidelines:**
  + The person who originates the research concept will be the lead author or senior (i.e., last) author depending on the situation. This individual will also be the leader of the writing team, except in situations involving researchers who need significant mentorship by a senior investigator. The mentor may assume leadership in such cases without changing the order of authors.
  + The order of authorship beyond the first or senior author will be determined by the writing team, led by the Primary Investigator. Order should be based on each author’s involvement in the research project and in the authorship of the research publication. The writing group is encouraged to resolve conflicts in a consensus manner. In the event however that the conflict cannot be resolved internally, an appeal to the Executive Committee of the East Africa IeDEA Consortium will be made. Resolutions offered by the IeDEA EC will be final and no appeal can be made.
* **Circulates the penultimate draft of the manuscript/abstract/presentation/poster** **to co-authors for comment**
  + Papers: **14** days should be provided to co-authors for review
  + Abstracts: **3** **working** days should be provided to co-authors for review
  + Presentations/Posters: **7** days should be provided to co-authors for review
* **Addresses co-author comments and creates the penultimate version of the** **manuscript/abstract/presentation/poster**
* **Submits manuscript/abstract/presentation/poster to the EA-IeDEA EC for review**
  + Creates a single (powerpoint format preferred) slide summarizing the manuscript/abstract/presentation/poster
  + Forwards the manuscript/abstract/presentation/poster and slide to the Project Managers for circulation to the EC.
    - Papers: **14** days prior to planned submission
    - Abstracts: **3** **working** days prior to planned submission
    - Presentations/Posters: **7** days prior to presentation
  + Publication/presentation materials should be submitted to:
    - [Yee](mailto:Yee) Yee H. Kuhn [ykuhn@iu.edu](mailto:ykuhn@iu.edu)
    - Marion Achieng [machieng@idi.co.ug](mailto:machieng@idi.co.ug)
* **Addresses EC Comments**
* **Submits the manuscript/abstract/presentation/poster to the journal/meeting** as per the guidelines established by the journal/meeting
* **Takes responsibility for addressing any revisions** requested by the publishing entity and for ensuring that the co-authors review revisions prior to re-submission.

**Failure of investigators to adhere to these procedures may result in loss of access to the East Africa IeDEA Regional Consortium resources for a prescribed period of time decided by the EC.**

Co-authors:

* **Actively participate in the development of a publication/presentation** by attending conference calls and responding to e-mails
* **Review and comment on the manuscript/abstract/presentation/poster** 
  + All reviews must be completed within the timelines outlined above
  + Failure to provide a review of the manuscript within this time frame will result in the potential author being eliminated from the author list
* **Sign the journal’s co-authorship and copyright assignment forms**
  + Within **3 working days**
  + Failure to do so may result in elimination from the authors’ list

Project Managers (U.S. and East African):

* Register all submitted concepts into the concept participation query log
* Send all concepts to the EC for review and approval
* Ensure that Site Participation Queries are sent out and that the responses are received and documented for all sites.
* Communicate with the data management team about sites that have not approved participation in the concept.
* Provide the Primary Investigator with a prioritized list of site representatives who wish to participate in their concept
* Circulate to the EC all manuscript/abstract/presentation/poster immediately after receipt from the authors
* Forward all comments from the EC to the Primary Investigator and copy the East Africa IeDEA PIs.
* Track all publications/presentations in the East Africa IeDEA Bibliography.

Executive Committee:

* **Reviews of presentations/publications** 
  + Timeline:
    - Within **14 days** of receipt of a manuscript
    - Within **2 working days** of receipt of an abstract
    - Within **6 days** for a Poster/presentation
  + Reviews will concentrate on the following:
    - Does the publication/presentation appropriately represent the Consortium and does it describe adequately and accurately the clinical and research programs which generated the data included in the study?
    - Are the scientific and analytical methods appropriate for the project and of the highest quality?
    - Are the conclusions supported by the results?

Comments, approvals and objections will be sent to the Project Coordinators within the allotted time frame.

* Responses:
  + If no comments are received from an EC member who is also a site PI within the allotted time, then it will be assumed that approval by the site has been obtained.
  + If no objections from the EC are received within the allotted time, then the manuscript/abstract/presentation/posterwill be considered as having been approved.
  + If objections are noted, then the Primary investigator will be asked to revise and resubmit unless there are substantive issues, at which point an EC conference call will be arranged to discuss the manuscript/abstract/ presentation/poster with the investigator. A vote of the EC members present on the call will be taken as to whether to proceed with the publication/presentation and a simple majority vote will decide the issue.