

**CONCEPT SHEET: MULTIREGIONAL ANALYSIS**

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| --- | --- |
| **Date of EC approval:** | *(to be added after EC approval)* |
| **Tracking number:** | *(to be added after EC approval)* |
| **Title:** |  |
| **Concept Lead:**Name, institution, IeDEA affiliation, email |  [ ]  Early-stage investigator\* [ ]  Not Applicable If yes, please specify if this IeDEA research will be a direct component of a formal training program and whether it is linked to a grant. [ ]  Masters degree [ ]  PhD degree [ ]  Post-doctoral training[ ]  NIH D43 [ ]  NIH K-series grant (K01, K08, K23, K43)[ ]  Other training-related grant, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  Other non-training grant, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Collaborators:**Names, institutions, IeDEA affiliations | *(Name individuals who are expected to work with the Concept Lead to carry out this project. If the list is incomplete, please note if additional regional representatives are to be determined.)* |
| **IeDEA Liaison:**Name, institution, email | *(This is required if the Concept Lead is external to IeDEA. The liaison is an MPI or an MPI-approved regional investigator who would work with the Concept Lead to accomplish the project aims and ensure adherence to global SOPs.)*[ ]  Not Applicable |
| **Lead Data Manager:**Name, institution, IeDEA affiliation, email |  |
| **Lead Statistician:**Name, institution, IeDEA affiliation, email |  |
| **Where will data be merged?** | *(Clarify if the analyses will be done at an institution other than that of the lead statistician.)* |
| **Working Group(s)** | Indicate which of the following IeDEA Working Groups are involved with the proposed project and would be responsible to review the concept and related research products. Please select all that apply.[ ]  AYANI [ ]  Cancer [ ]  Data Harmonization [ ]  Hepatitis [ ]  Mental Health [ ]  Mother & Infant [ ]  Pediatrics [ ]  Sentinel Research Network (SRN) [ ]  Site Assessment [ ]  Strategic Data [ ]  Substance Use [ ]  TB & Lung Health [ ]  TB Sentinel Research Network (TB-SRN) [ ]  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Not applicable |
| **Abstract:**(±200 words) | Background and objectivesMethods |
| **Project outline:** (±1000 words)Provide specific details about the study methods, using the IeDEA Data Exchange Standard tables for variables and definitions. | BackgroundObjectives and hypothesesStudy designEligibility criteriaKey variables and definitions OutcomesData collection and statistical methodsSample size considerationsReferences |
| **Ethics** (check all that apply)**:** | [ ]  This concept uses the IeDEA standard dataset and is covered by the core IeDEA ethics approvals.[ ]  This concept uses other IeDEA data and is covered by supplemental IeDEA ethics approvals (e.g., SRN).[ ]  This concept requires additional collection of health-related data, measurements or tests, or sampling of biological material not included in IeDEA datasets. Additional ethics approval is required.\*\*[ ]  This concept does not fall into the ethics categories above.*Describe why*: |
| **Dataset** (check all that apply)**:** | [ ]  This concept requires new patient-level datasets.[ ]  The concept lead plans to request existing patient-level datasets generated for a previous concept. *(Datasets cannot be automatically reused. Data must be re-requested to allow sites/regions to opt out.)* *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., commentary). |
| **Target conference(s), journal(s):** |  |
| **Projected milestones:** | Circulation of concept sheet: <month and year>Circulation of abstract: <conference name and year> Circulation of draft paper: <month and year>Submission to target journal: <month and year>  |
| **Acknowledgement of IeDEA authorship policies:** | Authorship for research products (e.g., abstracts, manuscripts) associated with approved concepts must adhere to IeDEA authorship policies. Authorship allocations on IeDEA multiregional concepts are under the authority of the regional MPIs and the EC. Naming collaborators on a concept does not automatically denote future authorship on associated research products. Regions may choose points of contact who help to coordinate regional participation, whether or not they will be co-authors. By checking the box below, the Concept Lead for this proposal acknowledges that they have reviewed the IeDEA authorship policies relevant to this proposal, which may be found in the IeDEA Global Standard Operating Procedures (SOP) posted in the *Resources* section of the [IeDEA website](https://www.iedea.org/resources/). In addition, IeDEA multiregional publications accepted on or after 1 July 2025 must follow the NIH publication policy. This includes submission to PubMed upon acceptance (with no embargo period). Non-compliance may result in delays in award processing and/or impact future funding of the lead/corresponding author or region’s institution. All multiregional IeDEA publications must include the below text in addition to the standard acknowledgement, available in the *Funding Acknowledgements* section of the IeDEA website.* *This manuscript is the result of funding in whole or in part by the US NIH. It is subject to the NIH Public Access Policy. Through acceptance of this federal funding, NIH has been given a right to make this manuscript publicly available in PubMed Central upon the Official Date of Publication, as defined by NIH.*

[ ]  **Concept Lead has reviewed and agrees to IeDEA authorship policies.** |

\* IeDEA encourages the participation of trainees and other junior researchers in global research, and tracks when multiregional concepts are led or co-led by “early-stage investigators.” These are defined as individuals who *at the time of concept submission* are in an active training/educational program or who have completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years.

\*\*Details around additional review requirements need to be confirmed prior to study/analysis implementation.

**Next Steps**

All IeDEA Multiregional Concept Sheets are reviewed by the IeDEA Executive Committee (EC). Here are the steps for submitting your concept:

1. Please **ensure all sections have been completed** and the document is clean (edits and comments are removed). Instructions in italics may be deleted.
2. Ensure that the affiliated regional MPIs have **reviewed and approved** the concept.
3. Concepts that are developed within or have relevance to one or more IeDEA Working Groups (see above list) are required to **obtain their approval**. For information on the Working Groups, Chairs, and technical leads, see <https://www.iedea.org/working-groups/>. Please contact Aimee Freeman (afreeman@jhu.edu) with questions and to circulate the document to the appropriate Working Group(s).
4. Once the document is ready for submission to the EC, you can **upload it to the IeDEA Hub** at the following link: <https://redcap.link/iedeasubmit>.

The concept will be screened by IeDEA Administrators for completeness and clarity prior to circulation. If you have questions about the template or online submission form, contact Aimee Freeman. For questions about the IeDEA Hub upload process, contact the Harmonist team at harmonist@vumc.org. The IeDEA global SOPs may be found here: <https://www.iedea.org/resources/>.