Regional Prospective Observational Research in Tuberculosis (RePORT) International:
Principles and Procedures for RePORT International Research Collaborations

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1. OVERVIEW OF REPORT INTERNATIONAL

1.1 Background

The Regional Prospective Observational Research on Tuberculosis (RePORT) International Consortium is a multinational collaboration of research networks conducting observational and translational research on tuberculosis (TB). The RePORT program was created with bilateral funding from the U.S. National Institute of Allergy and Infectious Diseases (NIAID) and governments of RePORT network countries. As of November 2023, the global consortium comprises researchers from individual country networks in Brazil, China, India, Indonesia, the Philippines, South Africa, South Korea, and Uganda. Each RePORT country-level network conducts studies of patients with pulmonary TB and/or their close contacts using a Common Protocol of clinical and laboratory activities, maintains biorepositories with well-characterized specimens, and collaborates with specialized laboratories. Given its scope, the RePORT International consortium has the capacity to study infrequent but critically important outcomes of *M. tuberculosis* infection and TB disease with sufficient statistical power and generalizability.

RePORT International began in 2012 as a cooperative strategy between the NIAID Division of AIDS and interested governments to address the threat of TB, which affects the lives and well-being of people across the globe and poses an increased risk for people living with HIV. The initial RePORT International collaboration included TB research investigators from India collaborating with US-based TB research investigators, followed soon by the addition of a newly formed Brazil consortium. Subsequently, a South Africa Medical Research Council TB research consortium was added (2016) and an Indonesia-NIAID endeavor (INA RESPOND) started enrolling in 2017. China and the Philippines joined the consortium in 2017.

The RePORT International Coordinating Center (RICC) coordinates RePORT multi-national research and associated activities. RICC 1.0 (2015-2019) was managed by Family Health International 360, with funding overseen by The Civilian Research & Development Foundation (CRDF) Global. RICC 2.0 (2020-2023) saw a transition to an investigator-led coordinating center managed by Rutgers University with partners Johns Hopkins University and Vanderbilt University Medical Center. With RICC 3.0 (2023-2028), funding has transitioned from CRDF to the National Institute of Allergy and Infectious Diseases (NIAID), though management of the coordinating center remains with Rutgers University, with the addition of a new partner, Frontier Science.

1.2 Mission and Scientific Agenda

The mission of RePORT International is to advance TB science globally, with an emphasis on translational research to provide new tools for TB prevention and care. To this end, RePORT International promotes harmonization of data across the RePORT consortia and development of TB research capacity and infrastructure.

1.3 Key Definitions

The following terms are used throughout this document:

A. **Groups**
   a. **RePORT** stands for Regional Prospective Observational Research in Tuberculosis. Outside this document, where clarity is needed to distinguish the consortium from other similarly named

platforms such as NIH Research Portfolio Online Reporting Tools (RePORT), the consortium may be referred to as “TB-RePORT.”

b. The **RePORT International Consortium** consists of the RePORT International Coordinating Center and its partnering country-level RePORT networks, along with collaborating scientists. In this document, “RePORT International” or “RePORT” refers to the RePORT International Consortium.
c. The **RePORT International Coordinating Center (RICC)** is the coordinating center for the RePORT International Consortium. The designation of the current center is RICC (3.0).
d. **RePORT Country Networks** are country-level research groups participating in RePORT, including RePORT India, RePORT Brazil, RePORT South Africa, RePORT China, RePORT Indonesia, RePORT Philippines, RePORT Uganda and other member networks that may join in the future.
e. **RePORT Country Coordinating Centers** (also **RePORT Network Data Centers)** are the administrative and leadership centers (coordinating and data centers) for the national RePORT networks.
f. **Study Sites** are the individual TB research sites participating in the RePORT country networks.
g. The **RePORT International Executive Committee** (EC) is the central communications and management group of RePORT International.
h. **RePORT International Working Groups** (WGs) are groups of RePORT investigators from multiple RePORT country networks who meet regularly and are focused on a scientific or operational topic.
i. **Scientific Advisory Group (SAG):** Group of external experts recommended by the Executive Committee who can provide additional advice on specific RePORT projects.
j. **Global Research Advisory Board (GRAB):** Group selected from RePORT network countries, representing diverse stakeholders affected by TB research, who provide guidance on overarching network activities.

B. **People**

a. **RePORT International Coordinating Center Principal Investigators** (RICC PIs) are the Principal Investigators of the coordinating center for the RePORT International Consortium and also serve as the Chair(s) of the Executive Committee (EC).
b. **RePORT Network Principal Investigators** (Network PIs) are the Principal Investigators of the country-level RePORT networks.
c. **RePORT Investigators** includes all Network PIs, co-investigators from RePORT-participating institutions, and other contributing researchers who are considered members of RICC or of one of the national RePORT networks.
d. **External (non-RePORT) Investigators** include investigators outside the RePORT International Consortium and its participating sites.

C. Research

a. **Multi-country research projects** or “multi-network projects” are studies and operational activities undertaken by two or more RePORT country networks.
b. **RePORT International projects** include those projects using data or specimens from two or more RePORT country networks or projects supported by RICC RFA funding.
c. **Concept sheets** are templated documents that propose the use of existing data and specimens for a specific analysis, publication. or other goal.
d. **Study protocols** describe additional study recruitment, patient-facing procedures, or advanced laboratory analyses beyond the content of the concept sheet template.

e. **Biospecimens** include the primary biospecimen and its simple derivatives, and are clinical specimens directly collected from the participants during RePORT Common Protocol study visits. Examples of biospecimens include whole blood and its derivatives (such as sera, plasma, and peripheral blood mononuclear cells; PBMCs), RNA, nasopharyngeal and oral swabs, sputum, induced sputum or nasopharyngeal aspirate or gastric lavage, saliva, urine, extrapulmonary TB specimen, and stool.
f. **Cohort A** is a prospective observational study as described in the RePORT Common Protocol, open to enrollment for individuals with active pulmonary TB.
g. **Cohort B** is a prospective observational study of participants who are close contacts or household contacts to of persons with active pulmonary TB.
h. **High-value Specimens**: High-value specimens are those which are scientifically important or those which are a challenge to collect. These may include, for example, specimens from TB activation cases among household contacts, TB relapse/failure cases, biopsies, CSF, synovial fluid, bronchoalveolar lavage, etc. Only concept sheets with high scientific merits are prioritized for high-value specimens. These include biospecimens from:
    i. Cohort B TB prevalent or activation cases
    ii. Cohort B TB activation cases enrolling in Cohort A
    iii. Cohort B conversion or reversion of infection status
    iv. Resistance to infection despite exposure to active pulmonary TB
    v. Pediatric active TB cases
    vi. TB treatment failure cases in Cohort A
    vii. TB relapse/recurrence cases in Cohort A
    viii. Deaths
i. **Data** mean a representation of information, numerical compilations and observations, documents, facts, maps, images, charts, tables and figures, concepts in digital and/or analog form.
j. **Raw data** are primary data collected from a source that has not been modified or changed. For example, data coming out from a sequencing machine will be considered as raw data.
k. **Processed data** means the raw data that have been cleaned to derive certain relevant information.
l. **Biospecimen/Data Sharing** encompasses the release of biospecimens and/or data and their transfer to approved institutional or external investigators.

D. **Common Protocol (CP)**: Standardized data elements and harmonized procedures for enrollment of TB cases and household contacts across the country study sites for establishing a data and specimen repository for TB research. In this document, CP may refer to the original Common Protocol or subsequent revisions.
E. **Minimum Global Dataset:** The RePORT International minimum global dataset defines the essential study variables that must be collected by every RePORT country to comply with the RePORT Common Protocol.

1.4 Organization of the RePORT International Consortium

The RePORT International consortium is composed of the participating RePORT International networks, the RePORT International Coordinating Center, and partner funding agencies.

1.4.1 RePORT Country Networks

As of November 2023, RePORT country networks currently include five active networks ("voting networks") in India, Brazil, South Africa, Indonesia, the Philippines, and three participating networks ("non-voting networks") working on start-up activities or reorganization in China, South Korea, and Uganda. Details of all current RePORT country networks can be found on the RePORT International website (reportinternational.org).

1.4.2 RePORT International Coordinating Center (RICC)

The RePORT International Coordinating Center (RICC) coordinates RePORT multi-country research and associated activities.

1.4.3 Governmental Organizations Involved in RePORT International

As described above, financial support for RePORT is provided by NIAID with co-funding from country governments. NIAID has substantial scientific and programmatic involvement in the RePORT Consortium through technical assistance, advice, and coordination, and in facilitating communication among external partners.

The role of the NIH staff within RePORT International is to assist and facilitate the research activities. NIH staff and country governmental representatives can participate on RePORT International concept sheets, protocol teams, and governing committees.

2. ROLES AND RESPONSIBILITIES

RePORT International is a collaboration of participating RePORT networks, the RePORT International Coordinating Center, and other groups and committees charged with the scientific, management, and operational support of the consortium. The consortium is led by a chair and co-chair(s), who are accountable to the National Institute of Allergy and Infectious Diseases (NIAID) Program Officers. Additional information concerning these entities is provided in this section.

2.1 RePORT Country Networks: Coordinating and Data Centers

The RePORT country-level coordinating centers are responsible for overseeing their networks' participation in RePORT International research collaborations, training activities, and meetings. Ownership of data and specimens remains with the country-level RePORT networks. Data and specimens are shared for specific analyses, quality assurance activities, or collaborative projects.

Country coordinating centers have the following responsibilities:

A. Ensure their national RePORT protocol and data collection follows the Common Protocol and the Minimum Global Dataset (once revised, for RePORT countries beginning a new funding cycle)
B. Share RePORT multi-country concept sheets and other documents with their network investigators and obtain network-level approval for participation, data sharing, specimen sharing, or publication as appropriate.
C. For approved RePORT International concept sheets, send data to RICC or to the designated lead investigators and facilitate identification and shipping of specimens, while following all country and institutional regulations.

D. Conduct data and specimen quality assurance and control activities to ensure high-quality data and specimens for RePORT International activities.
E. If data queries arise during RePORT International projects, route data queries to either the central or site data managers, as appropriate.
F. Provide RICC with updates on enrollment and project progress according to specified intervals (e.g., quarterly), for tracking and NIH reporting.
G. Participate actively in the RePORT International research agenda, including scientific and operational working groups, the Scientific Review Committee (SRC), Executive Committee (EC), and contributions to abstracts and publications.
H. Attend annual RePORT meetings, when feasible.

The internal activities of RePORT country networks are not managed by RePORT International and are outside the scope of this document.

2.1.1. Voting Privileges

Voting privileges on the SRC and EC require an active status in RePORT International. Each active country-level RePORT network has one vote on the EC, to be determined by the PIs of that network.

To participate in voting, RePORT networks must meet all of the following criteria:

A. Maintain at least an active “Cohort A” or “Cohort B” aligned with the Common Protocol and/or clinical data and a biorepository from prior cohorts. Planned cohorts (enrollment starting/in progress) are acceptable.
B. Demonstrate willingness and ability to share data and samples for RePORT International projects (e.g., participation must not be prohibited by national regulations, site protocols, or other administrative or legal principles).

Active voting privileges may be revoked at the discretion of the EC if a cohort does not meet these requirements.

2.2 RePORT Country Networks: Study Sites

The RePORT study sites report up to RePORT country-level coordinating centers. Sites will make their own decisions regarding participation in a given concept analysis or study, according to the procedures of their country networks. Responsibility for site management belongs to the RePORT country networks as part of their country-level activities.

RePORT site investigators and staff are eligible to participate in RePORT International Working Groups and other RePORT International activities.

2.3 RePORT International Executive Committee (EC)

The RePORT International Executive Committee (EC) is the central communications and management group of RePORT International. The EC ensures a cooperative, integrated, and focused scientific effort across the multiple networks, sites, and laboratories. The EC is responsible for the following activities, which are described in detail in subsequent sections:

A. Holding monthly meetings,
B. Monitoring the activity of RePORT International Working Groups through periodic updates,

C. Reviewing and voting on internal and external concept sheets for feasibility, financial need, and suitability for RePORT International (subsequent to review by RICC, applicable working groups, and the Scientific Review Committee), and
D. Signing off on abstracts, manuscripts, and other scientific material on behalf of RePORT International prior to submission.

The EC includes the US and International PIs of the RePORT country networks, the RICC Director, Co-Director, Director of Operations, Director of Administration, the Working Group chairs, select RePORT investigators, and support staff. The NIH RePORT Program Officers serve as *ex officio* members of the EC.

2.3.1 RePORT International EC Chair(s)

The RePORT International Consortium EC Chair is a current RICC PI with experience reflective of the consortium's scientific agenda and operational scope. Responsibilities include directing the consortium and executing its plans as determined by the Executive Committee and National Institutes of Health (NIH); ensuring collaboration with other research networks and groups, including industry, as appropriate; and serving as the consortium's executive representative. Other responsibilities include but are not limited to oversight of consortium policies and procedures, regulatory compliance and performance evaluation, review of publications, and collaboration with the community.

A current RePORT network PI may serve as Co-Chair. The Co-Chair should be affiliated with a different RePORT country, if applicable. The Co-Chair is nominated and elected by a majority vote of EC members. The vote will occur by the EC voting members within 30 days of nomination. An EC Co-Chair will serve for a period of five (5) years. There are no term limits if re-elected. A special election of the voting members is held if it becomes necessary to replace an EC Co-Chair before the end of the term.

The EC Chairs and Co-Chairs have the following specific responsibilities:
A. Lead the consideration and approval of policies and procedures of the Consortium,
B. Lead the review and approval of all research proposals that will be conducted by RePORT International, and
C. Represent the EC as full members of the Leadership Group of the RICC.

EC Chairs and Co-Chairs with a specific conflict of interest must abstain from participating in decision-making related to that issue. In such cases, they may defer to other Chairs or members of the RICC Leadership Group. The Chair and Co-Chair are the signing authorities of any letters of support for grant proposals. If both the EC Chair and Co-Chair are on a proposal, the conflict shall be acknowledged and the Chairs sign.

2.4 RePORT International Coordinating Center (RICC)

The goals of the RePORT International Coordinating Center (RICC) are to provide logistical, financial, and coordinating activities for the RePORT International Consortium; to define and implement scientific priorities of the global consortium; to provide support for the RePORT Working Groups and EC; to harmonize data from the national RePORT networks for multi-network studies; to coordinate access to specimens in the network biorepositories; to identify, catalyze, and guide TB, TB/HIV, and TB/COVID-19 research within and across RePORT networks; to ensure quality control, monitoring, and further development of TB diagnostic laboratories, RePORT specialized laboratories, and biorepositories; to promote site capacity building and investigator training; and to mentor early stage investigators across the RePORT consortium.

2.4.1 RePORT International Leadership Group (LG)

The RePORT International Leadership Group (LG) is the scientific and operational leadership group of RePORT International. The LG is a sub-group of the EC that sets the strategic direction for the network and coordinates with funding agencies. The LG prioritizes project elements and adjusts priorities as required to accommodate unanticipated opportunities or problems. The LG is responsible for the following activities:

A. Communicate with NIAID representatives and consider funding challenges and opportunities.
B. Conduct periodic strategic planning to assess network progress and identify barriers to productivity. This may include identifying and addressing long-term technical and strategic issues regarding the collaboration, tracking progress at country data centers and sites, and proposing remedial actions for RICC-funded projects.
C. Endorse activities of the RePORT International Coordinating Center such as conference planning, revisions of the Common Protocol, and the development of training programs.
D. Represent RePORT International to regional and global organizations.

The LG includes the PIs of RICC, the Co-Chairs of the EC, the Associate Directors, the Director of Global Operations and Program Manager, and RePORT Country Pis.

2.4.2 Administrative Core

The RePORT International Coordinating Center Administrative Core supports the logistic, financial, and coordinating activities of the RePORT Consortium and oversees communications internally within RICC and externally to stakeholders and partners. The Administrative Core monitors operations, workflow processes, and chains of responsibility among investigators/staff, identifies the review/approval processes, and describes the management processes across the RePORT Consortium and its members. The Core promotes the interactions among the country RePORT networks to empower the EC and working group chairs in meeting RePORT International goals and objectives.

The Administrative Core organizes internal communications to ensure effective management of sites and protocols, tracks milestone performance, and supports planning for future initiatives. The Core develops and maintains a portfolio of materials available to the RePORT Consortium for communications to engage potential new partners and promote awareness to their respective governments and sponsors. Such tools may include videos, slide sets, social media highlighting special events, lists of publications, opportunities for interested researchers, and annual reports, all of which promote development of interest in RePORT activities among various constituencies. The Core also manages development and distribution of the newsletter and any social media presence.

The Administrative Core supports the RICC PIs and EC Chair(s) in the administrative and governance activities of RICC. The Core is responsible for financial aspects of RICC and the RePORT International consortium. In collaboration with institutional research offices and under the direction of the RICC Director, the Administrative Director and budget analyst will be responsible for financial compliance, disbursing/establishing subcontracts, monitoring core expenses, processing invoices, and providing plans for managing resources, reallocating funds, and obtaining, tracking, and projecting sub-award spending. The Administrative Core prepares NIH reports, including RICC annual progress reports, funding renewals, and grant applications such as administrative supplements. The Core provides management and oversight of compliance with regulators across the RePORT Consortium sites and tracks IRB, IACUC, IBC, and other regulatory submissions/status and their expiration dates, working with US and international study teams to ensure timely submission of

regulatory documents, adherence to international privacy laws, and communications to the appropriate agencies.

2.4.3 Data Core

The RICC Data Core is responsible for harmonization of RePORT data from the RePORT country networks and preparation of analytic datasets for RICC-supported studies. RICC data managers will work with counterparts from the country-level RePORT networks to receive data, map data to the RePORT Data Exchange Standard, and prepare analysis datasets. For RICC-sponsored studies, RICC is also responsible for sharing with country-level networks any raw data generated from lab studies using their specimens.

The RICC Data Core will define a minimum dataset necessary for all RePORT country networks. The RICC Data Core will maintain paper case report forms for the Common Protocol and corresponding REDCap data entry templates, and track additions and modifications of the REDCap data entry template. RePORT networks have to collect the variables defined in the minimum global dataset, but may add their own supplemental forms for country-specific data collection and research studies.

The RICC Data Core will explore and support the development of tools in support of RePORT International activities, including summary reports of RePORT International data holdings, internal and public data dashboards, virtual specimen repositories, and maintenance of core datasets.

In RICC 3.0, the Data Core consists of data leads, data managers, and program coordinators at Rutgers University, Vanderbilt University Medical Center, and Frontier Science.

2.4.4 Ad Hoc Groups

Time-limited groups can be convened by RICC to manage tasks such as the revision of consortium documents (e.g., Bylaws, Common Protocol), the development and testing of new software platforms, or preparations for a Consortium Meeting.

2.5 Scientific Review Committee (SRC)

The Scientific Review Committee (SRC) is the “intellectual clearinghouse” of RePORT International and is composed of EC members and appointed country-level network investigators to ensure broad representation from leadership and networks. The SRC provides scientific input on RePORT projects, prioritizing actionable feedback for early-stage investigators. The SRC is supported by the RICC Admin Core and an SRC administrator. The SRC solicits, as necessary, additional scientific expertise from within or external to the consortium. SRC members will review the scientific feasibility (e.g., Is the proposed science relevant to RePORT International? Should the project be high-priority?) and questions regarding scientific overlap and duplication of prior scientific work. Additional internal reviews (lab review, genetics review) may be conducted if biospecimens are requested.

The SRC working with RICC also develops an annual Request for Applications (RFA) for RICC project funding that supports multi-country research on RePORT International scientific priorities. Jointly with RICC, the SRC coordinates the review of submissions to the RFA, abstracts for the RePORT annual meeting, and proposals for pilot funding of site preparedness research. When necessary to avoid conflicts of interest, the SRC engages an external group (e.g., as determined by NIH) to perform the review.

A secure web-based platform will capture concept sheets, abstracts, and pilot grant proposals, distribute them for confidential review, and hold the review comments centrally for SRC decisions. Proposed reviewers with potential conflicts of interest (e.g., Investigators from the site that is proposing the concept sheet) may participate in discussions but should recuse themselves from scoring or participating in the final evaluation process. A simple majority is required for approval.

2.5.1 SRC Leadership

The SRC is led by two (2) SRC Chairs representing different RePORT countries. The SRC Chairs are elected from among current SRC members. An SRC Chair serves a two-year term separate from SRC membership.

2.5.2 SRC Membership

The SRC will have at least five (5) members, including the two co-chairs. Membership encompasses an odd number of voting members to avoid ties, a balance of junior and senior investigators, and investigators from multiple countries. Although a representative from each RePORT network is ideal, this is not required. *Ad hoc* members are invited to ensure relevant areas of expertise (e.g., microbiology, biomarkers, biostatistics) for review of specific projects.

SRC members are nominated and elected by the RePORT International EC. SRC elections take place annually, replacing half the committee each year. Members serve a two-year term and can run for a second term.

The SRC also includes at least one non-voting member from NIH and one non-voting SRC administrator. The SRC administrator schedules regular meetings, tracks proposals, tallies votes, maintains a list of submitted/approved/rejected projects and their status, prepares and distributes meeting minutes, ensures adherence to timelines for Pilot Funding program, and coordinates the review of Annual Meeting abstracts.

2.6 Working Groups (WGs)

There are multiple Working Groups (WGs) within the RePORT consortium, including both scientific and operational WGs. Each WG is chaired by RePORT investigators who coordinate regular WG conference calls and develop the RePORT scientific agenda around these topic areas. Multi-country research concepts may be generated from within the WGs, or the EC or WG Chairs may ask one or more WGs to review a concept or scientific product of an analysis that includes their focus population or addresses their thematic area of interest. The WG review is intended to help assess feasibility and provide feedback for optimal design and implementation of the analysis. Additional ad hoc WGs may be formed on a temporary basis for specific projects. Information on RePORT WGs and their leadership is available on the RePORT International website (reportinternational.org).

2.6.1 Scientific Working Groups

The Scientific Working Groups (SWGs) provide the technical expertise of the consortium. They advise on protocols in development and under guidance by the SRC, and assist in the review of concept sheets and the development of protocols and grant proposals as required.

SWGs can be initiated by the RePORT International EC based on investigator interests and consortium needs. The EC and chairs of SWGs solicit nominations for membership from the RePORT network PIs. Membership

should be based on expertise or country representation. Regular and ad hoc meetings will be scheduled for the SWGs. Regular meetings should occur monthly.

Current or planned SWGs may include the following:

A. Subclinical TB
B. Long-term Consequences of TB

2.6.2 Operational Working Groups

The Operational Working Groups focus on the research-supporting and research-adjacent activities of the consortium. Current Operational Working Groups include the following:

A. Data Harmonization: reviews research proposals for data availability, monitors data calls, discusses data quality strategies, maintains the definitions of the Global Minimum Dataset together with the RICC Data Core.
B. Capacity Strengthening: surveys investigators, sites, and labs for training and capacity building needs; identifies, collates, or develops training materials; conducts trainings.

2.6.3 Working Group Leadership

Each WG is led by two or more WG chairs. Chairs of the Operational WGs are selected by RICC. Chairs of the Scientific WGs are nominated by the WGs or RICC according to interest and capacity and are confirmed by the WG.

2.6.4 Working Group Membership

Working Group membership is generally limited to RePORT investigators (e.g., representatives from participating research sites, coordinating centers, data management and analysis centers), other investigators directly affiliated with RePORT regional research, and NIH program staff. RePORT networks appoint members of their network to participate in the Working Groups. RICC and NIH representatives can also participate. Investigators external to RePORT can be invited to join by RePORT investigators.

2.7 Advisory Boards

2.7.1 Scientific Advisory Group (SAG)

The RePORT International Scientific Advisory Group (SAG) is a group of external experts recommended by the EC who provide additional advice on specific RePORT projects. Core principles of the SAG include the following:

1. Given lack of specific expertise or possible conflicts of interest, the SAC will be composed of at least 3 individuals who represent the following areas: epidemiology, translational/clinical sciences, pharmacology, microbiology, new diagnostic tests/technologies, and adherence technologies.
2. These members should not be affiliated with RePORT or NIH but should be form RePORT countries.
3. SAC members will be compensated for their time per a statement of work at a pre-decided hourly/daily rate and will be retained as contractors/vendors by the RICC.
4. The SAC can review RFAs and full proposals for research should expertise and/or a conflict of interest exist among the SRC members.

2.7.2 Global Research Advisory Board (GRAB)

The RePORT International Global Research Advisory Board (GRAB) is a group of individuals selected from RePORT network countries, representing diverse stakeholders affected by TB research, who provide guidance on overarching network activities. Core principles of the GRAB include the following:

1. The GRAB members will consist of a group of diverse individuals from RePORT countries. Each country will recommend two members who represent at least two of the following sectors: Affected communities, TB survivors, public health advocacy groups, non-governmental organizations, and funders.
2. The GRAB should be demographically varied by sex, age, and educational level.
3. Members must sign a declaration of interests form prior to approval of membership.
4. Membership will rotate in a staggered fashion after a term .
5. After the inaugural term, the GRAB membership and selection criteria can be re-assessed by the EC for additional terms including a call-for-applications with a scored selection process.

3. MANAGEMENT OF RePORT INTERNATIONAL PROJECTS

RePORT International projects include both multi-network research ("collaborative research") and projects funded by a RICC Request for Applications (RFA), both of which form integral parts of RePORT. Collaborative research activities include the identification of research questions to be addressed with combined data sets from multiple RePORT country networks and other potential external research collaborators, the definition of key information to be obtained across countries, and the development of protocols for hypothesis testing, sample selection, data harmonization, lab testing, and data analyses. RICC RFA-funded projects are permitted to leverage data or specimens from a single RePORT country, but are classified and managed as RePORT International projects in acknowledgment of their funding source. Non-research collaborative projects may involve the development of data tools, dashboards, training, or other resources in support of the RePORT consortium.

RePORT International projects are conducted through the development, execution, and completion of concept sheets. **RePORT International concept sheets are required for research analyses and studies funded by RICC or involving two or more RePORT networks**, regardless of study design or use of samples. Individual concepts for cohort database analyses and other studies will be reviewed, approved, and managed according to the below procedures and processes.

When proposed RePORT International data use and research activities fall outside of the below parameters, investigators must contact the EC Co-Chairs and RICC Admin Core for further clarification.

3.1 Core Collaborative Principles

The following management principles form the core of RePORT International study operations:

A. Ownership of RePORT country network cohort data, specimens, and other study-related data remains with the sites, as represented by the RePORT Country Coordinating Centers and Data Centers, led by the network Principal Investigators (PIs).
B. Relevant concepts and protocols for RePORT International projects must be reviewed and approved by the RePORT EC in advance of any request for data or specimens.

    a. Additional Working Group reviews and approvals may be required, as appropriate (see below).
    b. The review process seeks to ensure that proposed concepts and protocols are a) scientifically sound; b) methodologically viable; c) feasible within the limits of RePORT global resources; and d) not duplicative of ongoing efforts.

C. All active RePORT country networks, represented by their Country Coordinating Centers, have one vote each on any concept proposal submitted to the EC for approval, regardless of whether or not they are invited to contribute data or choose to participate in the research in the future. Networks may formally abstain from voting.
D. A RePORT country network can choose whether or not to contribute data and/or specimens (by individual sites or the entire network) to a multi-network cohort analysis or other research project to which they were proposed to join.
E. Data transferred from the RICC Data Core to a RePORT investigator or to an external partner for analysis of specific research concepts may only be used for that specific concept's analyses, unless specified in the approved concept sheet and Data Use Agreements
F. Specimens transferred from the RePORT country biorepositories to a RePORT investigator or to an external partner for analysis according to a specific research concept may only be used for purposes defined in that specific concept sheet, unless otherwise specified in the approved concept sheet and Material Transfer Agreements
G. Additional permissions from the EC and the participating RePORT Country Coordinating Centers are required for the use of the same data or specimens for a different concept.
H. Concepts initially approved for one scope of work must be revised and resubmitted for EC review should the concept leads want to develop a more complex analysis or change the scope of the planned research outputs.
I. A single concept may be associated with multiple abstracts and manuscripts, but the concept sheet must include a general description of publication plans.
J. Scientific products (e.g., abstracts, reports, manuscripts) from RePORT International projects require review and approval by the RePORT EC before submission to a conference/workshop or journal, external presentation, or other form of distribution.
    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. Associated Working Groups are expected to review these products and presentations prior to or at the same time as the EC review.
    c. Scientific products should acknowledge the RePORT network funding.
K. Other multi-country research involving two or more RePORT networks (e.g., supplement-funded studies, linked grants) are similarly subject to the policies defined in the RePORT International governance documents.

3.2 Concept Sheet Development and Review

Submission of concept sheet proposals is required for all proposed investigations involving analyses using existing data sets, the collection of new data (questionnaires, clinical and physical measures), and/or use or collection of laboratory specimens.

RePORT International studies involving use of existing data and specimens from two or more RePORT networks with the goal of producing a conference abstract, presentation, manuscript, report, or other deliverable should submit a concept sheet via the standard review process for multi-network concepts. The process for concept development is outlined in Figure 1: RePORT International Concept Proposal Workflow.

Where there are questions about the concept management process, the narrative SOPs (this document) take precedence.

A. Concepts must be developed using the standard and current version of the RePORT International concept sheet template, available at https://reportinternational.org/collaborate-with-us/ .
    a. **RICC Review:** Draft concepts must be shared with RICC for a review of general content and completeness. Investigators must consult with RICC prior to submitting a concept if the concept requires RICC resources (e.g., data harmonization work, funding for lab tests). Although final allocation of resources is determined by the EC, RICC will determine whether resources exist and whether the project is administratively feasible.
    b. **WG Review:** Concepts associated with thematic or content-specific Working Groups also must reviewed in their respective working groups prior to submission to the EC.
    c. **Data Review:** Investigators are encouraged to work with RICC data managers and the Data Harmonization Working Group during the concept drafting stage to facilitate the selection of variables that align with available multi-network data and application of the RePORT Data Exchange Standard definitions, and to improve the efficiency of future data requests and transfer processes.
B. **SRC Review:** RICC-vetted concepts are subsequently reviewed by the RePORT Scientific Review Committee (SRC) for scientific rigor. Review outcomes include “accept”, “revise”, or “reject.” Accepted concepts are sent to the EC for their review.
C.
    a. Concept sheets and unsolicited proposals will be reviewed during SRC meetings that will be scheduled approximately every 4 weeks. Proposals submitted 2 weeks prior to the call will be reviewed, to ensure adequate time for review.
    b. Concepts requesting RICC pilot funding (in response to the Annual RFA or otherwise) will solicited and reviewed according to a specific timetable determined by the SRC and LG, and administered by the Executive Director, RICC Admin Core, and SRC leadership.
D. When it is ready for **EC Review**, the concept sheet should be emailed to the RICC Admin Core at tbricc@njms.rutgers.edu.
    a. Additional information about the concept may requested by the Admin Core.
    b. Investigators are requested to provide a tentative but realistic timeframe for completion of proposed concepts. The status of the project will be tracked by the RePORT Consortium.
E. Designated members of the RICC Admin Core will review the submission for completeness and clarity and assign a concept sheet tracking number. Any concept sheet submitted with required sections incomplete, tracked changes remaining, or outdated forms will be returned to the author for correction before it is circulated for review.
F. Once cleared, the proposed concept will be distributed for EC review, along with any relevant supporting details provided in the submission process. A targeted end date for review, comment, and voting will be set for **no less than two calendar weeks** after initial EC distribution.
    a. Although two weeks is the default review period, additional time may be given to allow for conferences, weekends, and holidays.
    b. During or subsequent to the EC review process, the country network PIs will distribute the multi-network concept to their country networks or to assigned reviewers for local decisions regarding participation, according to their internal network policies and practices. Each country-level RePORT network will decide through its own established procedures whether they will contribute data and specimens to the research and recommend cohort representative(s) to be part of the Writing Group for that concept.

i. EC approval can be granted independent of site participation decisions.
ii. Country RePORT networks should determine site participation, data and specimen sharing, and Writing Group members **within four weeks** of concept approval by the EC.

c. Network PIs are responsible for communicating to the lead concept investigators and RICC any additional details regarding network approval and site/cohort participation that are needed for proceeding with the concept and associated data/specimen requests within four weeks of concept approval by the EC.

G. The EC will provide feedback, engage in discussion, and determine if the proposal is appropriate. Ideally, the concept will be presented on the next scheduled monthly EC conference call to allow for additional questions, clarifications, and discussion.

H. If approved, the Admin Core will notify the lead concept investigators and the RICC LG. The lead investigators will submit the final version of the approved concept to the RICC Admin Core for tracking.

I. The RICC Admin Core will save the final version and track the progress from concept approval to conclusion or publication.

J. 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.

K. Concepts that need to be substantially amended or revised to reflect major additions or changes in scientific aims or how data and specimens will be used for that project should go through additional review processes. These additional review steps may vary by concept (e.g., review by a working group, network PIs, or full EC) and will be determined by the EC Chair and the RICC Admin 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.

3.2.1 Concept Sheet Participants and Roles

Multi-country studies encompass many roles for investigators, contributing experts, statisticians, data managers, coordinators, and others. The following roles are named in the concept sheet template:

A. **Proposing Investigators**

a. **Concept Sheet Lead/First Author.** This individual is responsible for leading the development of the concept sheet, presenting the concept to the appropriate RePORT review group, establishing a project Writing Group, organizing project-specific conference calls, providing concept updates to the RICC Admin Core, drafting the introduction/background to the manuscript, participating in the analysis, circulating draft versions, and submitting abstracts and manuscripts according to consortium-defined timelines.

b. **Senior Author:** The Senior Author is the PI or most senior investigator actively involved in the project. This individual provides mentorship for the first author and is responsible for the accuracy and integrity of the manuscript. The Senior Author is expected to make substantial contributions to the conception or design of the project and interpretation of data; or have drafted the work or substantively revised it; and to have approved the submitted version (and any substantially modified version that involves the author's contribution to the study); and to have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

c. **Writing Group:** The Writing Group comprises at minimum the concept sheet lead, one investigator from each data or sample-contributing network, and a senior investigator. Where RICC has provided project coordination and data management for multi-network projects, RICC investigators or RICC Data Core members should also be allocated two slots. (see “Authorship” section.)

B. **RePORT Collaborating Investigator:** External investigators interested in working with RePORT data and/or samples must work with a selected (or assigned) RePORT partner. This RePORT Collaborating Investigator can help to determine the feasibility of the project and facilitate the concept development and review process. Interested investigators who do not have a current RePORT partner can contact RICC**.**

C. **Statistician(s):** The lead statistician is responsible for creating the data analysis plan, conducting or overseeing the data analysis, and sharing the findings with the concept sheet lead and senior author. Additional statisticians may participate in a project.

D. **Data Manager(s) and Data Site**: The concept sheet should describe whether data management will be performed by RICC, by the individual RePORT network, or by an external group, and who the specific data managers will be.

The RICC Admin Core oversees all ongoing concept sheets and may delegate oversight to the SRC and RePORT Working Groups. The SRC and SWGs may also include additional site investigators, site staff, or other collaborators with relevant experience. The group members can advise on project revisions, monitor concept sheet progress, and provide feedback on concept publications (abstracts, posters and manuscripts) prior to EC review.

3.3 Multi-network Protocol Review

Studies involving additional participant recruitment or participant study procedures in addition to those specified in the Common Protocol should prepare a **study protocol** in addition to one or more concept sheets.

Study protocols associated with other research involving two or more RePORT networks should be reviewed by the EC prior to local or national IRB submission, with sufficient time provided for substantive feedback and discussion. When these studies are led by RICC or RePORT investigators, it is expected that oversight of the protocol development process will be the responsibility of both RICC and the SRC. The process for initiating EC review of study protocols follows the one outlined for concept sheets in section 3.2. Study protocols should be emailed to tbricc@njms.rutgers.edu.

3.4 Review of Specimen Requests

The RICC Data Core coordinates requests for specimens for RePORT International projects. Upon receiving a concept sheet that includes a specimen request, the Data Core contacts the individual RePORT country networks and biorepositories for a specimen inventory check to ensure the necessary samples are available.

The Data Core tracks the number of requests for inventory checks and specimen requests per country to monitor the burden of RePORT International projects on RePORT country biorepositories.

3.5 Return of Laboratory Results

When laboratory analyses are funded by RICC for RePORT International projects, each participating RePORT network must receive access to the data generated from their patient samples within 12 months of when the data were generated. Storage and exchange of such lab datasets is facilitated by RICC.

3.6 Authorship

Authorship on RePORT International abstracts, manuscripts, and other research products must follow ICJME criteria. ICJME criteria include the following:

A. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
B. Drafting the work or reviewing it critically for important intellectual content; AND
C. Final approval of the version to be published; AND
D. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Lead authorship should be limited to those individuals who have contributed in a substantive way to the project and/or the project's content. All co-authors should be directly involved in the planning and contribution to some component of the work which led to the paper (conception, design, conduct - including cohort data collection, analysis, or interpretation) or interpreting at least a portion of the results, writing a draft of the article or revising it for intellectual content, and final approval of the version to be published.

Authorship allocations by network and decisions about group authorship should be made prior to requests for review of research products (e.g., abstracts, reports, manuscripts), even if some co-authors are still to be named.

A. Authorship slots are generally distributed among the concept lead's team, RICC, and data-contributing networks. To the extent possible, the lead network should seek balanced representation across the participating groups. This may be based on levels of contribution to the analysis and abstract, the numbers of patients contributed to the analysis, and other factors. Participation of investigators involved in the collection of data and specimens should be prioritized.
B. Writing teams and projected distribution of author shots must be proposed in a concept sheet.
C. Authorship for a RICC-managed multi-country study shall include the following author slots:
    a. Author slots for the concept leadership team
    b. One (1) author slot for each data- or specimen-contributing RePORT site
    c. Author slots for coordination, biostatistics, or data management
    d. Other co-authors (e.g., content experts, additional site representatives) may be added with the approval of the concept leads and the EC/SRC.
D. 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 RePORT representatives. All data-contributing countries should have representation of at least one (1) author.
    a. If the authorship restriction results in a total number of authors that is less than what the Writing Group deems representative, the manuscript may be published under group authorship instead. In this case, the masthead may include the concept lead(s) and state "on behalf of RePORT International," with the concept leads responsible for final selection of authors.

E. If a manuscript is published under group authorship, the Writing Group should be listed in the appendix and include all individuals who have made substantial contributions.
F. All multi-country abstracts, manuscripts, and reports, regardless of restrictions on the numbers of masthead authors, **must have one authorship slot for the consortium, such as "…on behalf of RePORT International."**

Concept sheet leads are responsible for ensuring adherence to authorship guidelines. The EC must review and approve all authorship allocations. Authorship allocations are monitored by the RICC Admin Core to ensure fair representation of the global nature of RePORT International work.

3.9 Acknowledgement of country investigators and funding

A. **All RePORT funding grants for all data- and specimen-contributing RePORT country networks must be acknowledged and listed in submitted and final published manuscripts.** This may include funding for other linked grants as well. The most up to date version of the RePORT global and national network acknowledgements shall be made available on the RePORT International website (reportinternational.org)
B. Depending on the manuscript and the scope of the collaboration (e.g., within or beyond RePORT International), investigator lists characterizing the leadership of the individual participating networks should be included in the acknowledgements or an appendix.

4. REVIEW OF RePORT INTERNATIONAL SCIENTIFIC PRODUCTS

4.1 Overview

As indicated in Section 3.1, scientific products (e.g., abstracts, manuscripts, reports) arising from RePORT International projects require review and approval by the RePORT EC before submission to a conference/workshop or journal, external presentation, or other form of distribution. These products include and are not limited to data reports (e.g., for modeling inputs, infographics, online resources), conference abstracts, manuscripts and reports for publication (e.g., online, peer-reviewed journal), conference posters, and presentation slides. Abstracts for the RePORT Annual Meeting are managed separately (see Section 4.3).

The concept lead investigators are responsible for educating themselves on RePORT International procedures and ensuring adherence to RePORT International practices. They act as overall scientific leaders and manage the workflow from concept to publication. This includes providing regular updates to their co-authors, the SRC, RICC, and the EC, as appropriate. 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 in accordance with RePORT International authorship policies, ensure that accepted abstracts are presented at conferences and workshops, and share draft documents and presentations for review.

The requirements for review and voting are listed by research product in **Table 1**.

Table 1. Review and voting requirements for RePORT International scientific products.

Item	Co-authors	Scientific Review Committee (SRC)	Executive Committee
Concept sheet	Review	Review / Vote	Review / Vote
Study protocol	Review	Review / Vote	Review / Vote
Abstract (Conference)	Review	--	Review / Vote
Abstract (Annual Meeting)	Review	Review / Vote	--
Manuscript	Review	--	Review / Vote
Report	Review	--	Review / Vote
Conference poster	Review	--	Review
Presentation slides	Review	--	Review
Other products	Review	--	Determined by RICC

Review timelines vary by research product. The RICC Admin Core tracks the review process.

All active RePORT country networks, represented by their Country Coordinating Centers, have one vote each during EC voting on any scientific product for which voting is required. Networks may formally abstain from voting. A simple majority is required for approval.

4.2 Abstracts (Conference)

All abstracts for international, regional, and national meetings (e.g., conferences, workshops) related to approved, RePORT International multi-network concepts require formal approval by the RePORT EC prior to submission.

A. Abstract submitters are encouraged to notify the RICC Admin Core in advance if they plan to submit an abstract to a given conference. This will improve communications and help the EC to anticipate reviews.
B. Prior to submission of an abstract for RICC EC review, all co-authors must have reviewed and approved the abstract.
C. To have adequate time for EC review, concept leads must submit proposed abstracts to the RICC Admin Core **at least seven (7) full calendar days prior to the conference abstract deadline**. Abstracts should be submitted to the RICC Admin Core via email to tbricc@njms.rutgers.edu). For major TB conferences, individual conference-specific deadlines will be set by the RICC Admin Core and may take weekends or holidays into consideration.
D. The RICC Admin Core will circulate abstracts to the EC for review.

E. Prior to conference submission, revisions requested by the EC should be incorporated or the concept leads should explain why they were not incorporated. Concept leads should send final submitted versions of abstracts to RICC at tbricc@njms.rutgers.edu
F. Questions about these procedures can be discussed with the RICC Admin Core.

4.3 Abstracts (Annual Meeting)

Abstracts for the RePORT International Annual Meeting are managed separately from the official RePORT International review process, as these abstracts may not be linked to a RePORT multi-network project (e.g., abstracts may be related to single-country RePORT research) and are for an internal conference only.

Abstracts submitted to the Annual Meeting are reviewed by the SRC and external reviewers, rather than the RePORT EC.

A. Abstract submitters are encouraged to notify the RICC Admin Core in advance if they plan to submit an abstract to the RePORT Annual Meeting. This will improve communications and help the SRC to anticipate reviews.
B. Prior to submission of an abstract for the Annual Meeting, all co-authors must have reviewed and approved the abstract.
C. The RICC Admin Core sets the deadlines for submission of Annual Meeting abstracts. Abstracts should be submitted to the RICC Admin Core via email to tbricc@njms.rutgers.edu.
D. The RICC Admin Core and SRC administrator will upload submitted abstracts to a secure, web-based platform, distribute them for confidential review, and hold the review comments centrally for SRC decisions.
E. Reviewers with potential conflicts of interest (e.g., Investigators from the site that is proposing the concept sheet) may participate in discussions but must recuse themselves from scoring or participating in the final evaluation process.
F. Abstract submitters will be informed of abstract selection once the SRC review process is complete.
G. Questions about these procedures can be discussed with the RICC Admin Core.

4.4 Posters and Presentation Slides (Conference)

Conference posters and presentation slides are reviewed by the EC, but not formally voted upon.

A. Prior to submission of a poster or slide set for RICC EC review, all co-authors must have reviewed and approved the material.
B. To have adequate time for EC review, concept leads must submit the files to the RICC Admin Core **at least seven (7) full calendar days prior to the conference upload or printing deadline**. Files should be submitted to the RICC Admin Core via email to tbricc@njms.rutgers.edu. For major TB conferences, conference-specific deadlines will be circulated by the RICC Admin Core and may take weekends or holidays into consideration.
C. The RICC Admin Core will circulate the materials to the EC for review.
D. Prior to poster printing or conference presentation, revisions requested by the EC should be incorporated or the concept leads should explain why they were not incorporated. Concept leads should send final versions to RICC at tbricc@njms.rutgers.edu
E. Questions about these procedures can be discussed with the RICC Admin Core.

4.5 Manuscripts (Journal Submission)

Manuscripts (both pre-prints and standard journal publications) related to RePORT International multi-network or RICC-funded concepts require formal approval by the RePORT EC prior to submission.

A. Prior to submission of a manuscript for RICC EC review, all co-authors must have reviewed and approved the paper.
B. Concept leads should submit the manuscript files to the RICC Admin Core via email to tbricc@njms.rutgers.edu. The EC review packet should include the following items
    a. Manuscript, with all authors, affiliations, references, funding statement, acknowledgments
    b. Tables and figures, with legends
    c. Supplemental material, if applicable
C. The RICC Admin Core will circulate materials to the EC for review.
D. The EC will review and comment on the manuscript and associated files within **fourteen (14) calendar days.**
E. The EC may request that a revised manuscript be recirculated for further review, prior to providing approval for formal submission to a journal. Revisions requested by the EC should be incorporated or the concept lead should explain why they were not incorporated. Concept leads should send revised documents to the Admin Core.
F. Revisions made during the process of a journal editorial review are at the discretion of the concept leads and co-authors. Substantial changes to previously approved manuscripts may require additional EC review.
G. Concept leads and the primary RePORT country network leading the concept analysis for a given manuscript are responsible for ensuring full compliance with the US NIH's Public Access Policy. This includes ensuring that all grant support is included in submitted manuscripts or reports, and that 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).
H. Concept leads are responsible for sending a copy of the published article and a single slide summarizing the publication to the RICC Admin Core at tbricc@njms.rutgers.edu.

4.6 Reports

Scientific reports related to RePORT International projects must also undergo EC review before submission. Annual reporting to funding agencies is not included.

4.6 Other Scientific Products

For other proposed RePORT International scientific products, investigators must contact the EC Chair and RICC Admin Core for further clarification on review procedures.

5. EXTERNAL COLLABORATIONS

RePORT International may be asked by external groups (e.g., WHO) or individuals to contribute data, specimens, or pre-analyzed results to an analysis, report, or manuscript outside the context of an existing multi-network concept. While individual RePORT country networks will independently manage requests limited to their network, when data or specimens from two or more RePORT countries are involved or the contributing

project has received RICC RFA funding, the proposed external collaboration qualifies as a RePORT International project. The proposed external project must be presented in advance to the RePORT EC for their consideration and to determine if a multi-network concept sheet should be developed. This process may involve additional preliminary discussions with RICC, sub-groups of RePORT investigators, and funding agency representatives. Additional RePORT Working Groups (e.g., Data Harmonization Working Group) may be asked to review, depending on the scope of the proposed research and complexity of the data or specimen request.

EC-approved external projects must have a designated RePORT Collaborating Investigator, who facilitates communication between the external investigators and RICC and guides the project through the submission, review, and finalization processes. Use of certified RePORT country laboratories for assays and RICC data services is encouraged. Data transfers for analysis by external collaborators partners require data transfer agreement between each participating RePORT country network and the external group.

External concept sheets must adhere to the same guidelines for concept sheets, including regular project updates, SRC review, return of results, and authorship. It is the responsibility of the project leads to ensure adherence to RePORT International requirements.

6. CONSORTIUM MEETINGS AND COMMUNICATION

As a large, multi-country research consortium, RePORT International requires clear communications and multiple pathways for information dissemination about RePORT studies and initiatives. RICC supports and coordinates most of the communications within RePORT through conference calls, in-person meetings, electronic and written materials, and announcements and postings through the RePORT International website. The website serves as a main driver of general and public communication. RICC also distributes a newsletter and may utilize social media platforms for communication purposes.

6.1 Meetings

RICC organizes two meetings per year: the larger Annual Consortium Meeting which is generally held in a RePORT network country, and the smaller Annual Leadership Meeting held at a RICC site.

6.1.1 Annual Consortium Meeting

In collaboration with RePORT International leadership, RICC organizes an Annual Consortium Meeting to bring together RePORT country investigators, data managers, and collaborators to discuss current research in the field, report on findings from RePORT studies, identify new collaborative projects, and encourage interaction among the networks. In addition, the meeting provides opportunities for training, identifying key issues, defining and discussing consortium procedures, clarifying roles and responsibilities of RePORT members, and discussing data-related issues.

The meeting generally includes scientific sessions to update RePORT members on the latest scientific research related to RePORT country-level and multi-country research. The meeting agenda generally includes two days of scientific presentations and discussion, one day of data harmonization meetings, and a half-day dedicated to consortium operations. Additionally, the Annual Consortium Meeting may provide training opportunities.

RICC is responsible for the overall logistics of the meeting, preparation of agendas and background materials and, subsequently, dissemination of any required materials. The meeting will be located in a RePORT country according to a rotating schedule. RePORT country networks are responsible for lodging and transport for their investigators to attend the Annual Consortium Meeting.

6.1.2 Annual Leadership Meeting

RICC holds a one- to two-day annual leadership meeting hosted at Rutgers University or another RICC leadership site. The meeting is generally held at the six-month mark in between Annual Consortium Meetings and serves as a means to measure progress to date and conduct strategic planning activities. Attendance includes the RICC Director, Co-Director, and Associate Directors, members of the RICC Administrative and Data Cores, WG chairs, network PIs, the RICC Program Scientist, NIH staff, and invited investigators.

6.2 Conference Calls

RICC organizes a weekly Administrative Core call and monthly calls for the LG, EC, SRC, Data Harmonization WG, Capacity Strengthening WG, and protocol teams. Other calls may be organized for ad hoc working groups. A list of conference calls will be distributed in the Monthly RICC Newsletter.

6.3 Consortium Website

The RePORT International website (reportinternational.org) provides a wide range of materials.

The design and maintenance of the RePORT website is the responsibility of RICC. Document posting requests or design/structure update requests are sent to the website manager. Questions and comments on the website may be sent to tbricc@njms.rutgers.edu.

6.4 Newsletter and Social Media

The RePORT International Consortium routinely distributes a newsletter to members, which generally includes study and other updates, concept sheets in development, a listing of new publications, current events at sites, upcoming meetings and conferences, funding opportunities, network and consortium metrics, member highlights, and consortium team and staff activities.

The consortium may utilize social media to keep members and the public aware of news and content related to the RePORT International scientific agenda.

The RICC Administrative Core is in charge of newsletter development and distribution, as well as the consortium's social media presence.

6.5 Other Communication Mechanisms

RICC will maintain mailing lists for the core RePORT scientific and operational groups. These mailing lists will be used to share meeting information and documents. RICC will request membership updates from the country networks and WG leadership on an annual basis.

7. RePORT INTERNATIONAL STANDARD DOCUMENTS

7.1 Governance Documents

The RePORT International governance documents include the Bylaws, WG charters, Consortium Agreement, and other policies and procedures that govern the management and operations of the RePORT International consortium. New governance documents and amendments of current documents must be shared with the EC and are accepted by a two-thirds vote of EC voting members.

The RICC Admin Core handles any requests for clarifications of the governance documents.

7.2 Common Protocol (CP)

The RePORT International Common Protocol (CP) was developed for collecting data and specimens from participants in the RePORT Consortium. It serves as a platform for coordinated TB research by establishing a common schedule of events, set of study procedures, definitions, and data standards that are used in the context of observational clinical TB research. The goal of the RePORT CP is to enable RePORT research studies to use pooled data and well-curated biological specimens for future analysis. The RePORT CP describes the populations and processes for collecting the specimens and data. Study activities and data collection are divided into **Core** (essential study procedures and data collection) and **Optional Modules**.

RePORT country networks must adopt all core elements of the RePORT CP. Country networks can adapt the Common Protocol for their country study procedures by (1) making minor changes to core elements if needed for cultural adaptation, and (2) adding new content to align with country research interests.

The Common Protocol shall undergo a revision every five (5) years, to align with RePORT grant renewal cycles. The goal of the revision process is to incorporate new scientific goals and streamline study activities by evaluating what data and specimens have been used or not used by the individual RePORT countries and the RePORT International consortium. All RePORT countries will be invited to provide input on the review process. The revision process will be coordinated by RICC.

A Common Protocol revision is reviewed and voted on by the EC. Approval requires a two-thirds vote of voting RePORT countries.

RePORT countries aligned with prior versions of the Common Protocol are grandfathered in until subsequent renewal of grant funding presents an opportunity for protocol revision.

7.3 Minimum Global Dataset

The RePORT International Minimum Global Dataset defines the essential study variables that must be collected by every RePORT country to comply with the RePORT Common Protocol.

The RICC Data Core and RePORT Data Harmonization Working Group (DHWG) are the managing bodies for the Minimum Global Dataset. Changes and additions will be presented to the DHWG for review.

7.4 Data Exchange Standard

The RePORT International Data Exchange Standard (DES) defines the tables, variables, and code lists that will be used for the exchange of data for RePORT multi-country collaborations and may include definitions and formats for more variables than are required by the Minimum Global Dataset.

The RICC Data Core and RePORT Data Harmonization Working Group (DHWG) are the managing bodies for the RePORT DES. Changes and additions to the DES will be presented to the DHWG for review. The DES will be maintained by RICC Data Core and the Harmonist team, and be available online at tbreportdes.org.

8. REPORT INTERNATIONAL COMPOSITION

8.1 Expansion of RePORT International

The RePORT International Consortium may expand through the addition of new sites and country networks. Candidate countries can be identified by the LG or other partners (e.g., NIH), or can contact RICC to nominate themselves for inclusion. In the initial consideration process, candidate countries should be reviewed by RICC, the LG, and NIH program, who shall consider the eligibility of the candidate country network, its potential contributions to the RePORT International scientific mission, and the availability of RICC resources to support an additional country network, including RICC capacity for additional data management, data quality assurance, statistical analysis, and administration.

Procedures for evaluation of new country networks are as follows:

A. A candidate RePORT country network is identified by RICC, NIH, RePORT partners, themselves, or other mechanisms.
B. A candidate RePORT country network confirms interest to RICC.
C. RICC works with the candidate RePORT country network to complete a **Country Implementation Plan** as part of a review of the country network's eligibility. The Country Implementation plan will include details on
    a. Candidate Country Network information: names of sites, locations, contact information
    b. Country team Principal Investigators: experience, qualifications, documentation of interest
    c. Country team co-investigators: experience, qualifications
    d. Research facilities, including clinical, laboratory, and biorepository capacity and certifications
    e. Descriptions of the actual or projected study populations for Cohorts A and B, including estimates of TB incidence, prevalence of HIV, and projected size of sub-populations of interest such as pediatrics.
    f. Descriptions of ongoing TB research and whether existing TB studies will be adapted
    g. Plan for adapting the RePORT Common Protocol
    h. Current data management approaches and capacity for adoption of the RePORT International data collection templates/Minimum Dataset
    i. Preliminary proposed variable mappings
    j. Capacity for samples shipments
    k. Willingness and Ability to contribute data and specimens to concept proposals and participate in other multi-network projects as outlined in Section 3.
D. Inclusion of the candidate network is discussed with the LG and NIH on the next available LG call.

E. If the application goes forward, the country candidate may be invited to give a presentation at the next EC meeting.
F. Final inclusion of candidate countries in RePORT International will be determined by a two-thirds vote of the EC, with one vote per active RePORT region. The candidate country shall not be present during the vote.

If the EC votes to include a new country in RePORT International, RICC will extend an official invitation and work with the country team to develop a timeline for onboarding and integration.

Figure 1: RePORT International Concept Proposal Workflow