RePORT International Coordinating Center
Data Producer Data Use Agreement

This RePORT International Coordinating Center Data Sharing Agreement ("Agreement"), effective as of 1 January, 2018 ("Effective Date"), is entered into between ***Family Health International d/b/a FHI* 360** ("FHI 360" or "RICC," as defined below)**,** a North Carolina, USA, non-profit corporation with its principal place of business at 359 Blackwell Street, Suite 200, Durham, NC, USA 27701, and ("Data Producer").

BACKGROUND AND PURPOSE

A. RePORT (Regional Prospective Observational Research for Tuberculosis) International is a collaborative research project under which research consortia in various countries collect and share tuberculosis research data pursuant to the RePORT International Common Protocol, in order to facilitate development of better treatment and prevention of tuberculosis via coordinated and collaborative approaches to tuberculosis research.

B. Data Producer is implementing the RePORT Common Protocol under Protocol Number H-32657 entitled "Biomarkers for Risk of Tuberculosis and for Tuberculosis Treatment Failure and Relapse Repository: Common Protocol for Collecting Data and Specimens from Participants in the Regional Prospective Observational Research for Tuberculosis (RePORT-India) Consortium" (the "Protocol") within the RePORT-India consortium and will contribute research data to RePORT International as more fully set out below.

C. FHI 360 is the RePORT International Coordinating Center ("RICC") and is responsible for, among other things, ensuring data quality and completeness and maintaining a harmonized database of the research data contributed by Institution and others within the RePORT International network.

D. Data Producer and RICC are entering into this Agreement to set out the terms and conditions applicable to the transfer and use of research data contributed to RePORT International.

Data Producer and RICC therefore agree as follows:

1. Transfers of Contributed Data.

a. As used in this Agreement, "Contributed Data" means data collected by Data Producer pursuant to the RePORT International Common Protocol, including, but not limited to, the required data elements listed in the RePORT International Data Elements Bank.

b. Data Producer will periodically transfer Contributed Data to the Consortium Data Management Center maintained by its consortium ("CDMC") as specified in the Memorandum of Understanding for RePORT International Partner Consortia, the RePORT International Data Elements Bank, the RePORT International RICC Data Transfer Plan, the RePORT International Data Quality Plan, and any other rules or processes established by RePORT International regarding the collection, transfer, use, or disclosure of Contributed Data. (collectively, the "Data Regulations").

c. Data Producer hereby authorizes the CDMC to process and de-identify the Contributed Data, and to periodically transfer de-identified Contributed Data to RICC, as set forth in the Data Regulations. Data Producer acknowledges and agrees that CDMC will be solely responsible for ensuring that

Contributed Data is transferred to RICC through encrypted or other secure method to ensure privacy and confidentiality, and is de-identified prior to transfer to the standard specified in the Data Regulations.

d. Transfer of the Contributed Data as provided herein does not confer ownership on either the CDMC or the RICC, but the CDMC and RICC shall have the right to share and use the Contributed Data as set forth in this Agreement and in the Data Regulations.

2. Use of Contributed Data.

a. RICC may use the Contributed Data to conduct reviews of data quality and completeness for purposes of improving the quality of the data being collected under the RePORT International Common Protocol, for research and analysis in connection with the RePORT International research project, and for any other purpose permitted under the Data Regulations.

b. RICC may disclose Contributed Data which is de-identified to any CDMC, Data Producer, or other authorized member of a Partner Consortium that has signed the MOU ("Members") to use for research or anaylsis purposes in connection with the RePORT International research project.

3. Data Producer Responsibilities.

a. Data Producer will collect all Contributed Data appropriately after having obtained informed consent from program participants and/or their parents or guardians, having monitored its veracity, and having generally complied with all applicable laws and regulations, including those requiring study team members to have completed internationally recognized human subjects protection training.

b. Data Producer will collect and transfer the Contributed Data in compliance with the applicable requirements of the RePORT International Common Protocol and the Data Regulations.

4. RICC Responsibilities.

a. RICC will not use or disclose the Contributed Data for any purpose other than those permitted under this Agreement, or as required by law.

b. RICC will not disclose the Contributed Data to any third party other than those specified herein without the consent of the CDMC.

c. RICC will use appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the Contributed Data other than as permitted by this Agreement or required by law.

d. RICC agrees not to attempt to re-identify the Contributed Information or to contact the individual data subjects.

5. Data Breaches.

a. Data Producer acknowledges and agrees: (i) that the CDMC is solely responsible for ensuring that Contributed Data is transferred to RICC through encrypted or other secure method to ensure privacy and confidentiality, and is de-identified prior to transfer to the standard specified in the Data Regulations; (ii) that the Contributed Data received by RICC shall not contain any indentifiable data or Protected Health Information (as defined in the Health Insurance Portability and Accountability Act of 1996); and (iii) RICC shall have no liability whatsoever to Data Producer arising out of or relating to any breach, compromise, or unauthorized use or disclosure of Protected Health Information.

b. In the event that RICC becomes aware of any use or disclosure of Contributed Data not permitted by this Agreement, RICC shall notify Data Producer within a reasonable time after it discovers such use or disclosure by contacting the ("Data Producer"). RICC will ensure that any agent, including a subcontractor, to whom it provides the Contributed Data agrees to the same restrictions and conditions that apply through this Agreement to the RICC with respect to the Contributed Data.

6. Term and Termination.

a. The term of this Agreement begins on the Effective Date and continues until all the Contributed Data transferred by Data Producer to RICC is destroyed or returned to CDMC.

b. Upon Data Producer's knowledge that RICC has breached a material term of this Agreement, Data Producer shall give RICC written notice of the alleged breach and an opportunity to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within the reasonable time-period specified by the Data Producer, the Data Producer shall discontinue disclosure to the CDMC. Data Producer may immediately discontinue disclosure of the Contributed Data to the CDMC if the Data Producer determines cure of the breach is not possible.

7. General Provisions.

a. Recipient and Holder understand and agree that individuals who are the subject of Contributed Data are not intended to be third party beneficiaries of this Agreement.

b. This Agreement shall not be assigned by Data Producer without the prior written consent of the RICC.

c. Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof. This agreement is a non-financial understanding between both parties. No financial obligation by or on behalf of either party is implied by a party's signature to this agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

FAMILY HEALTH INTERNATIONAL D/B/A FHI 360	**("Data Producer").**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____