Data Sharing and Use Plan

Reporting on the use of data derived from FIND materials as reported to FIND

A. Background

As part of FIND's mission to support the development and evaluation of new and existing tools to improve the diagnosis of poverty-related diseases in low- and middle-income countries, we provide access to materials: human specimen that are collected with patient consent and special reagents that are not commonly available. To ensure that FIND fulfils its obligations to the specimen and reagent providers, and complies with the general terms of global access with respect to making data available to the scientific community and other stakeholder, we encourage researchers who make use of these materials to, at the very least, make their findings available to FIND. This also enables FIND to validate its specimen collections using independent third party analyses, thereby confirming the quality of specimens that are available to all users.

B. Purpose

The FIND Data Sharing and Use Plan (the "Use Plan") describes how FIND manages the use, accessibility, transfer, validation, and disclosure of data obtained from research that uses FIND materials, and ensures that the interests of data contributors are respected.

The purpose of the Use Plan is to ensure that FIND will: (i) treat data and relevant information with respect for each contributor's interests; (ii) afford data and relevant information the level of data-sharing assigned by the contributor, which is intended to encourage interaction between contributors; and (iii) share data within the context of Global Access data dissemination requirements, to ensure that the scientific community is informed of such data.

This Use Plan defines goals, principles, and processes by which this purpose will be met.

C. Goals

- Define the processes that will be used to manage the validity, transfer, sharing, and disclosure of data reported to FIND derived from the use of materials (including specimens provided by the FIND Specimen Bank).

- Inform data contributors about data ownership, protection, privacy, access, use, and retention.

D. FIND's role

FIND shall control and manage the *Data Sharing and Use Plan* through this operating procedure.

E. Data Use Principles

- Data access and use of data by FIND will not jeopardize the activities including, but not limited rights to publication and Intellectual Property (IP) rights, of contributors.

- Data access and use of data by FIND will support applicable regulations for data validation, security, and IP rights.

- Upon each approved request of reagents or human specimens from the FIND Specimen Bank, FIND will encourage that data derived from research using these materials be shared with other researchers and the global health community.

- As specified by the data contributor, data sets will be accessible to FIND, and with the specific permission of the data contributor, to FIND's global partners and the broader scientific community.

- The scope of disclosure and confidentiality will be defined by the data contributor in the "FIND Data Transfer Report Template" during the data transfer.

- Data transfer, validation, and disclosure will be specified through the defined procedures outlined in Section I and Section J below.

- Partnership and collaboration between researchers working in related research areas will be encouraged and promoted.

F. Implementation of Data Use Principles

- Data contributors remain the owners of all data they contribute, and will always be able to access the data they have contributed.

- Data will be protected from unauthorized access and modification.

- Contributed data files will be stored and preserved in their original format.

- Data will only be accessible by authorized users consistent with the principles defined above, and the procedures outlined in Section I and Section J below.

- Processes for data transfer, validation, processing, and access will be documented, consistent, repeatable, and clearly communicated.

G. Data Transfer

All data contributors must comply with the specific requirements listed below:

- <u>Mechanism</u>: Data is transferred online by clicking on the data exchange link on the

notification e-mail received upon approval of the material request. Upon a successful submission of the data, an e-mail confirmation will be sent out.

- Format: Data must be submitted in an Excel workbook (.xlsx), or another format agreed to by FIND. Submissions must include clear information on the methodology and procedures used to collect the data. FIND provides an Excel workbook (yymmdd_FIND_Data_Transfer_Report_Template.xlsx) for data reporting at the time of
2sample distribution. The spreadsheet allows for the reporting of up to 10 results per aliquot. Data contributors should contact FIND to discuss data formats in cases where more than 10 results per aliquot are expected.

- Timeline: Data will be transferred to FIND within 4 weeks after generation of the results. Incremental transfers are possible.

H. Data Validation

FIND will use standard algorithms in the R environment and Statistical Analysis System (SAS) to import and analyze data, and will contact the data contributor if any queries regarding the submitted data arise. FIND will report back to the data contributor on the results of the analysis at the end of the process.

I. Data Withdrawal and Resubmission

Data contributors may request deletion, modification, or correction of submitted data at any time. In the case of deletion, the contributors are encouraged to re-submit the modified or corrected version of the data. All inquiries on the subject must be directed to materials@finddx.org.

J. Data Sharing and Disclosure

FIND may use and disclose the data to the extent agreed by the contributor and FIND. FIND offers three levels of data sharing to data contributors:

- Level 1: Data will be kept confidential by FIND, and FIND will protect data against unauthorized disclosure or use.

- Level 2: Data will be used by FIND and may be disclosed by FIND to other data contributors of the FIND Specimen Bank.

- Level 3: Unrestricted use – Confidential treatment of data is not required, and FIND may publish results (or re-publish, as applicable), but will not publish the raw data.

The data contributor is responsible for designating the appropriate level of data sharing at the time of data transfer (or after the completion of data transfer, in the case of a change in the data sharing level). Level 1 will be the default level.

K. Use of Data

Depending on the data sharing level (see section I), FIND may use the data for the following activities:

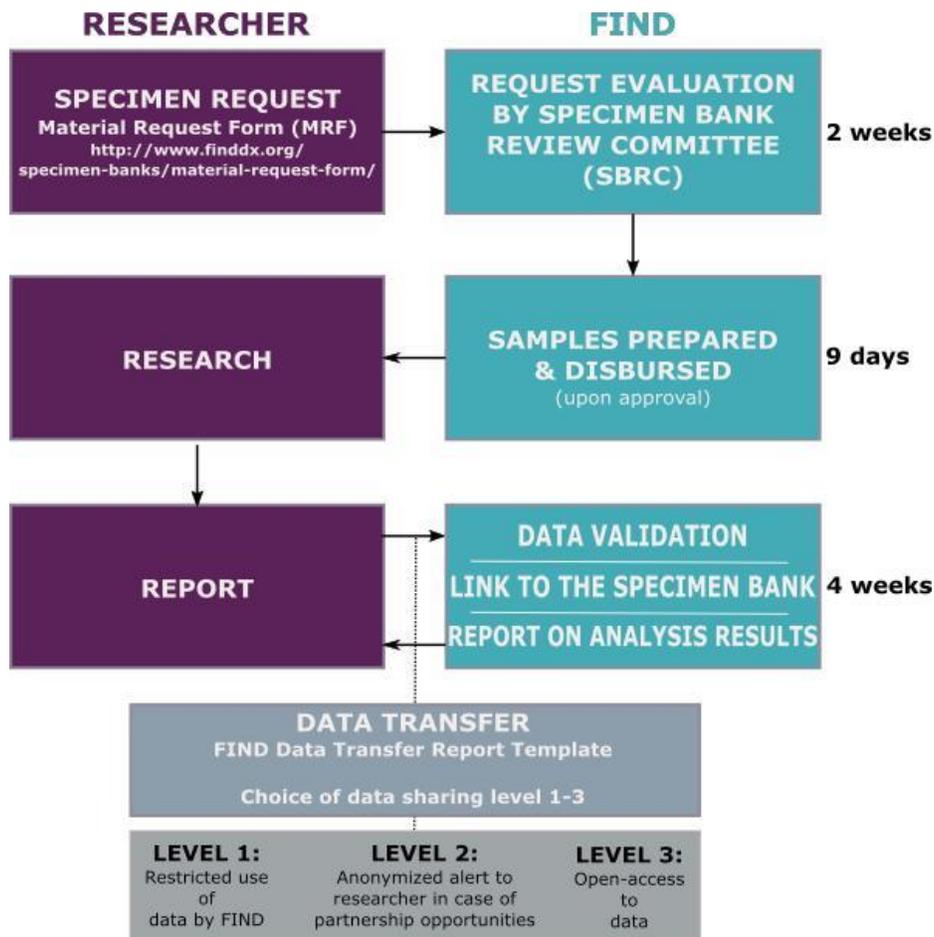| Use of Data for/to:	Level 1 (default)	Level 2 (only if data contributor agrees)	Level 3 (only if data contributor agrees)
Independent analysis of the data by the FIND team using standardized tools and best practices for Use Case/TPP-driven performance evaluation	✓	✓	✓
Support in turning biomarker/product, if promising, into a comprehensive diagnostic solution • Partner in grant • Support for success (S4S) programme • Clinical trials platform • WHO assessment	✓	✓	✓
Continuous improvement of the FIND Specimen Bank and its use • Better classification of samples that show conflicting results between microbiological tests and different biomarker-based assays • Improvement of the process for evaluating specimen requests and distributions • Review and publication of outcomes and high level results (organization, number of aliquots, purpose) in the Annual FIND Specimen Bank Report	✓	✓	✓
Combine data generated by different research groups on the same specimens and link to the FIND specimen database to compare and explore the additive value of combinations of biomarkers	✓	✓	✓
Matchmaking between data contributors to promote diagnostic performance and advances in the field • FIND will contact data contributors to offer partnership/ collaboration opportunities		✓	✓
Publish the status of a biomarker or an assay developed using the specimen bank, in order to contribute to further implementation and promotion of the biomarker or the assay of interest: • in publications (e.g., systematic reviews) with full respect to IP rights • in public presentations (e.g., to support funding)			✓

L. Data Security

Policies and practices will ensure data integrity and security, and address the following issues:

- Data encryption
- Data quality assurance
- Secure file transfer protocols
- Data backup and disaster recovery

M. Process Overview

Key steps and responsibilities from material request to data transfer are illustrated in the following chart:

N. Relevant Documents

- FIND Data Transfer Report Template