

endTB data sharing initiative Ethics framework

This ethics framework is intended to guide the endTB data sharing initiative (eDSI) to promote ethical, equitable and transparent access to endTB data while achieving the eDSI overall goals to increase the dissemination of knowledge to ultimately improve patient outcomes. Fulfilment of this purpose requires that the individuals and communities from whom data originated be accorded the respect and protection that is due to them, including protecting their interests, rights, safety, privacy and dignity.

This ethics framework is therefore designed to clarify the responsibilities of the eDSI, data subjects, contributors, and researchers and identify issues of ethics that arise in the sharing of human data. It details a set of principles and standards that all those involved in the eDSI agree to operate by.

OVERARCHING PRINCIPLES

I. Good Governance

Efforts to manage the use of data must include the involvement of the countries from which the data was collected (“countries of origin”) and a representation of affected communities, and all efforts must be executed in good faith.

II. Collaboration and Capacity Strengthening

The eDSI will support access to and research using the data. Through collaboration and capacity strengthening the eDSI will endeavour to enhance data management, data analysis and general research skills among researchers from high MDR-TB burden countries.

III. Timely, Accountable Data Access

The eDSI is committed to reducing barriers to data access as much as possible while balancing and maintaining the level of accountability necessary to protect the rights of data contributors and to do no harm to the individual or the community at large. The eDSI is also committed to maximizing public benefit by promoting research and innovation.

VI. Equity and Benefits Sharing

The eDSI advocates acceptance of the legal and ethical responsibility for ensuring fair and equitable sharing of any benefits that may arise from the data use. The eDSI is committed to promoting the adequate and timely sharing of results and benefits of data access with those affected by or involved in diagnosis and treatment of DR-TB. In addition, the eDSI will support access to data for research that promotes accessibility, availability, affordability and adaptability of drugs, and diagnostics for all countries in need, in particular those affected by DR-TB.

Gratefully adapted (without endorsement) from the Ebola Data Platform Ethics Framework (v. 19 March 2019).

This work is licensed under the Creative Commons Attribution-ShareAlike 4.0 International License by Médecins Sans Frontières. To view a copy of this license, visit <http://creativecommons.org/licenses/by-sa/4.0/>

V. Community and Stakeholder Engagement

The eDSI will engage and communicate with stakeholders, including DR-TB survivors, affected communities/patient activist organizations/community advisory boards, and any other interested organisations or individuals whose skills/competence directly contribute to the purpose of the eDSI.

VI. Compliance with Laws

The eDSI will comply with applicable laws including, without limitation, the applicable laws of the country of origin and international standards, including with respect to obtaining required ethical approvals from the country of origin, as well as obtaining all relevant international ethical approvals.

VII. Transparency

The eDSI is committed to operating transparently in its design and management. To that end, the eDSI will share information about the names of all governance body members, details about the governance of the eDSI, data access policies and procedures (including criteria for data access, any conditions on access, and appeals process) as well as, wherever possible, summary reports of the meetings.

VIII. Conflicts of Interest

The eDSI is committed to protecting the reputation and integrity of the eDSI and to ensuring trust and confidence in the governance arrangement related. This includes avoiding or managing conflicts as they arise, which will be done in accordance with the eDSI Conflict-of-Interest Policy.

IX. Data Quality

The eDSI will promote the management of data paying special attention to the relevance, accuracy, timeliness, and coherence of data to be shared.

X. Disputes

All disputes on eDSI policies and procedures will be addressed by the Steering Committee. Disputes regarding the data access decisions should be made to the Data Access Committee in the first instance and, if required, may be referred to the Steering Committee for final decision. All parties involved in the eDSI agree to work in good faith to settle disputes.

PRINCIPLES FOR THE eDSI, DATA SUBJECTS, AND CONTRIBUTORS

eDSI is committed to the principles of processing, storing and transmitting data in a lawful and fair manner. The eDSI shall ensure that robust data security mechanisms and controls, benchmarked against national and international standards, are in place to protect the privacy and rights of the data subjects.

I. Voluntary

Individual data contributors (or their legal representative for minor participants and deceased participants) have the right to opt out of having their data shared on the repository. To this end,

efforts will be made to inform them about the plans to place study data in the eDSI repository and on how to request withdrawal of their data.

II. Ethics Oversight

Access to data will be in accordance with applicable ethical standards and requirements (including formal ethics approvals as needed), and in compliance with international and national best practices relating to confidentiality and privacy, medical ethics, medical research ethics, research integrity, data protection and data access, including but not limited to the duties to not cause harm to individuals or groups, to respect persons' autonomy, confidentiality and right to informed consent.

Access to data should adhere to the terms of consent agreed with the data subject. For datasets for which a consent for future use in line with the charter of endTB data sharing initiative was not obtained, a general waiver of consent must be approved by the ethics committee of the country of origin that originally gave approval for the endTB study and by central E/IRBs when required. The request for the waiver will include information about the eDSI (e.g. governance framework, Charter, Ethics Framework) and that the repository is to allow research with important social value and that poses no more than minimal risks to the participants.

Where required by national regulations or practices, the eDSI will seek approval or positive opinion of the eDSI Governance Framework by the relevant country ECs/IRBs.

When required, the eDSI will seek approval or positive opinion of the eDSI Governance Framework by the relevant E/IRBs that have supervised endTB Consortium partners' work on the endTB project.

As required by national regulations or practices, the eDSI will submit periodic reports to the relevant ECs/IRBs about the requests approved (and reviewed) by the Data Access Committee.

The Data Access Committee may decide to seek approval from the relevant ECs/IRBs if, upon review of a data access application, it believes that the given research poses a potential risk of harm to patients or communities (e.g. risk of re-identification in small subgroups).

Following approval of a data access application by the Data Access Committee, the data will be released to the applicant only after both (i) approval or waiver from human subjects research requirements by the applicant's relevant ECs/IRB and (ii) signature of a Data Access Agreement which sets out minimum, legally binding, protections.

III. Confidentiality & Data Security

The eDSI will uphold privacy and data protection and put in place suitable technical and organisational measures to ensure data is held securely. The eDSI will not share directly identifiable data of any person.

IV. Respect the Interests and Protect the Rights of Individuals and Communities

The eDSI will respect the interests and protect the rights of the individuals and communities from which the data originated. The eDSI is committed to ensure that its activities shall do no harm both at the individual and community levels.

PRINCIPLES FOR THE eDSI AND RESEARCHERS

The eDSI encourages the rapid dissemination of information in an equitable manner. To that end, the eDSI will have a timely, and effective system to make data accessible in order to facilitate research and encourage rapid publication. Equitable access will be promoted by cost-free access to data. The eDSI is also committed to maximising public benefit by strengthening and promoting research and innovation by the main DR-TB-affected countries, through collaboration, training and capacity strengthening.

ACCOUNTABILITY

Accountability with regards to the above principles will be enforced by making public on the endTB website the following:

- eDSI governance
- Membership of the Steering Committee and Data Access Committee
- Approvals or positive opinions of the relevant ERBs
- Data protection measures
- Approved applications updates
- Outcome of approved research (publication, conference abstract or brief report)
- Annual activity reports of the SC