DNDi

Best Science
for the Most Neglected

POLICY ON SHARING AND SECONDARY USE OF HUMAN SUBJECT RESEARCH DATA

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I. Objective

This policy describes DNDi' s commitment to share data from DNDi-sponsored or supported Human Subject Research (HSR).

DNDi recognises the potential value, to researchers in public health and other actors, of the data gathered in the course of its research and development activities.

DNDi also recognises the ethical imperative to share and disseminate its data responsibly and in accordance with relevant standards of medical confidentiality and ethics, Good Clinical Practice, and data protection legislations.

II. Scope

The policy applies to:

- The sharing of data, both aggregated and participant-level, from DNDi-sponsored or supported HSR where DNDi is the owner of the data.
- Re-use of HSR data by DNDi for secondary research purposes.
- All DNDi staff and, as appropriate and when contractually agreed, to vendors or consultants performing these activities on behalf of DNDi.

III. Definitions

Human Subject Research - Human Subject Research (HSR) is systematic, scientific investigation that can be either interventional or observational and involves human beings as research subjects, commonly known as test subjects. In this policy, the HSR covers participants from either medical research or non-medical research work conducted by DNDi.

Data Requestor – Third parties external to DNDi requesting HSR data for scientific use including researchers, funders and other partners conducting secondary research with the shared data.

De-identified data - Refers to HSR Data where all directly identifiable information has been removed and indirectly identifiable information generalized in order to reduce the risk of identifying the data subject.

DNDi supported research - Refers to HSR activities where DNDi provides an in-kind support to the trials sponsored by other parties.

DNDi sponsored research – Refers to HSR projects where DNDi is the project owner and assumes sponsor responsibilities as defined in the ICH-GCP.

Good Clinical Practice - Is the international ethical, scientific, and practical standard to which all clinical research is conducted.

IV. Policy

1. Guiding Principles

DNDi is a signatory to World Health Organization - International Clinical Trials Registry Platform (WHO-ICTRP) Joint Statement[1] on reporting of clinical trial results and commits to sharing its HSR data in a manner that respects the following principles:

- **The respect of participants in medical research:**
  - DNDi conforms to applicable data protection laws when collecting and sharing HSR data.
  - DNDi shares HSR data for additional research purposes when it has the informed consent of subjects to do. Where informed consent for use of data for additional research purposes was not provided, an approach to information/consent and/or waiver thereof is approved by an appropriate ethics committee.
  - DNDi ensures the confidentiality of participants' medical data is fully protected and that the privacy of individuals and the dignity of communities is fully respected when HSR data is collected or shared.
  - DNDi ensures an appropriate level of data de-identification through technical or organizational methods to prevent re-identification of individual subjects when HSR data is shared.

- **Maximizing the benefits to participants and society, while minimizing any potential harm:**
  - DNDi aims to share its HSR data in order to facilitate, thanks to greater transparency, the validation of scientific and research results (including negative results), and the contributions made by research participants to the creation of additional knowledge.
  - DNDi seeks to ensure the sharing of HSR data balances the needs of researchers who generate the data, researchers who may wish to re-use the data, and the individuals and communities who participated in the research in the expectation of broader public health benefits.
  - DNDi seeks to minimize potential harm from data sharing including privacy invasion; biased analyses; unfair and competitive use of data; the undermining of public trust and incentives to conduct clinical trials.
  - DNDi shares adequate and relevant datasets limited to the data which are necessary for the research project in question.

2. Ways that DNDi shares Data

- **Registration of DNDi HSR**

  Before data collection, HSR sponsored by DNDi is registered on appropriate public databases and where possible and applicable provides a method for accessing HSR data upon publication of study results. Additionally, DNDi publishes the synopsis of clinical trial protocols on its global website (www.DNDi.org).

[1] World Health Organization, Joint statement on public disclosure of results from clinical trials, May 2017, https://www.who.int/news/item/18-05-2017-joint-statement-on-registration

- **Publication of clinical trial data**

  Within 24 months of last subject last visit, DNDi endeavors to publish the results (aggregated data) of clinical trials it sponsors in open-access peer-reviewed journals, even if results are negative, as per DNDi Scientific and Clinical External Communications Policy. DNDi endeavors to provide a method of accessing relevant associated HSR data upon publication of study results.

- **Data sharing with patients participating in clinical trials**

  DNDi aims wherever possible to ensure that participants in clinical trials it sponsors are informed of the results of the trial in a way that they can understand.

- **Sharing Individual Subject level data**

  Data Requestors who wish to request HSR will find information on DNDi's website describing the process. This process applies for researchers, funders and other partners conducting secondary research with the shared data.

  Appropriately de-identified or aggregated data will be shared directly by DNDi or via a third party subject to a positive outcome of the review and approval process and acceptance of terms of use by the Data Requestor.

3. Review and approval process

Requests for access to HSR data generated from DNDi-sponsored HSR will be managed by DNDi or an appropriate third-party. A group of experts with experience in R&D, ethics, legal and data protection will be responsible for:

- Receiving and reviewing data requests
- Recommending approval or rejection of data requests
- Ensuring that data is shared in compliance with this policy.

4. Compliance with data protection laws and contractual obligations

To comply with applicable data protection laws, Data Requestors seeking individual participant level data will enter into an appropriate agreement or terms of use. Data sharing may also be subject to contractual obligations which DNDi may have with its partners.

V. References

World Health Organization, Joint statement on public disclosure of results from clinical trials, May 2017, https://www.who.int/news/item/18-05-2017-joint-statement-on-registration.