

# InTBIR Data Sharing Principles Document

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## Background

The InTBIR Initiative, hereinafter referred to as InTBIR, is a cooperative effort of the European Commission (EC), the National Institutes of Health (NIH), the US Department of Defense (DoD), the Ontario Brain Institute (OBI) and OneMind that aims to coordinate and leverage international clinical research activities on traumatic brain injury (TBI) research.

The long-term goal of InTBIR is to improve outcomes and lessen the global burden of TBI by 2020 by supporting well-designed, hypothesis-driven studies collecting high quality data followed by rigorous statistical analysis. By taking advantage of widespread variability in how patients are treated, InTBIR aims to identify causal relationships associated with clinically meaningful outcomes.

One of the key aims of InTBIR is to promote the ethical sharing of data across the TBI research field and to facilitate collaboration. Accordingly, the calls for proposals under the InTBIR Initiative included a mandate for the collection of Common Data Elements (CDEs) and the establishment of databases to permit data sharing with other members of the InTBIR consortium. The requirement that, as of July 2018, all manuscripts submitted to International Committee of Medical Journal Editors (ICMJE) journals must contain a data sharing statement further highlights the importance of openness to collaborative research.

InTBIR has a duty to create a data sharing environment that is secure for the patients, that protects ownership, that allows for maximum use of data collected via studies funded by taxpayers, and that clearly assign authorship credit.

## Objectives

The aim of InTBIR is to promote the use of consistent defined standards within a CDE approach and to develop and implement a federated system for maximizing the use of patient-level information on clinical, phenotypic, genomic and imaging features.

The InTBIR Data Sharing Principles are intended to serve as a guide to collection, standardization, and sharing of clinical TBI data for comparative effectiveness research, ultimately resulting in better management and treatments for TBI. They strive to align with the ***FAIR Guiding Principles for scientific data management and stewardship***, which were developed to provide guidelines to improve the findability, accessibility, interoperability, and reuse of data.

The principles included in this document are subject to revisions by the InTBIR Leadership. They should not be considered static but are expected to evolve over the course of time. Specifics of operationalizing the InTBIR Data Sharing principles are not included within the scope of this document.

## Data Sharing

### Data Sharing Environment

InTBIR studies should strive to use Common Data Elements and standardized protocols to encourage consistency across datasets and familiarity with data elements and study procedures. InTBIR studies should securely store data within geographical regions or jurisdictions, and have compatible data for federation within and across geographical regions or jurisdictions.

### Data Quality

To ensure the quality of data made available via InTBIR, data made available to the data centers should:

- Comprise research/clinical assessments/information obtained via interviews, direct observations, laboratory tasks and procedures, record reviews, genetic and genomic data, neuroimaging data, neuropsychological assessments, data from physical examinations, etc., but must EXCLUDE demographic data that could permit easy re-identification of individual patients;
- Include supporting documentation that aims to make data accessible, understandable and usable by investigators unfamiliar with the dataset. Supporting documentation may, for example, include non-copyrighted data collection forms, study procedures and protocols (including patient consent documents), data dictionary rationale, exclusion criteria, website references, a listing of major study publications, and the definition of genomic analysis protocols;
- Be collected in a manner consistent with institutional policies, and local/national regulations and policies;
- Be collected using the International TBI Common Data Elements to the greatest extent possible  
<https://intbir.nih.gov/icdes>
- Be encoded using data formats that are consistent with commonly used standards;
- When available, feasible, and appropriate to study goals, follow standardized protocols for collection, storage, and transfer of biospecimens, imaging, genomics, and other research methods.
- Have quality assurance algorithms linked to the data sets whenever possible to ensure data formats and consistency.

### Patient security (*also see informed consent principles*)

The identity of research subjects must be protected. Each individual data center will adhere to national law and the respective legal requirements for data sharing in the country in which it is based.

Investigators providing data to any established data center should assure that:

- All data provided to the data center are consistent with all applicable laws, regulations, and institutional policies;
- The data have been encoded at the source using an identifier which is unique to each individual research participant (use of a Global Unique Identifier (GUID) as adopted in the US based Federal Interagency Traumatic Brain Injury Research (FITBIR) database, which enables data to be associated with a participant without exposing or transferring Protected Health Information (PHI), is strongly recommended);
- Algorithms that satisfactorily purge medical data sets of possible identifiers are used in the de-identification process whenever possible.

An Institutional Review Board (IRB) and/or the Data Protection Officer/Privacy Board (as applicable) of the entity providing data should determine that:

- The data made available for sharing for research purposes are consistent with the informed consent obtained from the research subjects from whom the study data was obtained.
- The data made available have been appropriately de-identified/anonymized (consistent with current standards and respective applicable legislative provisions) to ensure its use in a secure environment.
- Risks to individuals, their families, and groups or populations associated with the data have been minimized.
- Data should be used appropriately and only as far as explicitly allowed for by the respective informed consent documents.
- If consent documents stipulate restrictions concerning the use/re-use of the respective data, these should be prominently displayed in the data sets provided.

#### **Protecting ownership** (see *Publication Principles*)

At a minimum, all researchers who access InTBIR data are expected to acknowledge in all resulting presentations, disclosures, or publications of the analyses:

- The funding organization(s) that supported their work;
- The Contributing Investigator(s) who conducted the original study;
- The InTBIR initiative as such

#### **Data usage and quality control**

Clinical data collected should use widely accepted common data elements/data acquisition protocols and conform to the highest possible standards so it can be used by the widest possible array of users, whether academic, medical, clinical, or commercial.

Researchers should make data available to the research community as soon as possible after study completion. Access to data should be subject to relevant data use agreements and should be made available via a standard application process to ensure appropriate use of the data.

Consistent with protecting patient privacy, informed consents for collection of medical data obtained from patients should permit use of their de-identified (anonymous) data for research in as wide a range as possible. (See *Informed Consent Principles*)

#### **Data access privileges**

Data access privileges should be safeguarded by Data Centers and their specific policies. Overarching principles applicable to InTBIR data include:

- Data should be made accessible only for approved research as per the Informed Consent given following appropriate data security procedures;
- Compliance with applicable laws, regulations and local institutional policies and data handling procedures;
- Keeping the data obtained from InTBIR datasets confidential from non-authorized third parties;

- Adherence to the InTBIR Data Sharing Principles, including its provisions on publication of research results emanating from InTBIR data sets;
- Making data accessible at varying levels and giving permissions accordingly;
- Providing only descriptive summary information of accessible data for use by the general public;
- Data should be made accessible as permitted by secondary data use restrictions;
- Data accessibility will depend both on the embargo periods of the partner projects and on national regulations regarding the across jurisdiction transfer of clinical data;
- Access to data or certain components of the data will be restricted to qualified researchers who comply with all applicable rules, laws, regulations or policies (e.g., IRBs, human subjects, informed consent, etc.).

## Informed Consent Principles

### General principles

The InTBIR Informed Consent Principles recommend streamlined and standardised informed consent wording and content, with the intent to enable and reinforce data sharing across InTBIR studies, *including providing for explicit permission for cross-jurisdiction data transfer*. Wording should be based on an adaptation or extension of what has been used by the original InTBIR studies, thus minimising the need to go back to subjects for further consent.

The Principles aim to balance two important objectives: to facilitate data sharing and to respect and protect the participants who have contributed their personal data and materials to InTBIR. Accordingly, participants need to be informed that their data will be de-identified such that there is a low risk that identities of data subjects could be ascertained or otherwise associated with the respective data under study, either by InTBIR study staff or secondary data users (if for the latter consent has been given). The information sheet must also explicitly state that sufficient data encryption and protection standards are in place to guarantee that patient data will only be shared in a secure network.

## Publication Principles

The overall aim of the Publication Principles is to stimulate and streamline high-quality scientific output produced jointly by members of InTBIR.

### General principles

- For the purposes of this policy, the term “publication” refers to manuscripts in scientific journals.
- These principles refer to publications including data from **at least two InTBIR studies** or on topics of **general principles and policies relating to InTBIR**.
- InTBIR is strongly in favor of promoting extensive dissemination of InTBIR data and of data sharing.
- Publications across studies are strongly encouraged but should not jeopardize primary publications from individual InTBIR studies. Open Access publications are preferred.

## Specific goals

- Maximize and accelerate scientific output;
- Increase efficiency and avoid duplication for research;
- Define authorship criteria, fostering the participation of several different InTBIR study investigators (multistudy authorship) in the production of valuable scientific outputs;
- Maintain transparency towards InTBIR collaborators, and external data requests;
- Promote visibility of InTBIR

All study plans/titles should be listed on the InTBIR website (title, aim, PI), so as to be accessible to the InTBIR research community.

## Principles for publications emanating from InTBIR studies

Publications based on data generated under two or more of the participating InTBIR studies shall undertake to ensure:

- methodological soundness;
- correct use of and scientifically appropriate interpretation of the data;
- adherence to criteria for authorship;
- inclusion of appropriate acknowledgements.

**Authorship**, denoted as those on the first line(s) of the authorship attribution in a journal and in indexing services, should be based on appropriate effort and comply with the following four guidelines published by the International Committee of Medical Journal Editors (ICMJE, [http://www.icmje.org/roles\\_a.html](http://www.icmje.org/roles_a.html) ).

Primary authors should meet all four of the following criteria:

- 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 or critical revision of the work 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.

The corresponding author shall be responsible for notifying the InTBIR Leadership of all accepted manuscripts, including the journal title, date of publication, page number(s) and other reference information for the publication/presentation. The InTBIR Leadership will make a record of all accepted abstracts, presentations and publications relating to InTBIR, which will be posted on the InTBIR website.

Authorship credit will be automatically granted to all InTBIR Participants and Investigators who fulfil all four above-mentioned criteria. All publications using InTBIR data shall state the following at the end of the author list: "and the InTBIR Investigators," to represent those investigators involved in the data acquisition, who will be listed as collaborators in alphabetical order. Contributors who meet fewer than all four of the above-mentioned criteria will not be listed as authors but should be acknowledged.

All publications shall acknowledge the *source(s) of the data* as derived from two or more InTBIR studies. Data analyzed by Investigators external to the InTBIR studies should also carry a disclaimer stating that the publication/communication reflects the interpretation only of the author(s). All publications should

make explicit reference to the *sources of funding* [European Commission/NIH/CIHR/DoD/xxx, Grant Agreement/Contract no. xxx].

#### **Additional recommendations for all publications, including those emanating from single InTBIR studies**

We strongly encourage all studies funded under the InTBIR umbrella to include InTBIR in the acknowledgements section of every manuscript. This applies also to publications by investigators from outside the InTBIR studies using InTBIR data sets or where InTBIR has otherwise contributed to bonification of study methods, or interpretation of data. The addition of InTBIR in the acknowledgement section would also serve to increase the visibility of InTBIR globally, as InTBIR-derived or –linked publications shall be listed on an InTBIR publications depository accessible through the InTBIR website.

The publications' metadata will be added to the relevant InTBIR databases, e.g. FITBIR, OBI-BrainCode and the Human Brain Project.