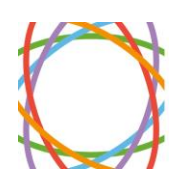# OBI DQF Standard Protocol Requirements

Version: 1.2 - Date: July 17, 2024

Required Protocol Information for Data Quality and Data Handling

In addition to standard protocol information requirements, OBI *recommends* the following information be included:

- Describe **what data** are being captured as part of this study.
    - e.g., WHO-QOL quality of life questionnaire, the MoCA cognitive assessment questionnaire, 10-minute resting state 3T MRI, 22 variants exome sequence VCF files, etc.

- Describe **when** the data will be captured. Please attach a *study visit schedule* table.
    - e.g., Clinical data will be captured at baseline visits, 2 weeks follow-up, 4 weeks follow-up and 8 weeks follow-up.

- Describe **who** will capture/enter/collect/transfer the data on/to Brain-CODE. Ensure that the clinical research team have the capabilities and qualifications to conduct the research study.
    - e.g., Clinical assessments will be collected directly by participants via patient-reported outcomes (PROs) for assessments ...
    - e.g., Specific assessments such as the ... will be collected from participants via coordinator interviews ...

- Describe **how** the data will be captured (what capture methods/tools will be used)
    - e.g., Clinical data will be captured using REDCap on Brain-CODE; MRI scans will be captured from the Siemens T3 at the hospital and transferred to Brain-CODE...

- Describe any **personal health information (PHI)** that may be collected as part of the study, and how participant privacy will be protected.

- Describe the **data retention period** required as appropriate for this study.

o   Please note that data collected will be stored indefinitely on the Brain-CODE platform.

> **Note:**
> More detailed information about the data collected, responsibilities, procedures, and timelines will be required in the study's Data Management Plan.
>
> Refer to Stage 1 document #1 "Study Design, Training, and Testing" for more information.

Standard Brain-CODE Language for Protocols

The following standard text copy that describes OBI's Brain-CODE platform that *must* be included in protocols in order to accurately describe where the data will be collected, stored, and shared:

- *"The data collected for this study will be captured, stored, and shared via the Ontario Brain Institute's (OBI) Brain-CODE neuroinformatics platform. Brain-CODE is a large-scale neuroinformatics platform designed to support the collection, storage, federation, sharing and analysis of different data types across several brain disorders, as a means to understand common underlying causes of brain dysfunction and develop novel approaches to treatment. Brain-CODE supports the principles of making data Findable, Accessible, Interoperable, and Reusable (FAIR). Brain-CODE was designed with best-practice privacy strategies at the forefront to enable secure capture of sensitive participant data in a manner that abides by ethical principles and government legislation while fostering data sharing and linking opportunities. Brain-CODE includes encryption and de-identification tools to protect participant data and enhanced validation certificates to guarantee authenticity of outward-facing software applications, as well as administrative, physical and technical safeguards and security processes. As a result, OBI was named a "Privacy by Design" Ambassador by the Office of the Information and Privacy Commissioner of Ontario in 2011. Working with a team of experts, OBI has developed clear and comprehensive policies and guidelines on data privacy and governance."*

- *"Data will be shared with third-parties for secondary use. Third-parties will own the derived outputs such as new data and analyses (the Work Product) that result from their use of the data."*

- *"For participants in Ontario, health card number (OHIP) will be collected and linked with data stored in independent databases, such as the Institute for Clinical Evaluative Science (ICES). For data entry onto Brain-CODE, the OHIP number will be encrypted upon entry into Brain-CODE and will remain encrypted at all times."*

Standard Brain-CODE Consent Language

The OBI standard consent language for storing and sharing data on Brian-CODE *must* be used without alteration. This consent language can be found on the Brain-CODE governance policies (p. 38) accessible here: https://braininstitute.ca/research-data-sharing/brain-code

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Next steps:
1. Once the study protocol is completed, ***submit it to OBI*** (governance@braincode.ca) for review and approval ***prior to submitting it to REB*** for approval.
2. A Data Management Plan *must* also be prepared and shared with OBI for review.
3. Finally, the Data Quality Checklist *must* be completed for Stage 1 and shared with OBI for review.

Refer to Stage 1 document #1 "Study Design, Training, and Testing" for more information.