



OBI DQF Common Data Elements Guidelines

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Introduction

In 2013, OBI and its research community identified via a Delphi consensus process a set of common data collection forms and measures to collect across all OBI Integrated Discovery Programs (IDPs) and optionally for other Data Producers, known as the Brain-CODE Common Data Elements (CDEs)¹. From 2022 to 2023 OBI conducted an evaluation of CDE usability and value in consultation with the IDPs to update the Brain-CODE CDEs.

OBI seeks to improve the usability and value of common data elements by establishing two categories of CDEs: **Core CDEs** and **Recommended CDEs**. Core CDEs are to be used by all IDPs, while Recommended CDEs are to be used by an IDP when a corresponding domain is part of the study protocol. Furthermore, all CDEs are intended to continue to be appropriate for participant reporting (i.e., Patient Reported Outcomes or PROs) on REDCap. IDPs can add additional measures to their assessments, but *should* consider participant burden, especially if protocols require that measures be collected in one sitting (e.g., during on-site visits).

Core CDEs

The following CDEs *must* be collected by all OBI funded studies within IDPs on REDCap:

- **Enrollment:** Brain-CODE Subject Enrollment and Informed Consent form
- **Demographics:** Brain-CODE Demographics form
- **Medical history:** Brain-CODE Medical History form
- **Quality of life:** WHO-QOL-BREF (for adults), KINDL-R (for children and adolescents)

Note: Medical history fields are coded using the MedDRA terms. The mapping table is available in the Vocabulary Mappings subfolder in the following file: "[OBI CDE Medical History MedDRA Mapping](#)".

¹ <https://doi.org/10.3389/fpsy.2022.816465>



Required if Collected, Recommended CDEs

The following CDEs are *highly recommended* PROs and *must* be used *if* the domain is required in the study protocol:

- **Depression:** PHQ-9 (for adolescents and adults), RCADS (for children)
- **Anxiety:** GAD-7 (for adolescents and adults), RCADS (for children)
- **Sleep:** PSQI (for adolescents and adults), CSHQ (for children)

For the list of CDE instruments please contact help@braincode.ca

Please remember to always send your **protocol** and **consent forms** to OBI (to governance@braincode.ca) for review and approval **prior** to submitting to REBs.

Additional Instruments

Other domains may be considered which represent a good opportunity for standardization across studies and IDPs.

The domains of *disability* and *social determinants of health* may be of potential interest to the OBI research community.

OBI will work with IDPs if sufficient cross-IDP interest exists to agree on a disability scale or social determinants of health measures.

Any additional instrument added to a study protocol *must* satisfy the following criteria:

- The instrument must have a license for data collection at no extra cost to OBI or be included in the IDP budget. IDPs must notify OBI if instruments have special licensing considerations or if there are licensing changes that will take place.
- The instrument must have a license that allows for collected data and data dictionaries to be shared at no extra cost.

Please note that norms and documents used for scoring measures will not be shared with third parties.