



DEFINITIONS AND POLICY FRAMEWORK

PART OF THE OBI GOVERNANCE POLICY

Available at: <http://www.braininstitute.ca/Brain-CODE-governance>

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1. The Governance Policy consists of the following documents, as amended from time to time and posted to the OBI website at www.braininstitute.ca:

1.1 Terms of Reference

1.2 Data Sharing Policy

1.3 Privacy Policy

1.4 Privacy Breach Protocol

2. Definitions

2.1 As used in the Governance Policy, as amended from time to time, the following definitions apply:

“**Advisory Committee**” means the independent committee that advises on the direction of Brain-CODE. The roles and responsibilities of this committee are outlined in the Terms of Reference.

“**Applicable Law**” means all applicable laws, regulations, guidelines (including but not limited to PHIPA and TCPS 2: Tri-Council Policy for the Ethical Conduct of Research Involving Humans) and policies.

“**Brain-CODE**” means the Ontario Brain Institute Centre for Ontario Data Exploration, and refers to the informatics platform designed to allow for the investigation and scientific query across several brain conditions as a means to understand common underlying causes of brain dysfunction, among other outcomes.

“**Data**” means records of information collected during the Study by the Participating Institution and disclosed to OBI for the Purposes, as more particularly described in the Data Sharing Policy. Data may be Raw Data or Processed Data, as defined herein and in the Data Sharing Policy. This could also refer to Data that is not contained within Brain-CODE *per se*, but made available through External Linkages.

“**Data Access Committee**” or “**DAC**” means the committee that is responsible for creating and maintaining data sharing policies for Brain-CODE. The roles and responsibilities of this committee are outlined in the Terms of Reference.



“**Data Sharing Policy**” means the OBI data sharing policy as amended from time to time, that forms part of the Governance Policy and which can be found on OBI’s website at <http://www.braininstitute.ca/Brain-CODE-governance>.

“**Data Use Agreement**” means the agreement signed by External Researchers on the Brain-CODE portal that details the permitted uses for the Data.

“**Direct Identifier**” means variables within Data that provide an explicit link to a study participant and can directly identify that individual, and may include PHI. The following shall be considered direct identifiers for the purposes of OBI: Name (including name of substitute decision maker, next of kin, *etc.*), telephone number, facsimile number, home address, electronic mail address, health insurance number, social insurance number, medical record number, account numbers including certificate and license numbers, vehicle identifiers and serial numbers, including license plate numbers, unique device identifiers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric identifiers, full face photographic images and any comparable images, elements of dates directly related to an individual, including birth date and date, date of death.

“**Electronic Service Provider**” is a person who supplies services for the purpose of enabling a Health Information Custodian to use electronic means to collect, use, modify, disclose, retain or dispose of personal health information and who is not an agent of a Health Information Custodian, as contemplated in O. Reg 329/04 of PHIPA.

“**External Linkage**” or “**Linkage**” refers to a process whereby Data in Brain-CODE are securely aggregated with Data from external databases using secure specialized software through an encrypted Direct Identifier or a set of common variables.

“**External Researchers**” means researchers affiliated with institutions independent of OBI.

“**Health Information Custodian**” has the meaning given to it in PHIPA.

“**Health Information Network Provider**” has the meaning given to it in O.Reg. 329/04 of PHIPA.

“**Informatics Steering Committee**” means the committee which, in collaboration with general management, serves as the final authority on issues related to the establishment and maintenance of Brain-CODE. The roles and responsibilities of this committee are outlined in the Terms of Reference.

“**Integrated Discovery Program**” is a program of collaborative research that is designed in keeping with OBI’s research system and funded by OBI.



“**Metadata**” means any information that describes Data in Brain-CODE, and includes but is not limited to the amount of certain types of Data available, the types of Data available and the sources of the Data.

“**OBI**” means the Ontario Brain Institute.

“**Participating Institutions**” means the hospitals, universities and research institutes. The term Participating Institution may also refer to any other organization that has Raw Data that can be placed into Brain-CODE.

“**PHI**” or “**Personal Health Information**” means personal health information with the meaning ascribed to it in PHIPA.

“**PHIPA**” means the Personal Health Information Protection Act (Ontario) as amended from time to time.

“**Processed Data**” means Data that has been processed, either by OBI through its Service Group, or locally by the Participating Institution to remove, to the extent possible, Direct Identifiers of an individual study participant. This applies to the majority of Data that will be placed in Zone 2 of Brain-CODE, as further described in the Data Sharing Policy.

“**Privacy Breach Protocol**” means the OBI Privacy Breach Protocol, as amended from time to time, that forms part of the Governance Policy and which can be found on OBI’s website at <http://www.braininstitute.ca/Brain-CODE-governance>.

“**Privacy Policy**” means the OBI privacy policy as amended from time to time, that forms part of the Governance Policy and which can be found on OBI’s website at www.braininstitute.ca.

“**Purposes**” means the purposes of Brain-CODE, being that OBI has created the Brain-CODE informatics platform in order to allow for the investigation, discovery and scientific query across several brain conditions, as a means to understand common underlying causes of brain dysfunction, among other outcomes.

“**Raw Data**” means Data that has not been processed to remove Direct Identifiers and may include PHI. This applies to Data that OBI collects from a Participating Institution in order to process it on their behalf, Data that will be placed in Zone 2 of Brain-CODE that cannot readily have Direct Identifiers removed (*e.g.* genomics and MRI data), and Data that have been subject to any other modifications. Further detail and a visual representation of the Zones are available in the Data Sharing Policy.

“**REB**” means research ethics board.

“**Service Group**” means In-DOC (a consortium led by the Ontario Cancer Biomarker Network, along with Baycrest Centre for Geriatric Care’s Rotman Research Institute and the Heart and



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Stroke Foundation Centre for Stroke Recovery (“RRI-CSR”, Toronto, Ontario); the High Performance Computing Virtual Laboratory (“HPCVL”, Queen’s University Site, Kingston, Ontario); and the Electronic Health Information Laboratory (“EHIL”, part of the Children’s Hospital of Eastern Ontario and affiliated with the University of Ottawa, Ottawa, Ontario)); or any other entity providing design and maintenance support to OBI in relation to Brain-CODE.

“**Terms of Reference**” means the OBI terms of reference as amended from time to time, that form part of the Governance Policy and which can be found on OBI’s website at www.braininstitute.ca.