

ONTARIO INSTITUTE  
BRAIN ONTARIEN  
INSTITUTE DU CERVEAU

**ONTARIO BRAIN INSTITUTE  
BRAIN-CODE INFORMATICS GOVERNANCE POLICY**

**September 25, 2020**

**Version 3.0**

**Brain-CODE**

**WELCOME TO BRAIN CENTRAL**

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## 1.1 Introduction to OBI and Brain-CODE

The Ontario Brain Institute is a provincially-funded, not-for-profit research centre seeking to maximize the impact of neuroscience and establish Ontario as a world leader in brain research, commercialization and care. Convergent partnerships are created between researchers, clinicians, industry, patients, and their advocates to foster discovery and deliver innovative products and services that improve the lives of those living with brain disorders.

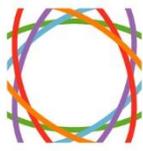
To facilitate collaboration and discovery, OBI has developed Brain-CODE, an extensible informatics platform that manages the acquisition, storage and sharing of multidimensional Data collected on a variety of brain disorders. The following Policy outlines the Governance of Data held in Brain-CODE. The Policy comprises six Sections, and is posted on the OBI website at <https://braininstitute.ca/research-data-sharing/brain-code>:

- 1.1 INTRODUCTION AND DEFINITIONS
- 1.2 VISION AND FUNCTIONS OF BRAIN-CODE
- 1.3 GOVERNANCE
- 1.4 PRIVACY POLICY
- 1.5 PRIVACY BREACH PROTOCOL
- 1.6 DATA SHARING POLICY

These Sections cover:

- the terms used throughout this document;
- the Brain-CODE Oversight Committees and the reporting structure;
- the policies related to the collection, use, modification, retention and disclosure of and access to Brain-CODE Data to protect the privacy of Study Participants;
- the reporting process for any breaches or improper use of Data on Brain-CODE; and
- the policies related to the sharing of Data with International, National and Local researchers.

OBI is committed to transparency with Brain-CODE stakeholders, including the Government of Ontario, Participating Institutions, and Study Participants. This Policy communicates practices related to the governance of Data on Brain-CODE to enable Data users to generate novel discoveries.



### 1.1.1. Definitions

As used in the Governance Policy, as amended from time to time, the following definitions apply. Defined terms are capitalized when used in the Policy.

**“Account”** establishes a relationship between a user and OBI that provides user rights to use Brain-CODE as per the permissions granted.

**“Applicable Law and Guidelines”** means all applicable laws, regulations, including but not limited to the [Personal Health Information Protection Act, 2004 \(Ontario\)](#) “PHIPA” and guidelines such as the [Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans \(“TCPS 2”\)](#).

**“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.

**“Brain-CODE Advisory Committee”** or **“Advisory Committee”** means the arm’s-length independent Committee that monitors and advises on the strategic direction of Brain-CODE. The roles and responsibilities of this committee are outlined in the [Terms of Reference](#).

**“Brain-CODE Data Access Committee”** or **“DAC”** means the Committee that is responsible for contributing to the Data Access Request process, including reviewing Data Access Requests received through the Controlled Access Mechanism. The roles and responsibilities of this Committee are outlined in the [Terms of Reference](#).

**“Brain-CODE Informatics Steering Committee”** or **“Informatics Steering Committee”** means the Committee that oversees the development, implementation and operations of Brain-CODE and also reviews Data Access Requests received through the Controlled Access Mechanism. The roles and responsibilities of this Committee are outlined in the [Terms of Reference](#).

**“Brain-CODE Information Security Committee”** or **“Security Committee”** means the Committee that oversees the privacy and security practices for all Data on Brain-CODE. The roles and responsibilities of this Committee are outlined in the [Terms of Reference](#)

**“Brain-CODE workspace”** means a virtual machine behind Brain-CODE firewalls that can be used to conduct analysis of Brain-CODE Data within a controlled environment.

**“Common Data Elements”** or **“CDEs”** are standardized data elements systematically collected across studies to enhance data quality and utility

**“Consent”** means that participants have provided consent to their data being uploaded to Brain-CODE, unless alternate consent methods have been approved by a Research Ethics Board (REB). Consent has the meaning ascribed to it in [Tri Council Policy Statement 2 \(2018\)](#).

**“Controlled Access Mechanism”** is the process by which Brain-CODE Data Users can request access to de-identified data.



“**Data**” means items representing facts that consist of text, numbers or images and stored in electronic information systems. The Data records are collected and transferred to OBI for the Purposes.

“**Data Access Request**” or “**DAR**” means the process whereby Data Users may make a request to access Data in Zone 3. There are two request mechanisms, Controlled and Public.

“**Data Exclusivity**” means the one-year period of exclusive use of the Data specified by the Data Producer to analyze the data and prepare for publication. This one-year period may be extended upon agreement between the Data Producers and OBI.

“**Data Governance**” means the collection of practices and processes which help to ensure the formal management of Data within Brain-CODE and includes methods, technologies, and behaviors around the proper management of Data.

“**Data Providers**” means organizations that hold data that OBI can link with Brain-CODE Data. These may include Prescribed Entities (e.g., Institute for Clinical Evaluative Sciences, Canadian Institute for Health Information) as defined in PHIPA, or other research organizations.

“**Data Producer**” means an investigator and their delegate(s) affiliated with a Participating Institution. Data Producers are responsible for creating or capturing Data that are uploaded to Brain-CODE.

“**Data Sharing Policy**” means the OBI Data sharing policy, which forms part of the Governance Policy.

“**Data Use Agreement**” means the written agreement between OBI and a Data User that establishes the permitted uses for the Data.

“**Data User**” means an individual person who has an account for Brain-CODE and may access Brain-CODE Data depending on the role-based permissions granted to them.

“**Data Transfer Agreement**” means the written agreement between External Institutions and OBI that establishes the permitted uses for the Data and the secure transfer of Data from Brain-CODE to local servers. It may also include provisions related to the transfer of Data back to Brain-CODE.

“**Data Withdrawal Request**” means the request received from a Study Participant to have their data removed from Brain-CODE. This request should be directed to the Participating Institution where the research study involving the Study Participant was conducted.

“**De-identified Data**” means Data that have been processed to remove Direct Identifiers of an individual Study Participant by OBI or the Service Group. The removal of Direct Identifiers in combination with technical, contractual and administrative controls result in circumstances that it being reasonably foreseeable that the Data will not be used to identify an individual. This definition of De-identified Data is for the purposes of OBI only and may not be directly aligned with other definitions, such as PHIPA.

“**Direct Identifier**” means variables within Data that can directly identify an individual. More detail about what is a direct identifier can be found in [Section 1.6.4 Data De-identification](#).



“**Disclosure**” means to make the Data available or to release it to another health information custodian or person, in alignment with appropriate laws, regulations and approvals.

“**Electronic Service Provider**” or “**ESP**” 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 described in PHIPA<sup>1</sup>.

“**External Collaborator**” is an investigator external to the study who has been granted access to Zone 1 data to collaborate on a study led by the ID Program. External Collaborators may be affiliated with academic institutions, non-for-profits, for-profit companies, patient advocacy groups, and other research-focused organizations. More information about Brain-CODE Zoned structure can be found in [Section 1.2.1. Functions of Brain-CODE](#).

“**External Institution**” means the institution with which an External Researcher is affiliated.

“**External Linkage**” or “**Linkage**” refers to a process whereby Data in Brain-CODE are securely linked to Data from external databases. Linkage may occur either within Brain-CODE or outside of Brain-CODE. This process is carried out in accordance with Applicable Laws and Guidelines and Brain-CODE Governance Policy and Security Policies.

“**External Researchers**” means researchers who are requesting data for access in Zone 3. External Researchers may be affiliated with academic institutions, non-for-profits, for-profit companies, patient advocacy groups, and other research-focused organizations. More information about Brain-CODE Zoned structure can be found in [Section 1.2.1. Functions of Brain-CODE](#).

“**Federation**” means an internal process whereby Data is brought together in a common physical or virtual space within Brain-CODE on the basis of having the same or similar requirements for access.

“**Health Information Custodian**” or “**HIC**” has the meaning ascribed to it in PHIPA.

“**Informatics team**” means the team of employees at OBI whose roles relate to the operationalization and management of Brain-CODE.

“**Integrated Discovery Program**” or “**ID Program**” is a program of collaborative research that must rank as excellent on an international stage, focus on the patient, integrate across Ontario and across disciplines, involve standardized assessments and have a translational thrust and funded by OBI.<sup>2</sup>

“**Intellectual Property**” means any intellectual property, including any invention, innovation, new and useful art, product, service, discovery, process, methodology, pattern, machine, process of manufacture or composition of matter or a formula therefore, new life form, work, material, computer software, compilation of information in whatever medium whatsoever, attendant, know-how or any new and useful improvement thereof whether or not protected or protectable by patent, copyright or registration of design

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<sup>1</sup> Applicable PHIPA rules can be found at: [http://www.e-laws.gov.on.ca/html/regs/english/elaws\\_regs\\_040329\\_e.htm](http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_040329_e.htm)

<sup>2</sup> Stuss, D. T. (2014). The ontario brain institute: completing the circle. *Can. J. Neurol. Sci.* 41, 1–11.



or trademark and all copyright, patent, trademarks, industrial design rights and any other intellectual property rights;

**“Metadata”** means any information that describes Data in Brain-CODE. It describes the amount of Data available, the types of Data available and the sources of the Data.

**“Non-human Data”** means Data that is produced from animals or other non-human subjects. Non-human Data that is uploaded to Brain-CODE will be made available through a Public Access Mechanism after the period of Exclusivity.

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

**“OBI-Funded Study”** is a study that is part of an Integrated Discovery Program where OBI has provided a financial contribution to the study. Any study funded in full or in part by OBI will have that study’s REB-approved data uploaded into Brain-CODE.

**“Participation Agreement”** means a comprehensive agreement between a Participating Institution and OBI that outlines the terms of the contract, and all relevant rules and guidelines related to how Data will be collected, used, transferred, stored, retained, and disclosed in Brain-CODE (**See Appendix D – OBI Informatics Participation Agreement Template**). The Participation Agreement must be signed by both parties prior to the upload of any Data to Brain-CODE. The Participating Institution appends a list of the investigators taking part in the research as a sub-schedule to the agreement.

**“Participating Institution”** means a research institute that has entered into at least one Participation Agreement with OBI. The term Participating Institution may also refer to another type of organization (i.e., private organization) that has Data that can be placed into Brain-CODE and has fully executed a Participation Agreement with OBI.

**“PHI”** or **“Personal Health Information”** has the meaning ascribed to it in PHIPA.

**“PHIPA”** means the Personal Health Information Protection Act, 2004 (Ontario) as it may be amended from time to time.

**“Prescribed Entity”** is an organization listed in the Regulation for the purposes of subsection 45(1) of PHIPA.

**“Privacy”** means an individual’s right to be free from intrusion or interference by others. *Individuals have privacy interests in relation to:* personal information, their bodies, expressed thoughts and opinions, personal communications with others, and the spaces they occupy.

**“Privacy Breach Protocol”** means the OBI Privacy Breach Protocol, as amended from time to time, that forms part of the Governance Policy.

**“Privacy by Design”** means an approach to engineering privacy directly into the design of new technologies and networked infrastructure as part of the core functionality.



**“Privacy Officer”** means a person knowledgeable in privacy who is responsible for the organization's Privacy Program including but not limited to daily operations of the program, development, implementation, and maintenance of policies and procedures, monitoring program compliance, investigation and tracking of incidents and breaches.

**“Privacy Policy”** means the OBI Privacy Policy as amended from time to time, that forms part of the Governance Policy.

**“Public Access Mechanism”** means the process by which Data that have not previously contained Personal Health Information can be accessed in Brain-CODE. This may include Non-human Data or anonymous surveys.

**“Purposes”** are the purposes of Brain-CODE, specifically that the Brain-CODE informatics platform was created to facilitate and expedite the investigation, discovery, or scientific query within and/or across several health conditions.

**“Raw Data”** means Data that have not been processed by OBI or the Service Group to remove Direct Identifiers and may contain PHI. Data that has been processed such as cleaned, curated, will still be considered Raw Data for the purposes of this policy.

**“REB”** means a Research Ethics Board. In some countries, they are also be referred to as an Institutional Review Board (IRB) or Research Ethics Committee (REC). For the purposes of this policy all will be referred to as a “REB”.

**“REB Exemption”** is the process whereby a researcher consults a REB and the board determines that the research proposed falls outside the local legislative requirements for review and provides documentation outlining that decision.

**“Regulation”** means Ontario Regulation 329/04 made under PHIPA, as it may be amended from time to time.

**“Research Activities Agreement”** means the comprehensive funding and data transfer agreement signed between the Integrated Discovery Program and OBI that includes the Brain-CODE Participation Agreement as a Sub-Schedule of the contract.

**“Security Officer”** means a person knowledgeable in the technical and physical security measures for the Brain-CODE platform and is responsible for informing, advising, and alerting stakeholders on matters related to information security.

**“Service Group”** means a service provider to OBI to provide technical expertise such as needed to maintain and upgrade the Brain-CODE platform.

**“Standardized Clinical Framework”** means a standardized assessment protocol that is implemented across the clinical sites that are part of an ID Program. This standardized protocol must include a standard set of assessments for each ID Program as well as Brain-CODE CDEs.”



**“Study”** means a research study conducted by a Data Producer under a Research Ethics Board-approved protocol and that uses Brain-CODE for the Purposes.

**“Study Description Schedule”** means the addendum to the Participation Agreement that outlines specific data elements that the Participating Institution and the applicable Research Ethics Board has granted permission to upload to Brain-CODE. The Study Description Schedule also includes a list of researchers involved in the study.

**“Study Participant”** means an individual person who has Consented to participate in a research study whereby the Data Producers for that study will be utilizing Brain-CODE.

**“Substitute Decision Maker” of “SDM”** means the third party that may provide consent for a Study Participant who lacks the capacity to provide consent. Assent will be sought when an SDM provides consent.

**“TCPS 2”** means the Tri-Council Policy Statement for the Ethical Conduct of Research Involving Humans.

**“Terms of Reference”** means the OBI terms of reference for its Committees as amended from time to time, which form part of the Governance Policy.

**“Terms of Use Agreement”** means an agreement, as amended from time to time, that all individuals must agree to prior to being given a Brain-CODE account.

**“Third Party Vendor”** means any entity other than the Service Group, providing design and maintenance support to OBI in relation to Brain-CODE.

**“Work Product”** means the result of an independent analysis of Data by a Data User.

**“Zone”** describes the relationship between the various sections of Brain-CODE which have different access permissions and mechanisms.

**“Zone 1 Data Use Agreement”** means an agreement between OBI and an External Collaborator to access Zone 1 data for the expressed purposes of the original study.

## 1.2 Vision for Brain-CODE

The three principles that underpin OBI’s vision for Brain-CODE are:

1. Brain-CODE as a useful, user-friendly, and valuable Data management tool.
2. Brain-CODE as a state-of-the-art research tool that promotes robust collaboration and Data sharing, adds value for researchers and promotes international capacity building and collaborations.
3. Brain-CODE as an innovative facilitator of Data Sharing, by making Data available in a controlled open access format, consistent with international best practices.

### 1.2.1 Functions of Brain-CODE

Brain-CODE has three primary functions:

1. Brain-CODE is a repository for Participating Institutions. Brain-CODE provides a safe and secure means to store and share Data and facilitate collaboration between Brain-CODE Users.
2. Brain-CODE enables the linking of Brain-CODE Data to other external databases.
3. Brain-CODE provides opportunities for De-identified Data to be made available to approved External Researchers.

To facilitate the three primary purposes described above, Brain-CODE has been structured with three Zones.

**Zone 1:** contains Raw Data provided to OBI by Data Producers affiliated with Participating Institutions. Some Participating Institutions may require the removal of Direct Identifiers prior to upload to Brain-CODE, however for the purposes of this policy this Data is considered Raw Data until OBI or the Service Group assess the Data to remove Direct Identifiers. Zone 1 is where the Data Producers can utilize their own Data. Participating Institutions are responsible for ensuring that Data is uploaded in alignment with the REB approved processes and data types.

**Zone 2:** contains Data that have been processed to remove Direct Identifiers. Data in Zone 2 can only be accessed by OBI or the Service Group, or Data Producers for the purposes of operating, maintaining, upgrading, troubleshooting, or generally managing Brain-CODE.

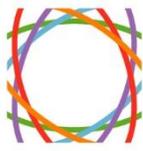
**Zone 3:** is where Data is disclosed to External Researchers in alignment with their Data Access Request. Prior to disclosure, Data will be subject to internal review processes and mechanisms.

## 1.3 Governance

### 1.3.1 Scope and Purpose

This section outlines the general structure and Terms of Reference for the various bodies and committees participating in Brain-CODE governance. The following committees will ensure that Brain-CODE maintains a high level of quality and security, consistent with OBI's vision and mandate:

- **Brain-CODE Informatics Steering Committee ("Informatics Steering Committee")**
- **Brain-CODE Advisory Committee ("Advisory Committee")**
- **Brain-CODE Data Access Committee ("Data Access Committee or DAC")**
- **Brain-CODE Information Security Committee ("Security Committee")**



### 1.3.2 Terms of Reference

These Terms of Reference represent the definitive guide to Brain-CODE informatics governance and administration. Unless stated otherwise in the sections below, these Terms of Reference apply to all committees participating in Brain-CODE governance and administration.

All committee members are responsible for maintaining confidentiality and any members external to OBI must enter into non-disclosure agreements prior to serving on any committees. Committee members will declare real and potential conflicts of interests and will recuse themselves from discussions and votes concerning matters where they are conflicted. All Brain-CODE committees will be supported by OBI administrative resources.

All committee members agree to uphold the Brain-CODE Guiding Principles:

- Privacy and Security
- Open and Collaborative
- Interdisciplinary and Integrated
- Patient-Centred
- Data Standardization
- Discovery for Health Impact

All committee members must receive at least three (3) business days' notice or agree to waive notice prior to any meeting. In the case of the Advisory Committee, this notice shall be extended to a minimum of fourteen (14) business days due to significant potential travel requirements.

### 1.3.3 Informatics Steering Committee

The purpose of the OBI Brain-CODE Informatics Steering Committee ("**Informatics Steering Committee**") is to provide oversight on issues relating to the establishment and management of Brain-CODE. The Informatics Steering Committee ensures that progress is timely, of high quality and remains in line with the vision of OBI. Specifically, the Informatics Steering Committee will:

- Monitor issues related to the establishment and management of Brain-CODE;
- Meet with the Service Group, to receive updates on the development of Brain-CODE;
- Ensure that Brain-CODE progress is timely and of high quality;
- Ensure Brain-CODE adheres to relevant regulations, including privacy laws and aligns with international best practices;
- Review and approve or deny Data Access Requests;
- Regularly interact with the Information Security Committee on matters related to the security and privacy of Brain-CODE controls and data in Brain-CODE; and
- Acts as a change management board, in collaboration with relevant members of the Service

Group and/or external expertise to advise on proposed changes pertaining to Brain-CODE.

#### **1.3.3.1 Membership**

The Informatics Steering Committee will consist of OBI senior management staff. In circumstances where outside expertise is required, the OBI President and Scientific Director may choose to appoint or invite someone external to the OBI for consultation.

#### **1.3.3.2 Reporting**

The OBI President and Scientific Director will provide regular reports to the Board on the activity of the Informatics Steering Committee, identifying any matters that require Board approval. The three other committees (Advisory Committee, Data Access Committee, and Information Security Committee) will provide regular updates to the Informatics Steering Committee.

#### **1.3.3.3 Working Groups**

The Informatics Steering Committee may recommend the establishment of additional time-limited working groups to address specific areas of need and/or interest. The Informatics Steering Committee may recommend individuals who are not part of Brain-CODE or OBI to serve on these working groups, provided that they will be contractually bound to maintain the confidentiality of any information divulged to them in the course of their work in the working group.

#### **1.3.3.4 Meetings**

These meetings shall be held on a quarterly basis, at minimum. Attendance by at least 50% per cent of members will constitute quorum. During meetings held by conference call, votes will be taken orally. A Chair will be appointed to preside at all meetings. In the absence of the Chair, an OBI executive will be appointed as Acting Chair.

The Informatics Steering Committee will keep records of its decisions.

#### **1.3.4 Brain-CODE Advisory Committee**

The OBI Brain-CODE Advisory Committee (“**Advisory Committee**”) is an arm’s length committee that advises on the direction and the progress of Brain-CODE. The Advisory Committee will:

- Advise on the trends and developments in informatics and analytics, in particular on any initiatives or collaborations that may contribute to the goals of OBI and Brain-CODE;
- Advise on the progress of Brain-CODE with respect to analytical methods, capacity building, expert training, collaborations, data sharing and analysis, and data opportunities while ensuring that Brain-CODE remains aligned with the vision of OBI and with international best practices and

- developments; and
- Receive reports on the work of the Informatics Steering Committee.

#### **1.3.4.1 Membership**

The Advisory Committee will consist of at least six (6) members. Members are appointed by the President and Scientific Director of OBI on the advice of the Informatics Steering Committee. Members are appointed for a two-year term with up to two (2) renewals. Additional term renewals can be negotiated upon agreement between OBI and the Advisory Committee member. The Chair will be appointed by the President and Scientific Director in collaboration with the Informatics Steering Committee

No member of the Advisory Committee shall be employed either by OBI or the Service Group.

#### **1.3.4.2 Reporting**

The Advisory Committee provides regular reports to the President and Scientific Director. These reports will outline any recommendations on the direction and progress of Brain-CODE.

#### **1.3.4.3 Meetings**

The Advisory Committee will hold meetings at least twice per year. At least one of these meetings will be in-person. Meetings that are not in-person will be held via teleconference or web/video. Additional meetings may be requested by the President and Scientific Director.

Travel costs for Advisory Committee members will be reimbursed according to the OBI Travel and Expense Reimbursement policy.

Attendance of fifty percent (50%) of members will constitute quorum. The Chair, or in his or her absence, an Advisory Committee member assigned by the Chair, will preside at all meetings. OBI will keep records of the Advisory Committee proceedings.

#### **1.3.5 Data Access Committee**

The purpose of the Data Access Committee (“DAC”) is to review and assess Data Access Requests submitted by External Researchers and submit a recommendation to approve or reject the Request to the Brain-CODE Informatics Steering Committee. The DAC will consider the scientific merit of the Data Access Request and assess if that Data usage will impact health and/or advance the understanding of health conditions.

##### **1.3.5.1 Membership**

The DAC consists of representatives from the ID Programs, OBI, the Service Group, and will include members knowledgeable in privacy and ethics. A community advocate and/or patient experience representative may also be a member of the DAC. There will be up to three representatives from each of

the ID Programs and non-voting representatives from the Service Group and from the Brain-CODE Informatics Steering Committee.

The Chair will be named by the President and Scientific Director of OBI, in consultation with the ID Programs. The Chair will be an OBI Executive, who will appoint someone in his/her absence. Members are appointed by the Informatics Steering Committee, in consultation with the ID Programs, for a two-year term with the possibility for up to two renewals.

With the approval of the Informatics Steering Committee, the DAC may appoint delegates to facilitate the review of requests for Data. At a minimum, the DAC members and its appointed delegates must represent the ID Programs that are receiving funding from OBI.

#### **1.3.5.2 Reporting**

The DAC provides reports, as necessary, to the Informatics Steering Committee. The DAC will review all Data Access Requests prior to release of Data. Their recommendation regarding approval or rejection of the request will be communicated to the Brain-CODE Steering Committee.

#### **1.3.5.3 Meetings**

Data Access Requests will be reviewed by select number of DAC members assigned for delegated review. DAC members are expected to submit their review within five (5) business days of the receipt of the request. Should the request be assessed to be of higher risk, OBI may consider implementing a review by the full DAC. The level of review will be proportional to the risk of the Data Access Request.

The DAC will hold a minimum of one meeting annually. Quorum will consist of fifty percent plus one (50% +1) of regular appointed members. During meetings held by conference call, votes will be taken orally. OBI will keep regular records of the DAC's proceedings.

### **1.3.6 Information Security Committee**

The Information Security Committee is responsible for recommending an appropriate Information Security Framework for the Brain-CODE platform and to identify, implement and maintain privacy standards for all Data and infrastructure in Brain-CODE.

#### **1.3.6.1 Membership**

The Information Security Committee includes members of the Informatics Team and the Service Group whose roles are relevant. At minimum, the Information Security Committee must include an Information Security Officer and a Privacy Officer. Members are appointed and serve under direction of the Informatics Steering Committee. If subject matter expertise is required and does not exist within the Committee, the

Security Committee may recommend individuals that are not part of Brain-CODE, OBI, or the Service Group to provide this expertise. Prior to divulging any confidential information, the individual will be contractually bound to maintain the confidentiality of all information revealed to them in the course of their consultation.

### 1.3.6.2 Reporting

The Information Security Committee reports to the Informatics Steering Committee. Reports from the Information Security Committee will provide guidance and recommendations to the Informatics Steering Committee on matters related to Brain-CODE security and privacy.

### 1.3.6.3 Meetings

Meetings of the Information Security Committee are held on a monthly basis. Urgent meetings may be called on an as-needed basis. OBI will keep records of the Security Committee proceedings.

## 1.4 Privacy Policy

### 1.4.1 Introduction

OBI is committed to protecting the privacy and confidentiality of individuals and security of Data it holds. OBI has adopted a *Privacy by Design* approach by creating and implementing protective measures. This Policy is specific to Brain-CODE and is based on the 10 Canadian Standards Association (CSA) Privacy Principles<sup>3</sup>.

The Privacy Principles are:

- Accountability
- Identifying Purposes
- Consent
- Limiting Collection
- Limiting Use, Disclosure, and Retention
- Accuracy
- Safeguards
- Openness
- Individual Access
- Challenging Compliance

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<sup>3</sup> The 10 CSA Privacy Principles may be found at: <http://www.csagroup.org/ca/en/legal/privacy/csa-group-privacy-statement>



#### **1.4.2 Accountability**

Ultimate accountability for OBI's compliance with this Policy rests with the President and Scientific Director of OBI, although other individuals within OBI and affiliated with the Service Group are responsible for the day- to-day activities that support the protection of individual privacy and the confidentiality and security of the Data.

##### **1.4.2.1 Privacy Governance**

The Informatics Governance Lead will act as the Privacy Officer for OBI and all Privacy-related questions can be directed to [governance@braincode.ca](mailto:governance@braincode.ca).

##### **1.4.2.2 Policies and Procedures**

OBI has implemented policies and procedures/processes to give effect to the Privacy Policy, provided in [Appendix K](#).

OBI will work with Brain-CODE Users and their respective Participating and/or External Institution(s) so that Study Participants are given appropriate notice of the loss or theft of, or inappropriate access to Data. This notification will occur as soon as reasonably possible (see: Privacy Breach Protocol). The Health Information Custodians and other Participating Institutions from whom such Data are collected are responsible for contacting participants and reporting to the Information Privacy Commissioner and other relevant regulatory bodies, as applicable. Breaches of this policy and related privacy procedures may be subject to disciplinary action up to and including termination of employment or affiliation with OBI.

#### **1.4.3 Identifying Purposes**

At or before the time Data are collected, OBI will work with researchers to ensure that the language of the Study Participant informed consent forms clearly and comprehensively set out the purposes for which Data are collected, used and disclosed. OBI may be required to disclose Data as required by law.

#### **1.4.4 Consent for Collection, Use and Disclosure**

The knowledge and consent of the individual Study Participant or their Substitute Decision Maker are required for the collection, use, or disclosure of Data, except where required by law.

Brain-CODE Data are collected with consent, unless the REB has specifically authorized collection without consent under PHIPA and/or TCPS 2, in accordance with high standards for the conduct of research in Canada and internationally.

OBI will support Participating Institutions to ensure that the Study Participants or their SDMs are advised of the purposes for which their Data are being collected, used and disclosed. To make the consent

meaningful, the purposes must be stated in such a manner that the Study Participant can reasonably understand how their Data will be used or disclosed. However, it is understood that not all uses of the Data can be predicted at the time of consent. Any new uses of the Data that were not included in the original consent must align with the core principles of privacy and confidentiality outlined in the Brain-CODE Informatics Governance Policy and with Applicable Law and Guidelines and will adhere to applicable oversight bodies' approvals.

A Study Participant or their SDM may request the withdrawal of their consent to have their data collected, used or disclosed on Brain-CODE. In addition, upon obtaining capacity to consent, a Study Participant may request withdrawal of their consent to have their Data collected, used and disclosed on Brain-CODE, notwithstanding that their SDM appropriately consented to their participation at the time of Data collection. Withdrawal of the consent will not have a retroactive effect, meaning once Data are used for analysis and scientific publication, shared in Zone 1 with external collaborators, or de-identified and shared in Zone 3, it is considered to have been used for research purposes, and consent for past use cannot be withdrawn. Specific processes, contact methods, and contact names for withdrawal procedures will be described in the Study Participant consent materials. In brief, the Study Participant will contact the Participating Institution where they participated in the research study, also known as a Participating Institution. The Participating Institution will notify OBI of a withdrawal request related to Data and provide the unique Study Participant identifier. OBI will then initiate the processes to label, segregate, and/or securely destroy the Data so that they are not subsequently used or linked from that point onwards. The Participating Institution will communicate with the Study Participant any concerns related to the Data Withdrawal Request.

#### **1.4.5 Limiting Collection**

OBI does not permit indiscriminate Data collection. OBI accepts Data with direct identifiers, aligned with the requirements of the research study, and applicable REB approval and Study Participant consent.

#### **1.4.6 Limiting Use, Disclosure and Retention**

OBI distinguishes how different types of data in Brain-CODE must be handled with respect to privacy and security.

##### **1.4.6.1 Limiting Use**

Data that contains one or more Direct Identifiers, such as that held in Zone 1, is securely held within Brain-CODE and only permitted to be accessed by approved Data Producers and External collaborators.

The following examples of limitation on Zone 1 and 2 Data Use are:

- A limited number of individuals involved in developing and maintaining Brain-CODE have access to Data in Brain-CODE, based on role;
- Only researchers approved by a qualified member of the ID Program or Study, and OBI, can access Zone 1 Data. The uses of this Data are limited to REB approved studies and to conduct

REB approved analysis;

- External collaborators may use Zone 1 Data under the direction of the ID Program with a signed Zone 1 Data Use Agreement and appropriate REB approval or exemption;
- Zone 2 De-identified Metadata is made available to Data Users in dashboards;
- The results of any Data Usage will not be used for a purpose that is reasonably contemplated to be detrimental to the individual or community.

#### **1.4.6.2. Limiting Disclosure**

Data stored in Zone 1 will be made available to those researchers involved in the study, as listed in the Study Description Schedule and their External Collaborators as described in [Section 1.6.19](#). Direct Identifiers will be removed prior to being made available into Zone 3. Direct Identifiers will not be disclosed except as permitted by Study Participants, their SDM, or required by law. Some Data that comes into Brain-CODE cannot be fully de-identified by having all Direct Identifiers removed. These situations will be given special consideration to ensure privacy is protected prior to any data sharing, either in Zone 1 or Zone 3. Some Data will be considered too sensitive to share in Zone 3.

Requests for disclosure of Data in Zone 3 will be reviewed to ensure that all disclosure is consistent with this Privacy Policy, and OBI's objectives. All Brain-CODE oversight Committees are bound by the Terms of Reference to ensure that its members are appropriately qualified, and processes are in place to meet the Committee's mandate.

The limitations on Data Use are as follows:

- Data can only be used to conduct the OBI approved analysis, with REB approval or exemption letters provided to OBI prior to access; and
- Data is only made available to individuals who have been approved and have signed appropriate contractual agreements; and
- Data Access Requests that are for a Dataset from less than 5 participants will not be disclosed in Zone 3.

Policies and Processes for limitations on disclosure can be found in [Appendix K](#).

#### **1.4.6.3. Limiting Retention**

The law requires that PHI be retained only for as long as necessary for the fulfillment of the purposes of the Study, and OBI applies the same standard to the Data held in Brain-CODE. However, the nature of the OBI mission may require that such Data are retained indefinitely to support longitudinal research. The Data retained indefinitely will be held as De-identified Data as defined by OBI, to ensure privacy of research participants.

#### 1.4.7 Ensuring Accuracy

The responsibility for ensuring that Data held in Brain-CODE are accurate, complete and up-to-date falls to the Participating Institutions and Data Producers contributing Data.

#### 1.4.8 Safeguards

Security safeguards appropriate to the sensitivity of the Data will be adopted. Descriptions of the nature and sensitivity of the Data stored within each Zone of Brain-CODE are outlined here and in the [Section 1.6 Data Sharing Policy](#). The processes in place to protect OBI information assets are more specifically described in the Brain-CODE Security Policy.

As an Electronic Service Provider, OBI shall take steps that are reasonable in the circumstances to ensure that personal health information in the HIC's custody or control is protected against theft, loss and unauthorized use or disclosure and to ensure that the records containing the information are protected against unauthorized copying, modification or disposal.

Examples of safeguards employed by OBI are as follows:

##### Technical Safeguards

- Data can only be accessed once permissions are granted to that Data User by OBI and the Service Group as approved by the ID Program staff, and upon Data User's agreement to Brain-CODE's Terms of Use
- Sharing of De-identified Data within a secure, controlled Brain-CODE virtual workspace environment in which all Data remain on Brain-CODE servers at all times;
- All Data on Brain-CODE servers are held behind secure firewalls and all remote access is performed over a VPN tunnel or other secure method;
- Health card numbers are encrypted before transfer into Brain-CODE and will remain encrypted at all times. Direct Identifiers are removed from Data before being made available to External Researchers in Zone 3. The encryption key is held by a secure third party.

##### Administrative/Organizational Safeguards

- All OBI staff, Service Group staff and Third Party vendor staff are required to complete Privacy and security training prior to accessing Data within Brain-CODE
- All OBI staff, as a condition of employment, are required to sign confidentiality agreements which are renewed annually
- External Collaborators must be granted permission to access Zone 1 Data by the ID Program Manager or other approved staff
- Prior to Zone 3 Controlled Data Access, all Brain-CODE Users must (at minimum) sign a Platform Terms of Use agreement and a Zone 3 Data Use Agreement. If Data is to be downloaded to an External Institution, a Data Transfer Agreement must be executed between OBI and the External Institution as outlined in [Section 1.6 the Data Sharing Policy](#).

##### Physical Safeguards

- The Brain-CODE Data server is protected by entry controls where access is limited to authorized personnel only.

- All visitors to the server are required to sign-in and sign-out and remain escorted at all times.
- All entrances are monitored by Closed Circuit Television (CCTV) at all times.

OBI employees and the Service Group will be kept aware of the importance of maintaining the confidentiality of Data and will be kept abreast of any updates to the privacy and security best practices. Each Participating Institution and Data Producer is responsible for ensuring that all personnel and members of research teams have undergone privacy and security training.

For more information about the policies and procedures related to Brain-CODE Safeguards, please see [Appendix K](#).

#### **1.4.8.1 Training**

OBI will work with Data Producers to ensure they have received training applicable to the Data, systems and procedures that support their research needs. Data Producers are also responsible for ensuring that their staff comply with training completion. In addition to the security and privacy training provided to Data Producers, privacy and security-related policies, practices and procedures will be made available in print or electronic format.

Additional details regarding privacy training can be found in [Section 1.4.8.1 Training](#).

#### **1.4.8.2 Third Party Assessments**

OBI will engage with external groups to conduct third-party assessments of OBI Privacy and Security Policies, practices and guidance. External assessments will occur approximately every 3-5 years, or as deemed appropriate by the Informatics Steering Committee.

#### **1.4.8.3 Expectations of Data Users**

Recipients of research Data must abide by any requirements set out by OBI with respect to the secure storage and transfer of the Data. Agreements are in place to identify responsibility for the Data and specify conditions with which Data Users must comply regarding linking, further use, and secure disposal of the Data.

#### **1.4.9 Openness**

OBI makes readily available specific information about its policies and practices relating to Data it uses and discloses. OBI only aims to amend the Brain-CODE governance policies on an as-needed basis to improve its processes and better support the research community but welcomes any feedback regarding its Governance Policies. These can be emailed to [governance@braincode.ca](mailto:governance@braincode.ca).

Alternatively, for any inquiries regarding this policy or OBI's privacy practices the President and Scientific Director can be contacted at (647) 847-9000 or by mail to:

Attn: President and Scientific Director,  
1 Richmond Street West, Suite 400  
Toronto, Ontario  
M5H 3W4

Transparency regarding Brain-CODE will be provided on the OBI website, Brain-CODE website, and in other public-facing communications materials as appropriate. The Governance Policies are available to the public on the OBI website, <https://www.braincode.ca/content/governance>.

#### 1.4.10 Individual Access

Individual Study Participants have the right to request access to their Data and, as applicable, that their Data be withdrawn from Brain-CODE. As described in [Section 1.4.4 Consent for Collection, Use and Disclosure](#) this access and withdrawal process will be facilitated by directing the Study Participants or their Substitute Decision Maker to the Participating Institution where they participated in the research study, where the Data was originally collected.

Should a participant contact a staff member at OBI, the request should be forwarded to:

Mail:

Attn: Program Lead, Informatics Governance  
1 Richmond Street West, Suite 400  
Toronto, Ontario  
M5H 3W4

Phone: (647) 847-9000

Email: [governance@braincode.ca](mailto:governance@braincode.ca)

An OBI staff member will respond to the request within ten (10) business days.

#### 1.4.11 Challenging Compliance with OBI's Privacy Policies and Practices

An individual may challenge OBI's compliance with this Policy. OBI has procedures in place to receive and respond to inquiries or complaints about its policies and practices relating to the handling of Data. OBI will inform individuals who make inquiries or lodge complaints of relevant complaint procedures. OBI will investigate all inquiries and complaints, and if found to be justified, will take appropriate measures, including, if necessary, amending its policies and practices.

Inquiries and complaints will be directed to the President and Scientific Director and upon receipt, will be reviewed and a response provided within thirty (30) days.





be included:

- Discoverer's name and contact information
  - Time and date of the breach itself (if available)
  - The origin of the breach
  - The discovery and immediate resolution steps (if applicable)
  - Background information about the data that has/potentially been breached (please do not send PHI via email to OBI)
  - Any information that has been retained by someone who did not have authorization to access it
- Start the process of containment in order to avoid any further breaches, if able.

If the discoverer is an OBI or Service Group employee:

- Notify his/her immediate supervisor and the OBI Manager of Informatics and Analytics or designate immediately, by email or in writing.
- Once the appropriate individuals are notified, the "discoverer" is relieved of the responsibility of communication and containment, but OBI may request consultation and further information during the documentation, investigation, and action phases.

These reporting requirements are in addition to, and do not replace, any obligations by the discoverer to report the breach to the organization with which they are affiliated (e.g., their Participating Institution).

### 1.5.3 Containment

In responding to a privacy breach, OBI will ensure that reasonable steps are taken to protect against further theft, loss or unauthorized use or disclosure as well as copying, modification, or disposal.

The containment process comprises the following steps, as applicable:

- Determine what, if any, information has been disclosed;
- Take reasonable steps to protect against further breaches occurring through the same means;
- Notify the Service Group to review and support the containment;
- Determine whether the privacy breach would allow unauthorized access to any other Data and take whatever steps are appropriate (e.g., change passwords, identification numbers, and/or temporarily shut down a system or server);
- Retrieve as much of the breached information as possible;
- Confirm no copies of the breached information were made or retained by any individual who was not authorized to retrieve or receive it;
- Written confirmation of the date, time, and/or method of secure disposal (if applicable, by the Service Group);
- Ensure appropriate documentation is completed – [Appendix A Breach Report and Investigation Form](#).

Individuals affected by the breach are to be notified in accordance with subsection 12(2) of PHIPA, or any other statute or legal agreement with OBI. The breach should therefore be assessed as quickly and as accurately as possible. OBI will notify the affected Health Information Custodian and/or other impacted organizations, so that they may fulfill their duty to provide notice to affected individuals.

#### 1.5.4 Communication

The OBI Manager of Informatics and Analytics (or designate) then:

- Brings the breach issue to the attention of the OBI Vice-President, Integrated Discovery & Informatics, the Senior Vice-President and Chief Operating Officer, and the President & Scientific Director;
- Initiates further investigation, documentation, and containment strategies;
- Brings the breach to the attention of the Information Security Committee, if applicable;
- Determines if additional resources are required to support the response by OBI, which may include Service Group staff, the Security Officer, external counsel and other necessary parties.

### 1.6 Data Sharing Policy

#### 1.6.1 Introduction

OBI is committed to the advancement of neuroscience and will support researchers to maximize the impact of their work. OBI's funding from the Ontario Government is contingent upon system innovation; enhancing collaborations; and building a data sharing model.

Consistent with its international counterparts, OBI recognizes the importance of sharing publicly funded research Data to catalyze scientific discovery. OBI requires all funded ID Programs to contribute Data to Brain-CODE to promote Data sharing and collaboration.

This Data Sharing Policy has been developed to ensure that the needs of the researchers to maximize productivity are supported while the objective of achieving system change through sharing Data is encouraged and grows.

Brain-CODE is an informatics platform that facilitates the use, collection, retention, disposal and sharing of research data to enhance understanding of brain health. Brain-CODE holds sensitive information and protection of the privacy of the Study Participants who have consented to have their data uploaded into Brain-CODE is of paramount importance. Taking a Privacy by Design approach<sup>4</sup> OBI is committed to ensuring that Data Governance for Data held within Brain-CODE is aligned with global standards, is based in meaningful participant consent, and allows for robust data sharing.

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<sup>4</sup> Cavoukian, A. (2011). *Privacy by design: The 7 foundational principles*. Toronto, ON: Information and Privacy Commissioner of Ontario.

### 1.6.2 Data Sharing Principles

Brain-CODE has been established to ensure that Data Producers have the maximum opportunity to use the Data. To ensure maximum value from the Data world-wide, it is the goal of OBI to ensure that Data are shared to maximize benefits in Ontario first and then across Canada and internationally.

OBI will uphold the following Data Sharing Principles, and will align all decisions regarding data sharing with these Principles:

- Maintain Confidentiality & Security of all Brain-CODE Data, including Data on Brain-CODE Users
- Foster an Open & Collaborative ecosystem
- Ensure that Data are Interdisciplinary & Integrated
- Uphold a Patient-Centered model
- Encourage Data Harmonization and Standardization
- Support Discovery for Health Impact

### 1.6.3 Data Types

Data will be held by OBI in two forms, as defined above in [Section 1.1.1 Definitions](#).

1. Raw Data
2. De-identified Data

Brain-CODE is an electronic database. Any biological samples arising from research activities bringing Data into Brain-CODE will be stored according to Participating Institutions' policies and any other applicable policies (e.g., ID Program policies). Participating Institutions and Data Producers are responsible for managing and keeping an up-to-date catalogue of the samples.

Data from non-human subjects can also be uploaded to Brain-CODE for storage and analysis. This Data is also subject to a period of Exclusivity, where the Data Producer has exclusive use of the Data. Once Exclusivity is over, this Data will be made available through the Public Access Mechanism.

### 1.6.4 Data De-identification

The following shall be considered direct identifiers for the purposes of OBI: All Names, telephone numbers, facsimile numbers, home addresses, electronic mail addresses, health insurance numbers, social insurance numbers, medical record numbers, account numbers such as 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 including fingerprints, voiceprints, retinal scans, or dental x-rays, full face photographic images, and any comparable images, and

full birth date and full date of death. These elements must be removed from the Data for Data to be considered De-identified for the purposes of OBI

### 1.6.5 Compliance

OBI will accept Data from Participating Institutions. The expressed written informed consent of Study Participants is required to transfer Data into Brain-CODE. This practice will remain in place, unless a REB has approved a modified consent process (e.g., consent obtained through electronic means). OBI will work with respective REBs to determine data sharing mechanisms on Brain-CODE in situations where participant consent cannot be or was not obtained. It is expected that Data Producers will utilize the Brain-CODE Standard Consent Language in their consent forms. [Appendix C – Brain-CODE Standard Consent Language](#).

To fulfill the mission of OBI in relation to the integrated approach to brain disorders and in accordance with its Research Activity Agreements. In the case of OBI-Funded Studies, OBI further requires that any Participating Institution that is receiving funding through the ID Program must submit Data to Brain-CODE, in alignment with the REB approval. Participating Institutions are required to prepare and maintain accurate and complete records of the work performed in connection with the submission of Data to Brain-CODE. Said records are to be in accordance with research best practices and Applicable Law and Guidelines and/or pursuant to the requirements imposed by the applicable REB.

Upon receiving REB approval and prior to Data upload, the Data Producer will provide the following to OBI: REB approval letters, REB-approved consent form(s) and assent form(s), and REB-approved study protocol and any additional supporting materials. Once the Data has been processed, cleaned, and/or verified, the Data Producer will provide OBI and the Service Group with quality control measures that have been conducted. This may include Standard Operating Procedures for Data collection and Data cleaning, as well as Data manipulations. For all contextual information (e.g., psychological measures), copyright law must be respected.

Some of this contextual information will be provided to External Researchers with their Zone 3 De-identified Data to help minimize the likelihood of misuse, misinterpretation and/or confusion. External Researchers may request additional contextual information and OBI, in collaboration with the Steering Committee, will determine whether a request for additional contextual information is reasonable and who must provide the information.

External Researchers requesting Data in Zone 3 will provide OBI with written documentation of the proposed use of the Data in the form of an REB approval package which includes the full REB submission package and REB approval letter from their local Institutional REB. Should the REB determine that ethics review is not required, an exemption letter from the REB will be required. If the External Researcher is from an Institution that does not have a local REB, OBI will work with the External Researcher to identify a mutually acceptable REB for review. All documents not in English or French will require a certified translation copy.

#### 1.6.6 Data Held in Databases External to Brain-CODE

Data in Brain-CODE may be linked with Data from external databases to augment and complement the Data in Brain-CODE for enriched analysis and enhanced Data outcomes. This process of linking data or transferring data will be done securely and may require the transfer of Data outside of Brain-CODE to other databases including Prescribed Entities, such as the Institute for Clinical Evaluative Sciences, as reasonably necessary to facilitate the Linkage. All linkages will occur in alignment with the REB approved Consent form(s).

#### 1.6.7 Access by Study Participant

Study Participants will be able to request access to their own Data through Participating Institutions that are the Health Information Custodians, conditional upon the local Participating Institutions' policies, rules and regulations. OBI's policies governing such access are further described in [Section 1.4. the Privacy Policy](#). This access will be at the discretion of the Participating Institution.

#### 1.6.8 Data Ownership

The ownership of Data generated through OBI-funded initiatives will remain with the Participating Institutions and are subject to Institutional Policies. Neither OBI, its agents nor subcontractors will claim right, title, nor ownership to these Data in Brain-CODE. All rights to these Data will be retained by the Participating Institution, as set out in the Participation Agreement. The ownership of any unique product, aggregation or analysis resulting from these Data will rest with the Data User, as discussed in [Section 1.6.11 Intellectual Property](#).

#### 1.6.9 Data Exclusivity

Researchers are encouraged to use Brain-CODE as their primary Data management tool.

Accessibility to Data is managed by the parameters outlined below:

1. OBI will work with Data Producers to initiate and develop an Exclusivity plan for Data held on Brain-CODE. This will be initiated at a mutually agreed timepoint where Data Producers have completed curation of the Data.
2. There will commence a one-year period of exclusive use of the Data by the Data Producers to analyze and prepare for publication. OBI recognizes that certain circumstances may preclude the researchers from achieving the goals that are set out in their Exclusivity plan during the one-year Exclusivity period. In such cases, the Exclusivity period may be extended upon discussion with OBI. If the Data Producer chooses to and formally agrees, the Data may be made available prior to the completion of the one-year period of exclusive use.

3. After the designated Exclusivity period, the Data will be made available via either a Public or Controlled Access Mechanism as outlined in [Section 1.6.14 Data Access Requests](#).

Metadata will not have a period of exclusivity and may become available to Data Users without a data access request. Examples of Metadata contributed to Brain-CODE are:

- Study name
- Number of participants
- Data Type

### 1.6.10 Standardized Data Collection

Efficient comparison of data requires data to be in the same format. To properly analyze the vast array of clinical, neuroimaging, and molecular Data stored in Brain-CODE, OBI has adopted the following standardization methods:

- Common Data Elements (CDEs) are intended to provide a general characterization of commonly assessed variables across each of the ID programs and allows for consistency in data collection across studies which increases opportunities for sharing and cross-study analysis. The complete list is available at <https://www.braincode.ca/content/about-brain-code>
- A Standardized Clinical Framework protocol may be implemented by the ID Programs, which includes a standard set of assessments in addition to Brain-CODE CDEs that will be implemented across clinical sites for the ID Program. This standardization of data collection will allow for increased data analysis opportunities.

### 1.6.11 Intellectual Property

Exclusivity periods allow Data Producers to apply for protection of their intellectual property in compliance with their own institutional policies/requirements. Any intellectual property resulting from the Work Product will belong to the Data User that created/developed the Work Product, not the Data Producer. However, OBI wishes to encourage collaboration, in which case, the intellectual property rights will be agreed upon by the respective parties in accordance with their respective institutional policies.

1. Ownership of Data in Zone 1 will remain with the Participating Institutions. The result of an analysis of Data by a Data User is considered a Work Product that will generally be owned by that individual and his/her organization, if any. Ownership of the Work Product will be maintained in accordance with applicable institutional intellectual property policies, and any applicable intellectual property terms set out in the Participation Agreement.



2. Notwithstanding any other term of the Participation Agreement signed by each Participating Institution, the Study Description Schedule, or any other document setting out the rights of the parties with respect to the Data, the Participating Institution hereby:
  - a. irrevocably grants OBI a non-exclusive worldwide license to use De-identified Data in order to disclose such De-identified Data to External Researchers;
  - b. irrevocably grants such External Researchers the right to use such De-identified Data for the Purposes and;
  - c. agrees that such External Researchers may use the requested data without any further consents required of the Data Producer nor the Participating Institution, as per the approved data request and applicable contractual agreements.

#### **1.6.12 Data Indexing**

Each Study Participant will have a unique identifier to allow for Federation of Data providing a means to index participants. This unique identifier will not contain any information that would increase the risk of re-identification of the Study Participant.

#### **1.6.13 External Researchers as Data Users and Linkage Partnerships**

OBI will authorize the disclosure of Data in Zone 3 to approved External Researchers in accordance with the requirements set out below.

1. To request access to Controlled Data in Brain-CODE, External Researchers must possess an affiliation with an accredited academic institution, think tank, company or other recognized research organization. External Researchers can be local, national or international members of the general scientific or health care community;
2. To request access to Controlled Data in Brain-CODE, External Researchers are to complete a Data Access Request and provide a plan for the use of those Data, approval from a Research Ethics Board, where appropriate, and a fully executed Data Use Agreement and Data Transfer Agreement, if applicable. External Researchers are required to provide annual status reports to OBI. These reports will describe any type of report or publication that results from work with Data, analytics tools, or other Work Product related to the use of the Data.
3. Data Access Requests will adhere to the steps set out in [Section 1.6.14 Data Access Requests](#).

Linkage partnerships may also be established between OBI and other Data Providers for the purposes of Data Linkage. To achieve these purposes OBI will authorize such Linkages in accordance with the requirements set out below:

1. OBI approved Linkage partnerships will link datasets in a manner that abides by the respective parties' Data Governance Policies while protecting the Data held in Brain-CODE.



2. A Data Sharing Agreement will be signed between all parties, as required.
3. Linkages will be performed by members of OBI, Service Group, and the Linkage partner(s).

#### 1.6.14 Data Access Requests

To request Data from Brain-CODE, you must register for a Brain-CODE account on the website [braincode.ca](http://braincode.ca). There are two types of data access mechanisms: Public Access and Controlled Access.

Public Access Mechanism: (For non-human and non-health Data)

1. Upon submission of the Public Data Access Request, the External Researcher will receive an email with instructions on how to download the Data.

Controlled Access Mechanism:

1. Upon submission of the Controlled Data Access Request (DAR), OBI will review the submission to ensure completeness, that REB approval or exemption has been granted, and verify the identity of the requestor. This review will ensure alignment with the Brain-CODE Informatics Governance Policy as a whole and any Applicable Laws and Guidelines. OBI may request any further information required for their review. The DAR may be subject to internal review mechanism as required.
2. OBI will assess the risk of releasing the data and determine what data protection mechanisms are required (e.g., Brain-CODE workspace). Data will be released on the condition that the External Researcher signs a Terms of Use Agreement and Data Use Agreement with applicable confidentiality requirements and provisions that prohibit any attempts to re- identify Study Participants using the Data and not to distribute or share any Data they are permitted to access. To the extent possible, Data will remain within the Brain-CODE environment where any analysis or other related manipulations would take place. Should it be required that Data be downloaded to the requestor's local computational infrastructure, this can be negotiated with OBI. Local download of Data will require a Data Transfer Agreement with the External Institution.
3. The request will then be reviewed by the Data Access Committee (DAC), who represent the Health Information Custodians.
4. The request will then be reviewed by the Informatics Steering Committee to ensure adherence to OBI's Principles. The Informatics Steering Committee will approve or deny the Controlled Data Access Requests based on input from the DAC.

Appeal of decision:

1. In the event that the Data Access request is denied, the External Researcher has the option to appeal that decision by emailing the request for the appeal to [governance@braincode.ca](mailto:governance@braincode.ca)

within fifteen (15) business days of receipt of the decision.

#### 1.6.15 Data Acknowledgement

All publications, presentations, or disclosures of analyses based in part or in whole on Data in Brain- CODE must acknowledge the ID Program/Data Producer name which have contributed to these Data, the OBI, the Brain-CODE platform, and the Government of Ontario. The following language must be used:

*“We would like to acknowledge the individuals and organizations that have made Data **[and analysis]** used for this research available including **[ID program name/Data producer name]**, the Ontario Brain Institute, the Brain-CODE platform, the Government of Ontario, as well as **[independent collaborator names]**.”* In addition, Data Users must reference primary paper(s) of the Data Producer(s), if any, that describe the study design, the study data, or any initial analysis of the data where appropriate. OBI also encourages that Data Users provide a web link in their publication(s), where appropriate, to the list of investigator names among the Data Producer(s) that are responsible for the primary collection of the data.

#### 1.6.16 Return of Results

OBI encourages Data Users to make analysis results and processing methods available to other Brain- CODE users through the Brain-CODE platform, subject to appropriate contracts or agreements and ethics approval in place. Some results generated via the use of Brain-CODE may be returned to Brain-CODE to expand the general knowledge base. OBI encourages the Data Producer to make such inventive contributions.

#### 1.6.17 Brain-CODE Users Personal Information

When signing up for a Brain-CODE Account, Brain-CODE Users share professional information with OBI including email address. This information will be stored securely behind firewalls and will only be used to communicate with you regarding the Brain-CODE Account. This information will not be used for any other purposes. This information will be stored for twelve (12) months after the Brain-CODE Account is deleted or becomes inactive.

External Researchers, when requesting Data via a Data Access Request, will submit information required for identity verification. This may include but is not limited to name, employer, Curriculum Vitae (CV), and email address. This information will be stored securely behind firewalls and will only be used for the purpose of verifying your identity in relation to the request for data access. This personal information will not be used for any other purpose. This information will be stored for five (5) years after the Data Access Request is approved.

#### **1.6.18 Privacy Breaches**

OBI employees, Participating Institutions, Service Providers and their employees and subcontractors, Third Party Vendors, and Data Users are responsible for immediately providing notice to OBI upon discovery of an unauthorized transfer, use, or disclosure of Data. In the event of a privacy breach, OBI will comply with Applicable Law and Guidelines in reporting details of breaches. OBI will assess the severity of the violation and respond appropriately, which may include contacting journals, funding bodies, and institutions. OBI reserves the right to restrict future access to Brain-CODE.

#### **1.6.19 Zone 1 Data Use Agreements**

Zone 1 Data Use Agreements are contracts signed between all required parties that will allow for the analysis of Data held within Zone 1 for the purposes of the original study design and analysis. The External Collaborator will only access Data that has been granted REB approval or been granted an REB exemption. This REB approval or exemption must be provided to OBI prior to data access. If the Data is to be downloaded locally to the External Collaborator's Institution, then Institutional sign-off will be required.

#### **1.6.20 Sharing Data with Publications**

No researcher shall include PHI in any publication or presentation. OBI recognizes that it is sometimes necessary to share Data with Publications. While it is preferred that only aggregate level Data is shared, if row level Data is required, it is OBI's policy that Data not be reported for groups or subtypes with five (5) or fewer participants.

OBI recognizes that journals may require that Data be deposited into another repository. Only derived data and/or finalized results without any linkage to participants may be deposited into these repositories. If the journal mandates that other Data from the study to be made available, please consult with [governance@braincode.ca](mailto:governance@braincode.ca) to determine an appropriate solution.

#### **1.6.21 Data Archiving**

Data in Brain-CODE will be archived once analyses are completed by the Data Producers as identified in the Exclusivity Plan. Data Archiving will occur by having access to identifiable information removed. The Data will continue to be made available to the Data Producers for additional analysis with additional REB approval for the new analyses.

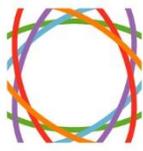
#### **1.6.22 Data Destruction**

If at any time OBI or Brain-CODE ceases to exist, all Data held within Brain-CODE will first be transferred to another institution with which OBI has entered into an agreement for the transfer. In the event that such an arrangement has not been made, the Data held within Zones 1 of Brain-CODE will be transferred back to each Participating Institution that first provided the Data. If any of the Participating Institutions cannot receive the Data in Zone 1, at law or otherwise, that component of the Data will be destroyed using secure destruction protocols. Destruction or secondary transfer of these Data may proceed at the discretion of the Participating Institution's REB.



Appendix A - Breach Report and Investigation Form

Form Completed by:		Date:
<b>Brief Summary of What Was Discovered</b>		
<b>Date and Time of Discovery</b>		
<b>Name of Agent/Individual Who Discovered the Breach</b>		
<b>Job Title</b>	<b>OBI Role</b>	<b>Name of Supervisor or Principal Investigator</b>
<b>Project Title (If Applicable)</b>		
<b>Detailed Sequence of Events</b> <i>(Include information on when the breach is believed to have occurred, and the type of Data that were breached. Use an additional page if necessary)</i>		
<b>Type of Privacy Breach</b>	Raw Data (potentially identifiable)	Processed Data
<b>Further Details:</b>		



**APPENDIX B – Communication Log**

Internal Communications			
Role	Notified by	Date	Time
Immediate supervisor			
Manager, Informatics & Analytics			
Vice President, Research & Informatics			
Senior Vice President			
President & Scientific Director			
Privacy Officer			
Security Officer (as applicable)			
Legal Counsel			
Service Group			
Others (list below)			
External Communications (as applicable)			
Health Information Custodian(s)			
Information and Privacy Commissioner of Ontario			
Steering Committee			
Funding Agencies			
Others (list below)			



## Appendix C – Brain-CODE Standard Consent Language

### Which data will be collected and why?

These data are being collected as part of an Ontario collaborative study on *[ID Program]*, and will be used in conjunction with data collected from persons with the same and different conditions. This will allow researchers to study the causes of the disorder, improve diagnoses, and develop treatments and interventions. In addition to the data that will be collected from *[study intervention]*, we will also be collecting your health card number and other demographic information like *[insert details]*. Your encrypted health card number or *[other data we collect in this study]* may be used to link with data stored in independent databases, such as OHIP, or other databases in a secure environment.

By providing consent to this study, you are agreeing that the data collected during this study will be stored electronically in a database developed and maintained by the Ontario Brain Institute (OBI). This database is known as Brain-CODE, and it will be stored in reputable facilities with high level security protocols. Brain-CODE will allow researchers to use the data collected in these collaborative studies to perform research and learn more about how *[disease]* affects the brain.

### What will happen to my data?

Brain-CODE is an open-access database. This means that researchers and organizations outside this study can request access to data that have been stripped of information that can identify you. Your health card number will be encrypted upon entry into Brain-CODE and will remain encrypted at all times.

### How will my information be kept confidential?

We wish to assure you that your privacy is very important to us. When you join the study, you will be given an ID number. Researchers will use this ID number to organize your data, instead of your name or other information that can identify you directly. Any data collected for study purposes that could potentially identify you will be stored in a highly secure manner and never be released or disclosed in a form that could identify you. We will use tools that remove identifying information using the most advanced tools available to minimize the risk of identifying you from the information we collect or release. This process will be applied to all data, including any new data that have been linked through other databases, such as OHIP.

*[Organization]* and OBI have entered into legal agreements to protect your data, and to set out the purposes for which these data will be collected, used, stored and disclosed. Steps have been taken to make sure your data are safe and the risk of identifying you is minimized. The OBI will continue to monitor these safeguards as new technologies evolve in order to limit any new risks to privacy.

### Who will have access to my information, and what will they see?

Data collected through this study and stored in Brain-CODE will be available to researchers in this study. A current list of these researchers and organizations can be found at: *[Email governance@braincode.ca for the program specific link]*.

## WELCOME TO BRAIN CENTRAL



Data from this study that have had identifying information removed using the most advanced tools available may be shared with local, national and international researchers and organizations that are not part of this study. This open approach is being used by researchers internationally to better understand disease. Access to data by outside researchers or organizations will require a detailed plan for the use of the data, and approval from a research ethics board, as described in OBI's Data Sharing Policy <http://www.braininstitute.ca/Brain-CODE-governance>. These researchers or organizations will be required to enter into an agreement with OBI that clearly states the safeguards that will be in place to protect those data, and the purposes for which these data may be collected, used, stored and disclosed.

OBI may take some of your data, combine them with data from many other people, and make them available to enhance the public's awareness of research. We will use tools to remove identifying information from these combined data sets, making the risk of identifying you minimal.

**If I decide later on that I no longer want to be part of this study, what happens?**

You can withdraw from the study at any point. No new data will be collected or linked to other data from that point on. Upon your request, any data that have not been processed to remove identifying information will be destroyed. However, we are not able to remove any data that have already been analyzed, processed to remove identifying information or linked with other data for placement in Brain-CODE. To withdraw from the study, contact *[Site PI; email; phone]*.

If you have any questions, please ask *[appropriate person at site]*. Further information about Brain-CODE is available at <http://www.braininstitute.ca/Brain-CODE-governance>.

Any of the information in this letter can be sent to you by mail, upon your request.



## Appendix D – OBI Informatics Participation Agreement Template

### ONTARIO BRAIN INSTITUTE

### BRAIN-CODE

### PARTICIPATION AGREEMENT

#### Background

- (A) OBI has created the Centre for Ontario Data Exploration (Brain-CODE), an informatics platform designed to allow for the investigation, sharing, and scientific query across brain conditions, as a means to understand common underlying causes of brain function and dysfunction, among other outcomes (the “**Purposes**”).
- (B) The Participating Institution(s) will work with OBI in contributing Data to Brain-CODE and in undertaking research with respect to the Data housed in Brain-CODE, as per the terms and conditions contained in this Agreement.
- (C) OBI has adopted a *Privacy by Design* approach to creating and implementing protective measures and has been designated a *Privacy by Design* ambassador by the Information and Privacy Commission of Ontario. The security and privacy policies are specific to Brain-CODE and are based on the the Canadian Standards Association Privacy Principles.

**FOR VALUE RECEIVED**, the OBI and each of the Participating Institutions listed on Schedule A agree as follows:

#### 1. Definitions

“**Agreement**” means this participation agreement, as amended from time to time, taken together with the various annexes and appendices.

“**Applicable Law**” is defined in section 4.1(b).

“**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 function and dysfunction, among other outcomes.

“**Brain-CODE Data Access Committee**” or “**DAC**” means the committee outlined in the Terms of Reference that is charged with the creation and maintenance of Data access and sharing policies for Brain-CODE.

“**Brain-CODE Services Agreement**” means an agreement entered into between OBI governing OBI’s services associated with Brain-CODE. For greater certainty, it is anticipated that a Brain-



CODE Services Agreement will only be applicable in respect of those Participating Institutions paying to use Brain-CODE, and may not apply to all Participating Institutions.

“**Consent**” is defined in section 4.1(d).

“**Data**” is defined in section 2.1.

“**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 <https://www.braincode.ca/content/about-brain-code>.

“**Direct Identifier**” means variables within Data that provide an explicit link to a Study Participant that can directly identify that individual, and may include personal health information (PHI). As listed in HIPAA, 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 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, as amended from time to time.

“**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.

“**Governance Policy**” is defined in section 2.

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

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

“**Participating Institutions**” means the hospitals, universities and research institutes that are also parties to this Agreement, either when this Agreement is originally signed or in the future by way of signing a joinder agreement in the form of Schedule A. The term Participating Institution may also refer to any other organization that has Raw Data or Processed Data that may from time to time be placed into Brain-CODE.

“**Personal Health Information**” or “**PHI**” 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.

“**Prescribed Entity**” has the meaning given to it in O. Reg 329/04 of PHIPA.

“**Processed Data**” is defined in Section 3.1(a).

“**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 <https://www.braincode.ca/content/about-brain-code>.

“**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 <https://www.braincode.ca/content/about-brain-code>

“**Purposes**” means the purposes of Brain-CODE, as described in the “Background” paragraph A.

“**Raw Data**” is defined in Section 3.1(b).

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

“**Service Group**” means Indoc, a consortium led by Indoc Research, along with Baycrest Centre for Geriatric Care’s Rotman Research Institute and the Heart and Stroke Foundation Centre for Stroke Recovery (“RRI-CSR”, Toronto, Ontario); the Centre for Advanced Computing (“CAC”, 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. “**Study**” is defined in section 4.1(a).

“**Study Protocol**” is defined in section 4.1(c).

“**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 <https://www.braincode.ca/content/about-brain-code>.

## 2. Background on Brain-CODE

OBI has created an overarching governance policy that sets out a more detailed description of Brain-CODE, how the platform is managed, its compliance with Applicable Laws and policies, which incorporates key internal OBI policies such as the Policy Framework, Terms of Reference, Data Sharing Policy, Privacy Policy and the Privacy Breach Protocol; collectively these documents as amended from time to time form the “**Governance Policy**”. The Governance Policy is available on OBI’s website and may be amended from time to time by OBI. OBI will give notice of any such amendments to the Participating Institutions. The information set out below is not meant to be comprehensive, but instead is provided as background to aid parties in understanding the terms of this Agreement.

### 2.1 General

Brain-CODE is OBI’s large-scale informatics platform where Data and other information from Participating Institutions and others (some of which will have received funding from, and entered into research activity agreement with, OBI) will be standardized and assimilated. “**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 s. 3.1 below.

### 2.2 Studies and Study Specific Amendments to this Participation Agreement

For each research project within the Study, a Study Description Schedule will be entered into between OBI and the Participating Institutions. The form of Study Description Schedule is provided as Schedule C to this Agreement. Where this Participation Agreement shall be a consistent base document across many Studies, the Study Description Schedule shall add research project specific supplements and amendments to this Participation Agreement that apply only to the research project referenced therein.

## 3. Data

### 3.1 Data Held by OBI

Data will be held by OBI in two forms:

- (a) “**Processed Data**” means Data that have been processed, either by OBI through its Service Group or locally by the Participating Institution, to remove Direct Identifiers of an individual Study Participant. This applies to the majority of Data that will be placed in Zone 2 of Brain-CODE.
- (b) “**Raw Data**” means Data that have not been modified from their original state or processed to remove any Direct Identifiers, and may include PHI. This meaning applies to Data that OBI collects from a Participating Institution in order to process it on their behalf, and to Data that will be placed in Zone 2 of Brain-CODE that



cannot readily have Direct Identifiers removed due to technical limitations (e.g., genomics and MRI Data).

### 3.2 *Data Held in Databases External to Brain-CODE*

Data in Brain-CODE may be linked with Data from external Databases to augment and complement the Data in Brain-CODE for enriched analysis and enhanced Data outcomes. This process will be carried out using a secure and privacy protecting linking protocol, and may require the transfer of data outside of Brain-CODE to **Prescribed Entities**, such as the Institute for Clinical Evaluative Sciences, as reasonably necessary to facilitate the Linkage. The linked Data undergo an analysis using specialized software to determine the risk of re-identifying of the Study Participant before any Data is disclosed.

### 3.3 *Three Primary Functions of Brain-CODE*

OBI functions as an Electronic Service Provider, as contemplated in Section 6 of O. Reg 329/04 of PHIPA. Brain-CODE 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.

Brain-CODE has three primary functions:

1. Brain-CODE is a repository for Participating Institutions, with capabilities in place to handle Raw Data. Participating Institutions and researchers will transfer Raw, or in some cases Processed Data required for their study to Brain-CODE in alignment with REB approvals and informed consent. Brain-CODE provides a safe and secure means to store Data, and facilitates the sharing of Data between researchers.
2. Brain-CODE provides long-term storage of Data and potential linkage of that Data to other external Data bases.
3. Brain-CODE provides opportunities for the Processed Data to be made available to approved third parties for the intended Purposes of further analysis, research and use.

To facilitate the three primary purposes described above, Brain-CODE has been structured with 3 Zones.

**Zone 1:** will contain the Raw Data (that may contain Direct Identifiers) and Processed Data (including encrypted health card numbers) provided to OBI in Zone 1 by researchers and Participating Institutions. Zone 1 is where the researchers can utilize their Data. Some Participating Institutions may choose to transfer Raw Data to OBI as an alternative to removing Direct Identifiers locally, or to store Raw Data on local hard-drives or servers. Participating Institutions will have ownership and control over the Data they provide to Zone 1.



**Zone 2:** provides long-term storage of the Data that have been processed to remove direct identifiers using the most advanced tools available (or encrypted, in the case of health card numbers). More rarely, Raw Data may be placed in Brain-CODE for long-term storage purposes, in each case as authorized by the Study Protocol and applicable Research Ethics Board.

**Zone 3:** provides storage where Processed Data stored in Zone 2 may be prepared by OBI or its Service Group for disclosure to third parties as recommended by the Data Access Committee for the Purposes. This is where the Data becomes accessible for broader use by approved third parties.

#### 4. Data Transfer to Brain-CODE

##### 4.1 Data Transfer

- (a) Each Participating Institution hereby agrees that it may, from time to time, only transfer Data for inclusion in Brain-CODE that it has collected during the course of the research study described in the Study Description Schedule (the “**Study**”) to Brain-CODE.
- (b) In transferring the Data the Participating Institution shall comply with the study protocol identified in the Study Description Schedule (the “**Study Protocol**”) and all applicable laws (including but not limited to PHIPA), regulations, guidelines (including but not limited to PHIPA and TCPS 2: Tri-Council Policy for the Ethical Conduct of Research Involving Humans) and policies (collectively, “**Applicable Law**”).
- (c) The Participating Institution will prepare and furnish Data in accordance with Applicable Law including without limitation obtaining all appropriate consents identified in the Study Description Schedule.
- (d) The Participating Institutions shall not disclose Data to OBI until the Participating Institution’s REB has approved the disclosure of Data to OBI for inclusion in Brain-CODE and approved the informed consent form (the “**Consent**”) as applicable with respect to the Study as identified in the Study Description Schedule, and consent from each Study Participant has been obtained as required by the REB.
- (e) The Participating Institution shall only transfer Data to Brain-CODE, where the Participating Institution has all rights to transfer such Data to Brain-CODE, to grant the license to use such Data (set out in section 6(c)) or to share or permit the sharing of such Data by the Participating Institution, or OBI, including without limitation, as contemplated by the use and disclosure of Data in Zone 3. As an example, and without limiting the previous sentence, the Participating Institution shall not transfer Data owned by third parties, where those third parties have not granted the Participating Institution adequate rights to use and disclose such Data for the Purposes.



- (f) Without limiting subsections 4.1(a) (b), (c), (d), and (e), the Participating Institution shall:
  - (i) use commercially reasonable efforts to ensure that all Data transferred or otherwise uploaded to Brain-CODE by, or on behalf of, such Participating Institution is accurate, and error-free; and
  - (ii) ensure that all Data transferred or otherwise uploaded to Brain-CODE by, or on behalf of such Participating Institution:
    - (1) does not contain any malware, viruses or other malicious code; and
    - (2) relates to the Study.
- (g) OBI may set limits on the quantum of Data that may be transferred to Brain-CODE.
- (h) Information regarding exclusivity of Data use by the Participating Institution that transferred the Data to OBI pursuant to this Agreement, and their collaborators, as well as timelines for open access Data sharing are detailed in OBI's Data Sharing Policy.

## **5. Managing Data in Brain-CODE**

### *5.1 General Privacy Obligations of OBI*

In its role of Electronic Service Provider, OBI agrees to comply with the rules set out in section 6 of O.Reg.329/04 to PHIPA.

OBI will use appropriate administrative, technical and physical safeguards (as more particularly described in the Privacy Policy) to prevent any unauthorized use or disclosure of Data in accordance with this Agreement and will promptly report to the Participating Institution any unauthorized use or disclosure of Raw Data of which OBI becomes aware. OBI will not make contact or attempt to make contact with a Study Participant who contributed Data to the Participating Institution without the prior written consent of the Participating Institution.

### *5.2 Privacy Obligations*

- (a) OBI and the Participating Institution will grant access to Data in Zone 1 only to their respective employees, contractors, agents and any authorized Study staff from other sites that are part of the same Study who require access to such Data consistent with:
  - (i) the Study Protocol approved by the Participating Institution's REB and as amended from time to time, provided that amendments are approved by the Participating Institution's REB;



- (ii) this Agreement; and
  - (iii) the Study Description Schedule, which shall identify the Study Protocol, the Consent and any other conditions or restrictions imposed by the Participating Institution relating to the use, security, disclosure, return or disposal of Data in Zone 1.
- (b) Each party will ensure that its employees, contractors, and other agents (including OBI's Service Group) are bound by privacy and confidentiality obligations that are no less robust than those contained in this Agreement.
  - (c) Where it receives only Processed Data from a Participating Institution, or once it processes Raw Data on behalf of a Participating Institution, OBI will not use Data to identify or attempt to identify any Study Participants or other individuals.
  - (d) OBI and its Service Group may use Data for the purposes of operating, maintaining, upgrading, troubleshooting, or generally managing Brain-CODE, provided that the Service Group is bound by OBI not to use any Data for unauthorized purposes, nor disclose such Data to third parties other than as authorized by OBI.
  - (e) OBI and the Participating Institution will also comply with any conditions placed on the disclosure of the Data in Zone 1 by the Participating Institution's REB, which the parties will identify in writing in the Study Description Schedule.
  - (f) OBI will not collect, use or disclose Data in Zone 1 except as necessary to fulfill its Zone 1 obligations, provided that OBI may process Data in Zone 1 and transfer such Processed Data to Zone 2.
  - (g) OBI will not use or disclose Data in Zone 2 except as necessary to fulfill its Zone 2 obligations, provided that OBI may use Data in Zone 2 in order to prepare it for transfer to Zone 3, and may transfer such Processed Data to Zone 3.
  - (h) Subject to a Study Participant's right to request through a Participating Institution removal of his/her Data in Zone 2 (which, for greater certainty will not affect Data in Zone 3), OBI's right to maintain Data in Zone 2 and use it to transfer to Zone 3 for further analysis prior to disclosure, in accordance with the Data Sharing Policy, of Processed Data survives the termination or expiry of this Agreement or the withdrawal of any Participating Institution from this Agreement.
  - (i) Further detail on privacy and data sharing is found in the Governance Policy.

### 5.3 *General Privacy Obligations of the Participating Institution*

The Participating Institution will, from time to time, be provided with various passwords to permit secure access to Brain-CODE and associated sites and databases (collectively the "**Passwords**"). Each Participating Institution is responsible for keeping all Passwords that



it or its authorized personnel or representatives hold or have access to confidential and shall not grant or permit unauthorized access to such Passwords. The Participating Institution shall immediately provide notice to OBI upon discovery of an unauthorized transfer, use, access or disclosure of Data or having knowledge that a Password may have been compromised in any way which may permit an unauthorized person or entity to access Brain-CODE or any associated sites or databases.

#### 5.4 *Permitted Disclosure and Destruction*

Notwithstanding anything to the contrary in this Agreement, OBI may:

- (a) disclose Data to regulatory authorities, provided that OBI uses commercially reasonable efforts to provide prior written notice of such intended disclosure to the Participating Institution;
- (b) disclose Data to Prescribed Entities as reasonably necessary to fulfill the Purposes of Linkage with external Data bases;
- (c) disclose Data as otherwise permitted by the Study Description Schedule;
- (d) disclose Data in order to comply with Applicable Law or judicial process, or with a court or regulatory order, provided that OBI gives prior written notice of such intended disclosure to the Participating Institution and takes all lawful actions that are reasonable in the circumstances to minimize the extent of such disclosure and obtain confidential treatment for such disclosure; and
- (e) securely destroy Data in Zone 1 as required by this Agreement or the Study Description Schedule or the Governance Policy or as instructed by the Participating Institution and provide a written confirmation of the manner of destruction in a form acceptable to the Participating Institution.

#### 5.5 *Audit Rights/Breach*

The Participating Institution retains, at its expense, the right but not the obligation to conduct audits of OBI's compliance with this section 5 upon reasonable advance written notice to OBI and at mutually acceptable times.

### 6. **Intellectual Property**

- (a) This Agreement does not change the Ownership of Data in Zone 1, which in most cases will remain with the Participating Institutions, or their employees, agents or collaborators as the case may be. The result of any independent analysis of Data by a Data user is considered a distinct entity ("**Work Product**"). and The ownership of Data shall not impart any right of ownership in any Work Product.,



- (b) Notwithstanding any other term of the Participation Agreement signed by any Participating Institution, the Study Description Schedule, or any other document setting out the rights of the parties with respect to the Data, the Participating Institution hereby:
  - (i) irrevocably grants OBI a non-exclusive worldwide license to use Processed Data in order to disclose such Processed Data to third parties,
  - (ii) irrevocably grants such third parties the right to use such Processed Data for the Purposes, including research, analysis, publication and exploitation of such research and analysis; and
  - (iii) agrees that such third parties may publish any research created by such researcher without any further consents required of the Participating Institution.

## **7. Publication**

No researcher shall include PHI in any publication or presentation. All publications that arise from the use of Data contributed by the Participating Institution will give acknowledgement, attribution, or co-authorship as appropriate in accordance with the International Committee of Medical Journal Editors (ICMJE) standards and any rules established by the Data Access Committee (see Governance Policy).

## **8. Termination/Withdrawal**

### *8.1 Right to Terminate*

- (a) OBI may terminate this Agreement, or its obligations with respect to one or more Participating Institutions (without affecting any obligations of the other Participating Institutions):
  - (i) on no less than ninety (90) days' notice in the event that its mandate is amended or its funding reduced or terminated, provided that if OBI receives notice of such mandate or funding being reduced or terminated in less than 90 days, it shall be permitted to terminate this Agreement on such shorter timeframe;
  - (ii) should the Participating Institution breach any term of this Agreement, provided that if such breach is a breach capable of being cured, OBI may only terminate this Agreement if such breach is not cured within 10 days of notice of the breach from OBI; or
  - (iii) in the event that such Participating Institution fails to make any payment to OBI when due or is otherwise in breach of the terms of any Brain-CODE Services Agreement with OBI;



- (b) Any Participating Institution may terminate its obligations under this Agreement:
  - (i) on no less than ninety (90) days' notice; or
  - (ii) should OBI breach any term of this Agreement, provided that if such breach is a breach capable of being cured, the Participating Institution may only terminate this Agreement if such breach is not cured within 10 days of notice of the breach from such Participating Institution.
- (c) Notwithstanding the above, Participating Institutions that are party to a research activity agreement with OBI, whereby OBI provides funding for specific Studies in order that Data may be contributed to Brain-CODE, may not terminate its obligations under this Agreement unless such research activity agreement is terminated.

### 8.2 *Effect of Termination on other non-terminating Participating Institutions*

If a Participating Institution terminates or is terminated as a party to this Agreement, such termination shall not terminate or otherwise affect this Agreement as it pertains to any other Participating Institution, rather this Agreement shall be deemed amended so as to remove the terminating Participating Institution as a party.

### 8.3 *Management of Information upon Termination*

If at any time this Agreement is terminated on account of OBI ceasing to exist, all Data held within Brain-CODE will first be transferred to another institution with which OBI has entered into an agreement with for the transfer. In the event that such an arrangement has not been made, the Data held within Zones 1 and 2 of Brain-CODE will be transferred back to each Health Information Custodian that first provided the Data. If any of the Participating Institutions cannot receive the Data in Zones 1 and 2, at law or otherwise, that component of the Data will be destroyed using secure destruction protocols. Destruction or secondary transfer of these Data may proceed at the discretion of the Health Information Custodian's REB.

Irrespective of the reason for termination of a Participating Institution's obligations under this Agreement, at the discretion of OBI or its successor and assigns, Zone 2 Data may continue to exist and be disclosed to researchers in Zone 3, and the license granted in section 6 concerning such Data shall continue in favour of OBI or its successor or assign. Alternatively OBI or its successors and assigns may, at their discretion, destroy this Data using secure destruction protocols.

## 9. **Liability for Brain-CODE**

- (a) As between the parties to this Agreement, neither party shall be liable for any special, incidental or consequential damages or damages for business interruption or lost revenue or failure to realize expected savings, even if that party has been



advised of the possibility of such loss or damage in advance. The foregoing disclaimer of liability shall apply regardless of whether such liability is based on breach of contract, tort (including without limitation negligence), strict liability, breach of a fundamental term, fundamental breach, or otherwise.

- (b) The obligations under this section survive the termination or expiration of this Agreement.

## 10. Insurance

OBI and each Participating Institution shall maintain, at its own cost and expense commercial general liability insurance (including any excess liability coverage) on an occurrence basis for third party bodily injury, personal injury and property damage, to an inclusive limit of not less than \$3,000,000 per occurrence. The policy shall include the following: (i) contractual liability coverage; (ii) cross-liability clause; (iii) a thirty (30) day written notice of cancellation, termination or material change. Each Participating Institution and OBI shall also maintain errors and omissions liability insurance, insuring liability for errors and omissions in the performance or failure to perform its obligations contemplated in this Agreement, in the amount of not less than \$3,000,000 per claim.

## 11. Addition of New Participating Institutions

New Participating Institutions may be added to this Agreement, subject to the following process:

- (a) OBI will approve the new Participating Institution;
- (b) any new Participating Institution must sign the joinder agreement in the form of Schedule B, whereby it commits to be bound by the terms of this Agreement as if it had been an original party hereto; and
- (c) OBI may update its website to reflect new Participating Institutions including the effective date of the addition of the new Participating Institution.

## 12. Miscellaneous Terms

- (a) **Survival.** The following sections shall survive termination of this Agreement: section 5.2(h), 6, 7, 8.2, 8.3, and 12.
- (b) **Relationship.** The Participating Institutions are and shall at all times remain independent from OBI and are not and shall not represent themselves to be the agents, joint ventures or partners of OBI. No representations shall be made or acts taken by the Participating Institutions which could establish or imply any apparent relationship of agency, joint venture or partnership with OBI. Participating Institutions are not required to fund OBI's operations and are not responsible for the costs of OBI operations. Participating Institutions have no right or interest in any assets of OBI.



- (c) **Force Majeure.** The parties agree that no party shall be held responsible for damages caused by delay or failure to perform its obligations under the terms of this Agreement when the delay or failure is due to fire, strike, flood, act of God, act of war, lawful acts of public authorities or delays or defaults caused by common carriers, which cannot reasonably be foreseen or provided against.
- (d) **Benefit of the Agreement/Assignment.** This Agreement shall enure to the benefit of and be binding upon the successors and permitted assigns of the parties. Participating Institutions may assign this Agreement to another entity that qualifies as a Participating Institution and with prior written approval from OBI. Any such assignment will be reflected with an update on the OBI website.
- (e) **Entire Agreement.** This Agreement including the Schedules constitutes the entire agreement between OBI and the Participating Institutions with respect to the subject matter hereof and cancels and supersedes any prior understandings and agreements between the parties with respect thereto. There are no representations, warranties, terms, conditions, undertakings or collateral agreements, express, implied or statutory, between the parties concerning the subject matter set out herein other than as expressly set out in this Agreement.
- (f) **Further Assurances.** The Participating Institution agrees that they will from time to time and at all times hereafter execute and deliver all such additional agreements and documents and do and perform all such acts and things as may be reasonably required by OBI to give effect to or better evidence or perfect the full intent and meaning of this Agreement.
- (g) **Amendments.** Except as set out below, no modification of or amendment to this Agreement shall be valid or binding unless made in writing and duly executed and delivered by all of the parties, provided that OBI may have side agreements amending the terms of this Agreement as between OBI and the Participating Institution or Institutions to such side agreement without any further consent or agreement by any party not signatory to such side agreement.
- (h) **Waiver.** No waiver of any breach of any term or provision of this Agreement shall be effective or binding unless made in writing.
- (i) **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein.
- (j) **Notices.** Any demand, notice or other communication to be given in connection with this Agreement shall be given in writing and may be given by personal delivery, registered mail or courier addressed to the recipient at the address contained on the signing page or to such other address or individual as may be designated by notice by any party to each of the other parties.



- (k) **Severability.** If any provision of this Agreement is determined to be invalid or unenforceable in whole or in part, such invalidity or unenforceability shall attach only to such provision or part thereof and the remaining part of such provision and all other provisions hereof shall continue in full force and effect.
- (l) **Counterparts.** This Agreement may be executed in any number of counterparts, each of which may be delivered in electronic means (including by .pdf attached to an email) each of which shall be deemed to be an original and all of which when taken together shall be deemed to constitute one and the same agreement.
- (m) **Attornment.** For the purpose of all legal proceedings this Agreement shall be deemed to have been performed in the Province of Ontario and the courts of the Province of Ontario shall have exclusive jurisdiction to entertain any action arising under or in respect of this Agreement. Each party hereby attorns to the exclusive jurisdiction of the courts of the Province of Ontario.

**IN WITNESS WHEREOF, the parties have executed this Agreement as of \_\_\_\_\_, 20\_\_.**

**ONTARIO BRAIN INSTITUTE**

By: \_\_\_\_\_  
Tom Mikkelsen, M.D., FRCP(C)  
President and Scientific Director

By: \_\_\_\_\_  
Kirk Nylen, PhD  
VP, Integrated Discovery & Informatics

Address for notice:

1 Richmond Street West, Suite 400

Toronto, Ontario M5H 3W4

**WELCOME TO BRAIN CENTRAL**



**SCHEDULE A**

**LIST AND SIGNATURES OF PARTICIPATING INSTITUTIONS**

<b>Name/Address for Notice</b>	<b>Signatures</b>
	By: _____ Authorized Signatory



**SCHEDULE B**  
**FORM OF JOINDER AGREEMENT**

Joinder Agreement

TO: Ontario Brain Institute  
("OBI")

AND TO: All Participating Institutions

RE: Participation Agreement among OBI and the Participating Institutions dated [date]  
relating to Brain-CODE

---

IN CONSIDERATION of OBI agreeing to allow me to become a Participating Institution (as that term is defined in the Participation Agreement), and other good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned hereby declares and agrees as follows:

1. The undersigned has been provided with a copy of the Participation Agreement and any amendments thereto, together with a complete and up-to-date list of all Participating Institutions.
2. The undersigned acknowledges that it has had an opportunity to read the Participation Agreement prior to signing this Joinder Agreement and to seek independent legal advice with respect to signing of this Joinder Agreement.
3. The undersigned covenants and agrees to be bound by the terms of the Participation Agreement in the same manner as if the undersigned had been an original party thereto.

**WELCOME TO BRAIN CENTRAL**



4. OBI covenants and agrees that the undersigned shall have all the same rights and entitlements under the Participation Agreement as if the undersigned had been an original party thereto.

5. This Joinder Agreement shall be governed by and construed in accordance with the laws of the Province of Ontario and the laws of Canada applicable therein and shall be binding upon the undersigned and their successors, permitted assigns and legal representatives.

**IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.**

**ONTARIO BRAIN INSTITUTE**

By: \_\_\_\_\_  
Tom Mikkelsen, M.D., FRCP(C)  
President and Scientific Director

Address for notice:

1 Richmond Street West, Suite 400

Toronto, Ontario M5H 3W4

**[NAME OF NEW PARTICIPATING INSTITUTION]**

By: \_\_\_\_\_  
Name:  
Title:

Address for notice:

[insert]



## SCHEDULE C

### FORM OF STUDY DESCRIPTION SCHEDULE

1. Description of Study.

[insert]

2. Description of Data elements to be transferred to OBI.

[insert]

3. Study Protocol (to be attached).

[insert]

4. Consent form (to be attached).

[insert]

5. Conditions, if any, imposed by Participating Institution's REB.

[insert]

6. Other conditions imposed by Participating Institution with respect to use, security, disclosure, return or disposal of Data.

[insert]

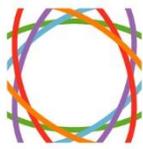
7. Intellectual property supplemental agreements.

[insert]

8. A link to the list of investigators involved in this study who will access and share Data in Zone 1.

[insert]

As referenced in section 12(f), the Participating Institution shall, throughout the course of the Study, provide updated documents and agreements as they become available to OBI.



ONTARIO INSTITUTE  
BRAIN ONTARIEN  
INSTITUTE DU CERVEAU

Dated:

IN WITNESS WHEREOF, the parties have executed this Study Description Schedule, as part of the Participation Agreement, as of the date written above.

**ONTARIO BRAIN INSTITUTE**

By: \_\_\_\_\_  
Tom Mikkelsen, M.D., FRCP(C)  
President and Scientific Director

**[NAME OF PARTICIPATING INSTITUTION]**

By: \_\_\_\_\_  
Name:  
Title:

**WELCOME TO BRAIN CENTRAL**

1 Richmond Street West, Suite 400, Toronto, Ontario M5H 3W4 | T: 647-847-9000 / 1-866-637-6301 | [braininstitute.ca](http://braininstitute.ca)



## Appendix E – Brain-CODE Terms of Use Agreement

I have requested a license to use Brain-CODE (the “**License**”). Brain-CODE (as the same exists from time to time, including any upgrades, replacements, or supplements thereof, “**Brain-Code**”) is an informatics platform that permits the storage, access and analysis of data (any information or data on Brain-CODE from time to time, is referred to herein as “**Data**”). I hereby agree to abide by the following terms:

1. I certify that the details of my identity that I have provided to Ontario Brain Institute (“**OBI**”) in association with applying for a Brain-CODE account, the License, or otherwise, are accurate.
2. I agree that I will only use Brain-CODE and the Data for the purpose of (i) conducting scientific research (ii) participating in scientific research where the data derived therefrom will become Data or (iii) browsing Data for my personal interest ((i), (ii) and (iii) collectively the “**Permitted Purpose**”) and not for any other purpose, including without limitation any commercial purpose, without the prior written consent of OBI.
3. Under no circumstances will I attempt to attribute, link, connect, or associate any Data with any natural person.
4. I will follow and adhere to OBI’s [Informatics Governance Policy](#) as the same may be amended from time to time. The Informatics Governance Policy can be found at <http://www.braininstitute.ca/brain-code>.
5. I will not try to hack in to, or gain access to areas of Brain-CODE and Data which I am not authorized to access.
6. I will not copy, decompile, reverse engineer, disassemble, modify, or create derivative works of the software comprising Brain-CODE or any part thereof.
7. I will keep the login details of my account for Brain-CODE, including all passwords, strictly confidential. I agree that I shall be liable for any damage caused to OBI or Brain-CODE, or any systems upon which Brain-CODE relies or is connected, on account of the use of my Brain-CODE account or login particulars, including third party access thereto.
8. I agree that I am fully liable for the confidentiality of any Data that I have downloaded or made copies of with respect to the obligations listed in this Agreement. I agree that I am fully liable for the unauthorized use of any such Data whether be me, or a third party, however such third party may have obtained access to such Data.
9. I may use the Data for the Permitted Purpose provided I include the following language in any publication, or any presentation or disclosure of the Data, or works derived from or including the Data:

*“We would like to acknowledge the individuals and organizations that have made data **[and analysis]** used for this research available including **[ID program name/Data producer name]**, the Ontario Brain Institute, the Brain-CODE platform, the Government of Ontario, as well as **[independent collaborator names]**.”*

## WELCOME TO BRAIN CENTRAL



10. I will immediately provide written notice to OBI upon gaining knowledge of the occurrence of any of the following: (i) unauthorized use of, or access to, Brain-CODE and/or the Data and (ii) abnormalities in the Data or evidence that certain Data is incorrect.
11. I will abide by all applicable laws that relate to the use of Brain-CODE and the Data.
12. OBI makes no representations that Brain-CODE or the Data are appropriate or available for use in any particular location.
13. OBI reserves the right to change, suspend, remove, or disable access to Brain-CODE or the Data at any time without notice. In no event will OBI be liable for the removal of or disabling of such access. OBI may also impose limits on the use of, or access to, Brain-CODE or the Data, as the case may be, without notice or liability.
14. If any aspect of Brain-CODE or the Data is governed by a separate license agreement, and the terms of that separate license agreement contradict or are otherwise incapable of being construed in conjunction with the provisions of this Platform Terms of Use Agreement (this “**Agreement**”), the provisions of that separate license agreement shall take precedence over those contained herein.
15. In the event that I enter into a Data Use Agreement with OBI, any provisions of the Data Use Agreement contradict and are otherwise incapable of being construed in conjunction with the provisions of this Agreement, the provisions of the Data Use Agreement shall take precedence over those contained in this Agreement, including without limitation the ability to download and share Data.
16. I expressly acknowledge and agree that use of Brain-CODE and access to the data are at my sole risk and that the entire risk as to satisfactory quality, performance, accuracy and effort is with me. To the maximum extent permitted by applicable law, Brain-CODE and the data and any services performed or provided by Brain-CODE ("services") are provided "as is" and “as available”, with all faults and without warranty of any kind, and OBI hereby disclaims all warranties and conditions with respect to the Brain-CODE and the data and any services, either express, implied or statutory, including, but not limited to, the implied warranties and/or conditions of merchantability, of satisfactory quality, of fitness for a particular purpose, of accuracy, of quiet enjoyment, and non-infringement of third party rights. OBI does not warrant against interference with your enjoyment of Brain-CODE or the data, that the functions contained in, or services performed or provided by, Brain-CODE will meet your requirements, that the operation of Brain-CODE or services will be uninterrupted or error-free, or that defects in Brain-CODE, the data, or services will be corrected. No oral or written information or advice given by obi or its authorized representative shall create a warranty.
17. To the extent not prohibited by law, in no event shall OBI be liable for personal injury, or any incidental, special, indirect or consequential damages whatsoever, including, without limitation, damages for loss of profits, loss of data, business interruption or any other commercial damages or losses, arising out of or related to your use or inability to use Brain-CODE or access the data, however caused, regardless of the theory of liability (contract, tort or otherwise) and even if OBI has been advised of the possibility of such damages.
18. Any rights I have to access Brain-CODE and the Data are non-transferable and not exclusive.
19. My obligations under this Agreement with respect to access to Brain-CODE continue for the entire period over which I have access to Brain-CODE. The following sections of this Agreement survive termination: 2,3, 4, 5, 6, 7, 8, 9, 11, 14, 15, 19, 20, 21, 22

## WELCOME TO BRAIN CENTRAL



20. No amendment to or modification of this Agreement will be binding unless in writing and signed by OBI.
21. This Agreement is governed by the laws of the Province of Ontario and the federal laws of Canada applicable therein. If for any reason a court of competent jurisdiction finds any provision, or portion thereof, to be unenforceable, the remainder of this Agreement shall continue in full force and effect.
22. The undersigned is hereby put on notice that the confidentiality and the terms of use of data are extremely important to OBI and any breaches of this Platform Terms of Use Agreement will be vigorously prosecuted.
23. It is my express wish that this Agreement and any related documents be drawn up and executed in English. Il est la volonté expresse des parties que cette convention et tous les documents s’y rattachant soient rédigés et signés en anglais.



## Appendix F – Zone 1 Data Use Agreement Template

### ZONE 1 DATA USE AGREEMENT

#### RESEARCH USE OF PERSONAL HEALTH INFORMATION

TO: The Ontario Brain Institute (“**OBI**”)

DATED AS OF: \_\_\_\_\_, 20\_\_

#### Background

This Data Use Agreement (“**Agreement**”), effective as of the last date of signature below, is entered into in favour of OBI as a condition to, and as consideration for OBI providing External Researcher with access to Data in Brain-CODE. Brain-CODE (as the same exists from time to time, including any upgrades, replacements, or supplements thereof, “**Brain-CODE**”) is a software platform that permits the storage, access and analysis of data (any information or data on Brain-CODE from time to time, is referred to herein as “**Data**”).

The undersigned (herein referred to as “**External Collaborator**”) has entered into a Platform Terms of Use Agreement in favour of OBI that, amongst other things, addresses a license to use Brain-CODE and Data (as defined in the Platform Terms of Use Agreement, and hereinafter the “**Data**”) for the Permitted Purpose, as set out therein.

#### Agreements made by External Collaborator

1. External Collaborator agrees that it shall only access the following Data in Brain-CODE, and shall not access any other information in Brain-CODE (*without limiting the more expansive definition of the term Data used in this Agreement, all of the data described below shall be considered “Data” for the purposes of this Agreement*):

[indicate data elements to be shared; including de-identification requirements; clarify if data will contain any PHI]

2. The Data is being provided to External Collaborator for the sole purpose of conducting the following study (referred to herein as the “**Study**”):

[Description of Study to be provided]

### WELCOME TO BRAIN CENTRAL



3. External Collaborator agrees that it shall only use the Data for the sole purpose of conducting the Study, including without limitation, performing analysis in respect of results of the Study (such permitted purpose, the “**Purpose**”). The External Collaborator agrees that it shall not use the Data for any purpose other than the Purpose.
4. External Collaborator shall use the Data in compliance with: (a) this Agreement, (b) the Platform Terms of Use Agreement, (c) the requirements of the Study, (d) applicable laws, (e) any Informed Consent forms associated with the Study, and (f) the REB approval approvals in respect of the Study.
5. External Collaborator shall follow and adhere to OBI’s Informatics Governance Policy as the same may be amended from time to time. The Informatics Governance Policy can be found at <http://www.braininstitute.ca/brain-code>.
6. External Collaborator shall use appropriate safeguards to prevent any unauthorized use or disclosure of the Data and shall promptly give written notice to OBI of any unauthorized use or disclosure of which External Researcher becomes aware, or of any breach to this Agreement, at the following address: 1 Richmond Street West, Suite 400, Toronto, ON, M5H 3W4, Attn: John Clarkson **and** by email to [governance@braincode.ca](mailto:governance@braincode.ca).
7. External Collaborator shall not use any Data or permit any Data to be used to identify or contact the individuals from whom such Data were collected.
8. External Collaborator shall keep all Data that it has downloaded or made copies of strictly confidential, and will not share any such Data with anyone or permit anyone to access or view such Data. External Collaborator agrees to be fully liable for the unauthorized use of any such Data whether by self, or a third party, however such third party may have obtained access to such Data. For greater certainty, External Collaborator agrees that the Data may contain “Personal Health Information” as such term is defined in the *Personal Health Information Protection Act, 2004*, and consequently the External Collaborator may be required to take special steps in regard to the use, storage and disclosure of such Data. Such special steps may be in addition to the obligations of the External Collaborator set out in this Agreement, and may include obligations pursuant to the *Personal Health Information Protection Act, 2004*.
9. External Collaborator shall give access to the Data only to its staff with a need to know for the purpose of conducting the Study, and who are bound by the External Researcher to comply with the terms of this Agreement. External Collaborator shall be liable for any breach of this Agreement (including the confidentiality terms herein) caused by any person or entity to whom External Collaborator has disclosed Data.

[List all personnel who shall have access to Data. Please include full names and institutional email addresses]



10. External Collaborator shall be granted a license to use Brain-CODE (the “License”), wherein any rights to access Brain-CODE and the Data are non-transferable and not exclusive. Obligations under this Agreement with respect to access to Brain-CODE and Data continue irrespective of whether the License has been granted or terminated, and for greater certainty External Collaborator agrees that OBI may revoke the License or access to Data at any time, at the sole discretion of OBI.
11. For greater certainty, this Agreement is in addition to, and not in substitution for the Platform Terms of Use Agreement entered into with OBI. In the event that any provisions of this Agreement contradict and are incapable of being construed in conjunction with the provisions of the Platform Terms of Use Agreement, the provisions of this Agreement shall take precedence over those contained in the Platform Terms of Use Agreement.
12. No amendment to or modification of this Agreement will be binding unless in writing and signed by OBI.
13. The term of this Agreement shall commence as of the effective date and terminate upon Study completion provided that the following Sections of this Agreement shall survive any termination of this Agreement: Sections: 1 through 14. Upon expiration of this Agreement, External Researcher shall destroy all copies (whether physical or electronic) that have been made of Data, and if requested by OBI, provide a certificate confirming the secure destruction of Data under this obligation.

Expected study completion date:

Should this DUA need to be extended beyond the expected study completion date listed above, please contact [governance@braincode.ca](mailto:governance@braincode.ca) to amend this agreement.

14. This Agreement is governed by the laws of the Province of Ontario and the federal laws of Canada applicable therein. If for any reason a court of competent jurisdiction finds any provision, or portion thereof, to be unenforceable, the remainder of this Agreement shall continue in full force and effect.

It is my express wish that this Agreement and any related documents be drawn up and executed in English. Il est la volonté expresse des parties que cette convention et tous les documents s’y rattachant soient rédigés et signés en anglais.

**By signing below, the External Collaborator agrees to be bound by the terms of this Agreement, effective as of the first date written above.**

**[External Collaborator], as External Collaborator**



By: \_\_\_\_\_  
Name:  
Title:

13. Address for notice: **[insert]**

-----[Below is for OBI internal purposes only]-----

**Acknowledged and Agreed by:**

**[IDP EXECUTIVE]**

By: \_\_\_\_\_  
Name:  
Title:

Address for notice: **[insert]**

**[OBI EXECUTIVE]**

By: \_\_\_\_\_  
Name:  
Title:

Address for notice: 1 Richmond Street West, Suite 400, Toronto, ON, M5H 3W4

**[INSTITUTIONAL CONTRACTS OFFICE – only forward if local download of Data is required]**

By: \_\_\_\_\_  
Name:  
Title:

Address for notice: **[insert]**



## Appendix G – Zone 3 Data Use Agreement Template

### DATA USE AGREEMENT

#### RESEARCH USE OF DE-IDENTIFIED DATA

TO: The Ontario Brain Institute (“**OBI**”)

---

#### Background

This Data Use Agreement (“**Agreement**”), effective as of the last date of signature below, is entered into in favour of OBI as a condition to, and as consideration for OBI providing External Researcher with access to Data in Brain-CODE. Brain-CODE (as the same exists from time to time, including any upgrades, replacements, or supplements thereof, “**Brain-CODE**”) is a software platform that permits the storage, access and analysis of data (any information or data on Brain-CODE from time to time, is referred to herein as “**Data**”).

The undersigned (herein referred to as “**External Researcher**”) has entered into a Platform Terms of Use Agreement in favour of OBI that, amongst other things, addresses a license to use Brain-CODE and Data (as defined in the Platform Terms of Use Agreement, and hereinafter the “**Data**”) for the Permitted Purpose, as set out therein.

#### Agreements made by External Researcher:

1. External Researcher agrees that it shall only access the requested Data in Brain-CODE, and shall not access any other information in Brain-CODE (*without limiting the more expansive definition of the term Data used in this Agreement, all of the data described in the Data Access Request shall be considered “Data” for the purposes of this Agreement*);
2. The Data is being provided to External Researcher for the sole purpose of conducting the study as described in the Data Access Request Form (referred to herein as the “**Study**”);
3. External Researcher agrees that it shall only use the Data for the sole purpose of conducting the Study, including without limitation, performing analysis in respect of results of the Study (such permitted purpose, the “**Purpose**”). The External Researcher agrees that it shall not use the Data for any purpose other than the Purpose;
4. External Researcher shall use the Data in compliance with: (a) this Agreement, (b) the Platform Terms of Use Agreement, (c) the requirements of the Study, (d) applicable laws, and (e) the REB approval in respect of the Study;
5. External Researcher shall follow and adhere to OBI’s Informatics Governance Policy as the same may be amended from time to time. The Informatics Governance Policy can be found at [https://www.braincode.ca/content/about-brain-code?qt-qtabs\\_about=2#qt-qtabs\\_about](https://www.braincode.ca/content/about-brain-code?qt-qtabs_about=2#qt-qtabs_about);
6. External Researcher shall use appropriate safeguards to prevent any unauthorized use or disclosure of the Data and shall promptly give written notice to OBI of any unauthorized use or

#### WELCOME TO BRAIN CENTRAL



disclosure of which External Researcher becomes aware, or of any breach to this Agreement, at the following address: 1 Richmond Street West, Suite 400, Toronto, ON M5H 3W4, Attn: John Clarkson;

7. External Researcher shall not use any Data or permit any Data to be used to identify or contact the individuals from whom such Data were collected;
8. External Researcher shall keep all Data that it has downloaded or made copies of strictly confidential, and will not share any such Data with anyone or permit anyone to access or view such Data. External Researcher agrees to be fully liable for the unauthorized use of any such Data whether by self, or a third party, however such third party may have obtained access to such Data;
9. External Researcher shall give access to the Data only to its staff with a need to know for the purpose of conducting the Study, and who are bound by the External Researcher to comply with the terms of this Agreement. External Researcher shall be liable for any breach of this Agreement (including the confidentiality terms herein) caused by any person or entity to whom External Researcher has disclosed Data;
10. External Researcher shall be granted a license to use Brain-CODE (the “**License**”), wherein any rights to access Brain-CODE and the Data are non-transferable and not exclusive. Obligations under this Agreement with respect to access to Brain-CODE and Data continue irrespective of whether the License has been granted or terminated, and for greater certainty External Researcher agrees that OBI may revoke the License or access to Data at any time, at the sole discretion of OBI;
11. External Researcher shall, upon request from OBI, provide updates related to use of the Data on an annual basis by completing the Annual Update form. In addition, External Researcher shall make results and processing methods available to other users through the Brain-CODE platform in a timely manner;
12. For greater certainty, this Agreement is in addition to, and not in substitution for the Platform Terms of Use Agreement entered into with OBI. In the event that any provisions of this Agreement contradict and are incapable of being construed in conjunction with the provisions of the Platform Terms of Use Agreement, the provisions of this Agreement shall take precedence over those contained in the Platform Terms of Use Agreement;
13. No amendment to or modification of this Agreement will be binding unless in writing and signed by OBI;
14. The term of this Agreement shall commence as of the effective date and terminate upon Study completion provided that the following Sections of this Agreement shall survive any termination of this Agreement: Sections: 1 through 14. Upon expiration of this Agreement, External Researcher shall destroy all copies (whether physical or electronic) that have been made of Data, and if requested by OBI, provide a certificate confirming the secure destruction of Data under this obligation;
15. This Agreement is governed by the laws of the Province of Ontario and the federal laws of Canada applicable therein. If for any reason a court of competent jurisdiction finds any

## WELCOME TO BRAIN CENTRAL



ONTARIO INSTITUTE  
BRAIN ONTARIEN  
INSTITUTE DU CERVEAU

provision, or portion thereof, to be unenforceable, the remainder of this Agreement shall continue in full force and effect.

It is my express wish that this Agreement and any related documents be drawn up and executed in English. Il est la volonté expresse des parties que cette convention et tous les documents s'y rattachant soient rédigés et signés en anglais.

**WELCOME TO BRAIN CENTRAL**

1 Richmond Street West, Suite 400, Toronto, Ontario M5H 3W4 | T: 647-847-9000 / 1-866-637-6301 | [braininstitute.ca](http://braininstitute.ca)



## Appendix H – OBI Confidentiality Agreement Template

ONTARIO BRAIN INSTITUTE

Confidentiality Agreement  
Annual Compliance Form for Staff

“Confidential Information” means information in recorded or unrecorded form that is not generally available to the public and is generated, collected or used in the course of our current and anticipated business activity, including our research and development activity.

Confidential Information does not include “Trade Knowledge,” which for the purposes of this agreement means information about processes, techniques and ideas which are commonly known by professionals in your trade.

You understand that Confidential Information does not need to be expressly marked as confidential to be protected under this agreement.

You further understand that Confidential Information includes business and marketing plans, bids and proposals, customer lists, lists of suppliers, surveys, plans and specifications, personal information of employees, information about the composition of work teams, purchasing and internal cost information, operating manuals, engineering standards and specifications, price and cost data, price and fee amounts, pricing and billing policies, quoting procedures, marketing techniques and methods of obtaining business, forecasts and forecast assumptions and volumes, contracts, customer information, quantity and specifications of products and services purchased, leased, licensed or received by customers or clients, work product and Intellectual Property.

Finally, you understand that in the course of your dealings with clients or applicants, you may receive information that is regarded as confidential, and whether covered by a non-disclosure agreement or not, you are obligated to respect their confidence.

During your employment you agree to:

1. use, communicate, copy, transfer or disclose Confidential Information only as necessary to fulfil your employment duties unless you have our prior written permission;
2. refrain from communicating or transferring Confidential Information through an e-mail account or system for sharing electronic records that is not administered by the company; and
3. take reasonable steps to protect Confidential Information from unauthorized use, communication, copying, transfer and disclosure by other employees and individuals.

After your employment ends, whether you resign or are terminated for any reason, you agree to:

**WELCOME TO BRAIN CENTRAL**



1. immediately return all company-owned computer equipment and all manuals, documents, papers and other records in your possession (whether in electronic or physical form); and
2. permanently refrain from using, communicating and disclosing Confidential Information for any reason except with our prior written permission.

I have read and understand the above Confidentiality Agreement regarding the confidentiality of the information that I may have access to in the course of my employment at OBI, whether working for OBI and/or any of its partners. I have discussed any questions I may have regarding this Agreement with my manager. I understand and accept the special nature of my role, the importance of confidentiality in my role and the damage that my failure to keep the Information confidential may cause the OBI and its stakeholders, and hereby agree to the preservation of the confidentiality and integrity of such Information and any policies regarding the same which may be implemented by OBI from time to time.

I also understand and agree that in the event that I breach the Policy that I may be subject to immediate dismissal for cause and /or legal action including injunctive relief to prevent me from disclosing any confidential Information and/or damages. Upon the termination of my employment (for any reason) I hereby undertake to return to the OBI any confidential information and/or property in my possession.

Print Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date:

Witness: \_\_\_\_\_

## Appendix I – Master Services Agreement Template



Template - Master  
Services Agreement.p

WELCOME TO BRAIN CENTRAL

## Appendix J – Zone 3 Data Transfer Agreement

(In development)

## Appendix K- Policies and Procedures

Privacy Policies:

- Procedures to enable the secure transfer of Data, as required.
- Procedures to ensure the secure handling of Data, and reporting if Data was inappropriately collected, used, disclosed or retained (see: Privacy Breach Protocol);
- Procedures to limit Data access only to those that need it in the course of their duties, as determined by OBI and performing periodic reviews of access to ensure compliance;
- Signing of confidentiality agreements by all employees of OBI, the Service Group, prior to commencement of employment or affiliation with OBI and renewal on an annual basis;
- Procedures to receive and respond to inquiries and complaints about OBI's information practices;
- Providing training and awareness activities, and communicating policies and practices surrounding privacy to impacted groups;
- Responding to requests for access to, or corrections of PHI. Such requests will be redirected to the applicable Health Information Custodian, as appropriate;
- Regularly conducting privacy compliance and operational reviews of ongoing and new activities and reporting these activities to the Brain-CODE Informatics Steering Committee and the Information Security Committee periodically.