ONTARIO BRAIN INSTITUTE
BRAIN-CODE INFORMATICS GOVERNANCE POLICY

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Introduction

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 from researchers on a variety of brain disorders. The following Policy outlines the Governance that is applied to all Data held in Brain-CODE. The Policy comprises five Sections, and is posted on the OBI website under Brain-CODE's Privacy, Security, and Governance section at
https://braincode.ca/content/governance :

1.1   DEFINITIONS
1.2   TERMS OF REFERENCE
1.3   DATA SHARING POLICY
1.4   PRIVACY POLICY
1.5   PRIVACY BREACH PROTOCOL

These Sections cover:
- the terms used throughout this document (Definitions),
- the Committees that oversee Brain-CODE and the reporting structure (Terms of Reference),
- all guidelines related to the collection, use, disclosure and access permissions for Data on Brain-CODE (Data Sharing Policy),
- the steps taken to ensure the privacy of participant Data on Brain-CODE (Privacy Policy), and,
- the process in place to report any breaches or improper use of Data on Brain-CODE (Privacy Breach Protocol).

OBI is committed to transparency with the scientists taking part in OBI-funded Integrated Discovery (ID) Programs, who are the prototypical users of Brain-CODE. This Policy clearly communicates all practices related to all Data on Brain-CODE, and sets the stage for users to generate novel discoveries through the many unique features therein.

1.1 DEFINITIONS

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

"**Applicable Law and Guidelines**" means all applicable laws, regulations, including but not limited to Personal Health Information Protection Act (Ontario) PHIPA and guidelines such as the Tri-Council Policy 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 arms-length independent Committee that monitors and advises on the direction of Brain-CODE. The roles and responsibilities of this committee are outlined in the Terms of Reference.

"**Brain-CODE Analytics Advisory Committee**" or "**Analytics Advisory Committee**" means the arms-length, independent Committee that monitors and advises on the direction of Brain-CODE with respect to Data analysis methods and analytics technologies. 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 creating and maintaining Data access and sharing policies for Brain-CODE, and managing the Data access system, including approving Data Access Requests. 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. 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, and reports to the Brain-CODE Informatics Steering Committee. The roles and responsibilities of this Committee are outlined in the Terms of Reference.

"**Brain-CODE Zones**" means the functional separation of Data on Brain-CODE as defined in Section 1.3.3.

"**Controlled Data**" means a classification that is applied to Data that may contain PHI, that has had PHI removed (*i.e.*, de-identified) or that is in use as a part of an ongoing study. Controlled Data are under a period of exclusivity. After the exclusivity period has elapsed Controlled Data may be accessed in Zone 3 through a Data Access Request.

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

"**Data Access Request**" means the process whereby users may make a request to access Data in Zone 3. This request requires a listing of the Data being requested, a Study Plan that outlines the purposes and

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uses of the requested Data, and approval from a valid Research Ethics Board, where appropriate. The Brain-CODE Data Access Committee will review all Data Access Requests.

"Data Producer" means the Participating Institution that has signed a Participation Agreement with OBI, and is generating Data that have been 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 agreement signed by External Researchers on the Brain-CODE portal that details the permitted uses for the Data.

"Data User" means anyone who has an account for Brain-CODE and has access to any Data for the Purposes.

"**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**" 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 contemplated in O. Reg 329/04 of PHIPA[1].

"**External Linkage**" or "**Linkage**" refers to a process whereby Data in Brain-CODE are securely linked to Data from external Databases using secure specialized software.

"**External Researchers**" means researchers who are not indicated in a Participation Agreement.

"**Federation**" means a process whereby Data in Brain-CODE are linked with one or more Databases external to Brain-CODE. Linkage may occur either within Brain-CODE or outside of Brain-CODE. This process is carried out in accord with applicable law and OBI Governance.

"**Health Information Custodian**" or **"HIC"** has the meaning given to it in PHIPA S.O. 2004, Chapter 3 Schedule A, s. 3(1).

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[1] PHIPA rules applicable to ESPs can be found at:
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_040329_e.htm

"**Health Information Network Provider**" or "**HINP**" means a person who provides services to two or more health information custodians where the services are provided primarily to custodians to enable the custodians to use electronic means to disclose personal health information to one another, whether or not the person is an agent of any of the custodians, as contemplated in O. Reg. 329/04 of PHIPA[2].

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

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

"**Metadata**" means any information that describes Data in Brain-CODE, with the intent to describe the amount of certain types of Data available, the types of Data available and the sources of the Data.

"**OBI**" means the Ontario Brain Institute.

"**Participation Agreement**" means a comprehensive Data transfer agreement signed between Participating Institutions and OBI that outlines all relevant rules and guidelines related to how Data are transferred, stored, and disclosed in Brain-CODE. It is required that a Participation Agreement be signed by both parties prior to the upload of any Data to Brain-CODE. This agreement was developed in consultation with privacy and security, legal, and ethics policy experts from OBI and participating institutions. Participating Institutions append a list of the investigators taking part in the research as a sub-schedule to the agreement.

"**Participating Institution**" means the hospitals, universities and research institutes with signed Participation Agreements with OBI. The term Participating Institution may also refer to any other organization that has Raw Data that can be placed into Brain-CODE and has completed a Participation Agreement with OBI.

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

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

"**Processed Data**" means Data that 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.

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

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[2] PHIPA rules applicable to HINPs can be found at:
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_040329_e.htm

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

"**Public Data**" means Data that do not have exclusivity, and may be accessed without any of the restrictions in place for Controlled Data. Metadata describing the Data available in Brain-CODE will also be Public Data.

"**Purposes**" means the purposes of Brain-CODE, being that OBI has created the Brain-CODE informatics platform in order to allow for the investigation, discovery and scientific query within and across several brain conditions.

"**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).

"**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 High Performance Computing Virtual Laboratory ("HPCVL", Queen's University Site, Kingston, Ontario); and the Electronic Health Information Laboratory ("EHIL", part of the Children's Hospital of Eastern Ontario and affiliated with the University of Ottawa, Ottawa, Ontario); or any other entity providing design and maintenance support to OBI in relation to Brain-CODE.

"**TCPS2**" means the Tri-Council Policy for the Ethical Conduct of Research Involving Humans

"**Terms of Reference**" means the OBI terms of reference as amended from time to time, which form part of the Governance Policy.

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

1.2 TERMS OF REFERENCE

1.2.1 Scope and Purpose

This document (the "Terms of Reference") 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")

Brain-CODE Analytics Advisory Committee ("Analytics Advisory Committee")

1.2.2 General Principles

These Terms of Reference represent the definitive guide to Brain-CODE 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 will be required to enter into non-disclosure agreements prior to serving on the committee) and avoiding potential and real conflicts of interest by recusing themselves from discussions and votes concerning those matters for which they are conflicted. All Brain-CODE committees will be supported by OBI administrative resources.

All committee members must receive at least 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 14 business days due to significant potential travel requirements.

1.2.3 Informatics Steering Committee

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

- Monitor all 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 all Brain-CODE progress is timely and of high quality;

- Ensure Brain-CODE adheres to all relevant regulations, including privacy laws;

- Adjudicate all requests to access Data from Brain-CODE, pursuant to the recommendations of the DAC; and

- Guide the Information Security Committee to ensure that individuals under their supervision are aware of their information security responsibilities.

1.2.3.1 Membership

The Informatics Steering Committee will consist of OBI senior management staff. These members represent OBI initiatives that may utilize and/or benefit from Brain-CODE.

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.

1.2.3.2 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. Typically, the four committees (Advisory Committee, Data Access Committee, Information Security Committee, and Analytics Advisory Committee) will provide regular reports to the Informatics Steering Committee.

1.2.3.3 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 that are not part of Brain-CODE or the OBI to serve on these working groups, provided that they protect and maintain as confidential any privileged information divulged to them in the course of their work with respect to these working groups.

1.2.3.4 Meetings

Meetings may be held at any time and place, as determined by its members. At minimum, these meetings shall be held on a quarterly basis. Attendance of forty per cent of members will constitute quorum. During meetings held by conference call, votes will be taken orally. The Chair, or in his or her absence an OBI executive as Acting Chair, will preside at all meetings of the Informatics Steering Committee.

The Informatics Steering Committee will keep records of its decisions.

1.2.4 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 that may contribute to the goals of OBI and Brain-CODE, or that OBI should collaborate with;

- Advise on the direction and progress of Brain-CODE, ensuring that it is aligned with the vision of OBI and with international developments;

- Ensure that Brain-CODE meets international best practices on Data organization, sharing and analysis; and

- Receive reports on the work of the Informatics Steering Committee.

All Advisory Committee members are responsible for maintaining confidentiality (and will be required to enter into a non-disclosure agreement prior to serving on the committee) and avoiding potential and real conflicts of interest by recusing themselves from discussions and votes concerning those matters for which they are conflicted. The Advisory Committee will be supported by OBI administrative resources. All Committee members must receive at least 14 business days' notice prior to each meeting.

1.2.4.1 Membership

The Advisory Committee will consist of at least 6 members. Members are appointed by the President and Scientific Director of OBI on the advice of the OBI Brain-CODE Informatics Steering Committee. Members are appointed for a two-year term with up to two renewals. The Chair will be named 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. The Advisory Committee members represent different stakeholders with interest in the field of bioinformatics and "Big Data" analytics. There will be at least one representative from each of the following domains: Data privacy and security (*e.g.*, the Office of the Information and Privacy Commissioner/Ontario), industry (clinical trials expertise), and bioinformatics.

1.2.4.2 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. At the request of the President and Scientific Director, the Advisory Committee will make inquiries and report in a manner independent of the Informatics Steering Committee.

1.2.4.3 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 50% of members will constitute quorum. During meetings held by conference call, votes will be taken orally. The Chair, or in his or her absence, an Advisory Committee member assigned by the Chair, will preside at all meetings. The Advisory Committee will keep records of its proceedings.

1.2.5   Data Access Committee

The purpose of the Data Access Committee ("DAC") is to develop Data access and sharing policies, which address eligible users, Data embargoes, acknowledgement and ethics requirements, and make recommendations to the Informatics Steering Committee regarding the release of Data to third parties. The Data Access Committee will:

- Create and review Data access and sharing policies;

- Manage Data access, closely examining Data Access Requests and ensuring that Data disclosed cannot be used to identify individuals who contributed to said Data; and

- Recommend the approval of Data access, in accordance with the Data access policy.

Under no circumstances will the DAC recommend issuing a third party access to Brain-CODE Controlled Data (see Data Sharing Policy) without a valid approval from the third party's REB. The DAC may also consider the scientific merit of the Data access, including the assessment of a user's affiliations and research hypothesis.

1.2.5.1 Membership

The DAC consists of between 13-17 members. The Chair will be named by the President and Scientific Director of OBI, in consultation with the ID programs. A privacy officer or equivalent from one of the Participating Institutions will also be included as a member of the DAC. Members are appointed by the Informatics Steering Committee, in consultation with the ID Programs, for a two-year term with the possibility for two annual renewals following the two-year term. Privacy officers will be recommended by a Participating Institution and serve for a one-year term.

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, Brain-CODE and may include one or more independent members of the community. There may be two representatives from each of following disease areas that have been initially prioritized by the OBI: addiction, neurodevelopmental disorders, cerebral palsy, concussion, depression, epilepsy, and neurodegeneration. Additionally, there will be at least one representative from the Service Group and the OBI Brain-CODE Informatics Steering Committee.

1.2.5.2 Reporting

The DAC provides reports, as necessary, to the Informatics Steering Committee. These reports will make Data access and Data Sharing Policy recommendations. The DAC will also make recommendations to the Informatics Steering Committee vis-à-vis Data access requests by third parties as required.

1.2.5.3 Meetings

Requests for Data will be reviewed as it arrives by the DAC, or by an appropriate delegate if a DAC member is unavailable. Recommendations will be provided to the Informatics Steering Committee within 60 days of the receipt of the request. The DAC will hold a minimum of one meeting annually, to a maximum of four, to discuss related matters. These meetings may be conducted via teleconference.

Quorum will consist of a majority of regular appointed members. During meetings held by conference call, votes will be taken orally. The Chair, or in his or her absence, a DAC member delegated by the Chair will preside at all meetings. The DAC will keep regular records of its proceedings.

1.2.6   Information Security Committee

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

1.2.6.1 Membership

The Information Security Committee consists of 6-8 members. At a minimum, the committee must include the Manager, Informatics & Analytics, an Information Security Officer and Privacy Officer, and at least one representative from each of the Service Group members whose role is relevant. Members are appointed and serve under direction by the Informatics Steering Committee. If subject matter experts are required where the expertise does not exist within the Committee, external expertise, with the approval of the Manager, Research & Informatics could be brought in for one or more meetings.

1.2.6.2 Reporting

The Informatics Security Committee reports to the Informatics Steering Committee through a common member, the Manager, Informatics & Analytics. Reports from the Informatics Security Committee will provide guidance and recommendations to the Informatics Steering Committee on all matters related to security and privacy.

1.2.6.3 Meetings

Meetings of the Information Security Committee are held on a bi-weekly basis by teleconference. On the occasion that individual members of the Committee are needed to attend other meetings with OBI as subject matter experts, they may be asked by the Informatics Steering Committee to attend such meetings in person.

1.2.7   Analytics Advisory Committee

The OBI Brain-CODE Analytics Advisory Committee is an arm's length committee that advises on the analytics direction of Brain-CODE. The Analytics Advisory Committee will:

- Advise the President and Scientific Director of OBI on the trends and developments in analytics for neuroscience Data, in particular on any methods, technologies, business practices, or initiatives that may contribute to the goals of OBI and Brain-CODE;

- Discuss and advise on the direction, challenges, and progress of Brain-CODE with respect to analytical methods, capacity building, expert training, collaborations, and Data opportunities while ensuring that any progress aligns with OBI's vision and international developments;

- Ensure that Brain-CODE meets or exceeds international best practices on Data curation and integrated Data analysis for discovery and sharing;

1.2.7.1 Membership

The Analytics Advisory Committee will consist of up to 8 members. Members are appointed by the President and Scientific Director of OBI on the advice of the OBI Brain-CODE Informatics Steering Committee. Members are appointed for a two-year term with up to two renewals. The Chair will be

named by the President and Scientific Director of OBI in collaboration with the Informatics Steering Committee.

No member of the Analytics Advisory Committee shall be employed by either OBI or by the Service Group. The Analytics Advisory Committee members represent stakeholders with expertise in the field of bioinformatics and "Big Data" analytics. There will be at least one representative from one or more of the following domains: clinical Data analysis, imaging Data analysis, genomic Data analysis, visual analysis, integrated Data analysis, knowledge representation, machine learning, and modelling.

All Analytics Advisory Committee members are responsible for maintaining confidentiality (and will be required to enter into a non-disclosure agreement prior to serving on the committee) and avoiding potential and real conflicts of interest by recusing themselves from discussions and votes concerning those matters for which they are conflicted. The Analytics Advisory Committee will be supported by the administrative office of the OBI. All members must receive at least 14 business days' notice prior to each meeting.

1.2.7.2 Reporting

The Analytics Advisory Committee provides regular reports to the Informatics Steering Committee. These reports will outline any recommendations on the direction and progress of Brain-CODE. At the request of the President and Scientific Director of OBI the Analytics Advisory Committee will make inquiries and report in a manner independent of the Informatics Steering Committee.

1.2.7.3 Meetings

The Analytics Advisory Committee will hold meetings at least twice per year. At least one of these meetings will be in-person and the additional meetings will be via teleconference. Additional meetings may be requested by the OBI President and Scientific Director.

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

Attendance of a majority of the appointed members will constitute quorum. During meetings held by conference call, votes will be taken orally. The Chair, or in his or her absence, an Analytics Advisory Committee member assigned by the Chair will preside at all meetings. The Analytics Advisory Committee will keep regular records of its proceedings.

1.3 DATA SHARING POLICY

1.3.1 Introduction

OBI understands that the success of our researchers is of paramount importance and therefore we must support researchers to maximize the impact of their work. OBI also understands that the funding it receives from the Ontario Government is contingent upon system innovation; enhancing collaborations and building a model where Data sharing is an integral part of the initiatives.

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 protected while the objective of achieving system change through sharing Data is encouraged and grows.

1.3.2 Oversight

Oversight for Brain-CODE, including its administrative structure and governance, is outlined in Section 1.2 above, the Terms of Reference. Therein, the roles of the DAC and the Informatics Steering Committee are described.

1.3.3 Three Primary Functions of Brain-CODE

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 patient consent. Brain-CODE provides a safe and secure means to store Data, facilitates the sharing of Data between researchers, and will encourage collaboration within and across the ID programs.
2. Brain-CODE provides long-term storage of Data and potential linkage of that Data to other external Data bases. This will be done in a secure fashion and in accordance with the Study Protocols and REB approvals.
3. Brain-CODE provides opportunities for the Processed Data to be made available to approved third parties for the intended Purposes of further analysis. This is where the Data becomes accessible for broader use based on guidelines described in this Data Sharing Policy.

To facilitate the three primary purposes described above, Brain-CODE has been structured with 3 Zones (Figure 1).

Zone 1: will contain, with approval of the applicable REB and study participant consent, the Raw Data (which 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. There will be two potential roles in Zone 1 for OBI, as defined by PHIPA: Electronic Service Provider or Health Information Network Provider (HINP).

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 REB.

Zone 3: provides storage where Processed Data stored in Zone 2 may be prepared by OBI for disclosure to third parties recommended by the Data Access Committee and approved by the Steering Committee for the Purposes. Prior to disclosure, Processed Data will undergo an analysis of the risk of re-identification and are subject to internal mechanisms further described in the Data Sharing Policy.
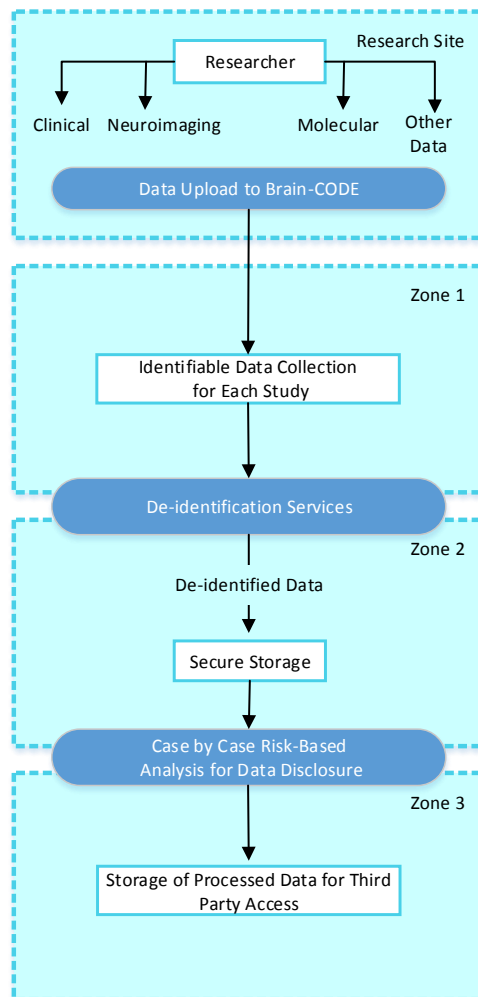

Figure 1 – Data flow and storage in Brain-CODE

1.3.4 Data Types

Data will be held by OBI in two forms, as defined above in [Section 1.2 above, the Terms of Reference](#):

1. Raw Data
2. Processed Data

Brain-CODE is an electronic Database. Any biological samples arising from research activities bringing Data into Brain-CODE will be stored at Participating Institutions, which are responsible for managing and keeping an up-to-date catalogue of the samples according to guidelines and policies relevant to that Participating Institution.

The expressed written consent of study participants, from whom Data have been collected, is required to transfer Data, which may include PHI, into Brain-CODE. This practice will remain in place, unless an REB has approved the transfer of participant Data without their consent.

1.3.5 Compliance

OBI will accept Data from Participating Institutions for secure storage in the applicable Brain-CODE Zone.

To fulfill the mission of OBI in relation to the integrated approach to brain disorders and in accordance with its Research Activity Agreements, OBI further requires that any Participating Institution that is receiving funding through the ID program must submit all Data from any OBI-funded study to Brain-CODE. Some of these Data will be standardized in a manner agreed upon by the researchers working in collaboration with OBI. 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 generally accepted research practices and/or pursuant to the requirements imposed by the applicable REB.

Data will also be accompanied by contextual information, or Metadata, to provide the Data user with any necessary details on the origin of the Data, or manipulations the Data have undergone. This will help minimize the likelihood of misuse, misinterpretation and/or confusion. Data will also be accompanied by the study protocols and methods used to capture the Data. This will help inform others about the mechanisms of Data capture and their relevance with respect to their research objectives.

1.3.6 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 will be carried out in a secure environment. In cases where linked Data sets are requested by Data users, the linked Data will undergo an analysis using specialized software to determine the risk of re-identifying study participants before any Data are disclosed.

1.3.7 Access by Study Participant

Study participants will be able to request access to their own Data through Participating Institutions that are Health Information Custodians (*i.e.*, where the Data were collected). Rules governing such access are further described in [Section 1.4, the Privacy Policy](#).

1.3.8   Data Sharing Principles

Brain-CODE has been established to ensure that Ontario researchers who produce the Data in OBI-funded ID Programs have the maximum opportunity to take advantage of their efforts to use the Data. At the same time 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 internationally.

Three principles that underpin OBI's vision for Brain-CODE are:

1.   Brain-CODE as a useful, user-friendly and valuable Data management tool for researchers engaged in our ID Programs.
2.   Brain-CODE as a state-of-the-art research tool that promotes robust collaboration and Data sharing, adds value for Ontario-based researchers first and promotes international capacity building and collaborations.
3.   Making Data available in a controlled open access format, in line with international best practices, through innovative approaches to Data sharing. In this connection, OBI supports the need to acknowledge Data producers and Data sources.

1.3.9   Data Ownership

The ownership of Data generated through OBI-funded initiatives will remain with the Data producers, namely the Participating Institutions. Neither the OBI, its agents nor subcontractors will claim right, title, nor ownership to these Data as entered into 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 1.3.11](#).

1.3.10   Data Exclusivity

Researchers are encouraged to use Brain-CODE as their Data management tool. As such, the researcher together with OBI will classify their Data as either Controlled or Public:

- **Controlled Data**: A classification that is applied to Data that may contain PHI, has had PHI removed (*i.e*., de-identified), or that is in use as a part of an ongoing study. Controlled Data are under a period of exclusivity. After the exclusivity period has elapsed Controlled Data may be accessed in Zone 3 through a Data Access Request (Figure 2) and related process as outlined in this document.
- **Public Data**: Does not have exclusivity, and may be accessed in Zone 3 without any of the restrictions in place for Controlled Data. Metadata describing the Data available in Brain-CODE will also be Public Data.

Accessibility to Controlled Data is managed by the parameters outlined below (see Figure 2):

1.   As defined in discussion with OBI, a plan for the exclusivity of the Data will be established based on the requirements on the study. This plan will outline a period to gather the Data. For OBI-funded studies, the ID program Executive and Publication Committee (where one exists) will develop the plan in discussion with OBI.

2. After the agreed-upon time period to gather the Data has elapsed, 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 beyond the control of the researchers 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, researchers may request a reasonable time extension from OBI. For clinical trials (including drugs, medical foods and medical devices), the exclusivity period may also 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. Data under exclusivity will be available to all researchers participating in the same Study, as outlined in the Participation Agreements.
4. After the designated exclusivity period, the Data will be made available as Public or Controlled Data.
5. Third party access to Controlled Data no longer under exclusivity will require a Data Access Request.

Public Data do not have exclusivity and may be accessed in Zone 3. Examples of Public Data contributed to Brain-CODE, which will become available immediately, and without restriction after becoming Processed Data, if applicable, are:

- Study name

- Number of participants

- Metadata associated with Data files and studies

Common Data Elements (CDEs) are intended to provide a general characterization of a number of commonly assessed variables across each of the ID programs; the complete list is available at https://www.braincode.ca/content/about-brain-code. A review of the CDEs will be completed by the ID programs' Executive with OBI to determine which CDEs for each study should be considered as Public Data and which should be Controlled Data.
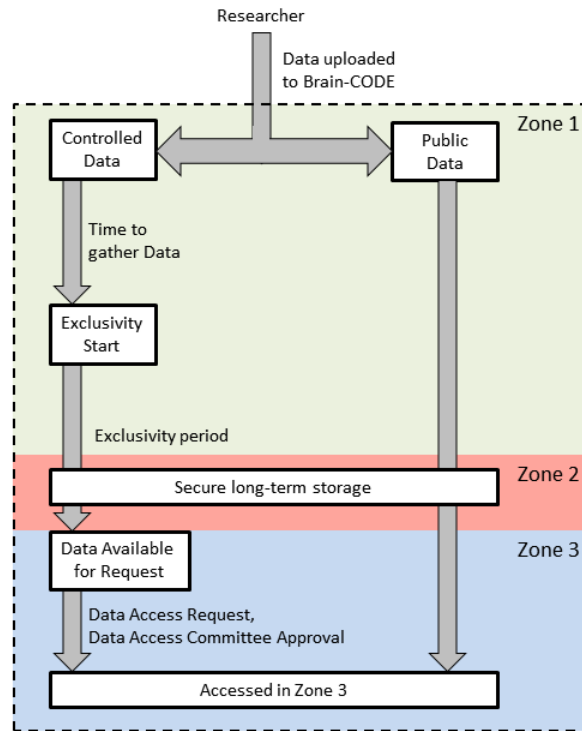
Figure 2 – Exclusivity and disclosure of Data in Brain-CODE

1.3.11 Intellectual Property

Exclusivity periods allow Data producers to apply for protection of their intellectual property or to publish results if they wish. Any intellectual property resulting from the work product (*e.g*., the result of a Data analysis) will belong to the Data user, not the Data producer. However, OBI wishes to encourage collaboration between Data users and Data producers, 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 independent analysis of Data by a Data user is considered a distinct entity ("Work Product") that will generally be owned by that researcher 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 Processed Data in order to disclose such Processed Data to third parties,
   b. irrevocably grants such third parties the right to use such Processed Data for the Purposes and
   c. agrees that such third parties may publish any research created by such researcher without any further consents required of the Participating Institution.

1.3.12 Data context

Each study participant will have a unique identifier to allow for integration of all Data (e.g., "omics", imaging and clinical Data), providing a means to index participants while maintaining anonymity. Data producers will also be responsible for submitting contextual information; for example, standard operating procedures for Data collection, copies of questionnaires, and Data manipulations. For all contextual information, copyright laws must be respected. The DAC will determine whether a request for additional contextual information is reasonable and who must provide the information, and make a recommendation to the Informatics Steering Committee.

1.3.13 External Researchers as Data users and Federation 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 detailed plan for the use of those Data to the DAC, and approval from a Research Ethics Board, where appropriate. External Researchers will provide annual status reports to the DAC. These reports, which will be kept strictly confidential, will describe any type of report or documentation that results from work with Data, analytics tools, or other components related to Brain-CODE.

3. Data Access Requests will adhere to the steps set out in [Section 1.3.14](#).

Federation partnerships may also be established between OBI and other data providers for the purposes of data linking. To achieve these purposes OBI will authorize such linkages in accordance with the requirements set out below.

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

2. A Data Sharing Agreement will be signed between both parties.

3. Linkages will be performed by the joint technical teams from both OBI and the federation partner.

OBI-funded IDP researchers with existing plans to link data with an OBI federation partner are encouraged to communicate detailed plans of these research intentions to OBI prior to the start of the one year exclusivity term in order to ensure that IDPs have the primary opportunity to link their existing datasets using Brain-CODE for the Purpose(s).

1.3.14   Data Access Requests

1. The DAC will review Controlled Data requests to ensure adherence to OBI's Governance Policies as a whole, and any Applicable Laws and Guidelines, including PHIPA[3]. The DAC will also examine the appropriateness of the Data requested for its intended use. In collaboration with OBI and the Service Group, the DAC will make use of algorithms to analyze the risk that the release of any Data requested, where appropriate, will lead to re-identification of study participants who have contributed Data.

2. The DAC will be responsible for verifying that only Processed Data, which have been subjected the most advanced de-identification tools available and have a minimal risk of re-identification, are disclosed.
3. Data will be released on the condition that the External Researcher signs a Data Use Agreement with applicable confidentiality requirements and provisions that prohibit any attempts to re-identify Data.
4. The DAC may then issue a recommendation to the Informatics Steering Committee to release the requested information.
5. To the extent possible, Data will remain within the Brain-CODE environment where any analysis or other related manipulations would take place, restricting the download of Data.

1.3.15   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 name/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.

1.3.16   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 in a timely manner. Some results generated via the use of

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[3]PHIPA may be found online at http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_040329_e.htm#BK4

Brain-CODE may be automatically returned to Brain-CODE to expand the general knowledge base. OBI encourages the Data producer to make such inventive contributions.

1.3.17 Privacy Breaches

In the event of a privacy breach, OBI will comply with applicable law and guidelines in reporting details of breaches. Further, OBI may report the violation, as it deems appropriate, to any journals where the Data User has submitted a manuscript, any bodies that fund research related to the breach, and the user's institution. Finally, OBI reserves the right to restrict Data users from future access to Brain-CODE.

1.4   PRIVACY POLICY

1.4.1   Scope and Purpose

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 to creating and implementing protective measures. This Policy is specific to Brain-CODE and is based on the 10 Canadian Standards Association (CSA) Privacy Principles[4].

1.4.2   Accountability

Accountability for OBI's compliance with this Policy rests with the President and Scientific Director, although other individuals within OBI and affiliated with the Service Group are responsible for the day-to-day activities that support the protection of privacy and security. OBI's Manager of Informatics and Analytics, or other appropriate delegate, may act on behalf of the President and Scientific Director, where appropriate.

OBI is responsible for information in its custody or control, including Data that have been transferred to an agent of OBI (such as OBI's Service Group). No such Data shall be used by agents of the OBI unless all the appropriate protections and security are maintained in place at all times.

A description of the Data that are to be held in each of the Zones of Brain-CODE is provided in Section 1.3.3:

A further sub-classification of the Data, based on periods of exclusivity by Data producers, is made in the Data Sharing Policy. With respect to the Data described above, OBI has implemented policies and practices to give effect to the Privacy Policy, including:

1.   Procedures to enable the secure transfer of Data into:

    1.1. Zone 1, where it will be collected and used, as described in the Data Sharing Policy.

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[4]The 10 CSA Privacy Principles may be found at: http://www.csagroup.org/ca/en/legal/privacy/csa-group-privacy-statement

1.2. Zone 2 after removal of Direct Identifiers using the most advanced tools,

1.3. Zone 3 for analysis and disclosure, as outlined in the Data Sharing Policy.

2. Procedures to ensure the secure handling of Data, and reporting if Raw Data, which may include PHI, is inadvertently or otherwise inappropriately collected, used, disclosed or retained by OBI (see: Privacy Breach Protocol).

3. Procedures to limit Data access only to those that need it in the course of their duties, as determined by OBI (*i.e.*, role-based access).

4. Signing of confidentiality agreements by all employees and agents of OBI, including the Service Group, prior to commencement of employment or affiliation with OBI.

5. Procedures to receive and respond to inquiries and complaints about OBI's information practices.

6. Providing training to OBI staff, and communicating policies and practices surrounding privacy to the Service Group.

7. Responding to requests for access to, or corrections of PHI. Such requests will be redirected to the applicable Health Information Custodian, as appropriate.

OBI will work with its partners 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), and will be led by the Health Information Custodians and other Participating Institutions from whom such Data are collected. 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 purposes for which Data are collected are identified through robust informed consent processes and as otherwise permitted or required by law (including as authorized by an REB under PHIPA).

1.4.4   Consent for Collection, Use and Disclosure

The knowledge and consent of the individual study participant or their guardian are required for the collection, use, or disclosure of Data, except where permitted or required by law.

Raw Data collected by OBI are collected with consent, unless the REB has specifically authorized collection without consent under PHIPA, in accordance with high standards for the conduct of research in Canada and internationally.

Through the Participating Institutions and their research-related consent processes, OBI makes reasonable efforts to ensure that the study participants or their guardians 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. Not all purposes for the Data can be predicted ahead of time;

however, any new purposes for which the Data may be used that are not communicated to the participant at the time of consent will adhere to the same core principles of usage and standards of privacy that were communicated to the participant in the first place.

Transparency regarding research supported by OBI will be provided on the OBI website and in other public-facing communications materials as appropriate.

A study participant or their guardian may withdraw consent at any time, subject to legal restrictions and reasonable notice. Withdrawal of the consent will not have a retroactive effect, meaning that once Raw Data are used by OBI to become Processed Data and are transferred into Zone 2, it is considered to have been used for research purposes, and consent for past use cannot be withdrawn. Upon reaching the age of consent, a study participant may withdraw their consent to participate, notwithstanding that their guardian appropriately consented to their participation, before they achieved the age of consent.

Processes regarding withdrawal procedures will be described in the study participant consent materials. In brief, a Participating Institution will notify OBI of a withdrawal request related to Data that have not had Direct Identifiers removed to the extent possible, and will provide the encrypted health card number or other unique study participant identifier. Upon receipt OBI will initiate processes to label and segregate, or securely destroy, the Data so that they are not subsequently used or linked or transferred to Zone 2 from that point onwards.

1.4.5   Limiting Collection

Brain-CODE can collect Raw Data from Data Producers, which may include PHI for study purposes, where it is required and there is informed consent in place, or if the REB has waived the requirement for consent. These Data will be stored in Zone 1 where only those researchers involved in the study will have access to it (*e.g.*, where this occurs across study sites involving two or more Health Information Custodians, OBI may act as a HINP). Direct Identifiers will be removed using the most advanced tools available prior to transfer into Zone 2.   OBI will provide Data Producers with a secure algorithm tool that will encrypt health card numbers prior to their entry into Brain-CODE, when appropriate participant consent and REB approval has been granted. Collection will be by fair and lawful means.

OBI does not permit indiscriminate collection. OBI distinguishes how different types of data (e.g. PHI vs. non-PHI) in Brain-CODE must be handled with respect to privacy and security. OBI will request that Health Information Custodians and other Participating Institutions collecting Raw Data for the purpose of a research study take steps to remove Direct Identifiers to the extent possible, unless necessary for the research study, and with REB approval and consent as applicable. When acting as an Electronic Service Provider, OBI is also able to remove Direct Identifiers, to the extent possible, in Zone 1.

The requirement that Data be collected by fair and lawful means is intended to prevent Participating Institutions and OBI from collecting information in a manner that misleads or deceives study participants as to the purpose for which Raw Data are being collected. This requirement means that consent with respect to collection must not be obtained through deception.

1.4.6 Limiting Use, Disclosure and Retention

Direct Identifiers will not be disclosed for OBI purposes except as permitted by study participants (or their guardians) or required by law.

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. To ensure privacy is not compromised by the indefinite retention of Data, Direct Identifiers will be removed prior to long-term storage in Zone 2.

Requests for disclosure of Data in Zone 3 will be reviewed by the Data Access Committee to ensure that all disclosure is consistent with this Privacy Policy, and OBI's objectives. The Data Access Committee is bound by its Terms of Reference to ensure that its members are appropriately qualified and processes are in place to meet the Committee's mandate. Assessments designed to evaluate the risk of Data disclosure will be carried out using tools developed by the Electronic Health Information Laboratory and/or similarly qualified collaborator. If required, OBI will undertake steps to ensure that this risk is reduced to a level that minimizes the risk of re-identification prior to disclosure.

1.4.7 Ensuring Accuracy

OBI will take reasonable steps to ensure that the Data it holds are as accurate, complete, and up-to-date as is possible. Participating Institutions contributing Data will also be required to take such reasonable steps.

OBI will employ privacy best practices as set out by the Information and Privacy Commissioner of Ontario that require Data linkages to be carried out in a manner that ensures:

- A minimum number of individuals involved in developing Brain-CODE have access to Data in Brain-CODE, based on role;

- Health card numbers are encrypted at the Participating Institution before transfer into Brain-CODE and Direct Identifiers are removed from Data using the most advanced tools available before transfer to Zone 2;

- The results of the Data linkage will not be used for any purpose that is reasonably contemplated to be detrimental to the individual;

- The consent of the individual is obtained, unless the REB has authorized proceeding without consent as permitted under PHIPA;

- Agreements are in place to identify responsibility for the Data and specify conditions with which users must comply regarding linking, further use, and secure disposal of the Data; and

- There are no other practical alternatives for conducting the analyses.

1.4.8 Ensuring 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 Data

Sharing Policy. The processes in place to protect OBI information assets are more specifically described in the Brain-CODE Security Policy.

The methods of protection include:

- Physical measures, for example, locked filing cabinets and restricted access to offices;

- Organizational measures, for example, policies, training, limiting access on a "need-to-know" basis; and

- Technological measures, for example, the use of passwords, secure computer networks, encryption and third party audits of privacy and security practices.

OBI will make its employees and agents, including the Service Group, aware of the importance of maintaining the confidentiality of Data. As a condition of employment or relationship with OBI, all new OBI employees/agents must sign a confidentiality agreement. This safeguard may also be facilitated though contractual provisions.

It is also mandatory for all new personnel and individuals maintaining Brain-CODE (OBI staff and Service Group members), including Brain-CODE, to receive privacy/security training at the commencement of employment and/or prior to being given access to OBI electronic systems. Failure to attend training will result in the denial of access to Brain-CODE. Each manager or Principal Investigator or designate is responsible to ensure that all personnel and members of research teams have undergone privacy and security training.

1.4.8.1 Training

OBI will work with Program Managers and/or Principal Investigators or their designates to ensure they have received a training module from the Service Group or another group charged with this task. The Manager and/or Principal Investigators are also responsible for imparting the importance of the training and compliance with the content described to recipients of the training. Additionally, access to privacy and security-related policies, practices and procedures will be made available in print or electronic format.

Ongoing or additional training:

Additional privacy training may be mandated and provided either in response to changes in process, standards or technology, as a matter of routine (*e.g.*, annual provision of training) or where OBI is facilitating access to additional resources where specific training is a condition of access to the resource(s).

1.4.8.2 Safeguards

Recipients of individual-level research Data must abide by any requirements received from OBI in respect of the secure storage and transfer of the Data.

1.4.9   Openness

OBI makes readily available specific information about its policies and practices relating to Data it collects, uses and discloses. OBI only aims to amend the Brain-CODE governance policies on an as-

needed basis from time to time 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. The Governance Policies are available to the public on the OBI website, https://www.braincode.ca/content/governance, which:

- Provides a general description of OBI's information practices;

- Describes how to contact the OBI Manager of Informatics and Analytics (the designated privacy contact person for Brain-CODE);

- Describes the circumstances in which OBI would receive Raw Data and the requirement to remove Direct Identifiers, using the most advanced tools available;

- Describes how Data collected by OBI are used for research purposes and describes these purposes; and

- Describes how an individual may make a complaint to OBI and/or to the Information and Privacy Commissioner of Ontario.

1.4.10 Individual Access

Consistent with PHIPA, OBI will facilitate the process of study participants or their guardians gaining access to their PHI by redirecting them to the appropriate Health Information Custodian (*e.g.*, public hospital or other health care provider that first collected the PHI and provided it to OBI).

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 Manager of Informatics and Analytics and upon receipt, will be reviewed and a response provided within 30 days.

If the inquirer or complainant is not satisfied with OBI's response, a personal interview may be arranged to review the issue. OBI may refer the inquirer or complainant to affiliated researchers and their associated Health Information Custodian if the inquiry or complaint relates exclusively to the processes and/or practices of the researcher/Custodian and does not relate to the practices of OBI.

Complaints may also be made to the Information and Privacy Commissioner/Ontario in writing: 2 Bloor St. East, Suite 1400, Toronto, Ontario, M4W 1A8 (telephone: (416) 326-3333 or 1-800-387-0073).

1.5 PRIVACY BREACH PROTOCOL

1.5.1 Introduction

The protection of the privacy interests of individuals who participate in research studies resulting in Data being held by OBI is considered *mission critical.* **This protocol imposes a mandatory requirement on all OBI agents, including the Service Group, to promptly notify OBI of an actual or suspected privacy breach.**

A privacy breach is considered a critical incident and will be investigated as such.

A **privacy breach** occurs when Data are collected, retained, used or disclosed in ways that are not in accordance with PHIPA and its regulations, Data transfer agreements, the Participation Agreement, any part of the Governance Policy, or other agreements and policies of OBI. Further, where Data, in particular Raw Data, which could contain PHI, are stolen, lost or subject to unauthorized access, copying, modification or disposal, OBI accepts the requirement under PHIPA for Health Information Custodians to notify affected individual(s). This duty may also apply to other Participating Institutes that are not Health Information Custodians.

It is recognized that **security breaches** are potentially part of, or can lead to, a privacy breach. A security breach occurs when, a person or entity, without authorization, gains access, either physically or electronically to OBI resources designated as secure, whether with malicious intent or not, and includes contravention of security policies. Such resources may be either physical space or an electronic network. Security breaches will be responded to in accordance with the Security Breach Policy until such time as it has been determined that a privacy breach has occurred, at which time this protocol will be followed.

Examples of **privacy breaches** include:

1. Knowingly storing Identifiable Data or anything that could be considered PHI in Brain-CODE without REB approval and consent, as applicable in the long-term, whether inadvertently or intentionally, and that is not a part of OBI's role as a HINP or ESP;

2. Unauthorized linkage of Data with databases external to Brain-CODE

3. Release of Data where re-identification risk assessment procedures have not been followed

4. Any other physical, technical or administrative breach

1.5.2 Discovery of Breach

The OBI-affiliated person, including any members of the Service Group, who discovers the breach (the "discoverer") is responsible to:

• Start the process of containment in order to avoid any further breaches

• Notify his/her immediate supervisor and the OBI Manager of Informatics and Analytics or designate immediately, in person or by telephone but not by means of a voicemail recording, and with a follow-up message confirming the content of the oral notification, by email or in writing.

- Once the appropriate individuals described below are notified, the "discoverer" of the breach is relieved of the responsibility of communication and containment, but must remain available for consultation during the documentation, investigation and action phases

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 process of containment will be initiated by the discoverer of the breach as appropriate, but this responsibility will be promptly assumed by the Manager of Informatics and Analytics or their designate.

The containment process comprises the following steps:

- 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 PHI or any Data that could be considered PHI (*e.g.*, an electronic information system) 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 method of secure disposal.

- 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, 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, Research and Informatics, the Senior Vice-President, and the President & Scientific Director and initiates further investigation, documentation and containment strategies.

- Determines if additional resources are required to support the response by OBI, which may include Service Group staff, the Privacy Officer, the Security Officer and external counsel.

- Determines the extent of the breach (*i.e.*, type of breach and whether it is an internal or external breach).

- Evaluates what further communication is required and notifies the appropriate individuals, based on the type of breach (see **Appendix B, Communication Log**).

Once the extent of the breach has been determined, the OBI Manager of Informatics and Analytics will bring the issue forward to the OBI Informatics Steering Committee as soon as possible, where members will be briefed on the situation.

APPENDIX A – BREACH REPORT AND INVESTIGATION FORM

Form Completed by:	Date:

Brief Summary of What Was Discovered

Date and Time of Discovery

Name of Agent/Individual Who Discovered the Breach

Job Title	OBI Role	Name of Supervisor or Principal Investigator

Project Title (If Applicable)

Detailed Sequence of Events (*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*)

Type of Privacy Breach	Raw Data (potentially identifiable)	Processed Data

Further Details:

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)				