

<b>Guidance Document</b>	HSREB Letter of information & Consent - Confidentiality Clause Guidance for Ontario Brain Institute Research Studies
<b>Effective Review</b>	Delegated & Full Board
<b>Version Date</b>	May 8 <sup>th</sup> , 2015 (Version 2.1)

**Confidentiality Language (to be used in LOI/C) for OBI funded study**

**Instructions**

**YELLOW** – to be filled in by study team

**GREEN** – select option for participant consent or SDM consent format

**BLUE** – optional language that can be removed if not applicable to the specific study

**This study is funded by the Ontario Brain Institute, also referred to as “OBI”**

Your study data and other personal health information is being collected as a part of this research study and will be shared with another organization called the Ontario Brain Institute. OBI is a not-for profit research institute that funds people to work together to find cures and better treatments for brain disorders. It includes not just doctors and researchers but patients, members of the medical community, government and other health-related organizations.

If you **(your child or SDM)** agree to participate, data collected during the study as well as personal health information will be transferred to an electronic database that is developed and maintained by OBI. This database of research data is known as ‘Brain-CODE’. Exactly what personal health information will be sent is listed in the section “**Which data will be collected and why?**” below.

All data that is entered into Brain-CODE is collected with the aim to allow researchers access to information which can help them study brain disorders. The data collected in Brain-CODE can help doctors and researchers study these diseases better and help identify the causes of different diseases affecting the brain. Using this information can help create ways to improve diagnoses and develop new treatments and interventions. By collecting information from persons with the same and/or different conditions, this database will give researchers access to information which can help them identify how common a disease is in the general population and the different ways in which a disease affects different individuals or groups. It also helps them see any similarities between brain disorders and discover trends in disease development. OBI will collect and store this information on a secure database that is accessible to only authorized personnel.

**Which data will be collected and why?**

In addition to the data that will be collected for the research study you are providing consent to participate in, we will also be collecting the following personal health information from your **(your child)** for the purpose of sending it to Brain-CODE:

- **health card number**
- **demographic information [list all identifiable information/date to be collected]**
- **additional data collection [If questionnaires/surveys are being filled out specifically for OBI, these should be stated]**

This additional data is only being collected to help researchers better understand common trends between **this disorder** and other brain disorders. This additional information is not required for the study that you are being asked to participate in, but for other research interests at OBI.

Your (your child's) encrypted Health Card number may be used to link with data stored in independent databases, such as OHIP, or other databases in a secure environment.

### **How will my information be kept confidential?**

All the information regarding protecting your privacy and confidentiality that was stated in the main study consent form is still applicable here. The following information outlines how your (your child's) personal health information will be kept confidential by OBI.

Any data collected as part of this study that could potentially identify you (your child) will be stored in a highly secure manner and never intentionally be released or disclosed in a form that could identify you (your child). We will remove identifying information using the best tools to minimize the risk of identifying you (your child) from the information collected or released.

Your (your child's) Health Card number will be encrypted before it leaves the [Organization (e.g., Western University, LHSC, SJHC, etc.)] and is sent to Brain-CODE so that other people outside of [Organization (e.g., LHSC, St. Joseph's, etc.)] cannot identify you. Your (your child's) Health Card number will remain encrypted at all times. Your Health Card number will never be decrypted outside of the [Organization (e.g., Western University, LHSC, SJHC, etc.)].

[Organization (e.g., sponsor, LHSC, SJHC, etc.)] and the OBI have entered into legal agreements to protect your data, and to set out the purposes for which this 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.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. [Organization (e.g., sponsor, LHSC, SJHC, etc.)] study staff and OBI will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small.

[Organization (e.g., sponsor, LHSC, SJHC, etc.)] will not have control of your (your child's) data once it is uploaded into Brain-CODE.

### **What will happen to my data?**

Brain-CODE is an open-access database. This means that researchers and organizations outside of this study can request access to your (your child's) study data that is in the Brain-CODE database. The data about you (your child) that will be accessible to other researchers will be 'de-identified', meaning that you (your child) cannot be identified.

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

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

The Principal Investigator (PI) and the study team for this research study will have access to all the study data and personal health information that will be collected and sent to Brain-CODE.

The following people/groups/organizations outside the study team may have access to your medical/clinical study records (including identifiable information) at the site where these records are held to check that the information collected for the study is correct and follows proper laws and guidelines).

Examples include:

- Representatives of Lawson Quality Assurance Education Program
- Representatives of the University of Western Ontario Health Sciences Research Ethics Board that oversees the ethical conduct of this study.
- *[Sponsor Name]*, and its affiliated companies *[include and specify a CRO if applicable]*
- Representatives of Health Canada or other regulatory bodies (groups of people who oversee research studies) outside of Canada, such as the United States Food and Drug Administration.
- **LIST other regulatory authorities (because they oversee the use of drugs/device in other countries)**

Data from this study that has had identifying information removed 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 that data, and the purposes for which this data may be collected, used, stored and disclosed.

Data that is collected through this study and stored in Brain-CODE will be available to researchers in this study. A list of these researchers and organizations can be found at: **[Insert link]**.

### **How long will my **(my child's)** data be stored?**

Data will be kept in Brain-CODE indefinitely.

Data collected locally (including identifiable data) will be kept for XX years [**NOTE:** if this is a Health Canada regulated study indicated 25 years].

### **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 has 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.