**DATABASE Informed Consent form: Information and template**

**Version Date: JULY 2024**

**Instructions:**

The Database Informed Consent Form Template has been designed to meet current regulatory, institutional and ethical standards. This template should be used when a) the main purpose of the research is to develop a database/databank; or b) a database/databank is an optional component of a broader study that requires a separate database consent form.

If participants may not be able to consent for themselves, two version of the consent form must be submitted (participant and parent/guardian). In an effort to reduce grammatical errors/changes, both versions of the consent should use “you” throughout (no “your child” language). The parent/guardian version must contain a disclaimer that “you” refers to “your child” (see sample language under “Introduction”).

**How to use this template:**

*GREY Highlighted text*: General instructions for the section

**BLUE text:** Guidance and example language.

**BLACK text:** Holland Bloorview approved template wording and/or examples that should not be altered without justification

Specific example language for your study may not be provided in this document. If there is no template language for your specific situation, please create your own.

**When writing the consent, please remember to:**

* **Use plain (lay) language that is easy for a non-medical person to understand; consent forms should be written at a grade 6 reading level**
* Delete this instructional page and all instructional language in the template
* Use a size and font of text that is consistent and easy to read (size 11 or larger is recommended)
* Define all acronyms and abbreviations when they first appear
* Use the term ‘study doctor’ when referring to physicians involved in the study, to ensure there is no confusion with the treating or primary care doctors
* Ensure that the final form is properly formatted and free of spelling or grammar errors.
* After all edits have been made, all text should be black
* If the REB requests changes to the consent form, submit both clean and tracked changes version of the updated consent form

*This template was adapted, with permission, from a combination of the SickKids REB template and Clinical Trials Ontario (CTO) template.*

**Consent to Participate in a Database**

**(Type of Consent (e.g., Participant Consent))**

*For studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) and where the main purpose of the research is to develop a database, include this summary of information as required by the US federal regulations. This summary should contain only the information that is most likely to assist a prospective participant in understanding the reason for or against participating in the research, as outlined below. Some items included in the summary section may be repeated in the subsequent consent sections if necessary to ensure the subsequent sections make sense or if the information is core to informed consent (e.g., risk of death), otherwise duplication should be avoided.*

Summary of Informed Consent Form

**Study Title**: *insert study title as written on the protocol*

Below is a summary of information about the database associated with the study. There is more information in the document (called an “informed consent form” that follows this summary. Please read the informed consent form. The research team will also talk to you about the study and you can ask any questions you may have.

**Participation in research is voluntary**. It is your choice whether you take part in this study.

Study purpose

The purpose of this databank/database study is *provide a brief description of the primary reason why the databank/database is being created, no more than 2-3 sentences.*

Duration

It is expected that study participation will last *provide expected duration.* Participants will be followed for *define period of time*. However, data collected from this study will be kept in the database/databank for research purposes for *provide expected duration.*

Study Procedures

*Briefly describe the data collection process and specify the types of data to be collected for the database/databank.*

We will collect *briefly describe the types of data to be collected* to be placed in a database/databank located at *specify location of server.* You will be asked to *indicate how data will be collected and the key procedures participants will undergo, and the length of time these will take.*

Risks.

*Describe the most important risks. Consider those most probable and/or highest magnitude of harm. Key information should not include the full list of risks.*

Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

*Include the risks participants are most likely to experience. This should not include the entire ‘very likely’ or ‘likely’ category from the main consent. Researchers must review the risks and identify those that are most likely. For a databank/database study, ensure to include the risks related to privacy and confidentiality.*

The risks you are most likely to experience are:

* Privacy breach – Unauthorized individuals or entities may gain access to the information
* Re-identification – Re-identified through the combination of different datasets or techniques

Benefits.

*Insert direct benefit, or state if there is no direct benefit. If direct benefit to participant is unknown but there is a greater benefit to society, include for example:*

There will be no direct benefit from participation but researchers hope that this study will fulfil its purpose and benefit others in future.

Alternatives.

You do not have to participate in this study to *receive medical care*.

**Study Title:** [insert study title as written on the protocol]

*If the study title is long or complicated for a lay person, a simplified version of the title should be added. This shortened title may also be used in the footer for each page of the consent form.*

**Principal Investigator):**

*Include the name and contact information (i.e., telephone number) of the Holland Bloorview Principal Investigator. Indicate “Dr.” only for doctors licensed to practice in Canada (Restricted to physicians, psychologist, dentists, chiropractors and optometrists); indicate “Nurse” only for nurses licensed to practice in Canada. All other Investigators should be referred by their credentials and, if applicable, country of practice.*

Jane Smith, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital Contact number 416.425.6220. ext.####

**Co-Investigator(s):**

*Include the name(s), department and contact information of all Holland Bloorview Co-Investigators.*

*If the Co-Investigators are students, list the program of study, Bloorview Research Institute affiliation and academic affiliation.*

John Brown, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital, Contact Number 416.425.6220. ext.####

Jane Dave, PhD candidate, Bloorview Research Institute, University of Toronto, Contact Number 416.425.6220. ext.####

**Database Identification:** *Include the name and location of the database/databank if external to Holland Bloorview*

This database/databank is managed by *[name of institution/organization]* in *[location of institution/organization]*.

**Study Sponsor or Funder (if applicable):**

* *The Sponsor is the individual or institution that takes the responsibility to initiate and/or manage the research: Enter the full name of all sponsor(s) as documented on the protocol and/or application form, including funding sources and any drug suppliers.*
* *For Funded Studies: Include the name of the funding body(ies). This includes internally funded sources and in-kind support (e.g., Equipment and drug suppliers).*

**Database Sponsor or Funder (if other than the study Sponsor or Funder):**

* *The Sponsor is the individual or institution that takes the responsibility to initiate and/or manage the databank: Enter the full name of all sponsor(s) as documented on the protocol and/or application form, including funding sources.*
* *For Funded Studies: Include the name of the funding body(ies). This includes internally funded sources and in-kind support (e.g., Equipment and drug suppliers).*

**Conflict of Interest:**

*Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. NOTE: A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker’s fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source.*

A conflict of interest can occur when a person or group has more than one interest. In research, the people who run or work on studies must tell you if they have a conflict of interest.

*If there are no conflicts, state:*

There are no conflicts of interest to declare related to this *study/database/databank*.

*If a conflict exists, see below example language:*

*Name of researcher*, declares that *he/she/they (may/will)* gain financially by being involved in this *study/database/databank* because *he/she/they* will be paid by *[sponsor (insert name of sponsor)]* for *his/her/their* time and effort during the *study/database/databank*. This may create a competing interest or conflict of interest.

***OR***

As a result of *his/her/their* participation in this *study/database/databank*, *name of researcher* has received (or may receive) one or more of the following benefits *[from sponsor(s) (insert name of sponsor)] (speaker's fees, travel assistance, industry-initiated research grants, investigator-initiated research grants, consultant fees, honoraria, gifts, intellectual property rights such as patents, etc.)*. This may create a competing interest or conflict of interest.

***OR***

The spouse of *name of researcher* owns shares in the company *[insert name of company/sponsor]* that is sponsoring the *study/database/databank* and may benefit financially depending on the outcome of the *study/database/databank*. This may create a competing interest or conflict of interest.

**Introduction**

***Note:*** *For the parent/legal guardian/Substitute Decision Maker consent, the following language must be included*

*As your child’s Substitute Decision Maker, you are being asked to provide informed consent on behalf of your child. If your child gains the capacity to consent for them self, your consent for them will end and consent will be sought from them. Throughout this form, first and second-person pronouns (e.g., “I”, “me”, “my”, “you”) means the person you are representing.*

We would like to invite you to take part in our *study/database/databank.* This consent form describes the *study/database/databank* and what it means to participate. This consent form may have words that you do not understand. Please ask the study staff to explain anything that you do not understand. Please take as much time as you need to think about your decision to participate or not, and ask any questions you have. If it is helpful to you, you are encouraged to discuss the *study/database/biobank* with family, friends, your personal physician, other health professionals, or any members of your community that you trust. All participation is voluntary and you are not under any obligation to participate.

**Why is this study/database/databank being done/created?**

Databanking involves the collection of your data to store and share for future research use. Data can include *survey responses, health records, etc*. A *database/databank* is a repository that collects, stores, and manages data over a long period of time. *Databases/Databanks* provide scientists with access to data for the purpose of conducting other research.

The [name] Database/Databank was created to collect and store health information and data of children with [specify condition] and their families. The health information and other data collected will be made available to medical researchers from Holland Bloorview and other institutions *[specify whether this includes or exclude industry]* to better understand what causes disease in children and families. The ultimate goal is to improve the diagnosis, treatment and prevention of diseases in children.

**What will happen if I agree to participate?**

You are being asked to consent to share [specify data types to be collected] for the purpose of storage in the [name] Database/Databank.

*Describe type of data to be collected, identifiability, amount and how it will be collected.*

Your medical records at Holland Bloorview will be reviewed and the following information will be collected for storage:

*Specify all information being collected: medical history related to the condition being studies, family history, results of tests and procedures including blood work, imaging, genetic testing, results of neuropsychological assessments, notes from referrals, admissions, clinic visits, copies of images, follow-up on vital status, etc.*

Your data will be maintained in [name] Database/Databank at [location] and will be kept [specify amount of time]. Your data will be de-identified before being sent to the database. This means that the data will be identified by [include the identification process] and information about your identity will remain confidential with the PI at Holland Bloorview.

**What type of research will be done on my data?**

*Describe the anticipated research/uses of the data and provide as much detail as possible. As per TCPS2, only broad consent is allowed for storage of data/human biological materials for future unspecific research. Broad consent must include specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, may prevent use by private industry, or prevent data from being sold etc.). State clearly in this section the specific restriction that applies for this database/study.*

Your data may be used for [analysis related to the main study only, any ongoing research about your disease and other related diseases (state disease condition or categories here), etc].

*If there will be future unknown research:*

It is not possible to predict all the different research topics in which data stored in *databases/databanks* might be used in the future, so it is not possible to tell you exactly for which research question your data will be used. However, this future research may include (*provide examples*).

*If the databank includes genetic information:*

[Insert appropriate language from the Genetic Research Consent Form Language document.]

**What are the risk, harms or discomforts of the study/database/databank?**

*Describe the risks, especially for genetic research (e.g., risk of linkage to the participant and potential for discrimination, how the use of the data could affect privacy, that genetic information cannot be protected from disclosure by court order, that there are unknown risks with unknown potential future use). A non-exhaustive list of examples is provided below.*

We will do our best to protect your data during storage and when they are shared with the database/databank. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot completely eliminate the risk of these occurrences.

**Are there benefits from being in the study/database/databank?**

*State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there is no known benefit, ensure this is stated. Note that possible incidental findings are not considered a benefit. Describe generalizable/societal benefits.*

Because this study/database/databank is on-going with no set end date, it is unlikely that you will get any direct benefit from taking part in this study/database/databank. Research on this database/databank may lead to better diagnosis and treatment in future for patients who have the same or a similar condition as you.

**What if the researchers discover something about me?**

*If incidental findings are anticipated as a result of the study, include the following section and address what information will be provided to participant.*

During studies, researchers may learn something about you that they didn’t expect. For example, the researchers may [insert anticipated incidental findings e.g. find out that you have another medical condition.] These types of findings are called secondary findings or incidental findings. You will be informed by the researcher in case of the discovery of an incidental finding which required medical attention.

**Who will have access to your study data?**

*Describe who will have access, how access will be obtained and under what conditions access will be granted and whether data will be sold. Ensure that you specify who this data will be shared with, for example, only other Holland Bloorview investigators, external academic researchers, for profit industry, etc.*

Only researchers associated with [name of database sponsor] are allowed to request data from the database. The researcher will have to submit a request which will then be reviewed by [specify committee name]. The [committee] will then review the request to ensure that the request is [specify criteria that the committee will review against] prior to deciding if the data can be released to the researcher.

Further details about the database/databank can be found at [study team to provide link to information or documents to be provided to study participants regarding the governance of the database/databank]

Researchers who would like to do future research using your data will sign agreements with *[Holland Bloorview, name of database, etc]*. These agreements will control how your study data will be used. They will not be permitted to disclose or to transfer study data to anyone else. They will also not be

permitted to use study data for purposes other than those included in the agreements. Researchers will also agree that they will not attempt to re-identify you from your study data.

*Describe any potential for linking with any other databases or registries.*

Researchers who do future research using the data in the database may link data with other databases contained in public or personal records. This could potentially increase the risk of re-identifying you.

*If the data may be shared with researchers who are not subject to TCPS2 (i.e. outside of Canada or institutions not eligible to administer Agency funds):*

Study data may also be shared with individuals or entities where research is not conducted under the same requirements as Holland Bloorview.

The information from the databank will be available only to researchers who have received Research Ethics Board approval for their research.

**How will my privacy be protected?**

*Language in this section is mandatory, unless otherwise indicated. Note that specific information that will be collected about participants through a chart review, surveys, questionnaires etc. should be described in the study procedures section.*

We will respect your privacy. No information about you will be given to anyone or be published without your permission, unless the law requires us to do this. [The Sponsor/Funding agency/Coordinating centre] is also committed to respecting your privacy.

If you decide to participate in this study/database/databank, the Holland Bloorview research team (study investigators, coordinators, nurses, and delegates) will collect personal health information about you, including things learned from the main study procedures. They will collect only the information they need for the purposes of the database/databank. “Personal health information” is health information about you that could identify you.

*If applicable:*

The research team will also collect some personal information about you (name, address, phone number, email) for the purposes of contacting you. This personal information will not be shared outside of the Holland Bloorview research team and therefore will not be transferred to the database/databank.

*Indicate how identifiable information will be protected:*

All information collected about you will be “de-identified” by replacing your identifiable information (i.e., name) with a “study number”. Only the “study code key” can connect the information collected about you to your identity. The study code key will be safeguarded by the Holland Bloorview research team and will not be available to the (Sponsor/Funding agency/Coordinating centre/database owner). Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

Holland Bloorview guidelines include the following:

* All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
* Electronic files will be stored securely on hospital or institutionally approved networks or securely on any hospital or institutionally approved portable electronic devices.
* All information identifying you will be stored in a location that is secure and private. Examples include your hospital/clinic/research file, copies of any part of your file, notes made from your file, or video/audio recordings.

Only de-identified study data will be transferred to [the sponsor; local/national/international research collaborators/industry partners/database owner].

*If data will be sent outside of Canada:*

Any study data sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. All information will be transferred in compliance with all relevant Canadian privacy laws.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

* Representatives of the Holland Bloorview Research Ethics Board and/or Institutional Representatives
* Sponsor Name, the company that makes the DRUG/DEVICE (including trade name) / INTERVENTION}, and its representatives and partner companies;

*For studies using smartphones, apps or applicable technology, describe any limits to confidentiality. Explain clearly if the data is being kept on the app temporarily or permanently and what implication this might have on their confidentiality.*

Data collected using the [insert app/tool/device name] resides on the [insert name e.g., Apple servers] and no assurance can be made about its confidentiality or that it will only be used for the purposes of this research study.

The research team will keep any personal health information about you in a secure and confidential location for (# of years) years/as long as the database/databank remains active and then destroy it according to Holland Bloorview policy. *Holland Bloorview policy recommended standard is 7 years for non-regulated studies. However, sponsor, databank agreements, publishing journal or professional affiliation standards for record retention should apply when necessary.*

If the study involves genetic research:

*Insert appropriate language from the Genetic Research Consent Form Language document.*

**Can I choose to withdraw my data from the study/databank/database?**

***Note:*** *requiring a written notification is not acceptable. It is the study team’s responsibility to document the request. Verbal notification is sufficient. Parents/clients should not be asked to go through the additional burden of writing a letter for documentation purposes.*

You can change your mind at any time during the research study. You do not need to give a reason to withdraw from the study/database/databank. Withdrawal from the study/database/databank will not have any effect on your participation in the main study or the care you or your family will receive at Holland Bloorview. If you decide to leave the study/database/databank, you can contact the Principal Investigator or a member of the study team to let them know. They will ensure the data are describe what will happen to data if participant withdraws consent, e.g., returned to the hospital from which they were obtained or destroyed.

*Describe any limits of the withdrawal, if applicable.*

No further data will be sent to the database/databank and your data will be removed from the database. However, it is not possible to withdraw data which has already been shared with other researchers.

*If data will be made anonymous at a certain point*

You can request withdrawal of your data until [insert expected time point], when the data will be made anonymous. It won’t be possible to withdraw these after this because the researchers will not know which data is yours.

**Will I be paid and/or reimbursed if I join this study/database/databank?**

*Describe any reimbursement and/or compensation provided to participants, or state if no compensation is provided.*

*If no payment/reimbursement:*

You will not be paid or reimbursed for any expenses related to being in this study/database/databank.

*If reimbursed:*

We will reimburse you for all your reasonable out of pocket expenses, such as meals, babysitters, parking and transportation costs to and from Holland Bloorview, up to a maximum of $XX, for your participation in this research study. If you stop taking part in the study, we will pay you for expenses incurred up until that point.

*If compensated:*

As a token of our appreciation, you will be given $XX [if providing gift card, provide category of stores or specific store name] for your participation in this research study. *If there are multiple visits, describe when they will be compensated (e.g, 2 gift cards, one at each visit; one gift card at the last visit)*

*If recognized:*

In recognition of your participation, you will be given a certificate of participation and/or # volunteer hours.

It is possible that future research conducted using your study data combined with the samples and study data from others will eventually lead to the development of new diagnostic tests, new drugs or other commercial products. If this happens, you will not receive any part of the profits from such products. The rights to the commercial products will belong to the sponsor, collaborators or future unknown researchers who will be using your data.

**What are my rights when participating in a research study/database/databank?**

You have the right to receive all information that could help you make a decision about participating in this study/database/databank. You also have the right to ask questions about this study/database/databank at any time and to have them answered to your satisfaction.

By signing this form you do not give up any of your legal rights against the principal investigator, sponsor or involved institutions for compensation, nor does this form relieve the principal investigator, sponsor or their agents of their legal and professional responsibilities.

**Who can I call if I have questions about the study/database/databank?**

If you have any questions during your participation in this study/database/databank you can contact the Principal Investigator, [PI NAME] at 416.425.6220 ext.#### or the research team members listed at the beginning of this consent form.

**Research Ethics Board Contact Information**

 This study has been reviewed by the Holland Bloorview Research Ethics Board (REB). The REB is a group of people who oversee the ethical conduct of research studies. The REB is not part of the study team. If you have any questions regarding your rights as a research participant, please contact the Research Ethics Office email: researchethicsboard@hollandbloorview.ca, at 416.425.6220 ext. 3161 during business hours.

**Consent to Participate in a Database Study**

**Study Title:** [add study title]

**By signing this research consent form, I understand and confirm that:**

1. All of my questions have been answered,
2. I understand the information within this informed consent form,
3. I allow access to my/my child’s medical records and data as explained in this consent form,
4. I do not give up any of my or my child’s legal rights by signing this consent form,
5. I have been told I will be given a signed and dated copy of this consent form,
6. I agree/agree to allow the person for whom I am responsible to take part in this study and have my/their data sent to the database/databank described above.

For participant consent:

|  |  |  |
| --- | --- | --- |
| Printed Name of Participant |  | Participant signature & date (DD/MMM/YYYY) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Printed Name of person who obtained consent |  | Role of person obtaining consent |  | Signature & date (DD/MMM/YYYY) |

For parent/guardian consent:

I consent on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of child) to participate in this study.

|  |  |  |
| --- | --- | --- |
| Printed Name of Parent/Guardian |  | Parent/guardian signature & date (DD/MMM/YYYY) |

**Person Obtaining Informed Consent:**

*My signature below signifies that I have explained the nature and purpose of the study and the risks involved to the study participant, and I have answered all questions to the best of my ability.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Person Obtaining Informed Consent (print) |  | Signature of Person Obtaining Informed Consent |  | Date(DD/MMM/YYYY) |

*Was the participant assisted during the consent process?* ***[ ]  YES [ ]  NO***

*If* ***YES****, please check the relevant box and complete the signature space below:*

⬜ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and appeared to be understood by the participant.

⬜ The person signing below acted as a translator for the participant during the consent process. Language: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name (print) |  | Signature |  | Date(DD/MMM/YYYY) |