**Observational (Non-Interventional) Study InformED Consent form:**

**Guidance Information and template**

**Version Date: October 2020**

This Observational (Non-Interventional) Informed Consent Form Template has been designed to meet current regulatory, institutional and ethical standards. The Holland Bloorview Research Ethics Board (HBREB) requires that study teams use this template when creating consent forms for their study. If study teams wish to use a consent form template provided by the sponsor, they **must** ensure all of the applicable consent form elements outlined in the Consent Form Checklist (available on the Holland Bloorview REB website) have been included.

**Please note that a separate Information Consent Form template exists for interventional studies.**

If participants may not be able to consent for themselves, two versions 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 and must be included in your informed consent form.

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 or below**
* 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 there is a possibility that participants will have capacity to consent, both a parent/surrogate decision maker and participant version of the consent form should be submitted
* 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 the SickKids REB template.*

**Consent to Participate in a Research Study**

**(Type of Consent (e.g., Participant, Parent/Guardian Consent))**

**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.

**Example:**

Jane Smith, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital Contact number 416.425.6220. ext.####, Email: jsmith@hollandbloorview.ca

**Co-Investigator(s):**

Include the name(s), affiliation and contact information of all study Co-Investigators.

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

**Example:**

Oliver Chan, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital, Contact Number 416.425.6220. ext.####, Email: ochan@hollandbloorview.ca

Narendra Singh, PhD candidate, Bloorview Research Institute, University of Toronto, Contact Number 416.425.6220. ext.####, Email: nsingh@hollandbloorview.ca

**Research Contact:** Include the name, telephone number and email address of at least one research contact/study coordinator

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

* Enter the full name of all sponsor(s) as documented on the protocol and/or application form, including funding sources and any drug suppliers(the Sponsor is the individual or institution that takes the responsibility to initiate and/or manage the research).
* 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. 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” may occur when a person or group has personal, professional and/or academic goals or responsibilities that may influence decisions about their research and / or you as a participant. The people who work on research studies must tell you if they have a conflict of interest. Having a conflict of interest does not mean the person has done anything wrong.

If a conflict exists, see below example language:

Name of investigator, states that he/she/they (may/will) earn money by being involved in this study. He/she/they will be paid by [sponsor (insert name of sponsor)] for his/her/their time and effort during the study. This may create a conflict of interest.

**OR**

Name of investigator 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.) as a result of his/her/their participation in this study. This may create a conflict of interest.

**OR**

The spouse/immediate family member of name of investigator has a financial interest in (e.g., owns shares in the company) [insert name of company/sponsor]. This company is sponsoring/funding the study. [Insert name of investigator] may benefit financially if the outcome of the study shows that the product helps patients. This may create a conflict of interest.

If no conflict of interest exists, state:

There are no conflicts of interest related to this study.

**Introduction**

***Note:*** *For the parent/guardian 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 themself, consent will be sought from them and your consent for them will end. Throughout this form, first and second-person pronouns (e.g., “I”, “me”, “my”, “you”) means the person you are representing, “we” represents the Holland Bloorview researchers.*

We would like to invite you to participate in our research study. This consent form explains the research study and what we will ask you to do. This consent form may have words that you do not understand. Please ask the study staff to explain anything you do not understand. You may take your time to think about the study and if you want to participate or not. Please ask any questions you may have. If you want to talk about the study with family, friends, your doctor, a health care professional, or any members of your community that you trust, this is okay. It is your choice if you want to participate or not. You do not have to be in this study.

**Why am I being asked to participate?**

*Explain why the participant is being asked to participate.*

You are being asked to participate in this study because you have [explain the main features of the population to which the research applies]*.*

Why is this study being done?

*Explain in lay language the purpose and specific goals of the study (what the study hopes to find out, the reason for conducting the study). Describe the background information relevant to the study, including (if applicable) the standard of care for the population.*

This study is being done because [insert goals of study] and/or we hope to find out [insert information].

If the study involves genetic research:

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

**How many participants will be in this study?**

If Holland Bloorview only:

At Holland Bloorview, we will invite up to [#] children / youth / parents / clinicians to participate in this study.

If multi-centre study:

We will invite about [# of global (worldwide) participants] people to participate in this study across/from [region NS, Canada, worldwide, etc.]. About [# of local participants] people will participate in this study at Holland Bloorview.

**What will happen if I join this study?**

*Describe all the* ***research study*** *activities in the study. Clearly identify and explain the procedures that are mandated by the study protocol. Procedures that are done as per standard of care do not need to be described. If procedures that are done as per standard of care are done at a different frequency, this change in practice should be described. If the study involves collection of samples, include this in the next section.*

Your participation in this study will involve [number of study visits and their duration]. The whole study will take [length of time of entire study].

You will be asked to [describe research activity that the participant will be involved in – see examples below]

Include a step-by-step description of the study activities.

* List and describe each test/procedure/survey/interview/focus group, how often it is to be done (i.e., every month, every day), the number of times it is to be done, and the amount of time it is expected to take to complete each research activity
* Include whether the test/procedure is different from the current standard of care or part of their typical care (i.e., an ‘extra’ sample of blood will be taken, you will be asked to complete a survey)
* If the study involves a device, include pictures
* For questionnaires, describe what types of questions will be asked
* If audio recordings or video recordings, describe what will be recorded, how it will be transcribed, and how it will be de-identified (if applicable)
* If collecting information from the patient’s health record, this must be described
* If the study involves multiple visits with different sets of procedures at each visit, consider using a table to illustrate this (see [APPENDIX A](#_APPENDIX_A:_Examples))

For example language for this section, please refer to [APPENDIX A](#_APPENDIX_A:_Examples) below.

**What samples will be taken as part of this study? (if applicable)**

*Describe samples to be collected as part of this study, including how they will be collected and in what amount. If samples will be collected at the same time as clinical tests, indicate this. For blood draws, volume must be indicated in ml and tea/tablespoons.*

The following samples will be collected from you:

For example language for this section, please refer to [APPENDIX A](#_APPENDIX_A:_Examples) below.

If the study involves genetic research:

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

**What are the risks, harms or discomforts of the study?**

***Nature of risks to include:*** *Describe all reasonably foreseeable risks, harms, or discomforts. Include both physical and psychological/emotional risks as applicable to the research; do not include risks from standard clinical care unless specifically increased in the research setting. Any social, legal, group or community risks should also be included here.*

***Information to provide:*** *Address frequency, severity, and long term impact or reversibility. Where applicable, specific symptoms for serious side effects of which the participant should be aware (e.g., in order to seek immediate medical assistance) should be included. Please also explain any steps you will take to minimize/address these risks, harms or discomforts.*

X-ray/CT-scan radiation exposure harm **must** be stated in the following format:

You will come into contact with about [insert ### mSV (milliseivert)] of radiation from these x-rays. This is about the same amount as [insert hours/days/years of] naturally occurring radiation that people are exposed to everyday from space and that naturally exists in the environment. The added risk of developing cancer from this amount of radiation is likely less than [insert probability (e.g. 1 in 500,000)].

When there is blood drawn for research purposes:

You may get pain, bruising, swelling or infection related to the blood draw. If these things happen, they should be minor and go away quickly.

If the interview/survey questions are of a sensitive nature, explain that they might experience emotional distress, explain what should they do and what type of help will be provided if this happens.

During the questionnaires and/or the interview, some of the questions we ask you may make you feel worried, stressed and/or sad or upset. If this happens, you may skip questions, take a break or stop answering at any time.

If your answers show us that there is a serious risk of harm to yourself or other people, we have to tell somebody about it. We will do this to protect you or another person. If we feel that you need help right away because you took part in this research study we will work with trained staff to get you the help you need.

Use of images:

If you have features like birth marks or tattoos, or use a uniquely decorated assistive device, these may be seen in the photos taken for this study. If this happens there is a chance that someone outside the study may recognize you.

Audio Recording:

Your name will not be part of the audio recording or written out from the recording. Even though we won’t use your name, your voice may still be recognizable as your voice. If anyone talks about things specific to you during the recording (like your name, or where you live), these will be removed from the written version.

Focus Group:

The Researchers on the study team will work hard to keep your information private. It is possible that some people who are also at the focus group may repeat things that were said in the meeting. We will ask everyone to respect each other’s privacy and not repeat what is said in the focus group to others.

Inconvenience of time:

Being in this study will take up your time. Each study visit will take about ## minutes/hours, for a total of ## minutes/hours.

Inconvenience of additional visits to Holland Bloorview:

Being in this study will include travelling to and from Holland Bloorview for ## research visits.

Confidentiality risk (for all studies):

The study team will work to protect your information, but there is still a chance that your information may be released by accident. The study team may be legally required to disclose certain information in some circumstances, such as (among others): if we learn of child abuse, if someone discloses suicidal intentions (killing themselves), if someone discloses that they suffer from a communicable disease, or if the court orders production of the study papers.

If the study involves genetic research:

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

If there are no known risks, harms or discomforts:

We don’t know of any risks, harms or discomforts from being in this study.

**Are there any benefits from being in the study?**

*A direct benefit comes as a direct result of participating in the study. The benefit should be fairly immediate, scientifically-based and clearly linked to research participation. The benefit to research participation may be indirect. Some examples of indirect benefits include: contributing to knowledge about a disability or condition, potentially contributing to the development of a device to help others, sharing a perspective based on lived experience to improve the lives of others, feeling good about helping others.*

If there are direct benefits to participants:

You may benefit directly from participating in this study if [describe anticipated direct benefit].

If there are no direct benefits to participants:

You will not benefit directly by participating in this research study.

If there are indirect benefits to participants:

You may benefit indirectly if [describe anticipated indirect benefit].

If there are no indirect benefits to participants:

You likely will not benefit from participating in this research study.

Describe benefits to society, be specific where possible:

We hope that the information learned from this study can be used in the future to help other people.

*\*\*NOTE incidental findings are not a benefit, they are an unexpected outcome of the research. Details about incidental findings need to be disclosed in the “What if the researchers discover something about me?” section, below.*

*Gift cards and reimbursement for parking are not benefits of research participation. These should be listed in the Will I be paid or reimbursed if I join this study section.*

**What are the optional part(s) to this research study?**

*If any components of the research study are optional, these should be listed and explained in this section. List all the optional components of the research study and provide clear instructions on how they should mark their preference (initials should be used).*

Example 1:

Allowing the study team to use photos of you for this study is optional. You may choose not to do this part of the study. All personal health information like your name, age, diagnosis, will be taken off of the photos. We will blur or remove physical marks like birth marks, tattoos and pictures of your skin on your face, as best we can, from the photos. However, there is still a chance that someone outside the study may recognize you from these photographs.

Please initial next to your preference:

|  |  |
| --- | --- |
| Options: | Initials |
| I **allow** the use of any photos that are part of my medical file. **I am aware that this may include photos of my face,** **identifiable physical marks such as birth marks, moles, and/or tattoos, or assistive devices.** I understand that these pictures will be sent to the <insert with whom the images will be shared.> |  |
| I **allow** the use of some photos which are part of my medical file. **I do not allow the use** **of any photos of my face/identifiable physical marks, moles, and/or tattoos or assistive devices.**  I understand that these pictures will be sent to the <insert with whom the images will be shared.> |  |
| I **do not allow** the use of any of my images. |  |

We will ask you for your consent before any photos that may identify you are used in publications. You may choose to remove the photos from use at any point during the study.

Example 2: Will parts of their interview be included in presentations or publications or in any other form of dissemination of results?

We may ask to use parts of your interview or things you said in presentations or publications. We will not include your name and voice. You have the option to say ‘no’ if you do not want us to use the things you said.

Please initial next to your preference:

|  |  |
| --- | --- |
| Options | Initials |
| I **allow** the use of parts of my interview in presentations and publications without my name or voice |  |
| I **do not** allow the use of parts of my interview in presentations and publications. |  |

If the study involves genetic research:

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

**What if the researchers discover something about me? (if applicable)**

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

If the study involves genetic research:

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

*Describe types of anticipated findings.* During the study, the 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”.

*Describe anticipated management plan. For example:*

If any new clinically important information about your health is learned as a result of your participation in this study, we will talk about what we’ve learned with you and refer you to another doctor.

**Example- Incidental Findings Language for studies involving imaging:**

**BRI MRI I*ncidental Findings Review* Workflow –**

For MRI imaging involving participants <19 years of age, a **radiologist** will review the scans for material/actionable in childhood incidental findings.

For MRI imaging involving participants >19 years of age **MR technologist** will review the scans for material incidental findings.

The MRI scan is being done to answer research questions, not to look at your body for your medical care. This research MRI scan does not replace one that a doctor would order, and it may not show problems that would be picked up by a medical MRI scan. A [insert appropriate reviewer (radiologist/MR Technologist)] will look at your scans from this research study. There is a small chance that the [insert appropriate reviewer (radiologist/MR Technologist)] will find something on the scans that is important to your health. If this happens, this information needs to be shared with you.

For client participants <19 years of age:

The Study Doctor/Investigator will contact your Holland Bloorview doctor about any important findings and provide them with a copy of the MRI scan and the report from the radiologist. By signing this consent form you agree to let us send your scan for review.

For typically developing participants <19 years of age:

The Study Doctor/Investigator will provide you with a copy of the MRI scan and the report from the radiologist for you to share with your family doctor. By signing this consent form you agree to let us send your scan for review.

For adult participants:

The Study Doctor/Investigator will contact you to provide you with a copy of the MRI scan for you to share with your family doctor.

Example- Incidental Findings Language where blood test results are part of the study:

The blood test is being done to answer research questions, not to look at your blood for your medical care. This research blood test does not replace one that your doctor would order, and it may not show problems that could be picked up by a clinical blood test. Research staff will review your blood test results as part of this research study. There is a small chance that the blood test results show a problem that could affect your health.

**Can I choose to leave the study?**

It is your choice to take part in this research study, you do not have to participate. If you agree now, you may change your mind at any time during the research study. The study team may ask why you decided to leave the study, but you do not need to give them a reason if you do not want to. Leaving the study will not have any effect on the care you or your family will receive at Holland Bloorview/on your employment/training at Holland Bloorview. If you decide to leave the study, you can tell the Principal Investigator or a member of the study team to let them know.

If participants will not be able to withdraw data and/or samples at all OR after a certain point, this must be described and provide an explanation as to why.

***Note:*** *requiring a written notification for withdrawal is not acceptable as this presents an extra burden to participants. It is the study team’s responsibility to document the request. Verbal notification is sufficient.*

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

If no payment/reimbursement:

You will not be paid or reimbursed for any costs you have related to being in this study.

If compensated:

As a thank you, you will be given $XX <if providing gift card, provide category of stores or specific store name> for being a part of this study. *If there are multiple visits, describe when they will be compensated (e.g., 2 gift cards, one at each visit). The REB prefers that gift cards be provided after each study visit whenever possible.*

If reimbursed:

We will repay 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 total of $XX, to help with the cost of study participation. If you stop taking part in the study, we will pay you for costs only up until that point or you will not receive payment for your time.

If recognized:

To thank you for your participation, you will be given a certificate of participation and/or # volunteer hours.

Commercialization (If applicable):

*The text below is sufficient for studies where there may be future commercialization of research findings but where commercialization is not the main intended outcome. However, if there is a definite plan for commercialization or there is an industry partnership, this section will need to include more detail about the plans and industry relationship as relevant.*

It is possible that a product may be created from the results of this study. The product may be sold and the researchers might make money. You will have no rights to receive payments or money from any products that may be created from this study or any future research studies using this research data.

**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 made public without asking you first, unless it is required by the law. [The Sponsor/Funding agency/Coordinating centre] will also respect your privacy.

If you agree to participate this study, the Holland Bloorview research team (study investigators, study team members, and delegates) will collect personal health information about you. “Personal health information” is information about you and your health that can be directly linked to you. They will collect only the information they need for this study.

If applicable:

The research team will also ask for some personal information about you (name, address, phone number, email) so that they can contact you. This information will not be shared outside of the Holland Bloorview research team.

Indicate how identifiable information will be protected:

All information the study team has about you will be “de-identified”. This means that your personal information (like your name) will be replaced with a number or code. Only the team at Holland Bloorview will have the list that can link your name with the code. This list will be safely stored and only available to the Holland Bloorview research team. It will not be made available to the (Sponsor/Funding agency/Coordinating centre). If someone who is not part of the research team were to see the study data, the chance of connecting you to the data is very small but it is still possible. The risk of being able to identify you can never be removed completely.

If de-identified/coded study data will be shared outside of Holland Bloorview, include the following:

De-identified study data, that does not have your name attached, will be sent to [the sponsor; local/national/international research collaborators/industry partners]. Study data is being shared so that [explain reason for data transfer].

If data or samples will be sent outside of Canada:

Study data and/or samples will be sent outside of Canada. The privacy and information safety laws in those countries may be different from Canadian laws. This may increase the chance that other people can see your information or samples. The study team will follow all Canadian privacy laws when sending your information/samples.

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:

* People from the Holland Bloorview Research Ethics Board and/or other Holland Bloorview Staff who oversee the conduct of research at Holland Bloorview;
* Sponsor Name, the company that makes the DRUG/DEVICE (including trade name) / INTERVENTION}, and its representatives and partner companies;
* If applicable: Representatives of Health Canada, a group of people who oversee the use of drugs and medical devices in research in Canada, and (if applicable) other regulatory bodies such as the United States Food and Drug Administration (FDA).

For studies using smartphones, apps or applicable technology, describe any limits to the confidentiality.

For example:

Data collected using the <insert app/tool/device name> will be stored on the <insert name e.g., Apple servers>. The study team cannot promise that people from other companies will not be able to see and use this data. If other people see the data, there is a chance that the data may be used for reasons other than this research study.

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

If the patients’ clinic chart will be noted of their participation:

*Note: The REB recommends noting participation in charts only when participation may affect care. If participants are not Holland Bloorview patients, this section is not applicable.*

The study team will make a note in your hospital or clinic chart that you have agreed to participate in this study. This is to help keep you safe. Your medical doctor may need to know that you are participating in a research study to help make medical decisions for your care.

If the study involves genetic research:

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

**Will information about this study be available online? (if applicable)**

*Note – if the study will be listed on clinicaltrials.gov, you must use the website’s mandated language to state this.*

A description of this study will be available on *insert web address*. This website will not include information about you or information that can identify you. You may search this website at any time.

**What if I am hurt during/in this study?**

*If physical or mental harm is a potential harm as a result of study participation, the following section should be included.*

If you are hurt as a result of being in this study, you will get medical care the same way you would get any other medical care if you were hurt or sick. Signing this consent form does not change how the study researchers, sponsors or institutions are supposed to take care of you if you get hurt. They still need to meet their legal and professional responsibilities. Signing this consent form does not change any of your legal rights.

If you need treatment for anything (such as injuries or illness) that are connected to you being a part of the study, you should contact the Study Doctor/Investigator right away. If it is an emergency, you should go to the closest hospital emergency department.

**How will I be informed about new information?**

We may learn new information during the study that you may need to know. We may also learn about things that might make you want to stop taking part in the study. If this happens, you will be told as soon as possible and we will explain what was found. If you decide to continue in the research study, you may also be asked to sign a new consent form that describes this new information.

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

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask any questions about this study at any time. If you are not satisfied with the answers, you have the right to say no to participating. Your privacy rights are legally protected by federal and provincial laws that require us to protect your privacy and personal information.

By signing this form you are not giving up any of your legal rights to seek compensation from the study doctor/investigator, sponsor or involved institutions if you are harmed. The study doctor/investigator, sponsor and/or their agents have legal and professional responsibilities. If you sign this form, they are still required to meet these responsibilities.

You will be given a copy of this consent form once it is signed and dated. You should keep this copy for your records.

**Will I receive study results?**

*If results are given to participants or their physicians, include here.*

Research results will be shared through [journal publications, academic conferences, any other means of disseminating information]. When the results of this study are shared, we will not reveal your identity. You have the right to find out the results of this study once the entire study is complete.

Explain how the participant can obtain or will be informed of the results, for example:

If you would like to know the results of this study, please contact the Study Doctor/Investigator.

OR, if the results will be publically available in the Clinical Trial Registry or on a study website/newsletter:The results of this study will be available on the clinical trial registry [provide information on registry] *or*

The results of the study will be available [time] from [Principal Investigator or web site, etc].

Explain the format in which results will be provided:

We can share the overall study results (the results from all participants put together). This means you will not know the results as they relate to you specifically.

OR

We will share with you the overall study results (results from all participants put together). We will also provide you with your personal results that [explain what personal-level information will be provided].

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

If you have any questions during your participation in this research study 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 help make sure that research studies are done in a way that protects the rights and wellbeing of the research participants that take part. The REB is not part of the study team. If you have any questions about your rights as a research participant, you may call the Research Ethics Office at 416.425.6220 ext. ####, or email msteele@hollandbloorview.ca during business hours.

**Consent to Participate in a Research Study**

**Study Title:** add study title

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

1. I have been given an opportunity to ask questions and all of my questions have been answered,
2. I understand the information in this informed consent form,
3. I allow access to my/my child’s medical records and specimens 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 understand that my/my child’s family doctor/health care provider will/may be informed of my participation in this study *(if applicable)*
6. I have been told I will be given a signed and dated copy of this consent form,
7. My care/services/employment will not be affected by my decision to participate and I am free to withdraw at anytime,
8. I agree/agree to allow the person for whom I am responsible to take part in this study.

For participant consent:

**I consent to participate in this study.**

|  |  |  |
| --- | --- | --- |
| 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) |

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

If the study PI or Co-I will be present during the consent discussion:

*As well, a signatory line for “investigator signature” (example below) must be added* ***if required by the sponsor****, but this may not replace the line for the “person obtaining consent” if this is a different person:*

**Investigator Signature**

Investigator Signature Printed name Date (DD/MMM/YY)

My signature above signifies that the study has been reviewed with the study participant by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the participant’s signature was obtained.

**If the participant/surrogate decision maker was assisted during the consent process:**

*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/YY) |

**If a Witness will/may be used as part of the consent process, please include the following:**

I attest that I am not involved in the research study, I was present during the consent discussion and that the consent process was accurately explained to, and apparently understood by the participant. I confirm that the participant named above read the information in the consent document and that the participant has agreed to take part in the research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Witness to the consent discussion Signature of Witness and date (DD/MMM/YY)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Role of person assisting in the consent process at Holland Bloorview

# APPENDIX A: Example Procedure Language

* Language below should be inserted under the heading “What will happen if I join this study?”

**If the study is a registry:**

This study is a long-term registry. This means that, if you agree to participate, we will collect information about you over the course of <insert time frame>. *Describe which activities will occur over the course of the registry (if questionnaires, collection of samples, review of health charts, see examples below). Describe how much time this will add to regular clinic visits and if any additional visits will occur.*

**If the study involves surveys/questionnaires:**

You will be asked to complete # questionnaires that will take about <insert approx. time to complete>. The questionnaires ask about <insert content of questionnaires>. *NOTE – if parents need to complete questionnaires or if the study team will help participants complete questionnaires this should be clearly stated.*

**If the study involves interviews:**

You will be asked to participate in an interview. A study team member will meet with you at location (e.g., Holland Bloorview, your home, a place in the community) to ask you questions about <insert content of interviews>. The interview will take about <insert approx. time to complete>.

**If the study involves focus groups:**

This research study includes a focus group. This means the study involves a group discussion. There will be about # participants in the focus group. You will be asked about your opinions/perceptions <insert> on <insert subject matter>.

**If audio recording:**

The interview/focus group (or other procedure, as applicable) will be audio recorded. After the interview/focus group, the audio recording will be transcribed. Transcribing means that someone listens to the audio and writes down all the words that are said. The written words will be analyzed by the research team. The transcription will be done by <insert who, e.g., members of the study team, a professional transcription service>. When we share the audio version, we will not share your name or any other identifying information. However, your voice will be heard and may be recognizable. The audio recording will be destroyed after it has been transcribed and checked to make sure the written version is the same as the audio version. <if otherwise state it here and explain>.

**If video recording:**

The interview/focus group (or other procedure, as applicable) will be video recorded*. Explain what parts of the participant will be video recorded. Will it include their face? What will be done to remove the identifiable information from the video, if any? How will the videos be analyzed, for what purpose, and by whom?*

**If the study involves review of health charts/medical records:**

As part of this study we would like to review your health/medical chart. We will collect information about [detail the data that will be collected; e.g., age, symptoms, the medicines you take, the treatment you’ve received, results from clinical tests etc. – be specific where possible].

**If images obtained as part of standard of care will be used in the study:**

We will collect <image type, e.g., MRI images of your knee joint> that were or will be collected as part of your usual medical care. If applicable:

**If the study involves imaging:**

*Describe the procedure the participant will have to undergo for the imaging and include the time (number and length of visits) required for the procedure. If applicable, describe use of anesthesia or contrast agent.*

We will take images of <describe what will be imaged, e.g., brain, heart, etc.>. We will use <describe imaging modality, e.g., x-rays, MRI, ultrasound, camera etc.> to take these images.

**If the study involves a complicated schedule of study activities, the REB suggests using a table to clearly outline what research procedures will be occurring at which visit. Example:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 |
| Procedure 1 | X |  | X |  | X |
| Procedure 2 | X | X |  | X | X |
| Procedure 3 |  | X |  | X |  |
| Procedure 4 |  |  | X |  |  |

**If any direct identifiers will be collected:**

We will collect the following personal health information that could identify you <list direct identifiers, e.g., name, address>.

**If data/samples/images/recordings will be being sent outside of Holland Bloorview:**

We will send information we get about you/your samples/images/recordings to [name of institution(s)]. [If applicable:] We will not send any information that could identify you [please adapt this sentence if you are in fact sending potentially identifying information (e.g., non-de-identified photos) to an external site]. *Describe how information will be sent securely.*

* Language below should be inserted under the heading “What samples will be collected as part of this study?

**If the study involves collection and analysis of biological samples:**

*Describe what sample types will be collected, in what amounts, how they will be collected, the intervals at which they will be collected, how they will be analyzed, and the purpose of the collection. For blood samples, describe amounts to be drawn in ml and tea/tablespoons. Describe the timing of the samples, and if they will be matched to clinical tests, if applicable. Describe what will happen to the samples after they have been analyzed (destroyed (when?), stored (how long and where?)).*

To protect your identity, the information that will be on your samples will be limited to specify which identifiers will be on the sample(s). If additional personal information is also being provided to the laboratory (e.g., on additional forms provided with the review materials), include a description of the information provided, e.g., The laboratory will also receive information containing your…)

Despite protections being in place to protect your privacy and your identity, there is a chance that information may be released by accident. The risk of being able to identify you can never be removed completely.