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

**Version Date: November 2018**

The Observational Informed Consent Form Template has been designed to meet current regulatory, institutional and ethical standards. The Holland Bloorview REB 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.

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

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., Parent/Participant 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.####

**Co-Investigator(s):**

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

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

**Example:**

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.####

**Research Contact:** Include the name and telephone number 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 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 a conflict exists, see below example language:

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

**OR**

As a result of his/her participation in this study, 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.). This may create a competing interest or conflict of interest.

**OR**

The spouse of name of investigator owns shares in the company [insert name of company/sponsor] that is sponsoring the study and may benefit financially if the outcome of the study shows that the product helps patients. This may create a competing interest or conflict of interest.

**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 take part in our research study. This consent form describes the research study 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 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 am I being asked to participate?**

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

You are being invited 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, up to [#] children are expected to participate in this study.

If multi-centre study:

It is anticipated that about [# of global (worldwide) participants] people will participate in this study throughout [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*** *procedures that are used in the study. Clearly identify and explain the procedures that are mandated by the study protocol. Procedures that are done as per standard 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 overall 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 procedures to be done.

* List and describe each test/procedure/survey/interview, 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).
* 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 collected 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.*

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

The radiation exposure from these x-rays is approximately [insert ### mSV (milliseivert)]. This is the equivalent of about [insert hours/days/years of] naturally occurring radiation everyone is exposed to from space and the naturally occurring radiation. The extra lifetime 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 draw for research purposes:

There is a possibility of pain, bruising, swelling or infection related to the blood draw. These discomforts are minimal and brief.

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, you may experience some anxiety, emotional and/or psychological distress due to the nature of the questions. You can skip questions, take a break or stop answering at any time.

If your responses indicate that there is a serious risk of harm to yourself or others, confidentiality will be broken in order to protect you or another person. If we feel that you need urgent care as result of participating in this research study we will intervene according to routine clinical care practices.

Use of images:

If unique features like birth marks or tattoos are captured in the photos taken for this study, there is a potential risk of loss of your confidentiality.

Audio Recording:

There is a potential risk of loss of your confidentiality because even though your name will not be part of the audio recording or the transcription, your voice may still be identifiable as your voice. If anyone mentions identifiers (e.g., your name, location), during the recording, they will be removed from transcript.

Focus Group:

Although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. It is possible that some focus group members may repeat things said in the meeting. The researchers will ask participants to respect the privacy of fellow participants and not repeat what is said in the focus group to others.

If there are no known harms:

We don’t know of any risks or harms associated with participating in this study.

Inconvenience of time:

There is an inconvenience of time. Each study visit will take about ## minutes/hours, for a total of ## minutes/hours for the entire research study.

Inconvenience of additional visits to Holland Bloorview:

There is an inconvenience of travel as you will have to come to Holland Bloorview for ## research visits.

Confidentiality risk (for all studies):

Despite protections being in place, there is a risk of unintentional release of information.

If the study involves genetic research:

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

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

*\*\*NOTE incidental findings are not a benefit, there 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.*

If there are no direct benefits to participants:

There are no direct benefits to you for participating in this research study

If there are benefits to participants:

You may benefit directly if <insert anticipated benefit>.

You may benefit indirectly if <insert anticipated benefit; do not include societal benefits here>.

Describe benefits to society, be specific where possible:

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease and/or health condition.

**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:

Providing photographs for research purposes is not mandatory. All personal health information will be removed from photographs. All efforts will be made to blur or remove identifiable physical marks like unique birth marks, tattoos and pictures of your skin on your face, from the clinical photographs of your skin. However, there is still a risk that you may still be identified from these images.

Please initial next to your preference:

|  |  |
| --- | --- |
| Options: | Initials |
| I **allow** the use of any photos which are part of my medical file, **including any photos of my face,** **identifiable physical marks such as birth marks, moles, and/or tattoos.** I understand that these pictures will be sent to the <insert with whom the images will be shared.> |  |
| I **allow** the use of any photos which are part of my medical file, **excluding any photos of my face.**  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 identifiable images of you are used in publications. You may choose to withdraw the photographs 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 decide to use parts of the transcription without your name and voice in presentations or publications in the format of quotations. You have the option to refuse. Please initial next to your preference:

|  |  |
| --- | --- |
| Options | Initials |
| I **allow** the use of parts of my de-identified transcription in presentations and publications. |  |
| I **do not** allow the use of parts of my de-identified transcription 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 obtained as a result of your participation in this study, we will discuss this information with you and refer you to a physician.

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

The MRI scan being done is designed to answer research questions, not to examine your brain for medical analysis. This research MRI scan is not a substitute for one that a doctor would order, and it may not show problems that would be picked up by a medical MRI scan. A radiologist will review your scans from this research study. In the very unlikely event that abnormal findings are found,

For patient participants:

The Principal Investigator will contact your Holland Bloorview Physician about any relevant findings.

For healthy volunteers:

The Study Doctor/investigator will contact your primary care physician. In case this is necessary, you will be asked to provide your family doctor’s name and contact information. If you are being treated by a physician at Holland Bloorview, he/she will be notified of any relevant findings.

For adult participants with reportable imaging:

We will contact you to help you arrange medical follow-up to interpret the significance of the findings, if any. We may also ask a radiologist, or other health professionals, to look at your scan and by signing this consent form you agree to the release of the scan for review. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.   
If abnormal findings are found, the Study Doctor/investigator will contact you to report these findings and recommend that you follow up with your family doctor.

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

The blood test being done is designed to answer research questions, not to examine your blood for medical purposes. This research blood test is not a substitute for one that a doctor would order, and it may not show problems that would be picked up by a clinical blood test. A research staff will review your blood test results acquired as part of this research study. In the very unlikely event that abnormal findings are found, the Study Doctor/investigator will contact your Holland Bloorview Physician about any relevant findings

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

It is your choice to take part in this study, participation is voluntary. You can change your mind at any time during the research study. The study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason to withdraw from the study if you do not want to. Withdrawal from 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 contact 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 expenses related to being in this study.

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 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 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 or you will not receive compensation for your time.

If recognized:

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

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 commercial product may be developed as a result of this study. You will have no rights to nor receive royalties from any products that may be created as a result of this study or any future research studies using this research study 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 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, the Holland Bloorview research team (study investigators, coordinators, nurses, and delegates) will collect personal health information about you, including things learned from the study procedures. They will collect only the information they need for this study. “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.

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). Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

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

De-identified study data will be transferred 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:

Any study data and/or samples, 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;
* 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> 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 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.*

Your participation in this study will be noted in your hospital or clinic chart. This is recommended to ensure your safety so that any treating physician will know that you are participating in a research study.

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 that can identify you. You can search this website at any time.

**What if I am injured 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 suffer an injury from participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this consent form waive your legal rights or release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

If you require treatment for any injuries or illness related to your participation in the study, you should contact the study doctor immediately.

**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 participating in the study. If this happens, you will be notified about any new information in a timely manner. You may also be asked to sign a new consent form that describes these new findings if you decide to continue in the research study.

**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 questions about this study at any time and to have them answered to your satisfaction. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

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

You will be given a copy of this signed and dated consent form prior to participating in this study.

**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, your identity will not be disclosed. You have the right to be informed of 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 be informed of the results of this study, please contact the study doctor *or*

If you would like to be informed of the results of this study, please let the study doctor know or, if the results will be publically available in the Clinical Trial Registry or on a study website/newsletterThe 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:

You will only be provided with overall study results (aggregate results from all participants). This means you will not know the results as they relate to you specifically.

OR

We will provide you with the overall study results (aggregated results from all participants). We will also provide you with 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 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, you may contact the Research Ethics Office at 416.415.6220 ext. #### during business hours.

**Consent to Participate in a Research 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 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. 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 was 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 involves a focus group. This means the study involves an interview and discussion in a group setting. 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. The audio recording will be transcribed after the interview/focus group and 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>. Your name or any other identifying information will not be included during the recording, except your voice. The audio recording will be destroyed after it has been transcribed and checked for accuracy <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 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 obtained as part of your usual 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 |  |  |

* Language below should be inserted under the heading “What will happen if I join this study?” OR “What samples will be collected as part of this study?”, as appropriate.

**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, there is a risk of unintentional release of information.