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

**Version Date: May 2021**

**Instructions:**

The Biobank 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 biobank; or b) a biobank is an optional component of a broader, complex study that requires a separate biobank consent form.

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**
* 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 clinical trial, 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 the SickKids REB template.*

**Consent to Participate in a Biobank**

**(Type of Consent (e.g., 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.####

**Biobank Administrator/Manager:** Include the name and telephone number of at least one research contact.

**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).

**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.

If a conflict exists, see below example language

Name of researcher, 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 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 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 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 research study/biobank. This consent form describes the research study/biobank 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/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 being done?**

Biobanking involves the collection of your biological samples or tissues to store for future research use. Biological samples include fluids (such as blood) and tissues which are collected from you during a routine or special procedure. A biobank is a type of facility that receives, stores, processes and distributes biological [samples](http://www.biobankcentral.org/resource/glossary.php#Biomaterials) as well as data related to those samples. Biobanks provide scientists with access to the samples and study data to conduct other research.

The [name] Biobank was created to collect and store biological samples and health information of children with [specify condition] and their families. The biological samples and health information 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.

If the study involves genetic research:

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

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

You are being asked to consent to donate [specify biological sample(s)]for the purpose of storage in the [name] Biobank.

*Describe specimen type, amount to be taken (per sample and total), when, from where and how it will be taken. See appendix below for sample wording.*

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

*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 samples will be maintained in [name] Biobank at [location]. The samples will be kept [specify amount of time, or… until they are used up, destroyed or returned to the hospital where you had your surgery or biopsy].

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

*Describe the anticipated research/uses of the samples and study data and provide as much detail as possible.*

Your samples and associated information may be used for [select an option below]

testing related to the main study only. This is considered “closed” consent.

any ongoing research about your disease and other related diseases (state disease condition or categories here). This option is considered “broad” consent.

for future research which is currently not known at this time. This is considered “open” consent.

If applicable: At the end of this consent form, you will be able to choose if you want to provide, closed, broad, or open consent.

If there will be biomarker research:

The research done on your samples may include looking at certain proteins called “biomarkers” that are believed to be important in the [specify: incidence of disease, response to treatment, growth of cancer in tumours, etc]. This biomarker research may help researchers understand:

* how your disease may behave with or without treatment,
* what kind of side effects a person will have when they receive different kinds of treatment,
* how the disease might respond to the study treatment,
* who will benefit the most from this type of treatment.

If there will be future unknown testing:

It is not possible to predict all of the ways in which samples stored in biobanks might be used in the future, so it is not possible to tell you exactly how your sample will be used. However, this future research may include (provide examples, e.g., genetic research).

If the study involves genetic research:

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

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

*Describe the risks, especially for genetic research (e.g., risk of linkage to the participant and potential for discrimination, how the use of the sample/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.*

For biospecimens collected as part of routine or diagnostic procedures:

There are no additional physical risks to you because samples will be collected at the same time as any procedure your treating doctor has planned.

For blood collected during special procedures:

For blood and blood product collection that is not done at the same time as routine blood testing for medical care, there is a risk of infection, bleeding, or bruising when a blood sample is collected from your vein. This risk is not greater than the risk of a regular blood draw.

For biopsies:

The risks of a biopsy include bruising, pain, bleeding, and rarely an infection at the biopsy site infection or blood clot underneath the skin.

If applicable:

If you participate in this study, it is possible that not enough tumour tissue will be left for other testing that may need to be done in the future. Please speak to your study doctor to discuss this possibility.

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?**

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

Because this research is on-going and will take many years, it is unlikely that you will get any direct benefit from taking part in this study. This research 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?**

*Describe types of anticipated findings.* 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.

If the study involves genetic research:

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

**Who Will Have Access To Your Samples and Study Data?**

*Describe who will have access, how access will be obtained and under what conditions access will be granted and whether samples will be sold. Describe any potential for linking with any other databases or registries and the possibility transfer of samples and/or information outside the country. Ensure that you specify who these samples/data will be shared with, for example, only other Holland Bloorview investigators, external academic researchers, for profit industry, etc.*

Examples:

Your samples and study data will be used only by scientists approved by the sponsor and will not be sold. Your samples and your study data, including how you have responded to the medicine, might be sent to other countries. If this happens, the sponsor will make sure that your sample and study data will be treated with the same strict confidentiality as described in the section on confidentiality.

**OR,**

Your samples and your study data may be given or sold by the biobank to qualified researchers in the international research community (which may include national and international researchers from academia, charitable organisations and ‘for-profit’ private companies, such as drug companies).

External researchers who would like to do future research using your samples will sign agreements with the Holland Bloorview. These agreements will control how your samples and study data will be used. They will not be permitted to disclose or to transfer study data or samples to anyone else. They will also not be permitted to use samples or 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 and samples.

The information from the biobank 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, 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.*

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

***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. Withdrawal from the study will not have any effect on the care you or your family will receive 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. They will ensure the samples are describe what will happen to samples 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. For example:

If tests have already been done on your sample(s) it will not be possible to withdraw those results. However, no further testing will be done.

If samples will be made anonymous at a certain point

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

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

*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.

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 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 samples and/or 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 samples and data.

**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.

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?**

If you have any questions during your participation in this biobank 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](mailto:researchethicsboard@hollandbloorview.ca) or at 416.425.6220 ext. #### during business hours.

**Consent to Participate in a Biobank 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
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.

**If applicable:**

**PLEASE INITIAL YOUR CHOICE BELOW BEFORE SIGNING:**

|  |  |  |
| --- | --- | --- |
| **Closed Consent:** |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_ | Initials | I agree to bank my/my child’s sample and personal health information only for the purpose of this study. My samples and information will not be shared. |
| **Genetic Testing:** |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Initials | I agree to have genetic tests done on my/my child’s samples |
|  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Initials | No genetic tests will be done on my/my child’s samples. |
| **Broad Consent:** |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_ | Initials | I agree to bank my/my child’s samples and personal health information only for the purposes of this study and for any other research related to (state disease) **excluding genetic testing**. I am aware that my/my child’s samples and information may be shared with researchers outside of Holland Bloorview for research that is not known at this time. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_ | Initials | I agree to bank my/my child’s samples and personal health information only for the purposes of this study and for any other research related to (state disease) **including genetics testing**. I am aware that my/my child’s samples and information may be shared with researchers outside of Holland Bloorview for research that is not known at this time. |
| **Open Consent:** |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_ | Initials | I agree to bank my/my child’s samples and personal health information for the purposes of this study and any other future research studies both related and unrelated to my (state disease). I am aware that my/my child’s samples and information may be shared with researchers outside of Holland Bloorview for research that is not known at this time. |

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) |

**Appendix: Sample Wording**

**Blood (Collecting Samples with Routine Procedures**)

[specify amount e.g., about XX mL (or YY teaspoons] of blood will be taken with a needle from a vein in your arm. Blood samples will be taken [specify timing – e.g., once before you take the study drug, 1 and 4 weeks after you start the study drug and 4 weeks after you stop the study drug.]. If possible, these samples will be taken at the same time as your study-related or clinical tests (e.g. at entry to the trial).

**Bone Marrow**

As part of your clinical care, you may need to undergo a procedure called a bone marrow aspiration or a bone marrow biopsy. If you agree to provide the Biobank with your samples, we will ask your doctor to take an extra amount (specify minimum amount) for the biobank. The extra amount of bone marrow or bone will only be taken if your doctor says it is safe to take this extra amount.

**Cheek Swabs**

A cheek swab collects cells that line your mouth. This is a painless procedure where a cotton swab is rubbed on the inside of your cheek.

**Saliva Samples**

[specify amount e.g., about XX mL (or YY teaspoons] of saliva will be collected from you. To collect the salvia, you will need to spit into a tube.

**Stool or Urine Samples**

You will be provided with a special container to provide a stool/urine sample. If possible, leftover samples from routine care will be collected. (**For parent consent form**: If your child is wearing diapers, you may be asked to provide the used diaper to allow the Biobank to collect stool or urine samples.)

**Tissue**

Undergoing surgery or procedure which requires extra tissue removal

When you undergo your surgery (specify the original planned procedure) or clinical procedure (specify, ex: fine needle aspiration biopsy), the surgeon/doctor doing the procedure will remove (a small extra amount of tissue, extra tissue which will need to be specified). This will be aside from the tissue required by your treating doctor. Extra tissue will be removed only if your treating doctor says it is safe. If the treating doctor determines that it will not be safe to take the tissue required for biobanking, the extra tissue will not be taken.

Collecting left-over tissue or specimens following testing

When you undergo your surgery or clinical procedure, any tissues or body fluids removed are usually sent to the Pathology laboratory for testing. The testing is done to help diagnose your condition. The amount of tissue taken is usually more than enough to do one test. This ensures that if re-testing is needed, there is enough tissue available to verify test results or do additional testing. In some cases, there will be tissue or fluids left-over after all the testing has been completed. This tissue or fluid may either be saved or discarded.

We are asking you to consent to donate any left-over tissue or fluids after testing has been completed. If you consent to be part of the Biobank, we will take any left-over tissue or specimens with your doctor’s consent. Even if you have signed this consent form, we will not take any left-over tissues or fluids if your doctor says that this may be needed for additional testing or storage for future testing.

**Other Body Fluids**

All organs of the body are lined with a fluid substance. Your brain and spinal cord are surrounded by cerebrospinal fluid (CSF). If your treating doctor does a spinal tap to get CSF for testing, (state minimum amount for storage) may be taken for the Biobank but only if your doctor says this is safe.

Your lungs and digestive organs are also surrounded by fluid. These organs may also contain fluids. (describe here).

**Old Samples**

You can donate any of your old samples that were initially collected for medical purposes such as diagnosis, monitoring of treatment or progression of disease. These are called archived samples. To donate any of your archived samples, your treating doctor will let you know if the samples are no longer needed or that there are enough samples left over for possible future testing you may need.