**CONJOINT HEALTH RESEARCH ETHICS BOARD CONSENT FORM TEMPLATE**

**Template Instructions:**

**Delete this boxed information**, all **instructional text** in **red**, and any sections of the consent template that are not applicable to your study.

Instructions and examples for informed consent authors are in *[italics]*

**Blue** text indicates information that the Principal Investigator should provide before the document is reviewed with the prospective research participant.

The font colour of the final consent form should be **black**.

The reading level of the consent should be approximately grade 8-10. Please use a readability index, such as [hemingwayapp.com](file:///%5C%5Cdtpfsrv1%5Cchreb%5CCHREB%5CWebsite%20Documents%5CConsent%20Form%20Templates%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CDownloads%5Chemmingwayapp.com), to confirm the level.

In the footer of every page insert the following information: Ethics ID, PI, Study Title, Version Number, Version Date, and page number expressed as ‘Page X of Y’ (e.g., 1 of 2).

**Note:** If you are conducting an interventional clinical trial, please also review the CHREB Clinical Trials/Interventional Research Consent Form template.



**UNIVERSITY OF CALGARY**

**SURROGATE CONSENT TO PARTICIPATE IN RESEARCH**

*This consent form is used when doing research on participants who are incompetent or deceased. If the participant is expected to regain competency, attach the “Regained Capacity Consent Form” found at the end of this form. The participant should review and sign the form when competency is regained, and receive a copy of the entire consent form.*

**TITLE**: [Insert the full title of the research project]

**SPONSOR:** [Put the name of the sponsor here.] *The sponsor is the individual or entity that is responsible for the oversight of the study.*

**FUNDER**: [Put the name of the organization/company providing funds, drugs and/or equipment here.] *For example, if the study is funded by the Canadian Institutes of Health Research (CIHR), then the University of Calgary would be considered the sponsor, and CIHR would be considered the Funder. If the funder and the sponsor are the same entity (for example, an industry-sponsored study), remove the Funder section and only include Sponsor.*

**INVESTIGATORS**: [State the name of the local Principal Investigator followed if desired by the names of co-investigators.]

[Put the main emails and contact telephone numbers (including area code) here]

# INTRODUCTION

[Insert name of the Principal Investigator], andassociates from the [insert department affiliation] at the University of Calgary are conducting a research study.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information.

Your family member was selected as a possible participant in this study because [explain why the potential participant is eligible to participate]. Your family member’s participation in this research study is voluntary.

*Effective January 21, 2019, consent forms of new studies falling under the U.S. Department of Health & Human Services (HHS) Regulations (i.e. United States federally-sponsored research projects) must include a concise and focused presentation of key information that is most likely to help the surrogate understand why they might or might not want their family member to participate in the study. These are studies conducted/supported by HHS (e.g., NIH) or conducted at an institution that assumes responsibility for the research and complies with* *45 CFR 46. Please review the Common Rule Consent Form Guidance on the CHREB website, here:* [*https://research.ucalgary.ca/sites/default/files/RSO%20Docs/CHREB/CHREB%20Guidance%20-%20Common%20Rule%20-%20revised%2005Feb2019.pdf*](https://research.ucalgary.ca/sites/default/files/RSO%20Docs/CHREB/CHREB%20Guidance%20-%20Common%20Rule%20-%20revised%2005Feb2019.pdf)

# WHY IS THIS STUDY BEING DONE?

*Describe in a few sentences what the study is designed to assess or establish. Use language that will be easily understood by the surrogate. Avoid jargon and technical terms.*

The purpose of this research study is to [complete this statement].

# HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About [state total accrual goal here] people will take part in this study [province wide/ Canada wide/ worldwide]. XX people will take part in this study through the University of Calgary.

**WHAT WILL HAPPEN IF MY FAMILY MEMBER TAKES PART IN THIS RESEARCH STUDY?**

If you agree to allow your family member to participate in this study, the following will take place:

* *List and describe the procedures/tests/activities and their frequency chronologically using simple language, short sentences and short paragraphs.*
* *Use bullets or number the paragraphs as appropriate.*
* *Describe types of questions in questionnaires/surveys or interviews.*
* *Specify the location of study activities.*
* *If the study will include experimental and non-experimental (e.g. standard of care) procedures, please specify which procedures are experimental.*
* *Clearly indicate if you will be accessing medical records, what kinds of data you will be extracting, and whether you will look at electronic databases such as Alberta Netcare or Connect Care. If the study is longitudinal please indicate if you will need to access records over time.*
* *If blood is taken, indicate total volume (for example, teaspoons and mL equivalent).*

# HOW LONG WILL THEY BE IN THE RESEARCH STUDY?

*Explain the duration of the study or how long the study will last.*

Participation will take a total of about [specify time and duration].

*When appropriate, state that the study involves long-term follow-up by specifying the timeframes and requirements for long-term participation.*

***Example*** *- Short-term, simple studies:*

* The participant will be in this study for XX days.
* Your family member’s participation in this study will last \_\_\_.
* Participation in this study will require about XX hours of the participant’s time.
* This study will require approximately XX hours of the participant’s time for each study visit.
* There will be a total of XX study visits over six months.
* The participant will be in the [insert clinic/centre name] for a total of XX days.

***Example*** *- Long-term, complex studies:*

* If you agree for your family member to participate in this study they will [describe the research intervention, e.g., they will take drug XX for XX months/weeks/until a certain event occurs]. After they complete [drug XX, procedure YY] the researchers will ask them to visit the office for follow-up exams every XX months for XX years.

*As per the Declaration of Helsinki, Section 34, please describe the provisions in place for post-trial access to the study treatment if it proves to be beneficial to participants. If there are no provisions in place, please describe what post trial care will be arranged for participants.*

# ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT MY FAMILY MEMBER CAN EXPECT FROM THIS STUDY?

* *List and describe any reasonably foreseeable risks, discomforts, and inconveniences, and how these will be managed.*
* *If there are significant psychological risks that might cause the researcher to end your family member’s participation in the study, please describe them.*
* *If blood is taken, include a statement noting the possibility of bruising or swelling while giving blood, or other possible discomforts at the site where blood is drawn. Indicate that there may be minimal chance of infection and that the discomforts experienced will be brief and transient.*

# ARE THERE ANY POTENTIAL BENEFITS TO MY FAMILY MEMBER IF THEY PARTICIPATE?

*Please note incentives such as cash, gift cards, and other material rewards are typically not considered benefits of participation, and should only be included in the section “WILL MY FAMILY MEMBER BE PAID FOR PARTICIPATING, OR DO THEY HAVE TO PAY FOR ANYTHING?”*

*If there is no anticipated direct benefit to the participant from the study, state this at the beginning of the section.*

*Describe any potential direct benefits to the participant first, followed by potential general benefits (e.g., to the group of patients to which the individual belongs, or to medical knowledge).*

***Example:*** There will be no direct benefit to your family member from participating in this study. However, this study may help the researchers learn more about [specify research area].

# WHAT OTHER CHOICES DOES MY FAMILY MEMBER HAVE IF THEY DO NOT PARTICIPATE?

**Example [*If the study includes treatment(s)]:*** Your family member’s other choices may include not getting treatment, getting standard treatment for their condition without being in a study, or taking part in another study. If you decide for your family member not to take part in this study, there will be no penalty to them. Your decision will not affect the standard medical care your family member receives.

**Example *[If the study does not include any treatment(s)]:*** You are free to choose for your family member not to participate in the study. If you decide for the participant to not take part in this study, there will be no penalty to them. Your decision will not affect the standard medical care the participant receives.

*If there is no alternative to participating, then the surrogate should be told.*

***Example:*** There is no current treatment for [complete this statement]. Therefore, the only alternative is for your family member to not participate in the study. The participant will still receive their regular care from their treating physician.

# CAN MY FAMILY MEMBER STOP BEING IN THE STUDY?

Yes. You can decide to stop your family member’s participation at any time. Tell the study doctor if you are thinking about stopping or decide to stop your family member’s participation.

***[if applicable]*** It is important to tell the study doctor if you are thinking about stopping your family member’s participation so any risks from the [drugs or intervention] can be evaluated by their doctor. Another reason to tell their doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for the participant.

# CAN THE RESEARCHERS REMOVE MY FAMILY MEMBER FROM THIS STUDY?

The researchers may end your family member’s participation in this study for a number of reasons, such as if their safety and welfare are at risk, if they do not follow instructions or if they miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

***[if applicable:]*** If you decide to stop your family member’s participation in the study, or the participant is removed from the study, or the study is stopped, the researcher will ask the participant to [complete this sentence. *For example, return for a final close-out visit or evaluation, return unused study medication, complete an exit telephone interview.*]

**WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT MY FAMILY MEMBER?**

*Under TCPS2 Article 3.4 (here: https://ethics.gc.ca/eng/tcps2-eptc2\_2022\_chapter3-chapitre3.html), if there is any foreseeable prospect of material, incidental findings, a management plan for such findings must be provided to the REB. Such findings might arise in imaging or genetic studies, for example. Participants must consent to receive information about materially relevant findings.*

During the study, the researchers could learn something about the participant that they didn’t expect. For example, the researchers may [e.g. find out that the participant has another medical condition.] The researchers will consult with medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care for the participant.

I consent for the researchers to share findings about the participant with me:

❑ YES

❑ NO

# WITHDRAWAL OF STUDY DATA

*Under TCPS2, study participants who withdraw from a research study should have the option to withdraw their data as well, unless there is a strong justification from the researchers as to why the data must be retained. For example:*

* *Data retention is advised for clinical trials to preserve study validity and avoid bias* [*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-retention-when-subjects-withdraw-fda-regulated-clinical-trials*](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-retention-when-subjects-withdraw-fda-regulated-clinical-trials)
* *If qualitative data have been incorporated into a thematic analysis it may be impossible to extract, in which case, advise participants of a deadline after which they cannot withdraw data.*

*Describe any circumstances that do not allow withdrawal of data once collected (e.g. data without identifiers).*

*Please note, although data may be withdrawn on request from the study analyses, the raw data must be kept for the minimum required data retention interval. See:* [*https://asc.ucalgary.ca/marrs/humansubjects/*](https://asc.ucalgary.ca/marrs/humansubjects/)

# WILL MY FAMILY MEMBER BE PAID FOR PARTICIPATING, OR DO THEY HAVE TO PAY FOR ANYTHING?

*Investigators are normally expected to reimburse or otherwise cover costs of parking for clinic visits that would not occur outside the context of the study. See also the CHREB position statement on payments to participants: https://live-research.ucalgary.ca/sites/default/files/teams/2/Ethics/CHREB\_guideline\_payment-May2024.pdf*

**No payment or reimbursement:**

The participant will not be paid for their participation in this research study. The participant will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

**Reimbursement for out-of-pocket expenses:**

The participant will be reimbursed for the following expenses [complete this sentence, e.g. parking.]

**Optional statement:** To be reimbursed, please be sure and save the receipts so that these can be provided to the research staff.

# WILL INFORMATION ABOUT MY FAMILY MEMBER’S PARTICIPATION BE KEPT CONFIDENTIAL?

*Inform surrogates of the extent to which the researchers intend to maintain confidentiality of records that identify the participant. Specifically:*

* *How data, records, and biospecimens containing private or personal information will be collected and used for the study.*
* *What methods are in place to code or de-identify information.*
* *How data, records, and biospecimens will be stored, and who will have access to them (including how they will be shared for future research.)*
* *How you will protect confidentiality if doing research procedures in public spaces (such as in a hospital room with other patients).*
* *Describe the potential sharing of data (de-identified or identifiable) with other researchers or collaborators (e.g., external investigators, transcriptionists).*

***Suggested Confidentiality Statements for All Consents****:* The researchers will do their best to make sure that the participant’s private information is kept confidential. Information about the participant will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. The research team will handle data according the Data Management Plan as outlined below:

*Please review the University of Calgary's Information Security Classification Standards here:* *<https://www.ucalgary.ca/legal-services/sites/default/files/teams/1/Standards-Legal-Information-Security-Classification-Standard.pdf>*

*Describe how identifiers will be linked to data and records.*

***Examples:***

* No identifiable information about the participant will be kept with the research data.
* [All/some] identifiable information about the participant will be replaced with a code. A list linking the code and the participant’s identifiable information will be kept separate from the research data.
* [All/some] identifiable information about the participant will be kept with the research data.

*Explain how participant identifiers will be linked to the research data/records.*

*Describe how the data/records will be maintained.*

*Data classified as Level 4 (identifiable human subject research data or identifiable patient health information) must be stored on a secure, encrypted, and password-protected server (e.g., Alberta Health Services or University of Calgary).*

*It is permissible, but not recommended, to store Level 2-classified data (de-identified or anonymized human subject research data) on an encrypted laptop/desktop.*

*Please review University of Calgary’s storage options here:*

* [*https://rcs.ucalgary.ca/index.php/Storage\_Options*](https://rcs.ucalgary.ca/index.php/Storage_Options)
* [*https://ucalgary.service-now.com/kb\_view.do?sysparm\_article=KB0030163*](https://ucalgary.service-now.com/kb_view.do?sysparm_article=KB0030163)
* [*https://it.ucalgary.ca/secure-computing-platform*](https://it.ucalgary.ca/secure-computing-platform)

*If your study is planning to use a storage platform that is not currently approved by the University of Calgary, please submit a ticket on the Service Now platform (*[*https://ucalgary.service-now.com/it*](https://ucalgary.service-now.com/it)*) for a review. This is to ensure that the platform meets the University’s security requirements.*

*Alberta Health Services considers the following data elements as identifiable, and all these elements must be stripped from the identifying health information to convert it to non-identifying (de-identified or coded) health information:*

1. *Names (including initials* *when extracted from patient records)*
2. *All geographic subdivisions smaller than a province, including street address, city, county, precinct, postal code, and their equivalent geographical codes, except for the initial three digits of a postal code if, according to the current publicly available data from the Census Bureau:*
	1. *The geographic unit formed by combining all postal codes with the same three initial digits contains more than 20,000 people.*
	2. *The initial three digits of a postal Code for all such geographic units containing 20,000 or fewer people are changed to 000.*
3. *All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.*
4. *Telephone numbers.*
5. *Fax numbers.*
6. *Electronic mail addresses.*
7. *Social insurance numbers.*
8. *Medical record numbers.*
9. *Health plan beneficiary numbers (i.e., PIN, ULI).*
10. *Account numbers.*
11. *Certificate/license numbers.*
12. *Vehicle identifiers and serial numbers including license plate numbers.*
13. *Device identifiers and serial numbers.*
14. *Web universal resource locators (URLs).*
15. *Internet protocol (IP) addresses.*
16. *Biometric identifiers, including fingerprints and voice prints.*
17. *Full-face photographic images and any comparable images.*

***Examples:***

* [All/some] research data and records will be maintained in a secure location at the University of Calgary. Only authorized individuals will have access to it.
* [All/some] research data and records will be stored electronically on a secure [computer or network] with [encryption and/or password] protection.

*Indicate what regulatory or other agencies might have access to the research records (e.g., Health Canada, the FDA, sponsoring company, authorized University of Calgary representatives). Explain who will have access to the research data/records/specimens and how they will be shared.*

***[If applicable:]*** The participant’s medical records and study data will be reviewed by the Study Sponsor of this study, or its representatives at [name study site]. Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at the participant’s identifiable research and/or medical/clinical study records held at [name study site] for quality assurance purposes. Health Canada and/or other foreign regulatory agencies may also review the participant’s identifiable research and clinical records for regulatory purposes. Copies of the participant’s identifiable information may occasionally be retained by these parties (i.e. the Study Sponsor, the University of Calgary, Health Canada/regulatory agencies). The least amount of information necessary will be released. By signing this form, you are authorizing such access and retention.

***[If applicable:]*** By signing this consent form, you understand that the research team will have access to the participant’s individually identifying health information for research purposes. In cases where the study involves an intervention such as a research-related medication, device, or other therapy, or the project includes research-specific lab tests and/or imaging, your signed consent will also be included in the participant’s electronic medical record(s), and healthcare staff will know that the participant is in a research study.

***[If applicable]:*** The participant’s study data will be coded (with a number) so that it no longer contains their name; however, some dates associated with their hospitalization or medical history could identify them.

***[If applicable]:*** The study investigators will make every effort to maintain the confidentiality of the participant’s research records, to the extent permitted by law (e.g., disclosed child abuse or neglect must be reported) and legal requests (e.g., court applications seeking disclosure of research data are possible).

**HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?**

*Explain how long the research data/records/specimens will be kept. Please consider the potential for future uses of study data, and data sharing requirements, and advise surrogates of this possibility. Please indicate if the data will be held in an identifiable or de-identified/coded state.*

*Describe retention of data and records:*

***Examples:***

* The researchers intend to keep the research *data/records/biospecimens* until the research is published and/or presented.
* The researchers intend to keep the research *data/records/biospecimens* for approximately **XX** years.
* The researchers intend to keep the research *data/records/biospecimens* indefinitely for future research.
* The researchers intend to keep the research *data/records/biospecimens* in a repository indefinitely. Other researchers will have access to the data for future research. *[Please indicate if the data will be held in an identifiable or de-identified or coded state.]*
* The researchers intend to keep the research *data/records/biospecimens* until analysis of the information is completed.
* *Data/records/biospecimens* collected for this study may be shared with other researchers for future studies that are unknown at this time. Any *data/records/biospecimens* shared with other researchers, will not include the participant’s name or other personal identifying information.
* The participant’s *data/records/biospecimens* will be stored [indicate the name of the institution where they will be stored, including any biobanks to be utilized]. We plan to keep the participant’s data and biospecimens for [indicate time frame or “indefinitely,” or until “used completely,” etc.].
* The participant’s *data/records/biospecimens* may be shared with investigators around the world. However, access to the data and biospecimens is controlled by [indicate which entity has control]. To use the participant’s *data/records/biospecimens*, researchers must get approval and they must agree not to try to identify the participant.

Any future use of this research data is required to undergo review by a Research Ethics Board.

**WHAT OTHER THINGS SHOULD I CONSIDER?**

**Use of My Family Member’s Biospecimens:**

*Include one of the following three statements in all consent forms that collect biospecimens for research.*

***Note:*** *These statements should not be altered except for specifying the type of biospecimens collected.*

*Any biospecimens shared with outside entities must be de-identified or coded.*

***If biospecimens will be kept by researchers:*** Any biospecimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of Calgary. Once the participant provides the biospecimens, they will not have access to them. The University may share the participant’s biospecimens in the future with other researchers or outside institutions. Information that identifies the participant will not be shared with anyone outside of the University of Calgary. The biospecimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. The participant will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the biospecimens.

***If biospecimens will be provided to an outside entity, such as the study sponsor or national group:*** Any biospecimens (e.g., tissue, blood, urine) obtained for the purposes of this study will be provided to [the Sponsor of this study (company name optional) or the name of the national group). These biospecimens will not include information that identifies your child directly. Once the participant provides the biospecimens they will not have access to them. The biospecimens will be used for research and such use may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. The participant will not receive any money or other benefits derived from such products.

***If biospecimens will be discarded:*** Any biospecimens (e.g., tissue, blood, urine) obtained will be discarded or destroyed once they have been used for the purposes described in the protocol.

***If the data/biospecimens are coded and can be linked back to the participant:***

We will protect the confidentiality of the participant’s information to the extent possible. The participant’s name and other identifying information will not be on any data and biospecimens they provide. The data and biospecimens will have a code that links to the participant’s identifying information. The code key will be kept in a locked location separate from their information. The code key can only be accessed by people who have permission.

***If the data and biospecimens are completely delinked from identifiers and cannot be linked back to the participant:*** The participant’s name and identifying information will not be on any data and biospecimens they provide. Investigators cannot link their identifying information to the data and biospecimens.

**Genetic Research**

***Examples:***

* When the participant donates their blood or tissue for genetic testing or research, they are not only sharing genetic information about yourself, but also about biological (blood) relatives who share their genes or DNA.
* There are laws in Canada that protect the participant’s genetic information, and privacy and confidentiality. However, laws in other countries regarding genetic information, privacy, and confidentiality may differ. The participant may not be afforded the same rights when your information and biological samples are sent to places outside of Canada.

# RESEARCHER CONFLICTS OF INTERESTS

*If a member of the study team has a personal financial interest in the outside entity funding the study or other personal financial interests in entities that might reasonably benefit from the research, a financial interests statement is required. Other potential conflicts of interest should also be disclosed (e.g. family interests, affiliations with the sponsor or funder).*

**USE OF DATA [AND/OR BIOSPECIMENS] FOR FUTURE RESEARCH**

*Please note, identifiable health information (i.e., that is drawn from clinical health records) cannot be held for unspecified future use. Non-health data, de-identified data and biospecimens can, however, be retained for unspecified future use.*

It is your choice whether or not to let researchers share the participant’s data and biospecimens for research in the future. If you say “yes,” you or the participant can change your mind later, but the data and biospecimens might still be used if they have already been shared.

The participant’s [identifiable / de-identified / coded] research [data / records / biospecimens] may be kept for use in future research to learn about, prevent or treat other health-related problems.

❑ YES

❑ NO

Additional tissue [and/or blood] may be taken for this research, as described in the WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION section above.

❑ YES

❑ NO

**CONTACT FOR FUTURE RESEARCH**

University of Calgary researchers may contact me in the future to ask the participant to take part in other research studies.

❑ YES

❑ NO

# IF MY FAMILY MEMBER SUFFERS A RESEARCH-RELATED INJURY, WILL THEY BE COMPENSATED?

*There are certain circumstances where the compensation clause is not needed. For example, research where injury requiring medical care is extremely unlikely, non-interventional studies, and low-risk studies.*

*If there is a potential for harm, there must be a statement regarding possible compensation if the participant is injured as a result of the research. This section is not about legal liability, but about whether the sponsor or researchers will voluntarily pay for medical costs incurred that are not covered by health insurance.*

It is important that you tell the researchers if you believe that the participant has been injured because of taking part in this study.

*If the sponsor will not voluntarily provide compensation for research related injury, use this statement:*

In the event that the participant suffers injury as a result of participating in this research, no compensation will be provided to them by [insert name of sponsor/funder], the University of Calgary, Alberta Health Services or the Researchers. However, the participant still has all of their legal rights. Nothing said in this consent form alters the participant’s right to seek damages.

*If the sponsor will provide compensation, use this statement:*

In the event that the participant suffers injury as a result of participating in this research, [insert name of sponsor/funder], but not the University of Calgary, Alberta Health Services or the Researchers, will assist them by paying for any treatment or services the participant’s doctors recommend that is not covered by their health care insurance. However, the participant still has all of their legal rights. Nothing said in this consent form alters the participant’s right to seek damages.

# WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

**The Research Team:**

You may contact [insert name(s)] at [insert phone number(s)] with any questions or concerns about the research or your family member’s participation in this study.

**Conjoint Health Research Ethics Board (CHREB):**

If you have any questions concerning the participant’s rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990 or email chreb@ucalgary.ca.

*[Required statement for applicable Clinical Trials:]* **Public Information about this Study:** ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you or the participant. At most, the website will include a summary of the results. You can search this website at any time.

# HOW CAN MY FAMILY MEMBER FIND OUT ABOUT THE STUDY RESULTS?

# *Describe how study results will be made available to the participants (e.g., summary on study website, summary individually provided to all participants, available on request, link to publication, invitation to community presentation).*

# WHAT ARE MY FAMILY MEMBER’S RIGHTS IF THEY TAKE PART IN THIS STUDY?

Your family member’s participation in this study is a choice. You can choose whether or not you want them to participate. Whatever decision you make, there will be no penalty to you or the participant.

* You have a right to have all of your questions answered before deciding whether the participant will take part.
* Your decision will not affect the medical care the participant receives.
* If you decide for the participant to take part, they can leave the study at any time.

# HOW DO I INDICATE MY AGREEMENT FOR MY FAMILY MEMBER TO PARTICIPATE?

Your signature on this form indicates that you have understood to your satisfaction the information regarding your family member’s participation in the research project and agree for them to participate. In no way does this waive your legal rights or the participant’s legal rights, nor release the investigators or involved institutions from their legal and professional responsibilities.

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

Name of Participant

**SIGNATURE OF SURROGATE**

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

Name of Surrogate Relationship to Participant

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

Signature of Surrogate Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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

Name of Person Obtaining Consent Contact Number

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

Signature of Person Obtaining Consent Date

**SIGNATURE OF THE WITNESS**

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

Name of Witness

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

Signature of Witness Date

*Under the International Conference on Harmonization, Good Clinical Practice (ICH GCP 2.8.10), where it is known that the participant cannot read (e.g., visually impaired, illiterate) or cannot read the presented consent form (e.g. English second language), the signature of an impartial witness independent of the trial must be obtained. The witness must be present for the consent process. The witness signature reflects that they believe the consent information was accurately presented to and understood by the participant, and that consent was freely given by the participant.*

A signed copy of this consent form has been given to you to keep for your records and reference.

*Before submitting your consent form, please check it over (or have it checked) for grammar, spelling and typing errors.*



**UNIVERSITY OF CALGARY**

**REGAINED CAPACITY CONSENT FORM**

**TITLE**: [Insert the full title of the research project]

**SPONSOR:** [Put the name of the sponsor here.]

**FUNDER**: [Put the name of the organization/company providing funds, drugs and/or equipment here.]

**INVESTIGATORS**: [State the name of the local Principal Investigator followed if desired by the names of co-investigators.]

Because your illness or injury made it impossible for you to participate fully in the informed consent process, the consent was obtained from your surrogate on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research project.

Informed consent is essential throughout a research project. This means in your situation, you are now being given the opportunity to consent to ongoing participation in this study.

Please check the appropriate box to indicate your decision:

* I wish to remain in the study.
* I wish to withdraw from the study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant

**WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?**

During the study, the researchers could learn something about you that they didn’t expect. For example, the researchers may [e.g. find out that you have another medical condition.] The researchers will consult with medical experts as needed to evaluate the findings and will then share these results with you. You will be helped with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:

❑ YES

❑ NO

**USE OF DATA** **[AND/OR BIOSPECIMENS] FOR FUTURE RESEARCH**

*Please note, identifiable health information (i.e., that is drawn from clinical health records) cannot be held for unspecified future use. Non-health data, de-identified data and biospecimens can, however, be retained for unspecified future use.*

It is your choice whether or not to let researchers share your data and biospecimens for research in the future. If you say “yes,” you can change your mind later, but your data and biospecimens might still be used if they have already been shared.

My [identifiable / de-identified / coded] research [data/records/biospecimens] may be kept for use in future research to learn about, prevent or treat other health-related problems.

❑ YES

❑ NO

Additional tissue [and/or blood] may be taken for this research, as described in the consent form.

❑ YES

❑ NO

**OPTIONAL PHYSICIAN NOTIFICATION**

*If providing notification of participation to the participant’s primary care physician is optional, the following must be included:*

We believe it is important that your primary care provider know that you are in this research study and may be [taking a drug/using a device] that could affect your health. With your permission, we will notify your provider that you are enrolled in this study.

I consent to my primary care provider being notified of my participation in this study.

❑ YES

❑ NO

Participant’s Initials: \_\_\_\_\_\_\_\_

**CONTACT FOR FUTURE RESEARCH**

University of Calgary researchers may contact me in the future to ask me to take part in other research studies.

❑ YES

❑ NO

**WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

**The Research Team:**

You may contact [insert name(s)] at [insert phone number(s)] with any questions or concerns about the research or your participation in this study.

**Conjoint Health Research Ethics Board (CHREB):**

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

# HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?

# *Describe how study results will be made available to the participants (e.g., summary on study website, summary individually provided to all participants, available on request, link to publication, invitation to community presentation).*

**WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?**

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

* You have a right to have all of your questions answered before deciding whether to take part.
* Your decision will not affect the standard medical care you receive [or your education or employment, as relevant].
* If you decide to take part, you can leave the study at any time.

**HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?**

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to continue your participation in the study. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

**SIGNATURE OF STUDY PARTICIPANT**

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

Name of Participant

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

Signature of Participant Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

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

Name of Person Obtaining Consent Contact Number

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

Signature of Person Obtaining Consent Date

**SIGNATURE OF THE WITNESS**

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

Name of Witness

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

Signature of Witness Date

*Under the International Conference on Harmonization, Good Clinical Practice (ICH GCP 2.8.10), where it is known that the participant cannot read (e.g., visually impaired, illiterate) or cannot read the presented consent form (e.g. English second language), the signature of an impartial witness independent of the trial must be obtained. The witness must be present for the consent process. The witness signature reflects that they believe the consent information was accurately presented to and understood by the participant, and that consent was freely given by the participant.*

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