**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 color 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:///\\dtpfsrv1\chreb\CHREB\Website%20Documents\Consent%20Form%20Templates\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\AppData\Local\Microsoft\Windows\INetCache\Downloads\hemmingwayapp.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 use the CHREB Clinical Trials/Interventional Research Consent Form template.



**UNIVERSITY OF CALGARY**

**CONSENT TO PARTICIPATE IN RESEARCH**

**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 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), then 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 contact telephone numbers here, including area code]

# 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 your 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. You will receive a copy of this form for your records.

You were identified as a possible participant in this study because [explain why the potential participant is eligible to participate]. Your 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 potential participants understand why they might or might not want 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 participants. 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 I TAKE PART IN THIS STUDY?

If you volunteer to participate in this study, the researcher will ask you to do the following:

* *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. Explain if you will record conversations (audio or video record).*
* *Specify if interviews/focus groups will be recorded.*
* *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. 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 I BE IN THIS STUDY?

*Explain the duration of the study or how long the study will last. This will help participants decide if they have the time to participate.*

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

*When appropriate, include estimates of the different aspects of the study and state that the study will involve long-term follow-up and specify time frames.*

***Examples*:**

* You will be in this study for XX days.
* Your participation in this study will last \_\_\_.
* Participation in this study will require about XX hours of your time.
* This study will require approximately XX hours of your time for each study visit.
* There will be a total of XX study visits over six months.
* You will be in the [insert clinic/center name] for a total of XX days.

*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 I CAN EXPECT FROM THIS STUDY?

* *List and describe any reasonably foreseeable risks, discomforts, inconveniences, and how these will be managed.*
* *If there are significant risks or harms that might cause the researcher to end the person’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 discomforts experienced will be brief and transient.*

# ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

*Please note incentives such as cash, gift cards, and other material rewards are not considered benefits of participation, and should be included in the section “WILL I BE PAID FOR PARTICIPATING, OR DO I 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 you from participating in this study. However, this study may help the researchers learn more about [specify research area].

# WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?

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

**Example *[If the study does not include any treatment(s)]:*** You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. Your decision will not affect the standard medical care you receive [or your education or employment, as relevant].

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

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

# CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the researchers if you are thinking about stopping or decide to stop. [*If the research study includes treatment:* They will tell you how to stop safely.]

# WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

*Under TCPS2, 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 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

# 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 void 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).*

*Provide participants with a deadline for requesting withdrawal of their data that is both meaningful for them and feasible for the researcher (e.g., "You may request that your data be withdrawn for up to 2 weeks after the interview”).*

*Please note, although on request data may be withdrawn 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 I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

*Investigators are normally expected to reimburse or otherwise cover costs of parking or daily expenses for clinic visits that would not occur outside the context of the study. See also the CHREB position statement on payments to participants.*

***No payment or reimbursement:*** You will not be paid for your participation in this research study. You will not be reimbursed for any out-of-pocket expenses, such as parking or transportation fees.

***Reimbursement for out-of-pocket expenses:***You will be reimbursed for the following expenses: [complete this sentence, e.g. parking.]

***Optional statement:***In order to be reimbursed, please be sure and save your receipts so that you can provide these to the research staff.

# WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

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

* *How data, records, 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 or records 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 or in a coffee shop).*

*Advise participants if you believe that the fact of their participation will be known (e.g. if they are doing an interview on work time) but you will keep all information they provide confidential.*

***Suggested Confidentiality Statements for All Consents:*** The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy. 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/policies/files/policies/im010-03-security-standard\_0.pdf*](https://www.ucalgary.ca/policies/files/policies/im010-03-security-standard_0.pdf)

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

***Examples:***

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

***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 on a laptop computer that is [describe protection and/or has encryption software].
* [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. the sponsoring company, authorized University of Calgary representatives). Explain who will have access to the research data/records and how they will be shared.*

***Recommended wording for focus groups:*** The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private.

***[If applicable]:*** Your medical records and study data will be reviewed by the sponsor of this study, or their representatives at [name study site]. Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable medical/clinical records [*and/or your research records*] held at [name study site] for quality assurance purposes. *Other relevant organizations may include the Study Sponsor, Health Canada and/or other foreign regulatory agencies*. By signing this form you are authorizing such access.

***[If applicable]:*** By signing this consent form you are authorizing [specify data custodian] to allow the research team access to your individually identifying health information for research purposes. Your signed consent form will also be included in your electronic medical record(s), and your healthcare team will be alerted that you are in a study. This is to ensure your healthcare team has information about the study so that they can treat you safely.

***[If applicable]:*** The study investigators will make every effort to maintain the confidentiality of your 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 participants of this possibility. Please indicate if the data will be held in an identifiable or de-identified state.*

*Describe retention of data and records.*

***Examples:***

* The researchers intend to keep the research data and records until the research is published and/or presented.
* The researchers intend to keep the research data and records for approximately **XX** years.
* The researchers intend to keep the research data and records indefinitely for future research.
* The researchers intend to keep the research data and records in a repository indefinitely. Other researchers will have access to the data for future research.
* The researchers intend to keep the research data and records until analysis of the information is completed.
* Data collected for this study may be shared with other researchers for future studies that are unknown at this time. Any data shared with other researchers, will not include your name or other personal identifying information.

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

**WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?**

**Use of My Specimens:**

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

***Note:*** *These statements should not be altered with the exception of specifying the type of specimen collected.*

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

***If specimens will be kept by researchers:*** Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of Calgary. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of University of Calgary. The specimens 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. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

***If specimens will be provided to an outside entity, such as the study sponsor or***

***national group:*** Any specimens (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 specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens 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. You will not receive any money or other benefits derived from such products.

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

**Genetic Research**

***Examples:***

* When you donate your blood or tissue for genetic testing or research, you are not only sharing genetic information about yourself, but also about biological (blood) relatives who share your genes or DNA.
* There are laws in Canada that protect your genetic information, and privacy and confidentiality (i.e., Genetic Non-Discrimination Act, Bill S-201). However, laws in other countries regarding genetic information, privacy, and confidentiality may differ. You 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 FOR FUTURE RESEARCH

*Please note, identifiable health information (i.e., that 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.*

My research data and/or specimens 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 me to take part in other research studies.

❑ YES

❑ NO

**IF I SUFFER A RESEARCH-RELATED INJURY, WILL I 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 you have 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 you suffer injury as a result of participating in this research, no compensation will be provided to you by [insert name of sponsor/funder], the University of Calgary, Alberta Health Services or the Researchers. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

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

In the event that you suffer 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 you by paying for any treatment or services your doctors recommend that is not covered by your health care insurance. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

# WHOM MAY 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 may 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 take part 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 4.8.9), where it is known that the participant cannot read (e.g., visually impaired or illiterate), 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 participant was presented with sufficient information to assure a truly informed consent.*

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.*