

SURROGATE CONSENT FORM (TEMPLATE)

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

*Red, italicized text is instructional, providing information to the consent form writer. It should be deleted when writing the consent form. Unless otherwise indicated, the remainder of the text is mandatory. This document is to be used as a template – cut text from your document and paste it into the appropriate sections in this one. Ensure the consent form is written in the second person through the whole document (including the compensation clause), except for the headings.*

*In the header or footer of every page insert the following information: Ethics ID, PI, Study Title, Version Number, Date, page expressed as page X of Y (specific/total).*

TITLE: *Insert the full title of the research project goes here.*

SPONSOR: *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 any co-investigators (see note above).*

*Put the main contact telephone numbers here, including area code.*

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

## BACKGROUND

*Explain why surrogate consent is being sought, and that the subject’s consent will be sought if competency is regained.*

*This section of the consent form is for describing the rationale for the study and its design and methodology. It should state whether this research is a continuation of a previous study, increased dosage, changing administration of a drug, a new patient population, etc. Explain such aspects of research design as randomization and double-blind studies.*

*If the study is a double-blinded clinical trial, participants must be reassured that the blinding can be broken should an emergency arise and their treating physician require the information.*

*If deception is necessary for the research, debriefing is required and a description of the final consent process after debriefing needs to be explained here.*

*It is interesting for the surrogate to know how many subjects will be enrolled* *at how many health-care centres.*

## WHAT IS THE PURPOSE OF THE STUDY?

*Provide a description of the purpose of the study. Be concise, but avoid overly technical language or jargon that participants might not be familiar with.*

## WHAT WOULD THE SUBJECT HAVE TO DO?

*Describe for the surrogate exactly what the research will involve for the subject. Include the frequency and number of each test, interview, office visit or questionnaire. Estimate how much time these procedures may take, and say if there is any follow-up. Inform the surrogate how long the study is expected to continue, and how long the subject might be expected to participate. For clinical trials identify those procedures that would not be a part of usual clinical care.*

* *Use bullets if they might help with clarity; and*
* *Use diagrams, charts or other illustrations if they would be useful. For example: flow charts of the sequence of events in the study or illustrations of medical equipment being used.*

## WHAT ARE THE RISKS?

### *List all known side effects and risks of the study, and/or the testing required for the research in order of the severity and likelihood of potential harm. Canadian law stipulates that subjects must be told about remote risks of severe harm, not just the more likely risks.*

## WILL THE SUBJECT BENEFIT IF THEY TAKE PART?

*Provide a conservative description of the probability and nature of direct and indirect benefits to the participants and to others.*

If you agree for the subject to participate in this study there may or may not be a direct medical benefit to the subject. The subject’s *name of disease* may be improved during the study but there is no guarantee that this research will help them. The information we get from this study may help us to provide better treatments in the future for patients with *name of disease*.

## DOES THE SUBJECT HAVE TO PARTICIPATE?

*Outline alternatives*

*If the study involves a disease or condition for which there are approved and/or standard treatments available, the subject’s surrogate must be informed.*

*Voluntariness and Withdrawal of consent*

*Explain to the surrogate that participation in this study is voluntary and that they may withdraw the subject from the study at any time without jeopardizing their health care. Tell the surrogate how they may withdraw the subject, and explain any limitations to data withdrawal. Also explain that the researcher can withdraw the subject from the study and reasons that might happen.*

*Inform the surrogate that if new information becomes available that might affect their willingness to have the subject participate in the study, they will be informed as soon as possible.*

***Withdrawal of Study Data***

*Describe any circumstances that do not allow withdrawal of data or biospecimens once collected. Advise the surrogate that the subject’s data cannot be withdrawn if they have been published or otherwise disseminated.*

## WHAT ELSE DOES PARTICIPATION INVOLVE?

*This is the section in which to describe any unique features of the research that have not already been discussed in the consent form and may affect the subjects.*

## WILL WE BE PAID FOR PARTICIPATING, OR DO WE HAVE TO PAY FOR ANYTHING?

*The CHREB is strongly disinclined to allow studies where participation in research means subjects will incur costs.*

*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*](http://www.ucalgary.ca/research/files/research/160617-2016guideline_payment.pdf)*.*

*Do not use the word “compensation” in this section. Compensation for injuries is to be set out below under the separate heading.*

## WILL THE RECORDS BE KEPT PRIVATE?

*Explain who will have access to information collected and to whom, if anyone, the identity of the subject will be disclosed. Include how confidentiality will be protected. You may state that the University of Calgary Conjoint Health Research Ethics Board will have access to the records.*

*For trials falling under FDA regulation, the following statement is mandatory:*

A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as required by the U.S law. This Web site will not include information that can identify you or the subject. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Authorized representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at the subject’s identifiable medical/clinical study records held at (*name site*) for quality assurance purposes.

*(Other relevant organizations may include the Study Sponsor, Health Canada and/or other foreign regulatory agencies)*

*Please consider the potential for future uses of study data, and data sharing requirements, and advise participants of this possibility.*

*For example:* “Data collected during the subject’s time in this research study will be de-identified and will be held in a database for future use by other researchers. Any future use of this research data is required to undergo review by a Research Ethics Board.”

## IF THE SUBJECT SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

*This is the compensation clause. There are certain circumstances where the compensation clause is not needed (e.g., minimal risk research such as that involving questionnaires or interviews).*

*In clinical trials and procedures there must be a statement regarding possible compensation if the subject is injured as a result of the research. This section is not about legal liability, but is about whether the sponsor or researchers will voluntarily provide coverage for any reasonable medical costs incurred that are not automatically covered by health insurance.*

*If the sponsor will not 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 the subject by *insert name of sponsor*, the University of Calgary, Alberta Health Services or the Researchers.The research subject still has all their legal rights. Nothing said in this consent form alters their right to seek damages.

#### *If the sponsor will provide compensation, use this clause:*

In the event that the subject suffers injury as a result of participating in this research, *insert name of* *sponsor*, but not the University of Calgary, Alberta Health Services or the Researchers, will assist them by paying for any treatment or services their doctors recommend that is not covered by their health care insurance. Nothing said in this consent form alters their right to seek damages.

## SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to allow the person you represent to participate. In no way does this waive the subject’s or your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw the subject from the study at any time without jeopardizing their health care *(or education or employment, as relevant).* If you have further questions concerning matters related to this research, please contact:

Dr. \_\_\_\_\_\_\_\_\_\_\_ (403) \_\_\_-\_\_\_\_

Or

Dr. \_\_\_\_\_\_\_\_\_\_\_ (403) \_\_\_-\_\_\_\_

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

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| --- | --- | --- |
| Participant’s Name |  |  |
|  |  |  |
| Surrogate’s Name |  | Signature and Date |
|  |  |  |
| Investigator/Delegate’s Name |  | Signature and Date |
|  |  |  |
| Witness’ Name |  | Signature and Date |
|  |  |  |

*Under 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.*

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

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 for grammar, spelling and typing errors.*



REGAINED CAPACITY CONSENT FORM (TEMPLATE)

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 agree or disagree with the decision made by your surrogate for you to participate. If you choose to withdraw from the study, any information that was collected while the researchers were acting on your surrogates consent will be destroyed.

Please check the appropriate boxes to indicate your decision:

* I agree with my surrogate’s decision.
* I do not agree with my surrogate’s decision.
* I wish to remain in the study.
* I wish to withdraw from the study.

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 participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care *(or education or employment, as relevant).* If you have further questions concerning matters related to this research, please contact:

Dr. \_\_\_\_\_\_\_\_\_\_\_ (403) \_\_\_-\_\_\_\_

or

Dr. \_\_\_\_\_\_\_\_\_\_\_ (403) \_\_\_-\_\_\_\_

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|  |  |  |
| --- | --- | --- |
| Participant’s Name |  | Signature and Date |
|  |  |  |
| Investigator/Delegate’s Name |  | Signature and Date |
|  |  |  |
| Witness’ Name |  | Signature and 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.*

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