**Pregnant Partner Release of Information Informed Consent Form (ICF) Template**

General Information

This Pregnant Partner Release of Information ICF Template has been designed to meet current regulatory and ethical standards. The ICF should follow the prescribed structure and format as set out in this template.

This consent form and reportable event form must be used in the event that data will be collected for a pregnant partner/child when a male research participant fathers a child while participating in a study that involves experimental therapy. Collection of information on the pregnancy, birth and infant health for a specified period can only occur if the main participant ICF indicated that the investigator planned to collect information from the partner should she become pregnant. The pregnant partner will then be given a separate consent document to sign, providing permission to collect the information.

When to use and how to submit

* TOH or UOHI Investigators must submit a **reportable event form** and a **Pregnant Partner ICF** as soon as the investigator becomes aware of the pregnancy. Pregnant partner/child information cannot be collected until the REB has reviewed/approved the reportable event and Pregnant Partner ICF, and consent has been obtained from the partner.
* The pregnant partner ICF will **ONLY** require French translation if the pregnant partner prefers the document to be in French. The translated document must be accompanied with a certificate of translation or letter equivalent.
* The Sponsor may require submission of the Pregnant Partner ICF along with the initial application, in which case an English only version is acceptable. (French translation would only be required at the time of the event if the partner prefers the document to be in French).

Obtaining Consent from the Pregnant Partner of a Research Participant

* The PI/delegate **cannot** **contact the pregnant partner**.
* The participant should inform the pregnant partner that the researcher would like to collect pregnancy/child information. The pregnant partner will need to contact the research team to discuss.

HOW TO USE THIS TEMPLATE

* Delete this instruction page and delete any parts of the consent template that are not relevant to your particular study.
* Only use the logos that are applicable to your study; for TOH and OHRI logos, only use one or the other.
* Instructions are printed in *italics/grey background*, with actual ICF text in ‘black’. Text in blue is instruction to add your study information.
* Sections highlighted in turquoise indicate words you should choose/information required based on your study design (e.g. study drug/device).

**REMINDER:**

The informed consent form is only one component of the informed consent process. Researchers still need to have an informed discussion with, and respond to any questions raised by, participants.

**Pregnant Partner Release of Information Informed Consent Form**

**Study Title**:*insert study title as written on the protocol*

**OHSN-REB Number***:* *insert number*

**Sponsor’s Study ID**: *Insert sponsor’s study ID (if applicable)*

**Study Doctor**: *insert name, department and telephone or pager number*

**Sponsor/Funder(s):** *Insert the name of the Sponsor or, if applicable, the funder(s) of the research*

*[Note: A 24-hour, 7-day a week phone number is required for all studies that include greater than minimal risk research procedures or interventions.]*

**Emergency Contact Number** (24 hours / 7 days a week): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Non-Emergency contact numbers are noted at the end of this document under the section heading “Contacts”.

Introduction

*This section provides general statements; please revise if the statements below do not truly reflect what the pregnant partner is being asked to consent to.*

You became pregnant while your partner was taking part in this research study of an investigational drug called [drug]. A copy of the informed consent form for the study, in which your partner is taking part, is available for your review. We would like to learn about any possible effects of [drug] on your pregnancy and your baby. We are asking you to consent to allow the collection of information concerning the outcome of your pregnancy. Your partner’s study doctor or research team will follow-up with the obstetrician regarding regularly scheduled visits.

Participation in this data collection is voluntary. Please read this Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like.

If you agree to participate in this data collection, we will collect information from you and your baby, and share this coded information with the sponsor conducting the main study your partner is enrolled in.

The information collected may include your and your baby’s:

|  |  |
| --- | --- |
| * Your Month and Year of Birth * Baby’s full date of birth * Medical Conditions * Results of Tests and Medical Procedures | * Medications * Baby’s sex |

How long will participants be in the study?

The study doctor and members of the research team will follow-up with you and your baby for [days/weeks/months] post-delivery. Over this time, you will be asked to visit the [institution] [number of visits] *Please revise to reflect what is actually happening in this data collection program. (e.g. all information collected from medical records and no clinic visits are required, or information collected [weekly/monthly]by telephone follow-up, etc.)*

What alternatives do participant’s have?

Your participation in the data collection is voluntary. Choosing not to participate in this data collection will not prevent your partner from continuing in the research study.

You may decide not to participate in the data collection, or agree to participate now, and then change your mind later without affecting the medical care or other servicesto which you, your partner or your baby are entitled or are presently receiving at this institution.

If you withdraw your consent, the study team will no longer collect personal health information about you or your baby for research purposes. *[If applicable:* Information given to the sponsor before you cancel this consent may still be used.*]*

*Participants should also be given the choice of having their data withdrawn from the study completely, or be provided with the reasons why this option may not be possible. (e.g. questionnaires are anonymous so there is no link between the participant and their questionnaire)*

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

***Note:*** *If there will be disclosure of personal identifiers, i.e., disclosed on any research-related information/documents including samples or scans, or as part of the unique identifier, these disclosures must be justified in the REB application and approved. Please ensure that you are aware of institutional and REB policies with respect to the disclosure of personal identifiers.*

If you decide to participate in this study, the study doctors and study staff will only collect the information they need for this study.

Records identifying you or your baby at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your and your baby’s original (identifiable) medical/clinical and study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

*Include only those organizations requiring permission for direct access to participant medical records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:*

* *Insert sponsor name, the Sponsor of this study*
* The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
* *Ottawa Hospital Research Institute or Ottawa Heart Institute Research Corporation*, to oversee the conduct of research at this location
* Health Canada (because they oversee the use of natural health products/drugs/devices in Canada) *include for studies under Health Canada oversight only*
* U.S. Food and Drug Administration (because they oversee the use of natural health products/drugs/devices in the United States) *include only if applicable (e.g., for studies with sites subject to US FDA oversight)*

Information that is collected about you and your baby for the study (called study data) may also be sent to the organizations listed above. Your and your baby’s name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your and your baby’s *disclose identifiers e.g., participant code, pseudo-initials, sex, and partial date of birth for adult participants (month and year) and full date of birth for the baby*.

The following organizations may also receive study data:

*Include organizations with permission to receive study data only (organizations with direct access must be included in the list above). Include a brief description of their role in the research.*

* *List other regulatory authorities* (because they oversee the use of natural health products/drugs/devices in other countries)
* *Identify any other organizations with permission to receive study data only*

If the results of this study are published, your and your baby’s identity will remain confidential. It is expected that the information collected during this study will be *include description of proposed uses of data, e.g., used for data sharing purposes, ad/or analyses and will be published/presented to the scientific community at meetings and in journals*. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the study intervention.

Your and your baby’s de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, scientific journals, or deposited in an online repository, information that links your study data directly to you and your baby will not be shared.

If information from this study is published, shared, or presented at scientific meetings, your and your baby’s name and other personal information will not be used.

Research records will be kept for a minimum of 25 years, as required by Health Canada.

At the end of the storage time, all paper records will be shredded and all electronic records will be securely deleted.

What are the potential risks?

There are no medical risks to you or your baby associated with collecting information about your pregnancy and birth of your child.

what are the benefits of participating in this study?

There is no direct benefit to you from your participation in this study. Your participation may allow the researchers to [explain]. This may benefit future patients.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

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

Principal Investigator Name Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

**Study Title**: *insert study title as written on the protocol*

SIGNATURES

* I have voluntarily contacted the researcher to discuss the possibility of monitoring my pregnancy and its outcome,
* I understand that I am being asked to participate in data collection about myself and my baby,
* I understand the information within this informed consent form,
* I have read, or someone has read to me, each page of this participant informed consent form,
* I allow access to my and my baby’s medical records as explained in this consent form,
* I do not give up any of my legal rights by signing this consent form,
* I will be given a copy of this signed Pregnant Partner Release of Information Informed Consent Form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Participant |  | Printed Name |  | Date |

**Investigator or Delegate Statement**

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signature of Person Conducting the Consent Discussion |  | Printed Name and Role |  | Date |