**Remove this page before submitting**

**Instructional Notes for the Pregnant Partner Informed Consent Form Template – 2021**

**(These notes are instructional and should not be included in the informed consent form submitted to the REB or given to the prospective research participant.)**

* This informed consent form (ICF) template is intended for use by investigators, study coordinators, or informed consent form authors when drafting ICFs. It has been designed to meet current regulatory and ethical standards, while using language approved by the Nova Scotia Health (NS Health) REB.
* Please read these guidelines carefully before submitting your application to the research ethics office. The REB requests that all ICFs follow the prescribed structure and format as set out in this template to facilitate REB review.
* All ICFs submitted to the REB must adhere to the requirements of the NS Health REB and the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) 2018 ed.](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)  All ICFs for clinical trials that have been submitted to Health Canada or the Food and Drug Administration (FDA), and Phase IV trials (i.e. post-marketing), must also follow the [International Conference on Harmonization (ICH) Guidance E6: Good Clinical Practice (GCP): Consolidated Guideline](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php).
* Sections may be omitted if they are not relevant to the specific protocol. Ensure sections are properly renumbered. The section headings should also follow the order suggested in this template.
* Please ensure you are gender neutral by using male/female/other for sex and 'they' as a pronoun rather than 'he/she.'
* *Instructions are in red italics*, examples are in green for use in the ICF. This template will serve you best if it is viewed electronically or printed in color. All red text should be edited appropriately for the specific protocol. After all edits have been completed, convert the text to black.
* Before submitting the ICF to the REB for review, take the time to review carefully for spelling, grammar and formatting issues that may have arisen during editing of this template.

**Informed Consent Form Pregnant Partner Template**

|  |  |
| --- | --- |
| **STUDY TITLE:**  | *Same as the Protocol and REB application When the title is cumbersome, a short simplified title may be included in addition to the Full Study Title.* |
| **CLINICAL STUDY REGISTRATION NUMBER:**  | *All clinical trials must be registered before REB approval as per EAF Form A9) (e.g. clinicaltrials.gov)* |
| **PRINCIPAL INVESTIGATOR:** | *Name, department, address and telephone or pager number*. |
| **STUDY SPONSOR:**  | xyz Pharmaceuticals *Must match the EAF* |
| **FUNDER:**  | This study is being funded by… *Must match the EAF* |

1. **Introduction**

You are being asked to provide information on your pregnancy and on the birth of your child because you have become pregnant while your partner is taking part in a research study. We are asking for your permission to collect medical information about your pregnancy, its outcome, and if appropriate, the birth and health of your baby. Taking part is voluntary and it is up to you to decide whether to participate or not. Before you decide, you need to understand the risks and benefits you might receive if you participate. This consent form explains this.

*If time permits* You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, or your family doctor.

Please ask the research team or the principal investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate.

The researchers will:

* Answer your questions;
* Be available to deal with problems and answer questions.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

1. **What Is Involved?**

Your participation is voluntary, if you agree to provide information, your involvement will begin with the signing of this form and will last throughout your pregnancy until the delivery of your child with follow up for a period of 6 months to a year. If you, or your baby, experience a medical problem during this time you may be requested to inform the study doctor, either directly or through your health care provider, until the problem is solved or becomes stable.

You or your new born child will not be asked to undergo any additional tests to those your health care provider would normally perform in taking care of your pregnancy and your new born child. If your partner’s study doctor believes that additional tests are needed to ensure you and your child’s safety, you will be notified and you will have the right to agree to or refuse these additional tests.

1. **What Is Expected From You?**

When deciding whether to provide information, consider the following carefully:

* You are being asked to provide information on your health, pregnancy, and your new born child. Your consent is voluntary and it will help us collect the data we need.
* You may withdraw your consent at any time.
* Your partner’s study doctor will not treat your pregnancy or your new born child. Routine monitoring of your pregnancy and post pregnancy according to normal practices is recommended.
* The personal and medical information about your health, pregnancy, and your new born child that you or your health care provider will provide to your partner’s study doctor may be viewed by a number of people or groups associated with the study and will be defined later in this document.
* Your personal information will be collected, but your privacy and that of your new born child will be protected by limiting access to elements of personal information that directly identify individuals, in particular names, contact details and any government issued identification numbers.
1. **What Are The Potential Risks And Discomforts?**

The only foreseeable risks associated with the collection of data on you, your unborn child or your new born child is the risk of a breach of confidentiality**:** As with all research, there is a chance that confidentiality could be compromised; we are taking precautions to minimize this risk. Your information will be de-identified before leaving the site and only an assigned patient identification number will be used for all documents containing your information. Your information will only be available to those involved in the study.

You may discuss with your health care provider any concerns you may have on the potential risks for you, your unborn child or your new born child due to the father’s exposure.

1. **Are There Any Benefits?**

You will not receive any direct benefit from allowing the collection of information about your pregnancy and its outcome. What we learn from your information might lead to better understanding of the effect of the study drug or treatment on pregnant women and their unborn babies.

1. **What Happens If You Change Your Mind?**

Your agreement to provide information on your pregnancy and its outcome is voluntary. You may withdraw your consent for data collection at any time with no effect on the care of your partner who is participating in the clinical trial. The collection of information may be discontinued at any time by your partner’s study doctor or the Sponsor without your consent.

Should you decide to withdraw your consent for data collection regarding your pregnancy and its outcome, we will no longer request information from you or your health care provider, however, information collected prior to your withdrawal of consent may continue to be used in future analysis of the safety of the drug or treatment. You do not waive any legal rights by signing the consent form.

1. **What are Your Costs & Legal Rights?**

You will not incur any costs. The Sponsor will not cover any costs related to your pregnancy or your delivery. You will not receive payment for providing your information.

Research Related Injury

As this is a safety monitoring research activity, no physical injury to you or your child is anticipated; however, a breach of your and your child’s privacy is possible. Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in this surveillance program. In no way does this waive your legal rights nor release the principal investigator, the research team, the study sponsor or involved institutions from their legal and professional responsibilities.

1. **How Will Your Confidentiality Be Respected And The Privacy Of Your Personal Information Maintained?**

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. If the results of this study are presented to the public, nobody will be able to tell that you were in the study.

However, complete privacy cannot be guaranteed. For example, the principal investigator may be required by law to allow access to research records.

If you decide to participate in this study, the research team will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your;

* Name,
* Address,
* Telephone number,
* Age or month/year of birth (MM/YY),
* Health Information of you and your baby during the duration of your pregnancy and 6 month to a year after the birth of your child.

Access to Records

Other people may need to look at yours and your child’s personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines. These people might include:

* Sponsor Name (as per title page), and its representatives and partner companies as per the title page of this consent form;
	+ The Nova Scotia Health Research Ethics Board (NS Health REB) and people working for or with the NS Health REB because they oversee the ethical conduct of research studies within the Nova Scotia Health Authority;

Use of Your Study Information

Any study data about you that is sent outside of the Nova Scotia Health Authority will have a code and will not contain your name or address, or any information that directly identifies you.

De-identified study data may be transferred to:

* The sponsor and companies working for and with the sponsor; and
* Regulatory authorities within and outside Canada.

Study data that is sent outside of the Nova Scotia Health Authority will be used for the research purposes explained in this consent form.

The research team and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of privacy breach is very small, it can never be completely eliminated.

The research team will keep any personal health information about you and your child in a secure and confidential location for 25 years and then destroy it according to NS Health policy. Your personalhealth information and your child’s will not be shared with others without your permission.

You have the right to be informed of the results of this study once the entire study is complete.

The REB and people working for or with the REB may also contact you personally for quality assurance purposes.

Please be aware that once your de-identified data is sent outside of Canada it may be accessed by regulatory authorities in other countries who may not have the same privacy laws as we do.

Your access to records

You have the right to access, review, and request changes to your personal health information.

1. **Who Can You Contact With Further Questions?**

Please contact your study doctor using the details provided on the first page of this information sheet if you have any questions, concerns or complaints about the collection of information.

You have the right to all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction before you make any decision. You also have the right to ask questions and to receive answers throughout this study.  You have the right to withdraw your consent at any time.

If you have questions about your rights as a research participant, and/or concerns or complaints about this research study, you can contact:

1. The Nova Scotia Health Research Ethics Board Office
	* email: ResearchEthics@nshealth.ca
	* Phone: 902-222-9263
2. Patient Relations (see <http://www.nshealth.ca/contact-us> for appropriate zone contacts)
	* Email: healthcareexperience@nshealth.ca
	* Phone: 1-844-884-4177 (for CZ)

**See next page for signatures**

1. **Consent Statement**
* I have read and understand the statements in this informed consent form.
* I have had the opportunity to ask questions and I am satisfied with the explanations provided.
* I voluntarily agree to provide information on my pregnancy, delivery, and new born child.
* I voluntarily agree that my health care provider may disclose to the team treating my partner any relevant information in his/her possession pertaining to my health, pregnancy, and my unborn child.
* I voluntarily agree that my baby’s health care provider may disclose to the team treating my partner any relevant information in his/her possession pertaining to my baby’s health.
* By signing this form, I do not waive any of my or my unborn or new born child’s legal rights.
* I understand that I will receive a copy of this signed and dated written consent form.

E-messaging (email and texting) can be used by a member or members of the research team to communicate with you while you are in this study. All communication done with you will be done only through a NS Health email account, or text by a phone issued to a research member through NS Health. All efforts are made to keep information sent or received private, but it is possible other people may be able to see, read, and change messages sent to or from NS Health.

[ ]  I give my permission to be contacted by a member or members of the research team from an NS Health email account or an NS Health cell phone by research staff to communicate during this study. \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (initials and date).

 Email YES [ ]  NO [ ]

 Text message YES [ ]  NO [ ]

[ ]  I do not wish to be contacted by email or text message, unless I otherwise give permission at another time during this study \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (initial and date).

[ ]  Not applicable.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ***\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_***

Signature of Participant Name (Printed) Year Month Day\*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ***\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_***

Signature of Person Conducting Name (Printed) Year Month Day\*

Consent Discussion

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ***\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_***

Signature of Principal Investigator Name (Printed) Year Month Day\*

***\*Note: Please fill in dates personally***

**I will be given a signed copy of this consent form.**

***Thank you for your time and patience!***