# *Partner Pregnancy Information Sheet and Consent Form Template*

1. This template is to assist researchers in the development of a Partner Pregnancy Participant Information Sheet and Consent Form. It is important that you adapt this template to suit the audience and nature of the research.
2. The language used throughout the form should be easily understandable. Use local and simplified terms rather than scientific terminology and abbreviations. We recommend that you refer to the [Plain English Campaign](http://www.plainenglish.co.uk).
3. This template covers pregnant partners only (not pregnant participants). All trials of new medicines where the risk to a foetus is unknown should prepare a Partner Pregnancy PISCF in advance, however it is acknowledged that it is not practical to prepare a PISCF for a pregnant participant, due to the information being dependant on the main study and at what stage the pregnancy occurs. Pregnant Participant PISCFs should be created in the event of a pregnancy and submitted as an amendment through a post-approval form.
4. Subsequently, a Pregnancy Follow-Up PISCF will be needed so that the mother can re-consent on behalf of her baby after the baby is born – a template for this is available on the HDEC website

# INFORMATION SHEET & CONSENT FORM: PARTNER PREGNANCY

|  |  |
| --- | --- |
| **ASSOCIATED STUDY:** | [Insert lay title] |
| **FORMAL TITLE:** | [Insert formal title] |
| **PROTOCOL NUMBER:** | [Insert protocol number] |
| **SPONSOR:** | [Insert sponsor name][Insert sponsor address] |
| **STUDY DOCTOR: STUDY SITE:** | [Insert Investigator name][Insert site name][Insert site address][Insert site telephone number] |

You are being asked to sign this form because your partner [received/is receiving] [drug name] as a research participant in clinical study [protocol number], and you became pregnant [within [duration] of the [last] dose / during the treatment period]. *Add if applicable:* [drug name] is experimental, meaning it is not approved for sale or use in New Zealand.

The sponsor, [sponsor name], would like to collect information about your pregnancy and its outcome, for drug safety purposes.

This form explains this research to you. [Dr name] will go over the form with you and answer any questions you have. You can also discuss the research with other people, such as your whanau or your general practitioner (GP).

If you agree to take part you will be considered a research participant, because your information will contribute to knowledge about the safety of [drug name].

If you decide to take part, you will be asked to sign and date this form. You will be given a copy of the signed form for your records.

**Voluntary participation and withdrawal**

Taking part in this follow-up is voluntary. You are free to say yes or no, or to change your mind and withdraw your consent at any time. Your decision will not affect you or your partner’s regular medical care, [*add if applicable:* or his participation in clinical study [protocol number]].

**WHAT IS THE PURPOSE OF THIS FRESEARCH?**

*Add as applies:* Available research suggests that the study drug may be associated with some risk to your foetus *or* The effects of [drug name] on you and your foetus are not known at this time.

[Sponsor name] would therefore like to collect information about you and your foetus for drug safety purposes. This information may help [sponsor name] to better understand how [drug name] affects pregnancy and pregnancy outcomes.

**WHAT DOES THIS RESEARCH INVOLVE?**

[Dr name] or his/her study staff will collect personal and medical information about you (for example, your ethnicity, age, medical history, and sexual history), any previous pregnancies (including miscarriages and abortions), and your current pregnancy. This information will include the outcome of the pregnancy (including if your pregnancy ends in a miscarriage or abortion). If applicable, and you provide additional consent, information will be collected about your child after delivery (for example, its birth weight and any medical problems). Your child will be followed for [duration]. *Add or delete information that will be collected, as applicable.*

*Add if applies:* Some of this information will be collected directly from you by a study doctor or nurse. *If there is additional monitoring:* The only additional monitoring to be done as part of this research is *[specify which monitoring/procedures are above standard pregnancy/infant follow-up; the purpose of the additional procedures and the form of follow-up e.g. visits, phone calls].*

*OR* *add as applies:* You will not be asked to provide study staff with this information yourself.

Information will [also] be collected from your medical records. These may include midwife, GP, specialist and / or hospital records. At the end of this document, you will be asked to provide the name and contact details of health service providers who have this information.

[Dr name] will not provide you with pregnancy care as part of this research. It is recommended that you receive appropriate pregnancy care, as the risk of [study drug] to you and your foetus is unknown.

**ARE THERE ANY BENEFITS TO TAKING PART?**

There is no direct benefit to you from taking part. The information may help the study sponsor better understand how [study drug] affects pregnancy and the foetus.

**ARE THERE ANY RISKS TO TAKING PART?**

We acknowledge that this situation may cause you stress and anxiety. If you become upset or distressed, [Dr name] can help arrange counselling or other appropriate support.

*Add any risks associated with additional monitoring / procedures, if applicable.*

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. While the risk is currently very small, the chance that someone might access and misuse your information (for example, by making it harder for you to get or keep a job or health insurance) might increase in the future, as people find new ways of tracing information.

**WILL I BE PAID TO TAKE PART?**

[Site name] will arrange for taxis or petrol vouchers to assist with transport to and from [research unit]. You will not be paid for taking part.

[Sponsor name] and [Dr name] will not be responsible for costs relating to your pregnancy, delivery, or care of your child, or for any counselling or support services you may use.

**IS COMPENSATION AVAILABLE IF I AM INJURED?**

Taking part in this pregnancy follow-up should not result in any physical injury to you or your foetus. No compensation for physical or mental injury is offered by [Dr Name] or the sponsor for participation in this research.

*If additional procedures are planned that may result in study-related injury, please delete the above statement, and replace with the HDEC Commercial Insurance template.*

If you wish, you may seek your own legal advice about your legal rights in this situation.

**WHAT WILL HAPPEN TO MY INFORMATION?**

**Your Identifiable Information**

This is information containing data that could identify you (e.g. your name, initials, or birth date).

Identifiable information will be stored on paper forms at [state where and security measures taken]. After the study your partner took part in is completed, the forms will be transferred to a secure site and stored for at least [duration], then destroyed.

Identifiable information will not be sent off site. Access may be provided to the following groups:

* [Dr name] and [site name] staff.
* Representatives from the sponsor, ethics committees, or health or government agencies from New Zealand or overseas, to make sure the information collected is correct.

**Your De-identified (Coded) Information**

To make sure your personal information is kept confidential, information that identifies you will not be included in any information sent to the sponsor. Instead, your information will be labelled with [state how data will be labelled e.g. ‘with a code’]. [Dr name] will keep a list linking this code with your name, so that [site name] staff can identify your coded information if needed.

Your coded information will be held by the Study sponsor and may be kept on the [sponsor name] safety database (a secure electronic database) indefinitely. Storage of your information will comply with local and international data security guidelines.

The following people and groups of people may access and use your and your foetus’s coded health information.

* [Sponsor name], and people and companies working with or for [sponsor name].
* The ethics committee responsible for approving this study.
* Health or other government authorities involved in approving studies and medications.

Coded information will be entered in the [sponsor name] safety database. The database is used to build a more accurate profile of the risks and side effects of [drug name]. This is an important part of developing safe medicines and continues even after medicines are approved for use.

The people or groups named above may check your coded information to make sure your data has been collected and used correctly.

Your coded information may also be shared to comply with NZ or overseas law (e.g. safety reporting requirements to health and government authorities). This means your information could be added to health or government safety databases.

Your coded information will be sent overseas, potentially to a number of different countries. You should be aware that some countries may have lower levels of data protection than New Zealand.

**Future Research Using Your Information**

No unspecified future research will be undertaken using your and our foetus’s collected health information.

**Rights to Access Your Information and Results**

Information about the safety of [study drug name] may be published or presented, but not in a form that would reasonably be expected to identify you.

You have the right to request access to your information held by [Dr Name]’s research team. You also have the right to request that any information you disagree with is corrected.

Please contact [Dr name] if you would like to access your information.

We understand that many Māori consider health information taonga. Use of information for research, and sending information overseas, may require careful consideration. There are a range of views held by Māori around these issues; however, it is acknowledged that individuals have the right to choose. It may be appropriate to discuss this with your whanau. Alternatively, you may wish to contact [Maori support], whose details are listed below

**WHAT IF I CHANGE MY MIND ABOUT TAKING PART?**

Taking part is entirely your choice. If you do take part, you are free to withdraw at any time without having to give a reason.

If you wish to withdraw, please tell [Dr name] or his/her study staff. If you withdraw your consent, your participation in this follow-up will end, and the study team will stop collecting information from you.

Information collected from you and your foetus up until your withdrawal from the study will continue to be used as described in this form.

*Add if the clinical study was blinded and/or placebo-controlled:*

**CAN I FIND OUT WHAT MY PARTNER [RECEIVED / IS RECEIVING] IN THE CLINICAL STUDY?**

Please ask [Dr name] if you would like to know whether your partner received / is receiving [study drug] or [active comparator name / placebo]. If your partner agrees, [Dr name] will be able to give you this information [state when]. *If there is a significant delay in providing this information, please provide the reason for the delay in plain English.*

*Add if applicable:* If you do find out what your partner is receiving, your partner will need to stop study treatment and will be withdrawn from the study.

# WHO HAS APPROVED THIS RESEARCH?

This research has been approved by a New Zealand Health and Disability Ethics Committee.

**WHAT IF I NEED MORE INFORMATION OR HAVE A QUESTION?**

If you have any questions, concerns or complaints about the study at any stage, you can contact Dr [Name] on [contact details].

If you want to talk to someone who isn’t involved with the study, you can contact an independent Health and Disability Advocate (telephone 0800 555 050; email advocacy@advocacy.org.nz).

Māori cultural support is available through [name and contact details].

You can also contact the Health & Disability Ethics Committee (HDEC) that approved this study (telephone 0800 4 ETHICS; email hdecs@moh.govt.nz).

**CONSENT FORM: PARTNER PREGNANCY**

* I have read and understand the information sheet for taking part in this research**.**
* I have had the opportunity to discuss the nature / purpose / possible risks of this pregnancy follow-up. I have had sufficient time to ask questions and all of my questions have been answered in a way I understand.
* I understand that taking part is voluntary; that I may refuse to participate or withdraw at any time without giving a reason; and that this will in no way affect my future health care or result in penalty or loss of benefits to which I am otherwise entitled.
* I understand how my and my unborn child’s personal information will be used and the steps that will be taken to help protect confidentiality.
* I consent to my and my unborn child’s information being processed by the sponsor and passed to other companies working with the sponsor, and I understand that my information may be forwarded to other countries worldwide.
* If I decide to withdraw from the study, I agree that the information collected up to the point when I withdraw may continue to be used.
* I agree to an auditor appointed by the sponsoring company, the ethics committee, or health or regulatory agencies reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
* I give permission to access my relevant medical records.
* *Include if required:* I understand the compensation provisions in case of injury for this study.
* I will be given a copy of this information and signed and dated consent form. By signing this consent form, I am not giving up any of my legal rights.

**Statement by Participant (Pregnant Partner)**

I hereby consent to take part in this pregnancy follow-up. I understand that I will receive a signed copy of this consent form for my records.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (full name)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature)

 \_\_ \_\_ / \_\_ \_\_/ \_\_ \_\_ (Date) Time: \_\_ \_\_ **:** \_\_ \_\_hrs

**Statement by Consenter (Investigator/designee)**

I have discussed this pregnancy follow-up with the above-named participant. The participant appeared to fully understand the information provided about the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (full name)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (signature)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (project role)

 \_\_ \_\_ / \_\_ \_\_/ \_\_ \_\_ (Date) Time: \_\_ \_\_ **:** \_\_ \_\_hrs

**Contact Details of Health Services**

Please provide the contact details of your midwives, doctors, clinics, or hospitals who have information about your pregnancy and previous pregnancies (including any miscarriages or abortions).

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| **Name of Health Service Provider**  |  |
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| **Address** |  |
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| **Telephone** |  |

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