# *Pregnancy Follow-up (Child) Information Sheet and Consent Form Template*

1. This template is to assist researchers in the development of a follow-up Participant Information Sheet and Consent Form for a mother to consent on behalf of her new-born child. It is important that you adapt this template to suit the 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 should be used in the event of a pregnancy for studies involving investigational medicines where the effect of the treatment on a foetus is not known. A pregnant participant or pregnant partner Participant Information Sheet and Consent Form should be used immediately after the pregnancy, however the mother will need to re-consent on behalf of her baby after the baby is born. Unless the chance of pregnancy in the study is high, this form does not need to be developed until a pregnancy occurs.

# INFORMATION SHEET & CONSENT FORM: PREGNANCY FOLLOW-UP (CHILD)

|  |  |
| --- | --- |
| **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 on behalf of your child 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 *or* 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 child 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 for your child to take part, your child will be considered a research participant, because his / her 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 your or your child’s regular medical care. [*Add if applicable:* Your partner’s participation in clinical study [protocol number], and his regular care, will not be affected by your decision].

**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 your child for drug safety purposes. This information may help [sponsor name] to better understand how [drug name] affects pregnancy outcomes.

**WHAT DOES THIS RESEARCH INVOLVE?**

[Dr name] or study staff will collect your child’s health information, from birth up until [duration] after birth. If your child experiences a medical condition at birth, the follow-up period may be longer, but will not be longer than [insert 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 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 child’s 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 your child with care as part of this research.

**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 outcomes.

**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 child’s information cannot be guaranteed. While the risk is currently very small, the chance that someone might access and misuse your child’s information (for example, by making it harder for to get or keep a job or health insurance) might increase in the future, as people find new ways of tracing information.

**WILL I / MY CHILD BE PAID TO TAKE PART?**

[Site name] will arrange for taxis or petrol vouchers to assist with transport to and from [research unit], if required. You will not be paid for your child’s participation.

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

**IS COMPENSATION AVAILABLE IF MY CHILD IS INJURED?**

Taking part in this pregnancy follow-up should not result in any physical injury to your child. No compensation for physical or mental injury is offered by [Dr Name] or [sponsor name] 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 CHILD’S INFORMATION?**

**Your Child’s Identifiable Information**

This is information containing data that could identify your child (e.g. 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/is taking] 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 Child’s De-identified (Coded) Information**

To make sure your child’s personal information is kept confidential, information that identifies him/her will not be included in any information sent to the sponsor. Instead, 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 child’s name, so that [site name] staff can identify his/her coded information if needed.

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

The following people and groups of people may access and use your child’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 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 child’s coded information to make sure it has been collected and used correctly.

Your child’s 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 it could be added to health or government safety databases.

*Add as applies:* Your child’s 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 child’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 your child.

You have the right to request access to your child’s 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 [Māori support], whose details are listed below.

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

Your child’s participation is entirely your choice. If you do give consent, you are free to withdraw your child at any time without having to give a reason.

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

Information collected from your child up until his/her withdrawal from the study will continue to be used as described in this form.

# 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@hdc.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: PREGNANCY FOLLOW-UP (CHILD)**

* I have read and understand the information sheet for my child’s participation in this research**.**
* I have had the opportunity to discuss the nature / purpose / possible risks of this research. I have had sufficient time to ask questions and my questions have been answered in a way I understand.
* I understand that my child’s participation is voluntary; that I may refuse to give consent, or withdraw my consent, at any time without giving a reason; and that this will in no way affect my child’s future health care or result in penalty or loss of benefits to which he/she is otherwise entitled.
* I understand how my child’s personal information will be used and the steps that will be taken to help protect confidentiality.
* I consent to my child’s information being processed by the sponsor and passed to other companies working with the sponsor, and I understand that my child’s information may be forwarded to other countries worldwide.
* If I decide to withdraw my child from the study, I agree that the information collected up to the point when I withdraw consent 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 child’s relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
* I give permission to access my child’s 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 Child’s Mother**

I hereby consent for my child to take part in this research. I understand that I will receive a signed copy of this consent form for my records.

 *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* (full name of child)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (full name of mother)

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

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

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

I have discussed this research with the above-named child’s mother. The mother 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** |  |
|  |  |
| **Telephone** |  |

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