**When to use this form:**

The Pregnancy/Pregnant partner Data Release Form is to be used to request consent for follow up on the progress of a pregnancy and the birth and health of a child when the participant or participant’s partner becomes pregnant. The Principal Investigator is required to nominate and justify a follow up time, but this is expected to be not less than 12 months following birth.

Where the form is used for the pregnant partner of a study participant, information about the trial, such as drugs used, risks etc. must be included in the data release form along with an explanation of why [sponsors name] is seeking data regarding the outcome of the pregnancy, birth and health of the child. This may be achieved, for example, by attaching a copy of the trial Participant Information Sheet.

This form can either be included with the original submission to Bellberry HREC, or approval can be sought if/when a pregnancy occurs, and the form is required.

***Pregnancy/ pregnant partner data release form***

|  |  |
| --- | --- |
| Study Title:  |  |
| Protocol Number:  |  |
| Principal Investigator: |  |
| Co-Investigators:  |  |
| Name of Participant/Pregnant Partner: |  |
| Participant Study Number: |  |

**Purpose of the form**

The purpose of this form is to request your consent to follow the progress of your pregnancy and the birth and health of your child. Signing this form is voluntary; it is up to you to decide whether to agree to the collection of this information or not.

[For pregnant partner] Provide a brief explanation of the study including details about the drug/s used, risks etc.

The reason for this request is that the risk to your unborn child is unknown and you:

* became pregnant while participating in the above study, or
* you became pregnant while your partner was participating in the above study, or
* you became pregnant [insert] days after you or your partner completed the study.

We ask for your permission to review your and your child’s medical records relating to your pregnancy, the delivery of your child and the health of your child up to [insert and justify length of time as stated in the protocol] of age.

**Confidentiality of records**

All information collected about your pregnancy, the delivery of your child and the health of your child is confidential to the limit allowed by law. Your data will be coded to hide your identity and the identity of your baby. In particular, your name and your child’s name will not be reproduced on any other paper or electronic document.

These data will not be disclosed voluntarily by [Sponsors name and co-sponsor(s)(if applicable)]. However, regulatory agencies may have to examine these data to ensure that the study is done properly.

Please be aware that if you are the pregnant partner of a study participant and you do not wish to provide such information, this will not prevent your partner from continuing with the study.

In most cases, privacy legislation allows you the right to access personal information collected from you and request corrections of any such information that is incorrect.

**Participant/pregnant partner statement and signature**

* I have had the reasons explained to me as to why data about the pregnancy, the delivery and the health of the child are required.
* I have had an opportunity to discuss this with my partner's study doctor and I have had my questions answered to my satisfaction.
* I freely agree to allow the data concerning the pregnancy and the outcome of this pregnancy to be held on the [Sponsors Name] Drug Safety Database and being forwarded to regulatory agencies as necessary.
* It has also been explained to me that this information collection is not intended to take the place of medical care from my/my child’s regular treating practitioner/s.

Participant/Pregnant Partner's printed name

Participant/Pregnant Partner’s signature

Date (to be personally dated)

A verbal explanation of the research project, including drugs involved, risks and reasons why [Sponsors Name] is seeking data about the outcome of the pregnancy, has been given to the person named above and I believe they understood that explanation. A copy of this signed and dated Pregnancy Data Release Form will be provided to the above named for their record.

Investigator Name (print)

Investigator signature

Date (to be personally dated)