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Royal Papworth Hospital NHS Foundation Trust

Papworth Road

Cambridge Biomedical Campus

Cambridge

CB2 0AY

Tel: 01223 638000

**PARTICIPANT INFORMATION SHEET**

Pregnant or Pregnancy Partner request for information

Study name and IRAS number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Name (please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant /Participant Partner Study Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Introduction**

*You/Your* *partner* are or have been taking part in the research study called \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Some of the drugs that *you/your partner* are taking for this research may move into the semen or via the placenta. This is why when you started in the study, you were asked to use birth control while taking the study drugs. The effects of the study medications on pregnancy and the developing foetus (baby still in the womb) are currently not known or not fully understood. For this reason, we would like to collect medical information about the pregnancy, birth and the health of your baby. We want to follow *your* pregnancy and try to find out if the study medications have any effect on pregnancy and the health of your baby.

**What will happen if I agree to provide information about my pregnancy?**

If you agree to sign this consent form, we will review and collect medical information relating to *your* pregnancy, the delivery of your baby and the health of your baby until 6 months after the end of the pregnancy for any important medical issues.

**Involvement of the General Practitioner**

We will be asking for consent to inform your GP of this pregnancy

**Who can I speak to if I have questions, concerns or complaints?**

If you are concerned about any aspect of this study you should ask to speak to one of the researchers (contact details below) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS) (contact details below*).*

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

[*CI/PI Name and title*] is the person in charge of this research study. You can call them at [*PI telephone number*].

[*Research Nurse/Clinical Trial Co-ordinator*] at [*number*].

Alternatively, you can speak to an independent contact:

Patient Advice and Liaison Service (PALS)

Royal Papworth Hospital NHS Foundation Trust

Papworth Road

Cambridge Biomedical Campus

Cambridge

CB2 0AY

Phone: 01223 638896

Email papworth.PALS@nhs.net



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CB2 0AY

Tel: 01223 638000

Study Number: P0

Patient Identification Number:

Study Name & IRAS Number:

**CONSENT FORM**

Version 2.0, dated 22/06/2023

**Local Investigator:**

 **Please initial box**

**Informed Consent and Authorization**

Your signature on this document means the following:

1. I confirm that I have read and understood the information sheet dated (version 2.0)

for the above Pregnancy request for information. I have had the opportunity to

consider the information, ask questions and have had these answered satisfactorily.

2. I have had the reasons explained to me as to why data with regard to the

pregnancy, the delivery and the health of the baby are required.

3. I agree my GP can be contacted.

4. I understand that relevant sections of my medical notes and data collected about

*my pregnancy* may be looked at by individuals from[*company name*], from regulatory

authorities or from the NHS Trust, where it is relevant to my taking part in this research.

I give permission for these individuals to have access to my records.

5. I agree to provide data on *my* pregnancy

**CONSENT:**

……………………………………………………….. ……………. …………………………………………

Name of pregnant individual (PRINT) Date Signature

……………………………………………………….. ……………. …………………………………………

Name of person receiving consent (PRINT) Date Signature

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept in medical notes.