Pregnancy Follow-Up Consent and

Release of Information Authorization

***Note to the Investigator:***  *If data is being requested for research purposes from the pregnant partner of a research participant, informed consent is required from the pregnant partner in addition to the research participant. No data may be collected unless signed consent and authorization has been obtained using an IRB approved consent document.*

# Title of Research Project: This should be the same as the protocol.

**Principal Investigator:** [PI listed here]

**Sponsor:** This should be the same as the protocol.

Introduction

We are asking for your permission to collect information about your pregnancy, its outcome, and the birth and health of your baby because you became pregnant while your partner was taking part in a research study, and you plan to deliver at one of the University of Vermont Health Network Affiliate Sites.

[If applicable]You may be asked to sign a separate medical release if you deliver outside of the UVM Health Network.

We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

What is the Purpose of the Follow-up?

The purpose of collecting information regarding your pregnancy and the health of your baby is to help the study team/sponsor to understand the effects, if any, of (insert study drug), the drug that your partner was given during his participation in the research study.

What Is Involved in the Follow-up**?**

Your study doctor will collect data from your and you baby’s medical record and may ask you questions regarding your pregnancy. After delivery, your study doctor will review your baby’s medical record and may ask you additional questions about the health of the baby.

The types of information that will be collected about your pregnancy and your baby’s health are

[list here].

The collection of information regarding your pregnancy will continue until your delivery and for [list amount of time] afterwards. The study doctor will also collect information about your baby’s health for a period of [list amount of time].

[If you are doing more than just collecting information, state so here.]

What Are the Risks and Discomforts of The Study?

The only risk is a breach of confidentiality. See Safeguarding Your Health Information below.

What Are the Benefits of Participating In The Study?

You will not directly benefit from allowing permission to collect and use your or your baby’s information. However, the information may help researchers to better understand the risks and effects of this investigational drug on pregnant women and their unborn babies. The research may help other people in the future.

What Other Options Are There?

You do not have to agree to allow the collection and use of information on your pregnancy, its outcome, and your baby’s health for research purposes.

Are There Any Costs?

There will be no cost to you or your healthcare payer/insurance company if you allow permission.

What Is the Compensation?

You will not be paid for taking part in this pregnancy follow-up.

What About Confidentiality of Your Health Information?

The protected health information we plan to use and collect for this study is listed below.

**This list should be edited and revised to be accurate and study specific.**

* Medical history and examinations
	+ Your year of birth
	+ Estimated and actual date of delivery
	+ After the baby is born:
		- Your baby’s birth weight and length
		- Your baby’s sex
		- Whether there were any complications during the pregnancy or delivery
		- Whether your baby had any birth defects
* Information that identifies you, such as your name, address, age, and sex
* Reports from hospital and clinic visits
* Laboratory and other test results
* X-ray and other images and reports
* Lists of medications you are taking
* Responses to health surveys and questionnaires
* Reports on mental health services and testing
* Reports about drug and alcohol treatment
* Health related video and audio recordings, and photographs
* Reports on testing for infectious diseases, including HIV
* Genetic testing results

Who is disclosing your health information for this follow-up?

* The University of Vermont Medical Center [insert appropriate affiliate hospital(s)]
* Other doctors’ offices and hospitals where you may receive medical care while this study is active.
* List other health care providers specifically by name if known

Who will use your health information in this follow-up?

Our research team will use your health information. We may also share it with those who assist with the conduct of oversight of the activities for this follow-up. The representatives from the institutions, organizations, and agencies are listed below.

[This list should be edited and revised to be accurate and specific to pregnancy follow-up. The list should include, as applicable, a clinical research organization, an independent data and safety monitoring committee, a coordinating center, collaborators and their home institutions, and foreign regulatory agencies.]

* The University of Vermont and its Committees on Human Research
* Officials from agencies and organizations that provide accreditation and oversight of research
* The University of Vermont Medical Center (**insert appropriate hospital(s)**)
* Other researchers and centers that are a part of this study, including individuals who oversee research at those sites
* The sponsor of this follow-up (**insert the name of the sponsor)**, or others who fund the research, including the government
* Company(ies) that provide drugs or devices for this research project
* Federal and state agencies that oversee or review research information, such as the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities

Your health information is protected by a federal law called the Health Information Portability and Accountability Act (HIPAA). Once your health information is shared outside of the University of Vermont Health Network, we cannot guarantee that these laws will continue to apply. As a result, your health information could be further disclosed for other purposes. In the absence of a Certificate of Confidentiality, it is also possible for a court or other government official to order the release of study data. The confidentiality of your health information cannot be guaranteed if you agree it may be used in this study.

How long will your health information be used for follow-up?

Your permission to use your health information will not end until the follow-up is completed. During this follow-up, you will not have access to your data. You may ask for your data once activities are complete. You have a right to receive a copy of the information in your medical record at any time.

What if you decide not to give permission for follow-up use of your health information?

If you decide not to allow the use and disclosure of your health information, you may not take part in this follow-up. Your decision will have no effect on your current or future medical care.

If you choose to stop taking part in this follow-up in the future, you may cancel permission for the use of your health information. You should let the research team know that you are cancelling your permission. A member of the research team will assist you in making your decision effective. The study will continue to use the health information already collected for the study before you cancelled your permission, and you cannot get back information that was already shared with others.

Who can answer your questions about the use and disclosure of your health information?

If you have questions or concerns about the use and disclosure of your health information, you should ask a member of the study team at insert phone number or the Privacy Officer at The University of Vermont Health Network, Inc, at (802) 847-2667.

Safeguarding Your Health Information

A record of your progress will be kept in a confidential form at the insert location. The security of your record will be maintained by the research team. The results of this may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law-enforcement responsibilities of the agency.

If applicable, include this section:

Financial Interest

You should also know that [investigator] has a significant financial interest (e.g. a separate relationship with the sponsor or a related company involving ownership or stock, payment for services or other significant financial payments) that could potentially compromise or influence the investigator’s professional judgment or actions in the performance of the study (e.g. the design, conduct, oversight, evaluation or reporting of the results of the study). The investigator has disclosed that personal financial interest to the IRB responsible for approving this study. The IRB reviewed the [investigator’s] financial interest and determined that any potential conflicts are being appropriately managed. However, negative impacts on individuals participating in this study, are always possible, and therefore the potential conflict is being disclosed to you. Please discuss with the Investigator any questions you may have about this.

**Contact Information**

You may contact Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_ the Investigator in charge of this study, at \_\_\_\_\_\_\_\_\_for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study you should contact the Director of the Research Protections Office at the University of Vermont at irb@uvm.edu or 802-656-5040.

**Statement of Consent**

You have been given and have read or have read to you a summary of this follow-up. Should you have any further questions, you may contact the person conducting the follow-up at the address and telephone number given below. Your participation is voluntary, and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this follow-up, and you understand that you will receive a copy of this form.

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Signature of Participant Date

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Name of Participant Printed

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Signature of Principal Investigator or Designee Date

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Name of Principal Investigator or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number:

Name of Faculty Sponsor:

Address:

Telephone Number: