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# Informed Consent and HIPAA Authorization Form

**Study Title:** *Insert Full Title of the Protocol*

Version Date: Month, Day, 20XX

Consent Name: Pregnant Partner Consent Form

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| --- | --- | --- |
| **Principal Investigator:** | Investigator Name | Telephone: (xxx) xxx-xxxx |

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word “we” means the study doctor and other research staff.

## Study Overview

Your partner is or has been participating in a research study to test whether a drug called XXXXcan XXXX ***(****describe the purpose of the drug/intervention in lay language)*.

When he enrolled in the study, your partner was asked to use birth control while taking the study drug because the effects of XXXX *[study drug]* on pregnancy and the developing fetus are currently not known or not fully understood.

As standard practice, XXX *[the study sponsor]* attempts to follow-up on all reports of pregnancy that occur in subjects or partners of subjects who participate in a XXX *[the study sponsor]* sponsored clinical trial.

You are being asked to provide information to Dr. XXX and XXX *[the study sponsor]* because your partner has reported that you became pregnant while he was enrolled in this study.

Information from your physician or other licensed medical practitioner will support XXX *[the study sponsor]*’s efforts to monitor and evaluate the effects of its Investigational Products and to submit reports, as required under law, to FDA or other Regulatory Authorities.

If you agree to participate, we would collect medical information about you and your fetus during your pregnancy. Additionally, we would follow the health of your child for 30 days after birth for any significant medical issues.

We would therefore like to ask for your permission that Dr. XXX *(the principal investigator of the study)* may contact your physician so that data regarding your pregnancy can be collected.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study (only if applicable).

Please see below for additional details about the study.

## What are the risks of this study?

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms, and in the database instead of names and other private information. A separate list will be maintained that will links each participant's name to the study identification number for futurereference and communication.

## Are there any benefits to taking part in this study?

There will be no direct benefit to you by allowing Dr. XXX or XXX *[the study sponsor]* to follow the progress of your pregnancy. However, the results may help investigators better understand the effects of exposure to XXXX *[study drug]* during pregnancy.

## Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

### What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

### What happens if you decide not to take part in this study?

Participation in this study is voluntary. Your health care provider at CHOP will continue to provide you with health care services even if you refuse to sign this form.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

### Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

### What choices do you have other than this study?

There are options for you other than this study including not participating in this study.

## What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

We need to collect health information about you in order to follow your pregnancy. This includes information about you from medical records. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

* Members of the research team and other authorized staff at CHOP and UPenn *(include UPenn only if applicable)*;
* People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
* Representatives of XXXX who is the study sponsor funding this research;
* The Food and Drug Administration;

*Include the following ONLY if applicable*

* The Data Coordinating Center at XXXX *(multi-center research studies)*;
* Groups monitoring the safety of this study *(e.g. DSMB)*;
* The National Institutes of Health *(or other funding agencies)* who is sponsoring this research;
* Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. *(Only include this statement when applicable – i.e., domestic abuse, child abuse, etc. )*

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

*CHOOSE one of the next two sentences, whichever applies and insert it at the beginning of the paragraph below.*

There is no set time for destroying the information that will be collected for this study. ***OR*** The identifiable information from this study will be destroyed XXXX years after the study is completed.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.
*Note: HIPAA requires that consent forms be maintained for 6 years after the study is completed. FDA has separate requirements for maintenance of data.*

*For studies that include a Certificate of Confidentiality (CoC), including but not limited to all NIH funded studies, include the following CoC language edited to be study specific:*

**Certificate of Confidentiality (CoC)**

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

* No one can be forced to share your identifiable information or biological samples for a lawsuit.
* Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data **or biological samples could be shared for:**

* **other scientific research;**
* **XXXXX other purposes;**
* **your medical treatment *(Since CHOP Policy requires all clinically relevant data to be stored in EPIC, this statement will rarely be applicable)*.**

The CoC does not prevent some disclosures.

* **(*Only include the next statement if a US federal or state government agency is funding the research)* The researchers can't refuse requests for information from those funding this research. The [Funding Agency] may need information to assess this project.**
* ***(if applicable, include the following)* The US Food and Drug Administration (FDA) may need information.**
* **You can still share information about yourself. You can also freely discuss your involvement in this research.**
* **The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.**

## Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. XXXXXX
The Children’s Hospital of Philadelphia
Division/Department of XXXX
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

## Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

### Will there be any additional costs?

XXX *[study sponsor]* will cover the costs of collecting follow-up information. There will be no cost to you for participating.

**Will you be paid for taking part in this study**?

You will not receive any payments for taking part in this study.

We may share your data with third parties (other researchers/institutions or for profit companies). Your data may be used for commercial profit. You will not receive any financial benefit from the use of your data.

Please ask Dr. XXXX if you have any questions about how this study is funded.

*Include any disclosures mandated by the Conflict of Interest Committee to follow the funding explanation.*

### Conflicts of Interest

*Include any language required by the Conflict of Interest committee here. Examples of conflict of interest language are below:*

*Individual Conflict:*

Some of the investigators on this study, Drs. ABC and XYZ, are paid consultants for XXX, the sponsor of this study.

One of the study doctors, Dr. ABC, has intellectual property/a patent pending on XXX, which is being evaluated in this study. If the study shows that XXX may be useful for XXX, Dr. ABC may receive income from this invention.

*Institutional Conflict:*

CHOP has a significant financial interest in the study drug being evaluated in this research study. In the event that the study drug proves to be effective, CHOP may receive significant financial benefit.

CHOP has a financial interest in intellectual property related to this research (which is licensed by XXX), and may gain financial benefit if the research is successful.

## What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. XXXX at xxx-xxx-xxxx. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children’s Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects’ rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

## What will be done with my data when this study is over?

*(Use one of the following three options regarding the use of data for future research.):*

***NO secondary (future) research*** *with or without identifiers:*

Your data will not be used for any future research after this study is complete.

*If* ***there is a plan for secondary (future) research*** *with or without identifiers, use one of the following (****without identifiers*** *or* ***with identifiers)****:*

*Statement regarding secondary (future) research* ***without identifiers****:*

We will use and may share data for future research. Information that can identify you may be kept permanently in a computer database at CHOP.
Your data may be shared with researchers/institutions at, or outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing your data for future research. We will remove identifiers before sharing them with others. This means that nobody who works with your data for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

If you leave the study, you can ask to have the data collected about you removed. You can also ask us to remove information that identifies you from the data. Some of this may not be possible if your data have already been shared.

*Secondary (future) research* ***with identifiers****:*

*If there is ANY chance of using the data for future research and they are linked to identifiers or identifiable information; either*

* *include an “Optional Future Use of Data” section (see main consent form template for guidance) ). Or*
* *if future use of individually identifiable data is mandatory for study enrollment, then this must be explicitly stated below (the header and option to document consent to the future use should be deleted).*

## Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Person Obtaining Consent |  | Signature of Person Obtaining Consent |
|  |  |  |
|  |  | Date |

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your participation as well as your child’s participation. You are also agreeing to let CHOP use and share your health information as explained above. If you don’t agree to our collecting, using and sharing your health information, you cannot participate in this study.

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| --- | --- | --- |
|  |  |  |
| Name of Subject |  |  |
|  |  |  |
| Signature of Subject |  | Date |

***Note:***

***Please do not edit the footer of the consent form (e.g. to include the study number). These fields will be automatically populated when the IRB stamps the consent form.***