

Consent and Authorization to Participate in a Research Study

KEY INFORMATION & OVERVIEW FOR:

{TITLE OF STUDY}:

This is an executive summary of the necessary information in the consent document. Include most crucial information from the potential participant's perspective. Be concise and write in 4-6th grade level. Details of the study will be included in the detailed consent portion of this document.

We are asking you to choose whether or not to volunteer for a research study about _____ *{insert general description of study}*. This page is to give you key information to help you decide whether to participate. We have included detailed information about the research study in the rest of this document. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

Briefly describe the purpose of the study and the procedures to be followed in lay terms. For complete descriptions, refer to the Detailed Consent.

By doing this study, we hope to learn _____. Your participation in this research will last about *{state in hours, days, months, years}*.

If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness include the following: The purpose of this research is to gather information on the safety and effectiveness of _____ *{state name of drug, device, etc.}*. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study for an alternate use or consistent with labeling indications.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

State the most important reason(s) {i.e. potential benefit(s)} a person may want to volunteer to participate in this study? For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant's perspective. For a complete description of risks, refer to the Detailed Consent.

If alternative treatments/procedures are key to the participant's choice, discuss those that might be advantageous to the subject or indicate if no known alternative exists. For a complete description of alternate treatment/procedures, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is _____ *{Principal Investigator}* of
_____ *{list department/organization}*. If you have questions, suggestions, or concerns
regarding this study or you want to withdraw from the study, his/her contact information is: *{PI
contact information}*.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research,
contact the Institutional Review Board Office at 515-241-8598.

DETAILED CONSENT:

[Name of Institution Where Research will be Conducted]

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

and

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Title:	
Protocol Number:	
Sponsor:	
Investigator:	

Describe all procedures in lay terms such that the description will be readable at the 4th - 6th grade level. Avoid long sentences and medical/technical jargon, and define any technical terms clearly whenever they are used. [MS Word has a tool to determine reading level: Tools>Options>Spelling & Readability.]

Introduction:

What is the purpose of this study?

Describe how this study is designed to solve the problem described above. Identify drugs and/or devices that are not FDA approved. Avoid any claims of effectiveness.

Who is doing the study?

Dr (*Principal Investigator*) is in charge of the study at [*name of this location*].

This study is sponsored by [*insert name of sponsoring company or agency*].

Who else will be in the study?

About (*# of subjects*) people will be in the study at this location. About (*# of subjects*) people will be in the study at other hospitals around the country (*include other countries if study is multinational*).

How long will you be in the study?

If you join the study, you will be in it for about (*amount of time*).

Pregnancy

The following passages may be changed, deleted or supplemented as appropriate to the protocol.

This study may cause harm to a fetus or a nursing child, or to woman's eggs or a man's sperm cells. If you become pregnant during this study or are pregnant now, the (*particular treatments or procedures*) in the study might involve risks to the embryo or fetus which are currently unforeseeable. Therefore, appropriate methods to avoid pregnancy must be used by all participants during the study.

Nursing mothers must discontinue nursing their child.

Women of child-bearing age will have a pregnancy test prior to participating in this study. This requires that blood be taken from a vein one or two days prior to the study. The results of the pregnancy test will be made available to the study participant prior to the start of the study.

If you are a woman and you become pregnant during this study, you must tell the study director, Dr [*name of principal investigator*], immediately.

If you are a man and your sexual partner becomes pregnant by you during the study, you must tell the study director, Dr [*name of principal investigator*], immediately.

What will happen to you if you decide to be in this study?

Tell the subject what to expect. Give a description of the procedures to be performed, the drugs to be administered, any hospitalizations, and any outpatient visits.

- *With whom will the subject interact?*
- *Where will the research be done?*
- *When will the research be done?*
- *How often are procedures performed?*
- *How much time is involved in any procedures?*

- What is being done as part of the research and what is being done as part of standard care?
- If applicable, include a statement about whether the research project might include whole genome sequencing (the sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.)

What are the possible risks of being in the study?

Describe the risks for each procedure or drug clearly in lay terms. Group the risks into categories such as expected, occasional, or rare and describe them as such. Quantify the risks where possible. For example, *expected* = more than 3 in 10; *occasional* = 1 in 10; *rare* = less than 1 in 20. Be sure to list **ALL** side effects, no matter how rare, that are known to be associated with the drug or procedure. On the other hand, there is no need to list effects for which there is only anecdotal evidence, or for which a causal relation to the drug or procedure has not been established with reasonable confidence.

Explain the ramifications of some risks. For example: what will happen to the subject if liver enzyme tests indicate an abnormality? What could happen (to the liver)? What are the potential consequences of this? What will be done (to the subject to investigate liver enzymes)?

Thoroughly explain the real and potential risks of fetal or reproductive harm. If not known, then indicate so.

The IRB suggests that risks be presented in table or bullet form rather than as a list or a paragraph.

Include the following statement only if research involves greater than minimal risk

There may be a risk or side-effect that we don't know about yet. You might develop a new condition or suffer an injury. If you do, you should tell the study doctor immediately.

What are the possible benefits of being in the study?

We cannot promise that you will benefit from being in this study. However, **possible** benefits include _____.

Describe the possible benefits of participation. Describe any potential direct benefits to the subject first, then any benefits to others. If benefits may not continue after participation in the study is over, be sure to inform the subject. For example, an investigational drug provided at no charge during study participation may not continue to be available at no charge if it becomes available for marketing.

If there is no direct medical benefit to participation state:

There are no medical benefits to you from being in this study.

What about new information?

Include a statement that if there are significant new findings developed during the course of the research which might relate to the participant's willingness to continue participation, then the information will be provided to the participant.

If we find out any new information that might affect your decision to stay in the study, we will share it with you.

What are your choices if you don't want to participate in this research?

If you do not want to be in the study, you have other choices for treatment such as: *list other treatment options*. OR (*if there is no alternative treatment*) The alternative to being in this study is to not participate.

What about the confidentiality of your medical information?

The members of the research team will collect information about you and your medical condition. This information is called **Protected Health Information**. The Health Insurance Portability and Accountability Act (HIPAA) requires that institutions have a Policy to protect your Health Information. The Notice of Privacy Practices of this institution is described in a booklet distributed to all patients. We are asking your permission to use your Protected Health Information and share it with others for the purposes of this research study.

If there is any reasonable expectation that the research will reveal information about child abuse or dependent adult abuse or any one of several communicable diseases, then the Consent Document must contain a statement indicating that the researcher is [most likely] mandated under Iowa Law to report the abuse or disease, even if a federal Certificate of Confidentiality protects other information obtained in the research.

Who may see, use, and disclose information about you?

Here again you must balance the needs of the protocol against a need to know requirement.

- Governmental agencies that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration

The persons who may use your Protected Health Information include the researcher, Dr [*name of Principal Investigator*] and his/her research staff, the Institutional Review Board and its staff, legal counsel, audit and compliance staff, officers of UnityPoint Health – Des Moines [*and/or another entity as appropriate*] and other people who need to see the information to help the Study or make sure it is being done correctly. These persons may share your Protected Health Information with staff of the organizations listed in the next section.

What information about you can be shared in this research study?

In this section you must balance the information that you think you will need against a requirement to request authorization for only the information that is necessary to carry out the research. If you decide you need additional Protected Health Information after you start the study, then you will have to get a new authorization from every subject.

- Your name, address, telephone number, date of birth, Social Security number and other details about you.
- Your health history [*and your family health history*].
- Results of tests carried out to determine whether you can join the Study such as: [*List any information about the subject relevant to determining whether a person is eligible for the trial such as physical examinations, and blood and urine tests*].
- Results obtained during the Study: [*List relevant information that might be obtained during the Study such as response to the Study activities or procedures, information learned in Study visits, phone calls, surveys, physical examinations, blood and urine tests, x-rays and other tests and any other medical information the investigators may learn from the subject during the Study*]
- Information in your medical record at [*insert name of hospital or clinic as appropriate*] that may be necessary for your participation in the Study.
- [*List any additional information that may be obtained from participants that is not covered by the activities and procedures listed in the Consent Form. Examples might include information about financial and social circumstances, or educational level*]

Is your information protected after it has been shared with others?

If your health information is disclosed to someone who is not required by law to keep it confidential, then that information may no longer be protected, and it may be used or disclosed without your permission.

Insert the following statement if appropriate:

The Sponsor of the Study, [.....], has voluntarily agreed to be bound by the provisions of the Privacy Rule of the Health Insurance Portability and Accountability Act.]

Can you decide not to authorize the use and disclosure of your Protected Health Information?

Yes. You do not have to authorize the use or disclosure of your Protected Health Information. However, if you do not give this authorization, then you cannot participate in the Study. Your regular medical care will not be affected if you do not participate in this study.

Can you revoke your authorization?

Yes. You may revoke your authorization to allow your Protected Health Information to be used or shared at any time by sending a written notice to the principal investigator, Dr [name], [address] or the Institutional Review Board Office, 1200 Pleasant Street, Des Moines, IA 50309. If you cancel your authorization, you will be withdrawn from the Study and no health information about you will be gathered after that date. However, information gathered before that date may be used or shared if it is needed for the study or any follow-up for the study.

Can you see your Protected Health Information?

Yes. You may see and copy your information after the Study ends.

Does your authorization have an end date?

The authorization to use and share your Protected Health Information does not have an end date. Your Protected Health Information will be used as long as it is necessary for the Study.

Can your participation in the study end early?

Yes. There are three ways your participation can end early.

1. You can leave the study voluntarily. Being in this study is voluntary. You do not have to be in the study if you don't want to. You can agree to be in the study now and change your mind later. If you decide to drop out of the study, you will not be punished in any way. If you want to quit the study, you should talk to (*Principal Investigator*) or one of the study staff members. *When appropriate, include the consequences of a participant's decision to withdraw from the study.*

2. (*Principal Investigator*) or the sponsor can take you out of the study without your permission. Possible reasons for taking you out of the study are:

Enumerate possible reasons for involuntary withdrawal (eg - continuing in the study would be harmful; subject does not adhere to protocol instructions; adverse event; pregnancy; you become incarcerated after enrollment). If you become incarcerated, please notify the principal investigator or study nurse immediately.

3. The sponsor of the study may end the study early. The sponsor of the study may find all the sponsor needs to know sooner than expected, or the sponsor may find that research subjects are being harmed in ways that were not expected.

If your participation in the study ends early, we may ask you to visit the (*Principal Investigator*) for a final visit. (*Explain why this visit is necessary for the subject's welfare.*) At this visit we will: *enumerate any procedures required for the final visit.* Your regular medical care will not change if you leave the study early.

What about money?

Use the following statement if relevant to this protocol.

The principal investigator, Dr [name] and [name of institution] are being paid to conduct this study.

Tell subjects what charges they (or their insurance company) will be responsible for. Tell subjects what is provided to them free of charge.

Insert the following sentences if appropriate.

Your tissue or blood samples may be used to develop products that are commercially profitable to [insert name of entity. Include a statement about whether or not the subject will or will not share in the profit].

If you agree to be in the study, we will pay you [indicate amount] for study-related expenses.

The IRB prefers payments per visit instead of one large payment at the end of study participation. Payments should not be excessively large - any payments of > \$600/year are required to be reported to the IRS (subjects responsibility, but they should be notified of this in the consent form).

What happens if you are injured or harmed in this study?

Edit the following paragraph as appropriate to indicate where emergency care for a study might be made available.

If you are injured or harmed in this study, emergency care will be available through UnityPoint Health Des Moines. However, UnityPoint Health Des Moines does not have a policy to pay you if you are injured by being in the study.

If you are physically injured due to any substance or procedure properly given under the plan for this study, and you follow the directions of the study doctor and staff (*parameters can be given to what it means to follow instructions*), the sponsor will pay the medical expenses for the treatment of that injury which are not covered by your medical insurance, by a government program, or by any other third party.

No other payment is being offered by the sponsor; however, you do not waive any legal rights by signing this consent form.

Indicate who will pay for emergency care.

Add another paragraph if the sponsor supplies specific information about compensation

If you think you have been injured because of participating in this research study, you should call (*Principal Investigator*) at (*Principal Investigator's phone #*).

Alternate language if the study involves more than minimal risk: Call (*Principal Investigator's 24-hour number*) 24 hours a day for study-related emergencies.

If you are unsure whether something is serious, it is always best to seek emergency help immediately by calling 911 or going to the nearest emergency room.

Any more questions about this research?

If you have any questions about this study, you can call the Principal Investigator (*Name*) or a member of the study team at (*Principal Investigator's phone #*).

Concerns and complaints

If you have questions about your rights as a research subject or any concerns or complaints about this research project, please feel free call the Principal Investigator or a member of the study team at the numbers listed above.

If you would like to talk to someone who is not associated with the research, please feel free to call any of the following.

Research Subject Advocate	515-241-8598
UnityPoint Health – Des Moines Institutional Review Board Office	515-241-8598
Director of Corporate Compliance/Privacy Officer - UnityPoint Health - Des Moines	515-241-6039
UnityPoint Health – Des Moines Compliance HelpLine	1-800-548-8778

All calls will be kept confidential.

Required Signature Section

You are not giving up any legal rights by signing this form.

You will receive a signed copy of this form to keep.

For Adults Subjects Capable of Giving Consent & Authorization on their Own Behalf

I consent to participate in the research study described in this form

and

I authorize the use and disclosure of my Protected Health Information as described in this form.

Name of Subject:		
Signature:		Date:
Person Obtaining Consent and Authorization:		
Signature:		Date:

The signature block may be altered to include space for the investigator's name and signature if the sponsor requires this information to appear on this form.

The IRB discourages signatures by witnesses unless what is being witnessed - such as having verified the identity of the research subject - is clearly specified.

For Adult Subjects not Capable of Giving Consent & Authorization on the their Own Behalf

**I consent to the participation of [*subject*] in the research described in this form
and**

**I authorize the use and disclosure of [*subject*]'s Protected Health Information as described in
this form.**

Name of Subject:		
Legally Authorized Representative		
Relation of Representative to Subject:		
Signature of Representative:		Date:
Person Obtaining Consent and Authorization:		
Signature:		Date:

The signature block may be altered to include space for the investigator's name and signature if the sponsor requires this information to appear on this form.

The IRB discourages signatures by witnesses unless what is being witnessed - such as having verified the identity of the research subject - is clearly specified.

For Minor Subjects not Capable of Giving Consent & Authorization on the their Own Behalf

I consent to my child's participation in the research described in this form

and

I authorize the use and disclosure of my child's Protected Health Information as described in this form.

Name of Subject:		
Name of Parent or Legal Guardian:		
Relationship to Subject:		
Signature of Parent or Legal Guardian:		Date:
Person Obtaining Consent and Authorization:		
Signature:		Date:

The signature block may be altered to include space for the investigator's name and signature if the sponsor requires this information to appear on this form.

The IRB discourages signatures by witnesses unless what is being witnessed - such as having verified the identity of the research subject - is clearly specified.