Drexel University

Note: This document contains only the language requirements for the institution. It is not a complete template.

This institution has footer requirements, please see footer.

This institution is required to use a stand-alone HIPAA form. Do not include HIPAA in consent form(s). If there is HIPAA in consent form(s), remove it, and include confidentiality.

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Drexel University

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

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**RESPONSIBILITY FOR COSTS**

This language replaces sponsor’s language.

You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered “standard of care” and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these “standard of care” charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

You [will or will not] be charged for the study [drug or device] [the site will pick which one if either is involved].

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study.

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**COMPENSATION FOR RESEARCH RELATED INJURY**

This text replaces sponsors text - INDUSTRY-SPONSORED STUDY – Do not include in minimal risks research.

If you become ill during this study, please contact Dr. [name] at telephone no. (XXX) XXX-XXXX. If you require immediate medical attention, you should go to the nearest emergency room or call 9-1-1. It is important that you inform all emergency medical staff that you are participating in this study.

If a “research-related injury” results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A “research-related injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.

The university and hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

It is important for you to follow your physician’s instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

There are no plans to pay you for any other injury- or illness-related costs, such as lost wages. You are not waiving any legal rights by participating in this research study.

If you are injured or have an adverse reaction, you should also contact the Human Research Protection Program at 267-359-2471.