POLICY:
STATEMENTS REGARDING RESEARCH-RELATED INJURY

For studies that involve a foreseeable risk of harm, federal regulations (45 CFR 46.116) require that the consent process include “an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.” As the wording in consent forms is intended to inform subjects about studies, not to limit liability, the University of Chicago Biological Sciences Division IRB has set the following policy to ensure that all compensation for injury statements meet both Federal and Institutional standards.

A. COMMERCIAL SPONSOR STATEMENTS

It is the policy of the University of Chicago and the Medical Center that commercial sponsors of clinical research at the Medical Center must agree to pay for treatment of injuries that are the direct result of the administration of a study drug or device, or any study procedure required to be performed in the study. This obligation of commercial sponsors is limited to research protocols designed or supplied by the commercial sponsor. The University and the Medical Center’s obligations for treatment of research injuries, as expressed in the language below and in Medical Center’s Policy on Research-Related Injuries, will be secondary to the commercial sponsor’s obligations under the clinical trial or other sponsored research agreement. University Research Administration is responsible for implementation of this requirement in commercially-sponsored research agreements.

The obligations of commercial sponsors to subjects who suffer a research-related injury must be expressed in the “What Are the Costs” section of the written consent form using the following language, which should immediately precede the applicable statement concerning the Medical Center’s obligations discussed in Part B. below:

The sponsor of the study, [insert sponsor name], has agreed to pay for the care of certain injuries directly resulting from this research. If you think that you have suffered a research-related injury, you must contact [insert PI/study doctor name] right away. The study doctor can help you obtain more information about the sponsor’s agreement to pay for research-related injuries.

Exceptions to this consent form language may be considered by the IRB, in consultation with legal counsel, on a case by case basis if requested by the commercial sponsor, but are not looked on favorably, and must satisfy the requirements of the Medical Center’s Policy on Research-Related Injuries.
**B. UNIVERSITY/MEDICAL CENTER STATEMENTS**

One of the following University of Chicago BSD/University of Chicago Hospitals statements must be included (without any modifications) in the “What Are the Costs” section of the written consent form, immediately following the commercial sponsor statement described in A. above (if applicable). **The appropriate statement should be chosen based upon the subject population being recruited.** The IRB recognizes that for studies that recruit both individuals with a disorder and condition and healthy controls, the use of both statements may be required. However, a separate consent form should be drafted for each of the populations with the appropriate costs statement included.

1. **For studies with therapeutic intent for the subject (including Phase I and II trials):**

   If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify ___________ [insert PI/study doctor name] as promptly as possible after your injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you, your insurance [or the study sponsor1] in the ordinary manner. If you think that you have suffered a research-related injury, you must let ____________ [insert PI/study doctor name] know right away.

2. **For studies involving healthy volunteers:**

   If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify ___________[insert PI/study doctor name] as promptly as possible after your injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research-related injury, you must let __________ [insert PI/study doctor name] know right away.

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1 Include only if study is commercially sponsored and the sponsor designed or supplied the protocol.