Hackensack Meridian *Health*

Hackensack Meridian *Health* Clinical Trial Agreement Requirements

Overview

Thank you for your interest in conducting research at one of Hackensack Meridian Health's (HMH) research entities. As a not-for-profit health care provider, HMH is the regional leader in providing innovative and accessible health care programs and services to individuals, families, and communities throughout Bergen, Hudson, Essex, Monmouth and Ocean counties. As part of HMH's mission to provide world class patient care and further medical research, HMH supports research with pharmaceutical, medical device and biotech companies. The purpose of this document is to provide industry sponsors with guidance regarding HMH's requirements with respect to certain provisions in a standard clinical trial agreement.

Subject Injury Coverage

HMH requires sponsor re-imbursement coverage for the cost of treating injuries arising from a human subject's participation in a clinical trial. Coverage may be reduced to the extent the injury is not caused by the study drug, device or protocol required procedures.

Indemnification and Insurance

Industry sponsors are required to defend, indemnify and hold HMH harmless from claims, investigations, damages and other losses arising from the conduct of the clinical trial. Defense and indemnification obligations, however, may be reduced to the extent a claim, investigation, damage or loss is determined to be the result of HMH's negligence. HMH does not offer a mutual indemnification to industry sponsors. Additionally, HMH also requires sponsors to carry sufficient levels of insurance to support sponsor obligations, such as indemnification and subject injury, under the clinical trial agreement.

Human Research Protection Program

Pursuant to HMH's Human Research Protection Program, clinical trial agreements are required to include language which obligates sponsors to promptly inform HMH of serious study related events that could pose risks to human research subjects in a clinical trial; develop a plan of communication to provide HMH with information of new findings or results which might impact the willingness of human subjects to participate in a clinical trial; and provide HMH with relevant study safety information for a certain period of time after the clinical trial has been terminated.

Publication of Study Results

The ability to timely publish research results is a key principle of academic freedom. Accordingly, HMH clinical trial agreements must contain publication clauses which allow HMH to publish research and study data results within a reasonable amount of time after the termination of the clinical trial. However, reasonable restrictions, such as a limited period of time for sponsor review of the publication for patent protection, are permissible.

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Confidential Information
In general, HMH may agree to confidential information provisions which restrict or prohibit the disclosure of sponsor and study related information, provided the non-disclosure obligations are not overly restrictive, contain standard exceptions and a term after which the non-disclosure period expires.

Intellectual Property
Standard clinical trial agreements with industry sponsors should provide HMH with royalty free license rights to study data generated by the clinical trial, as well as ownership rights to intellectual property generated by HMH as a result of the clinical trial which was not anticipated by the sponsor's protocol.

Governing Law
The law of the State of New Jersey must be included in standard clinical trial agreements as the law which will govern the agreement. Any suits or actions between the parties arising under the clinical trial agreement must also be brought in the courts of the State of New Jersey. In the alternative, the parties may stay silent on the issue of governing law and venue. HMH, however, may not agree to the law of, or venue in, another jurisdiction.

Compensation
Sponsors are required to provide sufficient funding to cover the full cost of the clinical trial, including HMH's indirect overhead rate and startup costs.

Use of Name
Unless required by law, sponsors are not permitted to use the name of HMH for any reason, including for any promotional or marketing purposes, without the written permission of HMH.