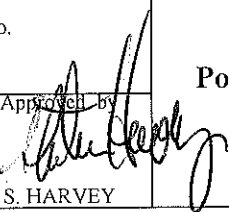


FINANCIAL MEMORANDUM

Memorandum No.	ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI Policy: Sponsor Payment for Costs Related to Subject Injury in For-Profit Sponsored Clinical Trials	Page
Approved by  S. HARVEY		Date Issued/Amended Replaces 11/10/17

The purpose of this memorandum is to set forth the guidelines allocating subject injury payment responsibility to for-profit sponsors who are sponsoring clinical trials that involve more than minimal risk.

Background:

The FACTS department is responsible for the review, negotiation and execution of commercial, for-profit sponsored clinical trial agreements along with reviewing ICF for consistency between both documents.

Regulatory Requirements:

For research involving more than minimal risk, federal regulations require that the informed consent documents inform patients whether medical care will be available if an injury or illness occurs as a result of their participation in the research.

Icahn School of Medicine at Mount Sinai (ISMMS) has adopted the position that for-profit sponsors must accept responsibility for the payment for all complications and/or injuries sustained by study subjects as a result of their participation in research.

Medicare Secondary Payer Rule:

Pursuant to 42 U.S.C. §1395y (b)(2)(A), the Centers for Medicare & Medicaid Services (CMS) will not pay "[if] payment has been made... or can reasonably be expected to be made... under a liability insurance policy or plan..." Liability insurance refers to insurance...that provides payment based on legal liability for [an] injury or illness... Furthermore, according to CMS "payments [that] are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance... and must be reported."

Procedure:

For studies that are initiated by a for-profit sponsor, FACTS, which negotiates these agreements, requires the for-profit sponsors assume responsibility for the reasonable costs of medical treatment for injuries directly resulting from participation in the study. This policy does not allow the billing of Medicare, Medicaid or third party insurance companies in lieu of recovery of such costs from the for-profit sponsor, nor does it allow restricting participation of human subjects on the basis of medical insurance coverage status or on the participant's ability to pay.

ISMMS will not agree to contractual provisions that condition the for-profit sponsor's payment responsibility, of research-related subject injury costs, on whether those costs are or are not covered by Medicare, Medicaid or a third party insurance company.

This position reflects our understanding of the April 2004 CMS interpretation of the Medicare regulations (referred to as the Medicare Secondary Payer Rule). Specifically, it is our understanding that CMS has interpreted the regulations to render the for-profit sponsor the primary payer even if the for-profit sponsor (in this case, a trial sponsor) takes the position that its benefits are secondary to Medicare, Medicaid or third party insurance companies. Accordingly, even if the contract were to provide that the for-profit sponsor's responsibility to cover research-related injury costs was secondary to Medicare, CMS considers the for-profit sponsor as the primary payer and Medicare the secondary payer. This means that the costs cannot be billed to Medicare, Medicaid or third party insurance companies. To comply with the regulations and for the sake of clarity, ISMMS will require that for-profit sponsors agree to pay for subject injury costs (related to the company product and/or a properly performed procedure) in all studies where the protocol is (for-profit)-sponsor initiated.

Revisions to Informed Consent Template:

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

[For protocols involving greater than minimal risk that are Sponsor Initiated(For-Profit) , add:] If you are injured or made sick from taking part in this research study, medical care will be provided. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury or illness.

This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

Delete: Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.