

**Emory University Office of Sponsored Programs
Policy on Sponsor Payment for Costs Related to Subject Injury in Clinical Trials**

Responsible Official: VP for Research Administration

Administering Division/Department: Office of Sponsored Programs

Effective Date: November 1, 2009

Last Revision: New Policy

Policy:

Defined Term:

- (1) “Subject Injury Costs”: As used in this policy, the term “Subject Injury Costs” are the costs that a subject in a study must pay for medical treatment for illness or injury that directly results to the subject from his/her participation in the trial.

Background and Regulatory Requirements:

- (1) A commercial sponsor of a clinical trial is not legally required to volunteer to pay Subject Injury Costs for any participant in a clinical trial. A commercial sponsor of a clinical trial may choose to pay for these costs.
- (2) The U.S. Veterans Administration is required by law to provide medical treatment for subjects who are injured in clinical trials conducted under its regulations.
- (3) Medicare requires that if the sponsor of clinical trial chooses to pay Subject Injury Costs for a clinical trial participant who has Medicare, then the study sponsor must be treated as the primary payer for those costs. Emory University has implemented this requirement as follows: Emory University will not agree to initially bill Medicare/Medicaid for any costs associated with an illness or injury incurred as a direct result of participation in clinical trial by a subject who has Medicare/Medicaid, and then bill the Sponsor for what Medicare/Medicaid does not pay.
- (4) Medicare requires that Medicare beneficiaries who participate in a clinical trial receive at no charge the same items or services that any other non-Medicare beneficiary in the trial receives at no charge. This requirement prohibits a sponsor from paying subject injury costs only for uninsured participants. Emory University has implemented this requirement as follows: Emory requires that a sponsor that pays for subject injury costs for uninsured persons also must pay these same costs for Medicare/Medicaid beneficiaries.
- (5) Emory does not generally agree to pay medical expenses for subject illness or injury that results from a subject’s participation in a trial.

Options Regarding the Structure of Clinical Trial Agreements and Informed Consent Forms with Respect to Sponsor Payment for Subject Injury:

OPTION 1: The sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

OPTION 2: The sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

OPTION 3: The sponsor may choose to pay for Subject Injury Costs for uninsured subjects or subjects with Medicare/Medicaid and to pay any part of Subject Injury Costs for privately insured subjects that are not covered and/or paid by their private insurance.

Option Selection and Wording of Clinical Trial Agreement and Informed Consent Documents:

- (1) A sponsor who wants to enter into a clinical trial agreement with Emory must select one of the foregoing OPTIONS with respect to the manner in which payment for Subject Injury Costs will be handled under such agreement. No other options are available.
- (2) The wording of the clinical trial agreement and the informed consent form for a clinical trial must be consistent, e.g., if the clinical trial agreement says that the Sponsor will not pay for Subject Injury Costs, then the informed consent must tell that subject that the Sponsor will not pay and that the subject must pay these costs.
- (3) The clinical trial agreement should be compared to the informed consent form that is approved by the IRB to ensure that the language between the two documents is consistent. If the language is inconsistent, one of the documents should be modified appropriately to reflect the agreement of the parties.
- (4) In the event of an inconsistency between an executed contract and executed informed consent, the following rules apply: (a) the subject should not be required to pay for any costs that were not listed as being the subject’s responsibility in the informed consent; and (b) the subject should not be charged for any cost that the sponsor agreed to pay because this may result in inadvertent double-billing.

Related Links:

Current Version of this policy is at the following website: _____

Contact Information:

Subject	Contact	Phone	Email
Questions Re. Policy	Director, Office of Research Compliance	(404) 727-2398	orc@emory.edu

Revision History:

None.