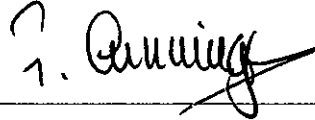


**Brody School of Medicine
East Carolina University
Policies and Procedures**

Topic: Research Related Injuries. Previously #A30, Section 1, Administrative and clinical operations

Original approval date: 04/20/2003

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Paul R. G. Cunningham, M.D. Dean

I. Purpose:

The purpose of this policy is to set forth how East Carolina University will protect individuals who volunteer as participants in human research from being held financially responsible, either personally or through third party payers, for healthcare costs arising out of a research-related injury or illness.

II. Policy:

Study sponsors are responsible for the healthcare costs for direct and unambiguous injury from interventions, drugs, devices, tests, or procedures to which human participants would not normally have been exposed had they not volunteered in a research study.

East Carolina University (ECU) will accept contracts from for-profit, commercial and/or industry entities that sponsor human research activities **only** when the sponsor assumes full responsibility for the reasonable healthcare costs related to direct and unambiguous research-related injuries to participants when the protocol was designed by the sponsor.

This policy does **not** apply to those human research activities supported or sponsored by federal agencies (such as DHHS, NSF), public or private non-profit agencies (such as foundations), cooperative group research that does not involve industry financial support, or entities that are State or privately funded educational institutions.

III. Definitions:

- A. Direct and unambiguous injury: physical injury or illness caused by the use of interventions, drugs, devices, tests or procedures required by the protocol which cannot reasonably be attributed to the participant's underlying medical condition or other, non-research related therapies.
- B. Participant: an individual, whether healthy or a patient, who volunteers to take part in a research activity or clinical investigation; a study volunteer.
- C. Research-related injury: direct and unambiguous injury which occurs as a result of an intervention, drug, device, test or procedure to which a human participant would not have been exposed had he/she not volunteered in a research study. "Research-related injury" does not include (1) the normal progression of any pre-existing diseases or conditions (2) injuries or illnesses caused by the negligence or misconduct of ECU or its agents, or (3) injuries or illnesses caused by the failure of ECU or its agents to follow the protocol or written instructions provided by the sponsor or on behalf of the sponsor.
- D. Sponsor: entity that provides financial or resource support to conduct human research activities.

IV. Responsibilities:

- A. It is the responsibility of the sponsor, at a minimum, to cover the reasonable costs associated with medical care necessary to treat direct and unambiguous injuries that result from a research-related activity. This responsibility will be reflected in all clinical trial agreements or research contracts between ECU and for-profit, commercial, and/or industry sponsors, or the clinical research organization hired by such sponsors to enter contracts on their behalf. Where a Master Agreement is in place, this language may also be reflected in a letter of intent, or indemnification, which will outline the extent of the commitment, signed by an authorized representative of the sponsor.
- B. It is a requirement of both the Principal Investigator and the Sponsor to ensure equitable selection of participants which does not restrict enrollment into a research activity based on the potential participant's healthcare coverage status or an individual's ability to pay.
- C. It is the responsibility of the Principal Investigator and the Sponsor to ensure that informed consent document(s) adequately describe who is responsible for costs associated with medical care necessary due to a research-related injury.
- D. It is the responsibility of the Principal Investigator to ensure that all Sponsors are made aware of this policy and that subsequent clinical trial agreements and research contracts involving humans accurately reflect this policy.

V. Exceptions

Exceptions to this policy will be allowed under the following conditions:

- A. Humanitarian Use Devices (HUD);
- B. Investigator –initiated studies where the protocol is designed and written by the investigator but a for-profit, commercial and/or industry sponsor provides drug, device, biologic, intervention materials and/or financial support;
- C. Aftermarket research activities where the drug, device, biologic, or intervention has been approved for the use intended in the activity; or
- D. Research activities that involve non-experimental/investigational (Category B) devices or Class I, II, or IIIb devices (which are similar to approved devices but contain minor modifications) that have been approved for payment by the Medicare Administrative Contractor (MAC)¹.

VI. Procedures

- A. For all industry, for-profit, or commercially sponsored trials of drugs, devices, biologics or other investigational interventions subject to this policy, provisions for healthcare costs related to research-related injury which involve third party payers are allowable only if all the following conditions are met:
 - 1. Participation in the study is not predicated on availability of third party coverage;
 - 2. Sponsor responsibility is not predicated on submission of claims to third party insurers; and
 - 3. Informed Consent process and documents clearly include language that:
 - i. identifies the responsibilities for which third party payers will be billed;
 - ii. what costs participant may incur costs associated with additional co-payments, deductibles, etc.; and

¹ Currently Palmetto Government Benefit Administrators (PGBA)

- iii. that the participants' life-time limits of medical coverage may be affected.
- B. All business decisions and any written agreements will be fully executed prior to the implementation of any of the IRB approved procedures, including participant identification, recruitment, advertisement, etc.
- C. The IRB has the authority to grant special exceptions to this policy, under only exceptional circumstances, as follows:
 - 1. The potential for direct benefit to the research participants is not otherwise available; and/or
 - 2. Due to the condition being studied, there is a documented likelihood of serious morbidity or mortality unless the investigational treatment is offered.

VII. Business decisions

- A. Financial solvency when conducting a research activity is not an IRB issue.
- B. When considering a proposed research activity, the investigator and appropriate administrative individuals should consult on budget issues before the investigator agrees to:
 - 1. Accept the contract;
 - 2. Submit the proposed research activity through e-PIRATE; and
 - 3. Commit the University and its affiliates to any research activity through verbal or written agreement.
- C. Should the IRB determine that one of conditions for approval involves a business decision which is beyond its scope of authority, the IRB will refer that business decision to the appropriate Dean and Vice Chancellor for consideration. The IRB approves research activities based only on ethical considerations as set forth by the federal regulations, state laws, and institutional policies.
- D. Decisions cannot be made by other entities or committees to approve a study for which the IRB has voted to disapprove.

References

Belmont Report
Association of American Medical Colleges
Institute of Medicine Report
Presidential Commission on the Study of Biomedical Issues