



UNIVERSITY POLICY

SUBJECT: ACADEMIC AFFAIRS

TITLE: HUMAN RESEARCH SUBJECTS:
MEDICAL CARE

CODING: 00-01-20-85:00

ADOPTED: 07/01/87

AMENDED: 05/07/99

I. PURPOSE

To set policy concerning medical care for human subjects who sustain physical injury or illness as a direct result of research conducted under the auspices of the University.

II. ACCOUNTABILITY

Under the direction of the Senior Vice President for Academic Affairs, the Deans and the Vice Presidents of the patient care units shall ensure compliance with, and the Research Deans shall implement this policy.

III. APPLICABILITY

This policy applies to all research involving human subjects except those categories of research that are specifically exempted in 46.101(b) of Part 46 of Volume 45 Code of Federal Regulations (45 CFR Part 46), Subpart A, "Protection of Human Subjects."

IV. POLICY

A. The University shall comply with all the provisions of 45 CFR Part 46, Subpart A. In accordance with section 46.116 of these regulations and allowing for the potential exceptions provided for in paragraphs (c) and (d) in this section, the following policies shall apply to all human subjects participating in research involving more than minimal risk of harm:

1. For those human subjects who sustain physical injury or illness as a direct result of participation in a research project conducted under the auspices of the University, the Principal Investigator of the research project shall take the following actions:
 - a. arrange for the hospital admission and/or outpatient treatment of the injured subject which shall take place, if practicable, at a University-owned or University-affiliated patient care unit.
 - b. immediately notify the Research Dean, the Dean, the Vice President of the patient care unit, and the IRB Chair.
2. The Research Dean, in consultation with the Dean and the Vice President of the patient care unit, shall arrange for a review to determine whether the injury or illness is the direct result of participation in the research. The review may be accomplished by two or more independent assessments by faculty members appointed by the Dean. These faculty shall not have any involvement with the research in question but may be

members of the IRB that reviewed and approved the original research protocol. Whenever possible, i.e., in non-emergency situations, this review shall take place prior to hospitalization and/or outpatient treatment of the subject.

The Research Dean shall inform the Dean and the Vice President of the patient care unit, the IRB Chair, the Senior Vice President for Academic Affairs, and the Director of the University's Office of Risk and Claims Management about the results of this review, and about the hospitalization and/or outpatient treatment of the injured subject.

3. Third-party payers, if any, shall always be billed first for the costs of the hospitalization and/or outpatient treatment provided to those subjects who sustain physical injury or illness as a direct result of participation in a research project.
4. For research designed to test an investigational practice (diagnostic, therapeutic or preventive drug or device) where there is an industrial sponsor (such as a pharmaceutical company), the Principal Investigator is required to obtain from the sponsor a written statement:
 - (a) indemnifying and holding harmless the researchers, the University, and the University's employees and agents in the event of injury or illness in a research subject as a direct result of participation in the research protocol, and
 - (b) stipulating that the sponsor shall reimburse the University for any and all reasonable and necessary medical and/or dental expenses incurred by research subjects taking part in the protocol which are due to injury from the research set forth in the protocol, but
 - (c) excepting situations where the injury results from negligence by the University, its employees or agents; where there is malfeasance by the University, its employees or agents; and when there is deviation from the research protocol.

The Research Deans shall ensure that such statements are obtained before the research may commence.

- B. All consent forms provided to research subjects participating in research involving more than minimal risk shall contain the following information:

1. For research on normal healthy volunteers:

"Participants in this study will be exposed to certain risks of physical injury, which include:" (provide a complete description if not provided elsewhere in the consent form, or refer reader to appropriate section of form). **"In addition, it is possible that during the course of these studies, new adverse effects of"** (fill in name of drug, device, procedure, etc.) **"that result in physical injury may be discovered. Medical and/or dental treatment will be arranged by UMDNJ for participants who sustain physical injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment. No additional financial compensation is available."**

Any exception to this statement must be approved by the Dean, the Vice President of the patient care unit and the Director of Risk and Claims Management.

2. For research on patients with a disease or medical condition:

"Participants in this study will be exposed to certain risks of physical injury in addition to those associated with standard forms of treatment, which include:" (provide a complete description if not provided elsewhere in the consent form, or refer reader to appropriate section of form). **"In addition, it is possible that during the course of these studies, new adverse effects of"** (fill in name of drug, device, procedure, etc.) **"that result in physical injury may be discovered. Medical and/or dental treatment will be arranged by UMDNJ for participants who sustain physical injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment. No additional financial compensation is available."**

Any exception to this statement must be approved by the Dean, the Vice President of the patient care unit and the Director of Risk and Claims Management.

3. For single-patient-treatment/compassionate-use protocols:

"Participants in this study will be exposed to certain risks of physical injury in addition to those associated with standard forms of therapy, which include:" (provide a complete description if not provided elsewhere in the consent form, or refer reader to appropriate section of form). **"In addition, it is possible that during the course of these studies, new adverse effects of"** (fill in name of drug, device, procedure, etc.) **"that result in physical injury may be discovered. Medical and/or dental treatment will be arranged by UMDNJ for participants who sustain physical injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment. Any costs not covered by the insurance carrier or other third-party payer will be solely at the expense of the subject. No additional financial compensation is available."**

Any exception to this statement must be approved by the Dean, the Vice President of the patient care unit and the Director of Risk and Claims Management.

By Direction of the President:

Vice President for Academic Affairs