Procedure

Subject: Procedure for Compensation for Medical Treatment if Injury Occurs During Participation in Research

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This procedure provides guidance for compensation or medical treatment if injury occurs while participating in research conducted at VU, VUMC or by VU and VUMC investigators as part of their institutional responsibilities.

I. Investigator Responsibilities.
   A. The Investigator will insert VUMC template language into Item # 6 of the informed consent document template regarding immediate necessary care for adverse events or injury. The informed consent template language is located on the HRPP website at http://www.mc.vanderbilt.edu/irb/.
   B. The Investigator will also incorporate the appropriate template language choice for compensation of the costs associated with immediate necessary care as follows:
      1. For all applications approved prior to adoption of this policy and for all studies with no benefit to human participants (normal volunteers) and some studies funded by federal departments, NIH, or other federal agencies for which no adverse event treatment funds are available from the sponsors, the following language preferably should be included in the consent document, unless specifically waived by the IRB: "If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred as a direct result of the tests or treatments that are done for research, they you and/or your insurance will not have to pay for the cost of immediate and necessary care provided at Vanderbilt to treat your injury. There are no plans for Vanderbilt [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury."
      2. For research sponsored by the Department of Defense, the following compensation language is required:
         "If you are hurt or get sick because of this study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the Principal Investigator for this study, (insert name and phone number here). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the Principal Investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Material Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221."
   C. The Investigator will provide the IRB with a copy of the contract page that includes the indemnification language or the injury clause agreed upon by the institution and the sponsor of the research, if applicable.
II. IRB Committee Responsibilities.
A. The IRB will review and approve the proposed compensation and injury language as a part of the new study submission.
B. The IRB will render its determination for approval of compensation or medical treatment for medical injury as follows:
   1. The IRB will verify that the template language for injury is contained in Item #6 of the informed consent document.
   2. The IRB will verify that the compensation language is congruent with the sponsor’s contract as approved by the Office of Research (Research Contracts) or, on campus, the Division of Sponsored Research, if applicable.
   3. The IRB will review the injury language to assure readability and understandability in relation to the proposed target study population.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA will review the informed consent documents verifying that the IRB template language for immediate necessary care is detailed in Item #6 of the informed consent document.
B. The RCA will verify that a copy of the sponsor’s agreement regarding compensation for injury while participating in a specific research activity has been submitted as part of the initial submission packet for review and approval by the IRB. If the copy is not included, the RCA will notify the Investigator and obtain the necessary copy.
C. The new study may be scheduled for IRB review without the contract language. However, the study cannot receive final approval until the contract is received by the IRB and the injury language in the consent document is verified to be congruent with the sponsor’s contract language.