Responsibility for Payment of Costs Associated with Subject Medical Injury in Industry-Sponsored Clinical Trials

Subject: Options for liability of costs for treatment of subject medical injury caused by participation in industry initiated and sponsored clinical trials or clinical studies

Defined Term: “Subject Injury Costs”: As used in this document, the term “Subject Injury Costs” are the costs incurred by UAB for the immediate medical treatment for illness or injury that occurs as a direct result of the tests or treatments provided to a subject as a part of his/her participation in a clinical trial or study.

UAB Position Statement: UAB expects sponsors of industry-initiated and sponsored studies to select one of the options below with regard to responsibility for payment of costs associated with Subject Medical Injury.

Option A: The sponsor will pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

Option B: The sponsor will pay for Subject Injury Costs for uninsured subjects or subjects with Medicare, Medicaid, Tri-Care or Champus (any federal payer) and to pay any part of Subject Injury Costs for privately insured subjects that are not covered and/or paid by their private insurance.

Basis: Center for Medicare and Medicaid Services (CMS) has documented that a Sponsor’s agreement to pay for costs to treat research related injury “if insurance denies” triggers the Medicare Secondary Payer rules in which case CMS states that the sponsor is responsible for payment for costs to treat injury, not Medicare.

UAB Process:

- If the industry sponsor will not agree to pay for Subject Injury Costs in the clinical trial agreement, the Principal Investigator of the study is responsible for working with the Clinical Trials Office Administrative Director to develop an agreement with UAB Hospital stating that any Subject Injury Costs will be paid by the PI or his/her Department/Division/Center at the UAB Health System established research rates.
- This agreement will be documented in a Memorandum of Understanding signed by the Principal Investigator, the Chair of the applicable Department, the Dean of the School of Medicine and a representative of UAB Hospital.

Richard Marchase

Selwyn Vickers

Will Ferniny

Policy/Guidance References:

- Compliance Advisory: Meade & Roach, LLP, CMS Issues Clinical Trials MSP Instruction, July 2010
- CMS' 2004 Informal Position in the "Lutz Letter"; CMS views clinical trial sponsor's agreement to pay "if insurance denies" as a plan or policy of insurance under which payment can reasonably be expected to be made in the event such injury occurs.
- 42 C.F.R. Section 411.50: Medicare is secondary to any liability insurance plan that is required or responsible to pay based on "legal liability for injury or illness or property damage."