

**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.

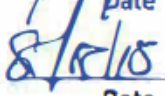
**Basis:** Center for Medicare and Medicaid Services (CMS) has documented that a Sponsor's agreement to pay for costs to treat research related injury "if insurance denies" triggers the Medicare Secondary Payer rules in which case CMS states that the sponsor is responsible for payment for costs to treat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

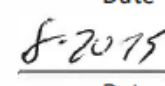
  
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**Policy/Guidance References:**

- Journal of Clinical Research Best Practices, Vol 9, No. 7, July 2013
- 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."