

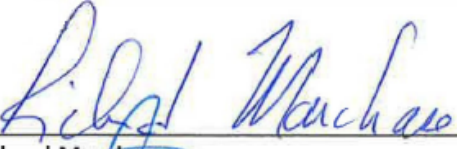

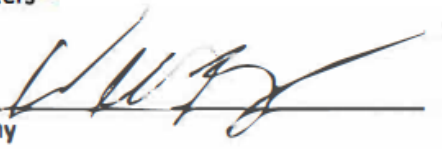
Responsibility for Payment of Conventional or Routine Care in Clinical Trials

Subject: Responsibility for payment of conventional or routine care (e.g. items or services the participant would have received absent a research study) provided to study participants in research studies

UAB Position Statement: UAB cannot accept a sponsor's offer to pay for or provide items or services (including category B devices) identified as conventional or routine care "if insurance denies or if the service is not covered by insurance".

Acceptable Sponsor Language: The sponsor understands/expects that all items and services identified as conventional or routine care will be billed to the patient/patient's insurance. The sponsor will provide no payment for these items and services.

Basis: CMS (Center for Medicare and Medicaid Services) rules require that CMS study participants and non-CMS participants be treated consistently with respect to items/services paid for or provided at no cost by the clinical trial sponsor. For example, we can't provide a category B device at no charge for a Blue Cross patient and bill the device to insurance for a Medicare patient. The only exception to this position is for patients who are determined to be indigent based on UAB's charity care application process. For patient's meeting this exception, the sponsor would be allowed to pay for their conventional care items and services.

 Richard Marchase	<u>8/18/15</u> Date
 Selwyn Vickers	<u>8/18/15</u> Date
 Will Ferniany	<u>8-20-15</u> Date

Policy/Guidance References:

- Meade and Roach, Compliance Advisory: CMS Clarifies Medicare Coverage for Research Services, October 2008
- CMS Clinical Trial Policy
<https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html>
- CMS MLN Matters SE0822 (1/9/09)