

**UAB OFFICE OF THE VICE PRESIDENT
FOR RESEARCH**

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MEMORANDUM

TO: Clinical Trial Collaborators

DATE: June 11, 2020

RE: Subject medical injury position statement

It is the position of the University of Alabama at Birmingham (UAB) that an individual participating in research shall not be held responsible for the cost of treating illness or injury caused by participation in industry-initiated and sponsored clinical trials or studies at UAB.

It is UAB's position that the commercial sponsor of a clinical study should take responsibility for the cost of treating research injuries caused by that sponsor's drug, device, or protocol. These obligations are described in the relevant clinical trial agreement. It is understood that the detailed and highly nuanced language contained in a contract (e.g., Clinical Trial Agreement) regarding this subject may vary from study to study. For example, a sponsor may desire to clarify their responsibility should not extend to injuries resulting from negligence of UAB. The contract, as the document setting forth the legal obligations between UAB and the sponsor, is the appropriate vehicle to parse out such distinctions.

The informed consent document plays a different role. Amongst other things, it is meant to convey UAB's subject medical injury position statement to individuals who are considering participation in a clinical trial. To this end, UAB's Institutional Review Board has adopted uniform informed consent language for industry-initiated and sponsored clinical trials or clinical studies consistent with UAB's position on subject medical injury. This language is not subject to modification at the request of a sponsor on a study-by-study basis, as UAB's commitment to individuals participating in research does not change on a study-by-study basis.

Sincerely,

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Christopher S. Brown
Vice President for Research

cc: Melinda Cotten, Assoc VP for Research Business Operations
Jason Nichols, Assoc VP for Research Engagement and Partnerships
Jonathan Miller, Asst VP for Research Regulatory Oversight
Adam McClintock, Director, Office of the Institutional Review Board