

Human Research Protections Program - HRPP
Supporting the work of the IRB and Providing HRPP Oversight



December 23, 2024

MEMORANDUM

To: Clinical Trial Collaborators

Re: Effect of Vanderbilt's subject injury policy on the informed consent

Vanderbilt University Medical Center's position is 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 spelled out in the relevant clinical trial agreement. It is understood that the detailed and highly nuanced language contained in a contract regarding this subject may vary from study to study. For example, a sponsor may desire to clarify that their responsibility should not extend to injuries to the extent resulting from the negligence of Vanderbilt University Medical Center or routine care procedures. The contract, as the document setting forth the legal obligations between Vanderbilt University Medical Center and the sponsor, is the appropriate vehicle to parse out such distinctions.

The informed consent form plays a different role. It is meant to clearly convey Vanderbilt University Medical Center's subject injury policy to its patients who are contemplating whether or not to participate in a clinical trial. To this end, Vanderbilt University Medical Center's IRB has adopted uniform language in its consent templates consistent with Vanderbilt University Medical Center's policy on subject injury. This language is not subject to modification at the request of a sponsor on a study-by-study basis as Vanderbilt University Medical Center's commitment to its patients does not change on a study-by-study basis. Since the informed consent form represents an understanding between Vanderbilt University Medical Center and its patients, the handling of any financial gap between the subject injury protection provided by a sponsor through the clinical trial agreement and that set forth in the informed consent form would be a matter solely between Vanderbilt University Medical Center and its patient.

Sincerely,

A handwritten signature in blue ink that reads "Wesley H. Self".

Wesley H. Self, MD, MPH
Senior Vice President for Clinical Research
Vanderbilt University Medical Center