

Compensation for Research-Related Injury

Policies

Business Policy Manual: [BPM-210](#), Sponsored Programs

Forms

None

Overview

It is the policy of the Office of Research, University of Missouri, that all commercial, for-profit sponsors contracting with the University to conduct research trials involving human subjects agree to include statements in the relevant clinical trial agreement (CTA) and in the informed consent form (ICF) that the sponsor assumes liability for and will pay all injuries to research subjects due to the test drug, device, or methodology.

Sponsor may elect to include exculpatory language exempting injury attributable to the negligence of University faculty, staff and students, failure to follow study protocol, pre-existing medical conditions, and the like. Examples of acceptable carve-outs include:

- Failure of institution, the investigator or any other study personnel to adhere to the terms of the study protocol or any written instructions (including, without limitation, package inserts, where appropriate) relative to the use of any product(s) used in the performance of the study, or comply with applicable FDA or other governmental requirements
- Any negligent or wrongful act of omission, or willful malfeasance, of institution, the investigator or any other study personnel
- The study subject's primary disease or any concurrent disease not caused by the administration of the study drug in accordance with the protocol
- The study subject's failure to comply with instructions contained in the ICF executed by such subject or communicated to the subject by study personnel

The intent of this directive is to ensure that the pecuniary liability for research subject injury is borne by the commercial/for-profit sponsors of such research and not the University.

Need Help?

Contact OSPA at muresearchospact@missouri.edu or 882-7560.

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