

Common Contract Issues in Clinical Trial and Other Sponsored Research Agreements

Contracting Party	The University of Louisville Research Foundation, Inc. (ULRF) is the legal entity which executes sponsored research agreements for the University of Louisville. ULRF is a limited agent for the University for the purpose of receiving grants and research agreements from external funding sources.
Indemnification by the University and by Respective Hospital/Facility Sites	Kentucky law does not permit the University to indemnify or hold harmless another party. Negligence claims against the University are subject to the Kentucky Board of Claims (KRS 44.070 et. seq.) The hospital/facility sites will not indemnify the CRO or Sponsor (nor provide cross-indemnification.)
Governing Law	Claims against the University must be brought under the Kentucky Board of Claims Act so we cannot be bound by another state's laws or agree to the jurisdiction of another state's courts. However, we can agree to leave the contract silent on governing law/choice of law.
Arbitration	The University cannot agree to binding arbitration, but we can agree to other alternative dispute resolution processes.
Warranties	The University generally does not provide warranties. Alternative promises are acceptable, such as to promise, represent, certify or agree.
Interest on Late Payments	The University is bound by the Kentucky prompt payment statute which allows for recovery of interest on late payments.
Intellectual Property, Options, Licenses	<p>University intellectual property (IP) rights are governed by Bayh-Dole Act and the University's Intellectual Property policy. Rarely can the University assign or exclusively license intellectual property in advance of its creation. The University can assign ownership in specific work products (e.g. reports) generated as a result of the research, but not the underlying technology or tools. If IP has had any federal funding, the U.S. has non-exclusive rights by law. The IRS has ruled such advance licensing may violate a University's non-profit status. Because of these complications, the University's preference is to grant exclusive options for licenses on terms customary in your industry.</p> <p>In the case of multi-center, industry sponsored, industry created protocols, the University will assign IP to the sponsor for any IP created by the University's conducting the study in accordance with the protocol.</p>
Publication Rights	<p>University researchers and their students need the ability to use data and other research work product for non-commercial educational and research purposes and the right to independently publish. This right can be provided under license, can be limited by a Sponsor's right of review or can be delayed for a short period to permit the protection of IP rights.</p> <p>In the case of multi-center, industry sponsored, industry created clinical trial protocols, the University researcher's right to independently publish may be waived with the researcher and his/her department chair's permission; provided the sponsor is willing to agree to make the clinical trial/study results public within two years of completion of the study.</p>
Royalties	Under IRS regulations, non-profit status can be jeopardized if royalty rates are set in advance. Instead, the University grants exclusive options to license on terms reasonable for the industry, including a good faith negotiation of fair royalties.