

University of Louisville Clinical Trials Environment

Contracting Party	<p>The University of Louisville Research Foundation, Inc. (ULRF) is the legal entity which executes clinical trial agreements for researchers who are faculty at 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.</p>
Hospital/Facility Sites	<p>University researchers typically conduct clinical trials at one or more of the following hospital/facilities: Norton Healthcare, Jewish Hospital HealthCare Services (JHHS), University Hospital, and the Veteran's Administration Medical Center. Each of these facilities, while affiliated with the University and permit research to be conducted at their facilities by University researchers, is a separate legal entity.</p> <p>The University obtains the appropriate approvals from the respective sites before subject enrollment is permitted.</p>
Preferred Contract Structure	<p>The preferred contract structure is for ULRF to execute a clinical trial agreement with the CRO/Sponsor and the CRO/Sponsor provide a letter of indemnification for each of the respective hospital/facility sites at which the study will be conducted.</p> <p>In the alternative, the respective hospital/facility may be willing to sign a separate facility use agreement between the site and the CRO/Sponsor. Three party agreements among ULRF, the site and CRO/Sponsor are discouraged as three-party agreements can significantly lengthen the time frame it takes to execute a clinical trial agreement.</p>
Indemnification for the University and Principal Investigator	<p>The CRO or Sponsor is expected to indemnify the University, ULRF and the PI for conducting the clinical trial. Such indemnification should cover the administration of any study drug/device and properly administered procedures conducted in accordance with the Sponsor's protocol. Exclusions should only apply to the extent those actions or inactions by the University or PI contributed to the liability/claim.</p>
Indemnification for the Respective Hospital/Facility Sites	<p>Each of the respective hospital/facility sites requires a letter of indemnification (LOI) equivalent to the terms provided for the University and Principal Investigator. This may be provided by the CRO or by the Sponsor separately.</p>
Institutional Review Board Fees	<p>The University Institutional Review Board (IRB) handles all research involving human subjects for University faculty at all hospital/facility sites. The University IRB has an FWA. CROs/Sponsors should pay the fees directly to the IRB upon invoice to avoid Facilities & Administrative charges on the IRB fee. If payment is not received before the IRB review is complete, the IRB will give a conditional approval to begin the study pending payment of the fee. See IRB Review Fees for more details.</p> <p>The University IRB also serves as the UofL Privacy Board for approval of HIPAA required research authorizations.</p>
Facilities & Administration Charges	<p>The University's Facilities and Administrative charge for industry sponsored clinical trials is 26%. All expenditures/expenses of the study are subject to these charges.</p>
Medical Professional Liability Insurance	<p>The University does not directly provide medical/professional liability insurance for its medical staff. Medical malpractice insurance is obtained by the physician via the professional services corporation/private practice group and is separate from the University's general liability insurance. This frequently requires revision to the clinical trial agreement provisions to accommodate this.</p>