

Negotiating Terms and Conditions in Agreements with the University of Cincinnati

Based on Ohio law, the following terms and conditions require consideration when negotiating with the University of Cincinnati, using a sponsor's template clinical trial agreement. Through this document, the hope is to save time and effort through transparency so the parties can efficiently finalize research agreements.

Non-binding Alternative Dispute Resolution

The University cannot agree to binding arbitration or binding mediation as a form of dispute resolution. Arbitration rules interfere with our right to be sued in the Ohio Court of Claims under Ohio laws, and the University's right to sovereign immunity.

Confidentiality

The University is a state entity and subject to Ohio's public records act. It is in the best interest of the both the University and sponsor to mark its written confidential information as "CONFIDENTIAL" and reduce to writing oral communications which sponsor considers confidential within fifteen (15) days of the oral communication.

Disclaimer of Warranties

Since research by its nature is unpredictable and without guarantee of predictable results, research is conducted on a reasonable basis. Agreement provisions cannot be accepted that guarantee results, impose penalties for failure to make progress by firm deadlines, or provide for withholding of payment if the sponsor is not satisfied with the results. In the performance of research, the University must explicitly disclaim certain warranties that may attach by operation of law. The disclaimer that appears in our research contracts are as follows:

INSTITUTION MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE OUTCOME OF THE STUDY RESULTS PROVIDED UNDER THIS AGREEMENT. FURTHERMORE, INSTITUTION EXPRESSLY DISCLAIMS ANY WARRANTY OF USE OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS WITH REGARD TO DATA, RESULTS, INVENTIONS, COPYRIGHTABLE WORKS, TANGIBLE STUDY PROPERTY, OR OTHER STUDY RESULTS PROVIDED HEREUNDER.

Governing Law

As an agency of the State of Ohio, the University cannot agree to the governing laws of a state other than Ohio. In the alternative, the University may remain silent on the governing law provision.

Indemnification

The University expects the Sponsor to indemnify and hold harmless the University, its trustees, its contracted hospital facilities, if applicable, Principal Investigator, officers, agents and employees from any and all liabilities, claims, actions or suits made by third parties arising from the University's performance of a study, including the Sponsor's use of the Study data, results and inventions and the negligence or willful misconduct of the Sponsor.

The Attorney General of the State of Ohio has issued opinions stating that indemnification by the University is more than likely unconstitutional under Ohio law. The University may, however, agree to be responsible for its negligent acts or omissions in the performance of its activities under the agreement. Pursuant to Ohio statute, the attorney general is the chief law officer for state universities, including the University of Cincinnati. The university shall not be represented by other counsel or attorneys unless approved by the attorney general.

Insurance

To support the sponsor's indemnification obligations, the sponsor must maintain a sufficient level of commercial general liability insurance, clinical trial insurance and products liability insurance, as applicable, or equivalent self-insurance, (e.g., \$3 million dollars per occurrence). The university's primary insurance is provided through a self-insurance program. That self-insurance is adequate to cover the specific types of risks which the university normally encounters while performing its activities as an institution of higher education.

Limitation of Liabilities

As a state entity subject to laws limiting the University's acceptance of liabilities in excess of the amount in its treasury, the University must specifically exclude any contingent unlimited liability that may or may not be covered by legislative appropriations or funds the University may have on hand. Following is sample limitation of liability language that is in all our research contracts:

EXCEPT FOR SPONSOR'S INDEMNIFICATION OBLIGATIONS UNDER SECTION __, IN NO EVENT SHALL EITHER PARTY NOR ANY OF ITS AFFILIATES, NOR ANY OF THEIR RESPECTIVE DIRECTORS, OFFICERS, AGENTS OR EMPLOYEES, BE LIABLE FOR ANY SPECIAL, PUNITIVE, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFITS OR GOODWILL.

Publication

University research is conducted openly and is intended to lead to the publication and dissemination of the results of research activities. The University recognizes the legitimate interest of sponsors to protect their proprietary or confidential information. When appropriate, publications may be reviewed by sponsors to allow the sponsor to request the removal of their defined confidential information and to allow for a reasonable amount of time to secure protection of patent rights. The University cannot accept any agreement language which prohibits the publication of research results or allows for sponsor editorial control over the publication of research results or conclusions.

Term of Agreement/Period of Performance

In the event a sponsored agreement is terminated, the sponsor will be expected to reimburse the University for all costs incurred through the date of termination and for all non-cancellable financial commitments. The University requests the inclusion of the language below on the topic of Term of Agreement. This one-year term is suggested to provide potential protection under the federal Anti-Kickback Statute's personal services safe harbor.

In the event that this Agreement is terminated or completed within less than one year of the Effective Date, the parties will not enter into a new Agreement for the provision of the same services on the same protocol until after the first anniversary of the Effective Date. For clarity, the preceding provision shall only apply if the arrangement is determined to fall under the Stark or Anti-Kickback law and related regulations.