

CRITICAL LANGUAGE IN UNM CONTRACTS

This tool is being provided to help assist HSC Principal Investigators and their staff understand why UNM cannot accept certain language in contractual agreements. Principal Investigators can also use this tool in their communications with sponsors prior to receiving a contract. We want to ensure the negotiation process is as smooth as possible. To assist with this, we are providing this tip sheet on critical contract language that cannot be accepted by the University and the reason why. **This is NOT an all inclusive list.** Please note these clauses can cause delay or non-acceptance of a contract.

Note: Disclaimer, FOR INFORMATIONAL PURPOSES ONLY – not intended for department/PI negotiations or to be sent to external sponsors. –All externally funded contracts require HSC Sponsored Projects Office negotiation and approval.

INDEMNIFICATION:

UNM requires that the sponsor indemnify UNM against liabilities and losses arising from the study because the sponsor has provided UNM with a protocol/contract to perform. It is fair and reasonable for UNM to request indemnification against losses arising from the sponsor's protocol or pharmaceuticals. **However, UNM cannot agree to indemnify a sponsor but can accept liability for the negligence of its employees, subject to the limitations of the tort claims act.**

Why is Indemnification unacceptable:

"The University of New Mexico is a state educational institution, created under Article XII, Section 11 of the New Mexico Constitution. As such, it is prohibited from contractually creating a general obligation against the University without submitting the question to the voters and creating a sinking fund, pursuant to Article IX, Section 8 of the New Mexico Constitution. Moreover, Section 23-1-5 NMSA 1978 prohibits the University from contracting any liability that might exceed authorized expenditures. Indemnification and save harmless clauses create potentially unlimited contractual liabilities and are therefore prohibited by the above provisions.

Additionally, Article IX, Section 14 of the New Mexico Constitution prohibits the state from pledging or lending its credit, directly or indirectly. In New Mexico, an indemnification clause is considered an improper pledge of the University's credit." ~Michelle Huff (University Counsel, 12/16/09 Official Memo)

CHOICE OF LAW/GOVERNING LAW:

UNM cannot contractually be bound by another state's law or venue. Governing law should be in the State of New Mexico or must remain silent in order to provide UNM's its rightful protections.

Why UNM can't be bound by another's state law:

“As a constitutionally-created entity of the State of New Mexico, the University is protected by various provisions by New Mexico's state laws. These laws include the New Mexico tort Claims Act [Sections 41-4-1 *et seq.* NMSA 1978, as amended] and the insurance protections afforded by New Mexico State Risk Management Division, among many others. By agreeing to be bound by another jurisdiction's laws, UNM would arguably lose any protections and immunities that it enjoys under the state laws of New Mexico. For this reason, UNM cannot agree to be bound by another jurisdiction's laws. Nor does UNM agree to venue in the courts of another jurisdiction. As a matter of long standing practice, the University has only agreed to contracts with an unqualified statement that New Mexico law governs, or that remain completely silent on issues of choice of law and venue.” ~Michael Anderson (University Counsel, 6/21/12 Official Memo)

RIGHT TO PUBLISH:

UNM and the PI must retain Publication Rights (with the exception of multi-center clinical trial studies). UNM does not allow a research sponsor to approve of or otherwise control University/PI publications. UNM and the PI must retain the right to publish without approval of the sponsor.

Why publication restrictions are not acceptable:

- 1.** It restricts academic freedom, undermines research integrity, and violates ethical obligations to patients and the public. Publication is necessary to fulfill the University's academic mission of dissemination of the research being conducted.
 - 2.** Allowing sponsor to approve or require changes may violate journal publications requirements. Journals often require an author to sign a statement that he/she accepts full responsibility for the conduct of the research/trial, had access to the data, and controlled the decision to publish.
 - 3.** Graduate students (if involved) may not be able to publish their dissertations if sponsor is allowed to approve or require changes. This can hinder their ability to graduate.
 - 4.** Potential to endanger future patients or subjects by allowing a sponsor to prevent dissemination of research results.
 - 5.** University's inability to publish research activity is related to the tax-exempt purpose of the University, so that it does not implicate unrelated business income tax.
 - 6.** Allowing sponsor to approve or require changes may subject the study to export control laws and may directly affect UNM's export control exemptions (Fundamental Research).
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INTELLECTUAL PROPERTY (IP) & DATA OWNERSHIP:

Intellectual Property and data ownership are highly complex topics and may not be applicable in all contracts. Generally speaking, a contract is issued to provide a service a sponsor is requesting. As with clinical trials, a sponsor is providing a protocol that must be followed. In both cases, it would be rare that new IP would be generated either by offering a service or following a protocol. However, often times IP is addressed in research contracts. This is to protect IP that has already been established by the PI and/or to address future potential IP to be developed through the research. Types of IP can include, new inventions, developments, and discoveries, patentable or unpatentable, copyrightable or uncopyrightable, including but not limited to biological materials, processes, methods, software, tangible research products, formulas and techniques, and know-how related thereto, which are conceived or reduced to practice in performance of the Research Project

Negotiating: UNM's position on IP is to ensure we retain ownership of what UNM had prior to entering into the contract and keeping the rights to any new discoveries. However, UNM will grant the sponsor an option to acquire an exclusive royalty-bearing license to UNM's rights to any Invention. If the Sponsor exercises the option, UNM will negotiate a license agreement with the Sponsor.

Negotiating IP and Data Rights with a Federal Sponsor will be different than negotiating with a For Profit Organization. When negotiating with a Federal Sponsor, we apply Federal Acquisition Regulation (FAR) clauses that are applicable to an Institution of Higher Education. These clauses allow the University to operate within the confines of academic freedom, which allow unlimited use of the data for educational purposes.

Data Ownership: UNM must retain ownership of raw data (i.e., lab worksheet, memoranda, notes, results of original observation), patient medical records, source documents, tangible items (i.e. tissue specimens), arising out of UNM's participation in a Study, however UNM can assign sole ownership of contract deliverables (i.e., copies of progress reports, case reports) to Sponsor.

STC: Existing inventions – all IP terms negotiated by our tech transfer office.

CONFIDENTIALITY:

UNM, as a state institution of higher education, practices research in an open environment, with the primary purpose of advancing knowledge. We accept proprietary information from industry only in carefully limited situations. We insist that the results of our research be freely publishable, except for the rare occasions in which we engage in classified research.

Negotiating

Our general stance on confidentiality is that everything has to be "marked" confidential which helps narrow the definition and makes it obvious what is confidential or not. If the sponsor does not agree to that then our fallback position is to say, "What a reasonable person would believe to be confidential..."

We also look for the period of time that confidential information has to be kept. Our first and preferred option is 5 years max. If anything more than that, a decision memo will have to be sent to Dr. Larson who usually won't agree to anything more than 7 years.

There are exceptions to confidentiality that we look for which are listed below.

- Information which is or becomes publicly known through no fault of the Institution;
- Information learned from a third party entitled to disclose it;
- Information already known to or developed by the Institution before receipt from the Sponsor, as shown by the Institution's prior written records;
- Information reasonably necessary to protect the Institution's interests in a lawsuit, alternative dispute resolution process, or government investigation;
- Information reasonably necessary to process insurance claims;
- Information required by law to be disclosed;
- Information developed independently, by Institution or Principal Investigator, without use or reference to information provided by Sponsor or CRO.

Lastly, we also need to retain one (1) copy of confidential information for archival purposes so that we know what is confidential.

**These are the areas in which the HSC Sponsored Projects Office receives the most pushback. In order for successful negotiations to occur, it is helpful for Sponsors to be aware of what a Public Institution can and cannot agree to.*