

Clinical Trial Agreement Indemnification Clauses: Protect Your Interests, Get Approval

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Indemnification

An obligation contractually assumed by or legally imposed upon one party to protect another against loss or damage from specific liabilities.

(continued)

Indemnification (2)

- Who indemnifies and who is indemnified?
- From what loss or damage?
- Expenses of claims and suits related to what injuries?
- Caused by – IN WHOLE OR IN PART?

(continued)

Indemnification (3)

- By any substance studied or any procedure performed in accordance with the provisions of the protocol
- What about for use by Sponsor of the results of the Study
- Product liability
- Indemnification without prior payment by Institution

(continued)

Indemnification (4)

- Key points
 - Determine the type of indemnity—one way or mutual
 - Letter of indemnification
 - Third-party beneficiary issues
 - Identify the indemnified parties
 - Employees, officers, directors, agents, **subcontractors, IRBs—OTHERS?**

(continued)

Indemnification (5)

- Types of claims the indemnity will cover
 - Negligence
 - Breach of agreement
 - Intentional misconduct (corporation and employee)
 - Violation of laws/regulations
 - IP INFRINGEMENTS – often missed

(continued)

Indemnification (6)

- “Carve outs” that negate or limit the obligation to indemnify
 - Failure to follow protocol
 - Failure to obtain informed consent, giving false warranties
 - Failure to comply with laws and regulations
 - Material admissions which prejudice the defense of the claim
 - Damage is caused by the party seeking indemnification

(continued)

Indemnification (7)

- The intention to indemnify another for its own negligence is unusual and extraordinary, and there can be no presumption that an indemnitor intends to assume the responsibility unless the contract by express stipulation provides for such beyond a doubt
 - **Humphrey vs. East Manufacturing**, 2003 U.S. Dist. LEXIS 22845 (USDC N.ILL 2003)

(continued)

Indemnification (8)

- Some states will not allow indemnification of negligence or failure to comply with law
 - N.Y. Gen. Oblig. Law §5-322.1 renders unenforceable any contract that purports to indemnify a party from liability for his own negligence. **Wausau Bus. Ins. Co. v. Turner Constr. Co.**, 143 F.Supp. 2d 336 (D.N.Y. 2001)
- A minority allow:
 - **Sharon Brooks v. Starr Commonwealth**, 2009 Mich. App. LEXIS 1218, citing
 - Sherman v DeMaria Bldg Co, 203 Mich App 593, 596-597; 513 NW2d 187 (1994).
 - "Michigan courts have discarded the additional rule of construction that indemnity contracts will not be construed to provide indemnification for the indemnitee's own negligence unless such an intent is expressed clearly and unequivocally in the contract."
- See also: : INDEMNIFICATION AND INSURANCE: THE RISK SHIFTING TOOLS (PART I) 79 PA Bar Assn. Quarterly 156, and (PART II) 80 PA Bar Assn. Quarterly 1

Conditions to Indemnification

- Notice of any claim or lawsuit
 - Right to defend the lawsuit
 - Subject to Institution's right to retain the counsel of its choice?
- Right to settle the claim
- Right to require the indemnified party to cooperate fully in the investigation and with defense of any such claim or lawsuit

Additional Indemnification Issues

- Costs of extra unanticipated tests, treatments and hospitalizations of patients required as a result of adverse events
- Costs covered by the subject's or patient's medical or hospital insurance or by governmental programs providing such coverage

(continued)

Additional Indemnification Issues (2)

- Non-medical indemnification (e.g., worker's compensation, third-party injuries, public health costs)
- Insurance

Indemnification Process

- Indemnification process
 - Involvement of the indemnified party
 - Settlement of claims
 - Retention of independent counsel
 - Notice provisions
 - Promptly v. specified timeframe
 - Consequences of failure to comply

Third-Party Indemnification

- Statutory and/or policy limitations on the ability to indemnify a third party
 - When the site's refusal to indemnify the sponsor is based upon statutory limitations look for language in the statute such as:
 - "to the extent allowed by applicable law..."

Indemnification Alternatives

- Alternatives to indemnification
 - Allocation of risk
 - Silence
 - Unilateral sponsor indemnification
 - Investigator as an “Independent Contractor”

Indemnification–Risks

- Allocation of risks
 - Each party is responsible for its own negligence
 - Establish that neither party will have any obligation for the other party's negligent acts
 - Limit obligations according to applicable laws

Sample Language: Allocation of Risks

- Sponsor and University each, respectively, agree to be responsible for the negligent and intentional acts of their respective employees, agents, representatives, divisions and affiliates that arise out of or are related to the performance of the services or manufacture and delivery of a product under this agreement

Sample Language:

Allocation of Risk-Site

- Investigator shall be responsible for all claims related to performance of the services under the protocol, including any loss, claim or demand arising from any injuries or damages resulting from Investigator's negligence, failure to adhere to the protocol, failure to obtain written consent, unauthorized warranties, breach of this agreement or willful misconduct

Sample Language

- The University is self-insured and agrees to provide insurance to the limits of the attached Certification of Self-Insurance

OR

- University, as a state agency of the State of Oklahoma, is self-insured. Liability coverage is provided under the State of Oklahoma Governmental Tort Claims Act, Title 51 Oklahoma Statutes Supplement 1989, Section 151 et seq. Contractor shall be liable only to the limits of the attached Certification of Self-Insurance

Independent Contractor

- In the conduct of research under this contract, Investigator is acting in the capacity of an independent contractor, and neither party shall by reason of this contract be obligated to defend, assume the cost of defense, hold harmless or indemnify the other from any liability to third parties for loss or damage to property, death or bodily injury; arising out of or connected with the research under this contract

Insurance

- Define types of coverage
- Set limits of coverage
- Uninsured or underinsured sites
- Foreign sponsors/sites
- Corporate insurance

(continued)

Insurance (2)

- Review coverage levels with broker
- Require other party to have adequate insurance and provide evidence
- Know which risks are covered and which risks are not (as determined by contract language and individual policy)

Limitations of Liability

- Governs the extent to which the parties will be liable to each other
 - Generally does not limit indemnification losses of third parties—unless contract states otherwise
 - Should be mutual
 - Define which liabilities are included and excluded
- (continued)

Limitations on Liability (2)

“In no event shall either party be liable to the other for any special, consequential, exemplary or incidental damages, whether or not foreseeable, arising from the performance of this agreement and the protocol”

Questions and Answers



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