



(W236)

Research Agreement Indemnification Clauses

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Instructor



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Learning Objectives

- By the end of this program, attendees will be able to:
 - Identify the parameters of statutory and common law indemnity and select the appropriate language to allow the parties to alter these obligations contractually
 - Identify common issues that arise in the "boilerplate clauses," describe how they interact with the other "risk management" clauses, and draft an appropriate response to common demands by the other party or parties in negotiation of the clinical trial agreement

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Learning Objectives (2)

- Draft effective contractual indemnification provisions that protect the clients – whether the indemnitor or indemnitee
- Identify the responsibilities of the client and sponsor
- Categorize the risk (high or low) from indemnification language
- Distinguish the difference of who is responsible according to law

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Indemnification

Definition

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

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Indemnification

Overview

- 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

Overview (2)

- For instance:
 - “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

Overview (3)

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?

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Indemnification

Overview (4)

- 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 *Overview (5)*

Special Situations

- Price-Anderson Act: Indemnification in connection with nuclear damages
 - See for instance:
 - ***Estate of Ware v. Hosp. of the Univ of Pa.***, 2014 U.S. Dist. LEXIS 63186 and LEXIS 61934 (E.D. Pa. May 5, 2014)

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Indemnification

Overview (6)

7.2 Indemnification of Institution

Sponsor shall indemnify and hold harmless Institution, its employees, officers, and directors (Institutional Indemnitees) from and against any claims, liabilities, losses, demands, causes of action, judgments, settlements and expenses (including, but not limited to, reasonable attorneys fees and court costs) (each a Claim) arising out of (i) the physical illness, injury or death of a Study subject as a direct result of treatment of such Study subject in accordance with the terms of the Protocol and this Agreement; or (ii) the use by Sponsor of the Study Documentation; provided, however, that Sponsor shall have no such obligation with respect to Claims arising from an Institutional Indemnitee's malpractice, negligence or willful misconduct in connection with the Study, breach of this Agreement or the Protocol.

(continued)



Indemnification

Overview (7)

7.3 Indemnification of Sponsor

To the extent not expressly prohibited by state law, Institution shall indemnify and hold harmless Sponsor, its affiliates and their respective employees, officers and directors (Sponsor Indemnitees) from and against any Claims arising out of the physical illness, injury or death of a Study subject due to (a) the failure of a Institutional Indemnitee to adhere to the terms of the Protocol and this Agreement; or (ii) the negligence or willful misconduct of an Institutional Indemnitee; provided, however, that Institution shall have no such obligation with respect to Claims arising out of the negligence or willful misconduct of a Sponsor Indemnitee.

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Indemnification

Overview (8)

- “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

Overview (9)

- 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)

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Indemnification

Overview (10)

- Other States 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



Laws Change, So Make Sure You Check

- ***Estes Express Lines, Inc. v. Chopper Express, Inc.***, 273 Va. 358 (Va. 2007)
 - Plaintiff argued that under longstanding law "indemnity agreements involving claims for personal injury are against public policy and void."
 - Va. Supreme Court held:
 - "... indemnity provisions, including those indemnifying a party against future liability for personal injury caused by its own negligence, ... does not jeopardize in any way the injured party's ability to recover."
 - Now allows indemnification against one's own negligence (except for construction contracts, where statute outlaws such clauses).



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

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Conditions to Indemnification (2)

7.4 Indemnification Procedure.

(a) Each party shall promptly notify the other party in writing of any Claim or potential Claim for which such party may seek indemnification, but in no event more than fifteen (15) days after the party seeking indemnification has knowledge of the Claim or potential Claim. Failure to provide timely notice shall not negate the obligation of the other party to indemnify except to the extent that the delay in notification resulted in additional damages or Claims to the party seeking indemnification.



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

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Additional Indemnification Issues (2)

- Medical Costs
 - Sponsor shall be responsible for the costs of a patient's unreimbursed, reasonable and customary medical treatment of any illness or injury sustained as a direct result of the patient's performance in the Study; provided, however that Sponsor shall not be responsible for costs attributable to:

(continued)



Additional Indemnification Issues (3)

- (i) Medical services provided to the patient by the Principal Investigator or Institution in the normal course of patient care;
- (ii) The negligence of Institution or Principal Investigator or their employees or agents;
- (iii) A patients pre-existing medical condition;
- (iv) Material failure of the Principal Investigator or Institution to follow the Protocol, the Instructions For Use (IFU), product literature or labeling, or any other written instructions appropriately provided to the Institution or Principal Investigator; or
- (v) Any willful misconduct by Institution, Principal Investigator, or other employees or agents of Institution or Principal Investigator.

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Additional Indemnification Issues (4)

- Non-medical indemnification (e.g., worker's compensation, third-party injuries, public health costs)
- Insurance
 - Does the contract state which provision is supposed to act first – the indemnification provision or the insurance provision?
 - Some Courts have held that in contracts including both indemnification and insurance clauses, the insurance coverage offers the first line of protection and the contractual indemnification only comes into play upon exhaustion or failure of the insurance.
 - The indemnity provision in a contract may apply only to amounts exceeding the coverage provided pursuant to the insurance provision.

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Insurance and Indemnification

- Without insurance, indemnification depends upon the financial condition of indemnitor
- Typical commercial general liability policies contain a contractual liability exclusion that often operates to eliminate the insurer's liability for indemnity
- Insurance policy endorsements are available to change the language and eliminate the exclusion
- Requirements to name other party as additional insured may also affect indemnity provisions in insurance

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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

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Indemnification Process Sample

7.4 Indemnification Procedure.

(b) Sponsor shall defend Institution in connection with any Claim against Institution Indemnitee, except for such Claims that arise out of or are related to the malpractice, negligence or willful misconduct, breach of this Agreement or Protocol by an Institution Indemnitee. Institution shall, and shall ensure, that each of its officers, agents, contractors and employees, cooperate fully with Sponsor in the investigation and defense of any Claim including, but not limited to, providing Sponsor with complete access to all relevant records, and providing accurate testimony and evidence. Sponsor has the right to defend any Claims in any manner it deems appropriate, including the right to retain counsel of its choice and has exclusive right to settle the Claims, provided, however, that Sponsor shall not admit fault on behalf of Institution, its officers, agents, contractors and employees without the prior written consent of such person. Institution may retain its own legal counsel at its sole expense.

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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..."

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Indemnification Alternatives

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

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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

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Sample Language: Allocation of Risks

Sponsor and Institution 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.

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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.

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Sample Language

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

OR

Institution, 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.

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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.

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Insurance

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

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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)

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Scope of Coverage

Insured Contract Definition Endorsement

- May limit “Insured Contracts” to extent the named insured’s assumption of tort liability is permitted by law
- May restrict ability of indemnitee to access insurance coverage
- Request copies of insured contract endorsements

Primary and Noncontributory – Other Insurance

- Additional insured can access other party’s insurance first



Sample Insurance Clause

- Insurance Requirements. During the term of this Agreement, each Party will obtain and maintain, at its own expense, the following coverage:
 - Commercial General Liability: Each Party shall maintain commercial general liability coverage (including contractual liability, personal advertising and products/completed operations coverage) for limits no less than \$1,000,000 USD per occurrence and \$2,000,000 USD in the aggregate;
 - Workers Compensation Coverage: Each Party shall maintain statutory limits and Employers Liability limits shall be at a minimum \$1,000,000 USD. Coverage shall include a waiver of subrogation endorsement in favor of Sponsor where applicable by law;

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Sample Insurance Clause (2)

- **Automobile Liability:** If either Party is driving onto the other's property or the surrounding area, that Party shall maintain automobile liability coverage with limits no less than \$1,000,000 USD each accident; and the policy definition of automobile shall include owned autos, hired or non-owned autos; and
- **Professional Liability:** If either Party is providing a professional service, that Party is required to maintain coverage for errors and omissions with limits no less than \$1,000,000 USD per occurrence/claim and \$2,000,000 USD in the aggregate.

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Sample Insurance Clause (3)

Insurance Conditions.

- Additional Insured: Each Party shall name the other as an additional insured by endorsement.
- Occurrence Form: The insurance policies shall be under an occurrence form, but if only a claims-made form is available then, in such a case, each Party shall maintain the claims-made insurance policy for at least five (5) years following termination of its Services under this Agreement.

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Sample Insurance Clause (4)

- **Financial Rating:** The insurance required pursuant to the Section above shall be carried with insurance companies with an A.M. Bests rating of A VII or better.
- **Certificate of Insurance:** Within thirty (30) days of signing this Agreement, each Party shall provide the other with its certificate of insurance evidencing the insurance coverage set forth in this Section. Each Party shall provide to the other, at least thirty (30) days prior written notice of any cancellation, non-renewal or material change in any, of such insurance coverage.

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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

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Limitations of 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.”



More Reading

- *AGREEMENTS TO INDEMNIFY & GENERAL LIABILITY INSURANCE: A Fifty State Survey*, Weinberg Wheeler Hudgins Gunn & Dial
- *Comparative/Contributory Negligence and Joint and Several Liability: A State by State Summary*, Comm. Transp. Lit. Comm., (ABA 2009)
- *Liability Considerations in Clinical Trial Agreements with Canadian Sites*, M B. Rajakaruna, Journal of Clinical Research Best Practices V.6,N. 6, 6/2010
- *Indemnity and Insurance Provisions in Commercial Contracts*, Gorenberg & Dandelles (ABA 2013)
- *Drafting and Enforcing Complex Indemnification Provisions*, Youngblood & Flocus (Practical Lawyer 2010)
- *Joint and Several Liability and Contribution Laws in all 50 States*, Matthiesen, Wickert & Lehrer (S.C 2014)

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Yet More Reading

- *Contributory Negligence/Comparative Fault Laws in all 50 States*, Matthiesen, Wickert & Lehrer (S.C 2014)
- *Additional Insureds: The Importance of Indemnity and Insurance Provisions in Contracts and Policy Language* (Marsh USA 2103)
- *A Survey of The Law of Non-Contractual Indemnity and Contribution: Compiled by the Product Liability Group of the Primerus Defense Institute*, (International Society of Primerus Law Firms April 2012)
- *Interaction between Indemnification and other Contractual Remedy Provisions Checklist* (Practical Lawyer 2013)
- *Indemnification: Banish the Word!: And Rebuild Your Indemnity Clause from Scratch* (Ammon 93 MI Bar Jnl. 44)