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NEGOTIATING and NAVIGATING INDEMNITY

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LEARNING OBJECTIVES

- By the end of this program, attendees will be able to:
 - Identify statutory, contractual, and common law indemnity parameters
 - Understand different and often competing indemnity approaches in clinical research, faculty human resources, and other paradigms
 - Identify responsibilities of sponsors, institutions, and researchers when responding to third-party claims
 - Understand responsibilities of institutions, sponsors, and researchers when responding to government investigations.

Learning Objectives

- Assess indemnification risks arising from different research endeavors.
- Determine when research staff may need separate representation due to conflicts of interest
- Determine impact of conflicts on indemnification
- Better navigate common interest privileges and avoid conflicts between institutions and faculty

INDEMNIFICATION *defined*

An obligation assumed by or legally imposed upon one party to protect another party against loss or damage from specific liabilities associated with third-party or direct claims arising in the ordinary course of a specified activity.

INDEMNITY's *rationale*

Joint Endeavors = Joint & Several Liability

- Indemnification mitigates joint and several liability by apportioning risks among participants
- Who should bear the risk? The party in best position to avoid it.
- Indemnity typically provides that each party will bear the joint endeavor risks that flow from their own noncompliance, mistakes, bad acts
- Covers ultimate risks of paying damages and expenses of responding to/litigating claims
- Public policy guardrails apply

INDEMNIFICATION *building blocks*

Indemnifier typically takes on a **duty** to:

- reimburse indemnified party for expenses incurred defending/paying damage claims
- or “hold harmless” indemnified party from all expenses associated with pending claims
- provide (pay for) defense of the indemnified party

Indemnifier usually obtains the **right** to:

- control defense of indemnified party
- pick defense counsel
- resolve or compromise dispute at issue

INDEMNIFICATION *sources*

Indemnification usually has a **contractual basis** in the:

- Research contract
- Vendor agreement or subcontract
- HR faculty handbook

Often includes an arbitration clause for resolving disputes about coverage

- Avoids public court litigation running parallel to underlying lawsuit or investigation

Liability caps, materiality qualifiers, and liability “baskets”

- Opportunity to customize governing law, principles, forum selection and remedies.

INDEMNIFICATION *benefits in research arena*

Rational indemnification clauses in research contracts and faculty/HR policies allow institutions to:

- Customize risks associated with experimental research
- Promotes academic freedom & inquiry among faculty
- Backstops the institution's and faculty exposure from lawsuits and damages challenging sponsor's products and protocols
- Backstops sponsor's exposure from liability risks arising from institution/faculty missteps
- Preserves and *promotes* common interest and forestalls intra-enterprise disputes about liability and coverage

INDEMNITY'S *scope*

Indemnity typically covers:

- Negligence and other tort liability
- Indemnitor's breaches of contract
- Indemnitor's non-compliance with laws/regulations governing research
- Intellectual property infringement or misuse
- Representations about research propriety/results

... arising in course of research or researcher's employment duties.

Indemnity typically *excludes*:

- Personal wrongdoing
- Gross negligence
- Criminal acts
- Improper use of products/services
- Sexual misconduct
- Unlawful discrimination
- Indemnitee's breach of contract
- Indemnitee's noncompliance with statutory/regulatory requirements

... and other liabilities falling outside the ordinary course of performance at issue.

INDEMNIFICATION *in a research contract*

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.”

INDEMNIFICATION *in a research contract*

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 Indemnatee to adhere to the terms of the Protocol and this Agreement; or (ii) the negligence or willful misconduct of an Institutional Indemnatee; provided, however, that Institution shall have no such obligation with respect to Claims arising out of the negligence or willful misconduct of a Sponsor Indemnatee.”

INDEMNIFICATION *in research contracts*

Carve-outs negating/limiting indemnity:

- Failure to follow protocol
- Failure to obtain informed consent, giving false warranties
- Failure to comply with laws and regulations
- Material admissions which prejudice defense of the claim
- Damage caused by the party seeking indemnification

INDEMNIFICATION *of researchers*

- “University will defend, indemnify and hold harmless its faculty members from and against any and all expenses, including reasonable attorney’s fees and disbursements, judgments or settlements, arising out of any act or failure to act by faculty members acting in good faith within the scope of their employment and in performance of their authorized or assigned duties.”
- “University reserves right not to defend or indemnify a faculty member where the injury or damage results from intentional wrongdoing, gross negligence, or willful violation or disregard of University policies and procedures.”

INDEMNIFICATION *of researchers*

- “University will not defend or indemnify faculty member where (a) the action is brought by, on behalf of, or in the right of, the University; or (b) the faculty member is aligned as a party adverse to the University.”
- “Not included: acts or failures to act by faculty members rendering professional services not within scope of their employment or not part of authorized duties.”
- “University shall presume that faculty member acted in good faith and within scope of their employment until evidence to the contrary proves otherwise.”

INDEMNIFICATION *of researchers*

- “Defense and indemnification are conditioned upon immediate delivery to University Counsel of any summons, complaint, process, notice, demand or pleading at issue.”
- “University must be given absolute and continuing right to take charge of claim or litigation, including right to direct any litigation, appoint counsel, and settle claims in a manner deemed appropriate by the University.”
- “University shall give prior notification to faculty member of any settlement proposals and allow faculty member the opportunity to comment upon the proposals, giving reasonable consideration to faculty members comments and concerns.”
- “Faculty members must provide University and its counsel full assistance and continuous cooperation throughout the defense of any covered claim or litigation.”

INDEMNITY *withheld from independent contractors*

“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.”

INDEMNIFICATION *carve-outs and nullifiers*

“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
- Failure to provide indemnitor w/ timely notice of indemnified claims
- Material admissions which prejudice defense of the claim
- Damage caused by the party seeking indemnification

INDEMNIFICATION *carve-outs and nullifiers*

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.D. Illinois 2003)

INDEMNIFICATION *carve-outs and nullifiers*

- Many states prohibit indemnification for indemnitee's negligence or failures 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 of states allow such indemnification:
 - *Sharon Brooks v. Starr Commonwealth*, 2009 Mich. App. LEXIS 1218 ("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

INDEMNIFICATION *subject injury issues*

- Costs of extra unanticipated tests, treatments and hospitalizations of patients required as a result of adverse events
 - Sponsor should indemnify against but might resist responsibility for costs attributable to **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 when providing patient care, (iii) **a patients pre-existing medical condition**
- Costs covered by the subject's or patient's medical or hospital insurance or by governmental programs providing such coverage – Institution may be in best position to pursue/resolve these issues
- Non-medical indemnification (e.g., worker's compensation, third-party injuries, public health costs) – Sponsor indemnification should be sought
- Insurance – which party is in best position to pursue/resolve?

INDEMNIFICATION *checklist*

- **Does protocol belong to the sponsor?**

- if Sponsor wrote the protocol, institution should seek one-way indemnity for performance of study and Sponsor's use of study results.

- **Is sponsor requesting indemnity from institution?**

- appropriate where institution wrote part/all of the protocol

- **Are appropriate parties indemnified?**

- the Institution, its regents, officers, agents, employees and all persons acting or purporting to act on its behalf

- **Are conditions and carve-outs reasonable things the Institution does in the ordinary course?**

INDEMNIFICATION *checklist continued*

- **Is there a reasonable notice provision?**

- consider “promptly” or “within such time as will not materially prejudice the rights of the Indemnitor” instead of hard/fast deadline of “10-days” or the similar short triggers.

- **Clauses requiring surrender of defense or full cooperation from State Institutions?**

- state statute, regulation or attorney general guidelines may displace traditional duty to “surrender” to indemnitor, and should be incorporated into clause where necessary

- **Topics beyond identifying parties, setting out scope of coverage, stating conditions and carve-outs, providing notice and defense of claims, use of results, negligence, product liability, etc.**

See generally www.utsystem.edu/offices/general-counsel/indemnification-clauses-checklist-sponsored-research-agreements-and/review-indemnification-clauses

QUESTIONS *and answers*