Managing Risk Through Effective Contract Negotiation

You don’t get what you deserve; you get what you negotiate.

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Office for Sponsored Research
Let’s Talk About…

- Indemnification: What is it, and why is it important?
- Subject Injury: The Contract v. ICF
- Subject Injury: What to do when a subject is injured
- Insurance
Indemnification: What is it?

- One of the mechanisms that both parties use to manage risk of participating in clinical trials and ensure that Risk does not outweigh potential benefits.
- Root is in the ICH GCP guidelines (5.8.1).
  - If required by the applicable regulatory requirement(s), the Sponsor should provide insurance or should indemnify the investigator/Institution against claims arising from the trial, except for those resulting from Institution malpractice.
The Basics: The Indemnification Clause

One party agrees to:

**INDEMNIFY**: Allows one party to legally shift a loss to another

**DEFEND**: Creates a *Duty to Defend* the indemnified party

**HOLD HARMLESS**: Bars the indemnifying party from bringing suit against the party being indemnified.
The Basics: What ‘s Included in the Clause?

1) Who are the persons being indemnified?

2) What conditions would trigger an obligation of indemnification?

3) What is the scope of the indemnification?
<table>
<thead>
<tr>
<th>According to the SPONSOR:</th>
<th>According to the INSTITUTION:</th>
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<tbody>
<tr>
<td>Only those directly involved in the conduct of the study</td>
<td>Everyone under the Institution umbrella: officers, directors, trustees, agents, employees (including Investigator), subcontractors, medical students and affiliated medical institutions</td>
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Mutual or Unilateral?

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<tr>
<th>According to the SPONSOR:</th>
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<td>Mutual; at the very least for INSTITUTION negligence or willful misconduct</td>
<td>Unilateral; Only Sponsor has indemnification obligations</td>
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<td>“Responsibility clause”</td>
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## What Triggers Indemnification by Sponsor?

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<th>For the SPONSOR:</th>
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<tr>
<td>PHYSICAL injury</td>
<td>ALL ACTIVITIES arising out of:</td>
</tr>
<tr>
<td>DIRECTLY related to</td>
<td>ANY activities carried out pursuant to</td>
</tr>
<tr>
<td>PROPER use/administration of the Drug or Protocol Procedures</td>
<td>the Agreement and the Protocol</td>
</tr>
<tr>
<td></td>
<td>Sponsor’s breach of this Agreement</td>
</tr>
<tr>
<td></td>
<td>Death, injury, property damage</td>
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<td></td>
<td>Use by Sponsor of the Study data/ results</td>
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<td></td>
<td>Bad protocol design</td>
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<td>Failure to comply with the law, including those relating to patient privacy.</td>
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Why “Use of Data and Results”?

- Research Institutions cannot warrant the results of its research or somehow guarantee accuracy of data. We provide the data "as is."

- Institution cannot control how a Sponsor uses those results. A Sponsor using the data does so at its own risk.

- Sponsors may use the data for drug marketing and development. Institution could be at risk for product liability and similar suits arising out of the sale or use of the drug.
SCOPE: What is covered?

ALL claims, damages, liabilities, losses, costs, expenses (including reasonable attorney fees) and legal actions
SCOPE: What may EXCLUDE a Party’s Indemnity?

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<td>Failure to follow the protocol or instructions</td>
<td>Permissible deviations; Limit to written instructions</td>
</tr>
<tr>
<td>Breach of the law/regulations</td>
<td>Limit to material breach</td>
</tr>
<tr>
<td>Negligence or willful misconduct</td>
<td>Limit to <em>Gross</em> negligence</td>
</tr>
<tr>
<td>Untimely notice</td>
<td>Limit to the extent Sponsor’s defense is prejudiced by the delay</td>
</tr>
<tr>
<td></td>
<td>“To the extent” bases obligation on relative fault</td>
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Other Rights and Obligations

<table>
<thead>
<tr>
<th>Of the INDEMNITOR (most often, the Sponsor):</th>
<th>Of the INDEMNITEE (most often, the Institution)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handles/controls defense</td>
<td>Timely notification of claims</td>
</tr>
<tr>
<td>No settlement without consent</td>
<td>Right to consent to settlement</td>
</tr>
<tr>
<td>No admission of wrongdoing by Indemnitee</td>
<td>Right to choose own counsel</td>
</tr>
<tr>
<td></td>
<td>Provides reasonable assistance</td>
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</table>
Other Considerations

- Limited indemnity by state institutions
- Limitation of Liability clauses
  - *Without limiting Sponsor’s indemnification and insurance obligations herein*, Institution understands and agrees that Sponsor makes no warranty, either expressed or implied, regarding the use of the product in the Study. Without limiting the foregoing, Sponsor expressly disclaims any implied warranties of merchantability or fitness for a particular purpose.
Indemnification: The Words

Sponsor agrees to indemnify, defend and hold harmless, and pay all reasonable legal or other costs, expenses or losses incurred by the Institution, its trustees, officers, agents, employees, including Investigator, medical students, and medical affiliates where the study is performed ("Indemnitees"), from and against any and all third-party claims, damages, liabilities, losses, costs, expenses (including reasonable attorney fees) and legal actions ("Claim") caused by or arising out of any activities carried out pursuant to this Agreement and the Protocol or by Sponsor’s breach of this Agreement, including death, injury, property damage caused by the use or administration the Study or Comparator drug or properly performed procedure required by the Protocol and the use by Sponsor of the Study data or results or Sponsor’s failure to comply with applicable law.
The above obligation of Sponsor shall not apply and Sponsor shall not be liable for any indemnification or expenses *to the extent* arising from or caused by (1) the willful, reckless, or negligent acts or omissions, or professional malpractice of the Indemnitees, (2) failures to comply with the Protocol, with Sponsor’s written recommendations and instructions relative to the use of the Study Drug, or (3) with any applicable FDA or other governmental requirements or law.
What is Subject Injury?

An injury caused by the treatment or procedures required by the protocol that the study subject would not have received if the subject had not participated in the study.
Why does it matter?

- Allocation of risk between parties
- No Federal or State laws mandate or assign responsibility for payment of subject injury
- Memorialize the parties’ understanding
- Federal law requires that research subjects are informed of potential adverse events/side effects that may occur during study and whether medical treatment will be available if the subject is injured

“Participants who are harmed as a direct result of research should be cared for and compensated. This is simple justice.” (National Bioethics Committee, Report August 2001)
Subject Injury Issues to Consider

- Who covers the costs?
  - Sponsor/Site/CRO/Subject/Third Party Insurer/Combination of these
- What injuries/costs are covered?
  - Costs that may be covered or excluded
- Who receives payment/reimbursement?
  - Site/Provider of treatment/Subject
- Where is SI addressed?
  - Contract/Informed Consent Form/LOI
Who will pay?

- Sponsor
- CRO (highly unlikely - but what about a failure to monitor?)
- Research Site
- Study Subject
- Study Subject’s insurance
- Provider of Medical Services
- Combination of the above
Consider This: What is covered?

- Is injury related to the drug/device/biologic or protocol-required tests and procedures?
- Who decides?
- Most agreements do not include injuries sustained concurrent with study participation but unrelated to participation
What exactly is covered?

- Medical costs associated with the diagnosis and treatment of physical injury
- Acute care
- Long-term care
- Typically does not include incidental expenses that may be caused by the physical injury
  - Lost wages
  - Pain and suffering
  - Punitive damages
- Survival
What is not covered?

- Pre-existing conditions
- Natural disease progression
- Injuries unrelated to the subject’s participation in the study
- Physician negligence, reckless misconduct, intentional bad acts, medical malpractice
- Site negligence, reckless misconduct, intentional bad acts, medical malpractice of employees
- Physician failure to follow protocol
Anything else?

- Injuries sustained by subjects who do not follow protocol or physician instructions
- Failure to “promptly” notify Sponsor
  - Advance notice not always possible, but site should be able to notify sponsor “promptly”
- Expenses covered by insurance or other third party payer
  - Does treating subjects differ based on status?
  - What about co-pays and deductibles?
What WE want:

- Sponsor agrees that it, and not Institution, is responsible for the costs of diagnosis, care and treatment of any undesirable side effects, adverse reactions, complications, illness or injury to a participant in the Study, which in the reasonable judgment of the Principal Investigator or Institution result from the Study participant’s participation in the Study, except to the extent such costs arise directly from (i) the negligent activities, reckless misconduct or intentional misconduct of Institution, the Principal Investigator or his/her staff or (ii) their failure to adhere to the terms of the Protocol.
What THEY want:

Sponsor will not provide payment for expenses to the extent they are in any way attributable to the negligence or willful misconduct of any person employed by or acting on behalf of the Institution. Sponsor will not pay for injuries unrelated to the Study Drug or procedures required by the Protocol which are in any way attributable to the natural course of an underlying disease or treatment process.
Consent: How much detail is needed?

- What are appropriate exclusions
  - Protocol violations?
  - Failure to comply with Sponsor's written instructions?
  - Negligence of the principal investigator/research institution?
  - Failure of subject to follow protocol requirements/PI instructions?
  - Progression of disease?

- How much care?
  - Emergency care only?
  - All costs up to $x.xx?
  - All reasonable and necessary costs of care?
  - Long term care?
  - Damages (e.g., indirect, consequential, etc.)?
Someone’s hurt: Who should I contact?

NMHC Office of Research

- **All Adverse Events Subject injuries** with a possible, probable or definite relationship to the research study must be promptly reported to the NMHC Office of Research if the injury occurs on NMHC property.

- Office of Research can be notified by sending a high priority email to accesspr@nm.org with the following in the email body:
  - a brief description of the event
  - subject’s name
  - the date of the AE (and admission/visit date**, if applicable)
  - basic research study information (IRB number, protocol title, PI name)

- Incident Reporting on NM Connect (NETS icon) Northwestern Event Tracking System- call 6-9880 for assistance
Insurance: Why is it necessary?

- No governmental mandates for clinical trial liability insurance
Insurance: What kind does each party need?

- Self-insurance
- Clinical Trials Insurance
- Products Liability
- General Liability
- Professional Liability
Sponsor Considerations

- Is Clinical Trial Insurance enough?
- How much coverage should Sponsor carry?
  - Type of drug/device test
  - Location of the test
  - Number of participants
  - Condition treated
  - Age of participants
  - Phase of testing
- What is the appropriate duration of coverage?
  - Extended Reporting Period provision (ERP)
Institution Considerations

- Ask to be added as an additional Insured on Sponsor’s policy
- Type of trial: Registry vs. Interventional
- What if the Sponsor is unable to meet required insurance minimums?
- Affiliated institutions may carry their own insurance
Participant Considerations

- Participant coverage usually excludes experimental or investigational treatments
- May also exclude routine care
- Medicare, you may know that it pays for many of the routine medical costs for people with cancer who are in approved clinical trials.
- Self-insurance loophole
- Affordable Care Act
Insurance and the World

- R&D has moved beyond US and Western Europe, and presents new challenges
- Unlike the US, the EU does require insurance for clinical trials
- In the EU, most require insurance to be written by an insurance company that is approved by regulators of the respective country
- Developed countries may have no insurance system at all.
Before We Part...

- Different types of trials mean different amounts of risk NU is willing to accept.
- Negotiations take time! Especially when we have to fight for what we need.
- The ICF: When in doubt if language is okay, ask us!
The End

Go be happy. Summer is upon us.

Thank you!

http://osr.northwestern.edu/