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AN OVERVIEW OF THE LEGAL RISKS OF CONDUCTING CLINICAL TRIALS AT ACADEMIC MEDICAL SITES

Session T208

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Conducting Clinical Studies Fosters Mission of Academic Medical Centers

- Faculty are encouraged to participate in clinical research as it supports the educational, patient care and research objectives of academic medical centers.
- Participating in clinical studies can enhance the reputation of an academic medical center and attract highly qualified medical professionals as well as students.

Legal Risks Associated with Conducting Clinical Trials

► Three Categories of Legal Risks Faced by Academic Medical Centers when conducting Clinical Studies:

1. Risks Associated with the Performance of the Clinical Study;
2. Risks Arising from the Use of the Clinical Study Data and Results; and
3. Regulatory Compliance Risks that are Secondary to the Performance of the Clinical Study.

**First category is more widely recognized but not necessarily the greater risk.*

Category 1 Risks: Risks Associated with Clinical Study Performance

- Risks involving Institutional Review Board (“IRB”) Responsibilities;
- Risks involving Study Recruitment and Enrollment;
- Risks involving Informed Consent Process;
- Risks involving Adverse Events/Study Subject Injury; and
- Other Potential Risks
 - Infringement of Intellectual Property from Use of the Study Device or Drug
 - DSMB Responsibilities

Risk Involving IRB Responsibilities

- Most Academic Medical Centers have internal IRBs to review and approve the protocols for the clinical studies their investigators conduct.
- These internal IRBs must comply with the applicable regulations and fulfill their obligations of ensuring:
 - 1. Adequate protection of rights/welfare of subjects;
 - 2. Benefits to subjects outweigh risks;
 - 3. Fair and equitable subject selection process; and
 - 4. Written informed consent signed by all subjects.

Risk Involving IRB Responsibilities

- Internal IRBs are being asked to take on coordinating roles for other sites
 - New risks arise from not clearly delineating responsibilities of the coordinating/central site from that of the other “local” sites
 - Level of knowledge – what was shared vs what you didn't ask about
 - Local rules (e.g. COI)
 - Differing state laws
 - Insurance coverage
 - Similar issues can arise with external IRBs

Risks Involving Study Recruitment and Enrollment

- Largely controlled by the Principal Investigator (PI) and his/her clinical staff.
 - But academic medical center bears full responsibility for any issues that arise.
- It is challenging for an Academic Medical Center to ensure that PI and his/her staff comply with eligibility requirements of the Study Protocol.
- Academic Medical Center must ensure that PI and staff are appropriately trained.

Risks Involving Informed Consent Process

- Informed Consent Form is a contract between the Study subject and the Academic Medical Center. See Abney v. Amgen, Inc., 443 F.3d 540 (2006).
- It is critical that Study Subjects be fully informed about the Study and understand the risks as well as what is expected of them.
- Note: Recent PA Supreme Court decision may have informed consent implications
 - Doctor had be the one obtaining medical procedure consent for major medical procedures

Risks Involving Study Subject Injury

- ▶ It is critical that the Study subject injury language in the informed consent form is **consistent** with the language in the clinical study agreement.
- ▶ A Study subject needs to be fully advised in the informed consent form as to what, if any, costs will be covered in the event he/she suffers an injury or illness as a result of participating in the clinical study.
- ▶ Most corporate sponsors have limitations/exclusions on the Study subject injury compensation they will pay and the Academic Medical Center must notify the Study subject of this in the informed consent form as it may impact a Study subject's decision to participate in the study.
- ▶ AMCs often have to deal with the Medicare Secondary Payer Rule and what "carve outs" are acceptable (e.g. subject following instructions)

Risks Involving Intellectual Property

- Your use of the drug or the device in the study could infringe on a patent or a copyright of another entity if the sponsor does not have appropriate rights for the drug or device
 - Typically addressed by warranty and/or indemnification clauses in the contract
 - Could be more difficult to address for investigator initiated protocols/studies (e.g. off label use, combinations with other products)
- How does conducting the study impact other research or background IP at your institution?

Risk Involving DSMB Responsibilities

- Depending upon your role in the clinical study (e.g. Investigator-Sponsor), you may be responsible for providing DSMB functions
 - Even if you contract this to an external entity, you can't completely exonerate yourself from responsibilities
 - Some potential issues:
 - Data accuracy
 - Responsibilities for interpreting the data
 - Delays or errors in notifications

Other Risks associated with conducting the study

- PIs and others needing to follow Good Clinical Practice (GCP)
 - Certification and training requirements
- Contractual gaps
 - What is the scope of your indemnification provisions?
 - What are the carve-outs?
 - Does the entity indemnifying you have adequate assets or insurance?
 - Are you an “additional insured”?

Category 2 Risks: Risks Arising from the Use of Study Data and Results

- Risks arising from Sponsor's use of Study data and results generated by Academic Medical Center;
- Risks arising use of Study data, results, inventions by Academic Medical Center or PI;
- Risks involving Contractual Confidentiality Breaches; and
- Data Breaches involving PHI, PII & Cyber Security.

Risks Arising from Sponsor's Use of Study Data and Results

- Most corporate sponsors require ownership or unrestricted right to use all study data and results.
- Thus, the Academic Medical Center has no control whatsoever over what the sponsor does with the data and results.
- This poses a significant potential risk to AMC's and their investigators because as the "creator" or "inventor" of such data and results, they could be listed as a defendant in a lawsuit filed by a third party.
- Authorship and role of the sponsor in the review and drafting of academic publications create additional potential liability.
 - E.g. how to address negative results
 - Having access to more than your site's data to validate results

Risks Arising From Use of Study Data By Academic Medical Center & Investigator

- Most corporate sponsors allow Academic Medical Centers & their investigators only limited rights to use Study data and results, such as:
 - Conduct of Study, including regulatory compliance
 - Publication (under CTA terms)
 - Non-commercial / internal research
 - Education
 - Patient Care
- Academic Medical Centers must ensure that their investigators are aware of the limitations and comply with them.

Risks involving Research Misconduct

- Plagiarism
- Fabrication
- Falsification

- What happens if there is an allegation or inquiry involving misconduct during the study?
- What if it moves into an investigation?
 - Obligations of confidentiality to the proceeding vs potential impact to the reliability of the data

 - When is it appropriate to share with sponsor?

Risks involving Contractual Confidentiality Breaches

- Corporate sponsors are very concerned about preserving the confidentiality of the Study data and results.
- A public disclosure, whether or not intentional, of a new discovery could prevent the sponsor from obtaining patent protection.
- Corporate sponsors are in a highly competitive environment and need to ensure that their new products in development are not known to their competitors.
- Corporate sponsors have obligations to comply with insider trading and other SEC rules regarding improper use of nonpublic information.
- Impact of FOIA like state statutes on “results” and the need to disclose negative results (e.g. safety concerns)

Category 3 Risks: Regulatory Compliance Risks Secondary to the Performance of a Study

- Billing Risks;
- Risks arising from Dissemination of Clinical Study Results;
- Risks involving payments from Sponsor Income

Billing Risks

- Distinguishing cost of standard of care treatment vs. costs of research-specific procedures can be challenging.
- Academic Medical Centers face serious regulatory consequences (including significant fines) for failing to keep these costs separate.
- Academic Medical Centers must implement clinical research management systems, ensure their staff understand the regulatory requirements and are thoroughly trained to comply with them.

Risks Arising from Dissemination of Clinical Study Results

The Food and Drug Administration Amendments Act (“FDAAA”) requires registration of certain categories of clinical studies on clinicaltrials.gov, and posting of basic results within 12 months following completion.

Additional reporting obligations apply for federally funded research with penalties for non-compliance that could extend to *all clinical study funding* for a non-compliant institution.

Thank You

Questions