Managing Clinical Research Risks in Academia

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Objectives of this course

This course highlights product liability and errors and omissions (E&O) risk exposures experienced by organizations engaged in clinical research and strategies that can be employed to reduce these risks.

Hospitals, universities, and academic medical centers are playing an increasing important role in furthering medical science research and medical product development. The impetus for translational research and medicine brings increased risk to the research institution.
Overview of the discussion

- Clinical Trials
- Investigational New Drug (IND)
- Investigational Device
- Legal Framework
- Interrelationships Between Parties
- Responsibilities of Parties
- Types of Clinical Trials
- Risk Factors Unique to Research Institutions (e.g., Academic)
- Protocol
- Informed Consent Form
- Clinical Trials Agreement
- Hypotheticals
- Considerations
What is a clinical trial and investigational drug or device?

- **Drugs/Biologics – 21 CFR 312.3**
  - “*Clinical investigation* means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.”
  - “*Investigational new drug* means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms ‘investigational drug’ and ‘investigational new drug’ are deemed to be synonymous for purposes of this part.”

- **Medical Devices – 21 CFR 812.3**
  - “*Investigation* means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.”
  - “*Investigational device* means a device, including a transitional device, that is the object of an investigation.”
• NDA = New Drug Application authorizes the marketing of drugs after FDA approval
• PDUFA = Prescription Drug User Fee Act date refers to FDA’s targeted deadline to approve the NDA
• Phase IV = may be optional or mandatory post-market surveillance study
• ANDA = Abbreviated New Drug Application is filed for generic marketing and does not require clinical trials
• IDE = Investigational Device Exemption application is filed before trials begin testing significant risk devices
• Feasibility Studies = There are a number of “feasibility studies” such as early, first in human, and traditional
• PMA = Premarket Approval is the process and clearance required by FDA to market significant risk devices
• 510(k) = Similar conceptually to the ANDA process for drugs; a shortcut to market a device if substantially equivalent to predicate device already tested
Legal, regulatory, and administrative guidelines – the framework

- **Federal Food, Drug, and Cosmetic Act (FD&C Act)**, enacted in 1938
  - Establishes the statutory foundation for FDA’s authority to oversee clinical investigations to test safety and efficacy of drugs and devices before market approval

- **Code of Federal Regulations (CFR)**
  - Regulations promulgated under the FD&C Act describing requirements and conduct of clinical trials
  - Examples
    - Institutional Research Board (IRB), sponsor, and principal investigator responsibilities

- **Guidance Documents**
  - These documents are advisory only and do not create or confer any rights for, or on, any person (e.g., they help explain the regulations)
  - FDA and International Conference on Harmonization (ICH)
Interrelationships of parties involved in clinical investigations

- Sponsor
- IRB
- Principal Investigator
- Contract Research Organization (CRO)
Important parts to 21 CFR for drugs/biologics and device investigations

- Drugs/Biologics
  - 21 CFR Parts 11, 50, 54, 56, and 312

- Medical Devices
  - 21 CFR Parts 11, 50, 54, 56, and 812

- 21 CFR 312 and 812 articulate the FDA requirements related to drugs/biologics and medical devices, respectively

- Where there is a 21 CFR 312 reference (drugs), there is likely a similar if not identical counterpart related to 812 (devices)

- Note: there are differences in 312 (drugs) and 812 (devices) (discussed below)
Investigator (Principal Investigator or “PI”) is an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the drug or device is administered or dispensed to a subject.

- Ensures the clinical investigation is conducted according to
  - the signed investigator statement (Form 1572),
  - the investigational plan (protocol),
  - applicable regulations
  - Note: no Form 1572 counterpart for general responsibilities in device investigations; instead, agreement between PI and sponsor
- Protecting the rights, safety, and welfare of subjects under investigator’s care
  - Example: not following protocol may represent a failure to protect these rights if noncompliance exposes subjects to more risk/injury
- Control drug/device under investigation
- Comply with provisions of 21 CFR 50 – informed consent is obtained properly
- Comply with provisions of 21 CFR 56 – IRB review, approval, and reporting
Specific responsibilities of investigator

- Investigator record keeping and retention (21 CFR 312.62)
  - Maintain adequate records regarding the disposition of the drug
    - E.g., dates, quantity, use by subjects
  - Prepare and maintain case histories on all observations to the investigation on all subjects receiving drug/control
    - E.g., to include case report forms and data such as informed consent forms and progress notes by Drs./nurses
  - Retain records for 2-year period following market approval of drug
    - If not going to be marketed, keep 2 years after discontinued
- Investigator reports (21 CFR 312.64)
  - Furnish all progress reports to sponsor
  - Immediately report to sponsor any serious adverse event (SAE) regardless of being referenced in protocol or investigator brochure
  - Final report to sponsor in the immediate aftermath of the investigation
  - Investigator must provide sponsor financial information so sponsor can disclose properly to FDA (reliance on investigator)
    - Keep sponsor updated through trials and for 1 year following completion
Specific responsibilities of investigator

- Requirements for devices under 21 CFR 812 for significant risk device investigations
  - Specific responsibilities (21 CFR 812.110)
  - Maintaining records (21 CFR 812.140)
  - Inspections (21 CFR 812.145)
  - Submitting reports to sponsor and IRB (21 CFR 812.150)
  - Prohibition of distribution/tracking (21 CFR 812.110 and 812.140)
  - Prohibition of promotion (21 CFR 812.7)
- Lots of overlap between 312 (drugs) and 812 (devices) in these sections, but there are differences
  - Unique/Additional requirements
Institutional Research Board (IRB) – 21 CFR 56

IRB: board/committee designated by institution to approve the initiation of, and continuing review of, research involving humans

- **Purpose**: ensure rights and welfare of human test subjects
- **Reviews initial/ongoing research activities (from investigator)**
  - Protocol, investigator’s brochure, consent form (and supporting documents), qualifications of researchers, reports from investigator including progress and injuries, compensation to subjects
- **Communication channel is to the investigator and institution (not sponsor)**
  - E.g., its decision to approve, disapprove, or request changes to the proposed investigation (IRB ↔ investigator); provide in writing
- **FDA does not certify IRB, but IRB registers with the U.S. Department of Health and Human Services**
  - IRB subject to FDA inspections
- **IRB must continue to monitor the research and the consent process as appropriate based upon the risk but at least once/year**
- **Overall**: risks to subjects are reasonable in relation to possible benefits and consent contains adequate description of investigation and its risks
General responsibilities of sponsor (21 CFR 312.50)

Sponsor: the party that initiates and takes responsibility for the investigation but does not actually conduct the trial, e.g., pharmaceutical companies or medical device firms, government agency, or academic institution

• Selecting qualified investigators
• Provide them with the information needed to conduct investigation properly
• Ensuring proper monitoring of investigation (e.g., data safety and monitoring board)
• Ensuring investigation is conducted in accordance with general investigational plan and protocol
• Maintaining effective IND (i.e., for drug studies)
• Ensuring that the FDA and investigator are informed promptly of new serious adverse effects or risks of the drug
Sponsor-investigator

- PI-initiated protocols are initiated by an *individual* (i.e., a natural person) who conducts the investigation (i.e., the sponsor-investigator)
  - E.g., employee of academic institution/research center
  - Note: PIs in sponsor-initiated trials often, but not always, involve employees of academic institutions

- The sponsor-investigator’s responsibilities in PI-initiated trials:
  - 21 CFR 312.50 (i.e., sponsor responsibilities), and
  - 21 CFR 312.60 (i.e., investigator responsibilities)

- Significant responsibility for PI

- Vicarious liability exposure for research center/academic institution
Party developing protocols and initiating **trials**

- **Sponsor-initiated trials**
  - The drug/device is owned (or licensed) and funds the investigation
  - Sponsor (or its agents) designs the study plan and protocol

- **Investigator-initiated trials (PI-initiated)**
  - Sponsor-investigator develops the protocol
  - The drug/device may be owned by a university and/or brand company
  - The brand company may act as a source of funding (i.e., industry-sponsor)
  - Examples
    - University’s patent(s) and industry-sponsor is a prospective licensee,
    - Investigator’s research discovers a new indication for drug approved but not approved for that indication

- **Incentives**
  - Sponsor-initiated: market-driven
  - Investigator-initiated: research accomplishments and new treatments for their practice
  - Note: altruism and economics play a role in each type
General flow for a clinical investigation

- Investigator/Research Center
  - SAEs
  - Proceed/Halt
- Sponsor
  - SAEs
  - Materials/PI reliance
- IRB
  - Materials
  - Inspect
- FDA
  - SAEs/Label change
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Risk factors unique to academic/research institutions

- Protocol
  - Key features

- Informed consent
  - Form (informed consent form (ICF))
  - Process
  - Elements
  - Evolution (hard copy → electronic)

- Clinical trials agreement (CTA)
  - Provisions
  - Differences in CTAs for (PI-initiated vs. sponsor-initiated)
The protocol

- Primary component to ensure subject safety and quality data
- Issue: complex
  - ICF and process (below), exclusion/inclusion criteria, drug administration schedule, scheduled data collection, tests, monitor side-effects, reporting of adverse events (AEs) and SAEs, when subject should be withdrawn, and endpoints
- Risk mitigation: brokers, risk control, insurers, risk managers at sponsor/institutions
  - Varying knowledge, incentives, and risk tolerance
- Examples
  - Does the ICF provide adequate warnings that mirror the exclusion criteria disclosed in the protocol?
  - Delegation by PI to others on study team (complex, not *per se* improper, must have qualifications commensurate with task)
- Delegation risks: screening inclusion/exclusion criteria, exams, evaluating AEs, assessing endpoints, informed consent
Informed consent

- Informed consent (IC) is a form and a process

- Provides potential subject with adequate information about benefits, risks and alternatives → informed decision about investigation participation → subject’s voluntary agreement to participate → continuing to provide information over the investigation

- Elements of IC (21 CFR 50.25)

- Process
Informed consent elements *(21 CFR 50.25)*

- Statement that the study involves research, purposes, procedures
  - Physician-patient ≠ investigator-subject relationship
  - Purpose: to evaluate safety, or efficacy, of drug/device
  - Procedures pertaining to study design and treatment
  - What’s required of the subject
- Description of reasonably foreseeable risks or discomforts to subject
  - Risks for the drug/device, but also for tests to assess study drug/device
- Description of reasonably expected benefits to subject or to others
- Disclosure of alternative procedures/course of treatment that may be advantageous to subject
- Statement describing extent of confidentiality of records identifying subject will be maintained and possibility that the FDA may inspect medical records
  - Will the sponsor also have access?
  - Do not imply absolute confidentiality
  - FDA inspections → no subject permission necessary → make this clear
Informed consent elements (21 CFR 50.25)

• For research with greater than minimal risk, explain the existence of compensation or medical treatments available if injury results, or where to get more information.
  – Be precise about if and how medical treatment and compensation will be addressed, or if it will not be provided.
  – E.g., “sponsor has set aside funds for medical costs... here’s how to seek reimbursement”
  – If no compensation or free medical care is provided, then it is recommended that the statement should state “…because of hospital policy, the hospital makes no commitment to offer free medical care for unfavorable outcomes of this investigation... however, you are not precluded from seeking recovery for injury related to malpractice, fault, blame on those involved in the investigation including the institution…”
  – No exculpatory language, such as “compensation is not available” or “medical costs will be your responsibility or your insurer’s responsibility”
  – Typically, most academic research institutions will prohibit billing subjects or their insurers for such medical treatments
  – ICF should be consistent with institution policy and CTA
Informed consent elements \(21\ CFR\ 50.25\)

- Explanation of whom to contact for answers to (1) subject’s rights, (2) research-related injury, and (3) the research study
  - Name of the person or office and telephone number to answer questions about these three topics
  - There should be two different groups responding to question (1) vs. (2) and (3)

- A statement that participation is voluntary, no penalty imposed for refusing to participate, and may discontinue at any time with no penalty or loss to subject
  - Consequences to withdraw language should inform, rather than intimidate
Informed consent – additional elements (CFR 50.25(b))

- Unforeseeable risk (e.g., pregnancy)
- Involuntary termination from investigation
  - Investigator may withdraw subject under circumstances without consent
  - Statement alone → not adequate
  - “…subject needs to follow study procedures…or else…” → not adequate
  - “…subject may be withdrawn if they don’t follow the instructions given to them by the investigator…” → adequate
- Additional costs to subject
  - Dependent on the investigation, sponsor, and site (e.g. academic)
  - If applicable, ICF must explain added costs (e.g., tests, procedures, etc.)
  - Consider institution policy
  - Subject’s insurance → explain may not be covered (although coverage may customarily apply outside the context of a clinical trial)
  - Other indirect costs → loss of income, transportation, may be appropriate
Consequences of subject’s decision to withdraw from the study
- If tests are needed for early withdrawal, state explicitly why and how the tests will be performed
  - “…tests will need to be done if you withdraw…” → not adequate

Statement providing significant new findings will be provided to subjects
- Important for unexpected AEs or increased frequency of disclosed AEs
  - E.g., phase I, new chemical entities, etc.
  - IRB should ensure that a system or plan is in place to provide such notifications

Number of subjects if material to decision to participate in investigation
Informed consent – **process**

- **IC is more than a form; it is a process**
  - ICF, recruitment materials, verbal instructions, Q&A sessions, assess capacity to consent, comprehension
- **Who?**
  - Who will conduct the consent interview?
    - Is there delegation?
- **What?**
  - Present the elements of the ICF and emphasize critical parts
- **When?**
  - Delay of consent may be necessary to avoid possible coercion
- **Where?**
  - Where is the interview being conducted?
    - E.g., pre-op/waiting room vs. Dr.’s lounge/office
- **How?**
  - How to assess comprehension and how to document consent?
    - E.g., ask open-ended questions and sign/date ICF
Informed consent – process

• Ultimately, the investigator is responsible for consent, but the IRB plays a significant role, and the sponsor to a lesser degree
• Informed consent → balance of too much/insufficient information
  – Eighth-grade level
• Long form → traditional
• Short form → used under certain circumstance (special rules)
• Electronic consents → becoming popular → benefits
  – Facilitates better understanding of benefits, rights, and risks
  – Manageability of screening/enrollment, compliance, and oversight
• Electronic consents → becoming popular → considerations
  – Sponsors/investigators → send text to IRB before locking it into a format
  – When using an outside vendor for graphics, voice over, animation, etc., third-party vendor and sponsor should jointly submit materials
  – IRB can provide conditional approval when most materials are presented
  – Mere conversion of text to digital → no conditional approval needed → final approval OK without further review
Clinical trial agreement (CTA)

• Agreement between the sponsor and the institution that defines parties’ roles, rights, and liabilities under various circumstances

• Example of provisions
  – the parties, if a CRO is involved, sponsor-initiated or PI-initiated, the scope of the work, fees, access to data, IP rights (and under what circumstances), publication rights/academic freedom, extent of confidentiality,…etc.

• Bodily injury claims and financial loss allegations typically include the following:
  – Indemnification, Subject Injury, and Insurance provisions
  – Balance of power of the parties plays a role
  – Sponsor-initiated or PI-initiated
  – Public institution or private
  – Provisions to attempt to limit liability
CTA – indemnification provision

- Sponsor-initiated trials often contain the following provisions:
  - Sponsor agrees to “indemnify, defend, and hold harmless” the institution
  - It is the sponsor’s test article, and sponsor should assume the liability for its testing
  - Except to the extent such liability is due to the negligence of the Institution

- Parties' leverage makes a difference
  - Indemnity obligations to institution → bodily injury and property damage or for all liability "arising out of" and/or "in connection to" the drug/device investigation?
  - Is institution indemnified unless it is grossly negligent or just negligent?
  - Reciprocal indemnification -> position of power but also will depend on whether the Institution is public or private due to sovereign immunity issues
    - sovereign immunity, which may be absolute or qualified depending upon relevant state law
• Sponsor-initiated trials, (continued)
  – Sponsor may settle, but it cannot settle admitting liability against institution
  – This indemnity should not be considered excess coverage to any insurance the institution may have
  – Sponsor is responsible regardless of its insurance limits and coverage
  – Consult with your legal counsel regarding appropriate indemnification provisions
CTA – sovereign immunity

• “Rex non potest peccare” → “the king can do no wrong/sin”
• Cannot bring suit against state (e.g., a public institution) unless it consents
• All 50 states have a version of sovereign immunity statute, which may be absolute or qualified immunity depending upon the state law
• Under these laws, the State will typically substitute itself for the defendant-Dr. allegedly causing the damage
  – Plaintiff must choose one (i.e., the state or the Dr.)
• Risks/benefits depend on the statute (e.g., is there a cap, administrative procedure only, are punitive damages available, are there provisions pertaining to the role of insurance coverage?)
• It matters because it plays a role in litigation strategy and risks to PI, institution, sponsor
• Public institutions will not waive this immunity in a CTA → procedure/limitations of recovery according to state statute
• Typically silent on institution indemnifying sponsor (even for institution's negligence)
CTA – indemnification provision

• PI-initiated trials
  – The trial/protocol was developed by the PI (i.e., the sponsor-investigator), typically, PI is employee of institution, sponsor-PI is solely responsible for the scientific and technical aspects of the study,…
    • So, industry-sponsor (providing $ and/or materials) should not be required to indemnify institution, right?
  – Indemnification obligations will vary significantly
    • Industry-sponsor providing broad indemnification to the institution
      – “sponsor shall defend, indemnify, and hold harmless…from any and all liability…arising out of/in connection with…”, or
    • Institution indemnifying industry-sponsor for institution’s negligence
      – “institution agrees to indemnify, defend, and hold harmless the sponsor for bodily injury claims caused by institution’s negligence…”, or
    • Silent
      – Sovereign immunity
      – Parties’ negotiating leverage
Summary of indemnification practices

- Sponsor-initiated/private institution
  - Institution may indemnify to the extent of its negligence
  - Not typically explicit
- Sponsor-initiated/public
  - Institution will not typically indemnify
  - Subject to sovereign immunity restrictions
- PI-initiated/private
  - Variations
    - *From* broad indemnification/defend obligations from industry-sponsor to institution (w/ no mention of institution’s negligence)
    - *To* institution indemnify/defend industry-sponsor for its negligence (w/ weak language relative to indemnity for product liability)
      - Negotiating leverage, nature of the test articles, institutional practice, etc.
- PI-initiated/public institution
  - Institution *may* indemnify sponsor for its negligence
  - Limited by sovereign immunity statutes
CTA – subject injury

• Sponsor-initiated
  – “sponsor is responsible for cost, care, treatment, diagnostics…related to the investigation…”
    • “except for costs resulting from a failure to adhere to the protocol…”, or
    • “sponsor is not responsible for medical expenses resulting from a violation of protocol…”
  – Billing third parties or the subject is prohibited typically
    • Medical expenses

• PI-initiated
  – CTA is typically silent regarding subject injury (silent)
  – CTA includes provisions regarding institution’s responsibility for medical costs
  – Sometimes, the institution will state that neither it nor the sponsor-investigator will bill subjects or their insurers (for subject injury)
CTA – insurance

- PI-initiated investigations → not a lot of information for this topic
- Sponsor-initiated trials, the CTA will/should have requirements from sponsor
  - Clinical trial/products liability insurance to cover the term of the CTA
  - Minimum of $5MM/occurrence and $10MM annual aggregate
  - Institution (and its affiliates) as additional insureds
  - Coverage is primary
  - Certificate of insurance (cert) prior to CTA effective date evidencing the above
  - The CTA may contain a provision that the sponsor agrees to purchase adequate tail coverage to…
    - “provide uninterrupted cover for all claims arising from…”, or
    - “for a minimum of three years after…”
- Recall, this insurance pertains to bodily injury from the study drug/device
  - Not financial loss
  - Not medical malpractice exposures to institution/research center and PI
CTA – other provisions

• No Warranty
  – “The institution makes no warranties, express or implied, regarding any performance under this agreement…the marketability, use or fitness for any particular purpose…the research, the results of the study,…”

• Limitation of Liability
  – “The institution shall not be liable for any special, consequential, indirect, incidental damages resulting from data loss, using the results from the study, a delay in the study, or an early termination of the study…”

• Inclusion will depend upon the balance of power between parties

• May not be effective
  – May not be found valid and/or applicable
  – Costs associated with enforcing/defending the position against sponsor
Exposures to research institution

- Bodily injury from the product (product liability)
  - Sponsor-initiated trial
    - Suit names many parties
    - Exposure to institution → filtered through the CTA (e.g., indemnity, defense, insurance, subject injury, etc.)
      - Remaining exposure to institution
  - PI-initiated trial
    - Multiple defendants named
    - CTA often not adequate cover to institution → exposure to institution
- Bodily injury from institutional negligence (medical malpractice)
  - PI, IRB, staff
  - Exposure to institution
- Financial loss to sponsor (errors and omissions)
  - Damages and legal costs
  - Delay in trial → sponsor suffers financial loss
  - Error in trial → trial must be repeated → sponsor suffers financial loss
Exposures to research institution

- Drug/Device (failure to warn)
  - Institution/trustees
  - Sponsor

- Medical malpractice (adhering to protocol)
  - Institution/trustees

- Bodily injury suits
- Dispute over cause?

- Delay in trial
  - Institution/trustees

- Error in trial
  - Institution/trustees

- Sponsor financial loss
- Sponsor- or PI-initiated?

- Indemnity and insurance?
- Adequacy of limits/cover?
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- Considerations
Hypotheticals

• There is an interplay between product liability (clinical trials) insurance coverage and the medical malpractice (med mal) coverage for the PI and institution

• Variables to consider include the following
  – PI is an employee/contractor, the trial is sponsor- or PI-initiated, deviation in protocol, other patients near the trial site, breadth of malpractice policies

• Other med mal policy considerations
  – Definitions of “medical services,” “professional services,” “patients,” “subjects,” “employees,” “consultant/contractors,” etc.

Please note that the coverage analysis presented is generic and is not a reference to coverage under any CNA policy.
Hypotheticals

- Sponsor-initiated protocol – PI is an employee
  - Subject is injured by the study drug/device, PI follows protocol, subject sues everyone including PI and institution
  - Coverage for institution?
    - Sponsor’s products-work hazard could cover
    - Institution should be an additional insured
    - Certificate of insurance evidences proper limits, cover, terms

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Hypotheticals

• PI-initiated trial – PI is an employee
  – PI follows the protocol, the study drug/device does not cause the injury, but subject is injured due to other institutional failure (e.g., reagents, equipment, other systems, etc.)
  – Coverage for institution?
    • Institution's med mal may cover
    • Possible coverage from a products-work hazard policy (if the institution had such cover)
      – Products-work hazard could respond to bodily injury claims arising from the institution’s clinical trials
      – Consider same carrier for med mal and products-work hazard policies → avoids coverage uncertainties on indefinite claims

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Hypotheticals

- PI is an employee of institution
  - PI participating in a trial, a *patient* asks PI to examine his lump, PI does not deviate from *subject* and follows trial protocol, sued by patient for injuries resulting from not treating/examining his lump
  - Coverage for institution?
    - Sponsor’s products-work hazard covering the trials would not cover
    - Institution’s med mal would likely cover
- PI is an employee of institution
  - PI participating in a trial, a *patient* asks PI to examine his lump, PI helps the patient, and deviates from protocol at the expense of *subject* in trial, subject is injured, sued by subject
  - Coverage for institution?
    - Sponsor’s products-work hazard covering the trials will not respond
    - Institution’s med mal *may* cover (e.g., clinical trial, subject and not patient, type of trial, etc.)

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Hypotheticals

- Sponsor-initiated trial – PI is a contractor
  - Trial underway, patient asks contractor-PI about lump, PI ignores patient and follows protocol to stay engaged on subject, patient sues research institution for ignoring lump that caused patient injury
  - Coverage for institution?
    - Sponsor’s product liability/clinical trials insurance not likely to cover b/c injury not caused by the study drug/device/protocol
    - Institution’s med mal will likely not cover unless the contractor-PI gets an endorsement from PI’s own carrier to cover off-site practice

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Hypotheticals

- Sponsor-initiated trial – PI is a contractor
  - Patient’s lump situation, contractor-PI treats patient, gets distracted, deviates from protocol in a way that affects subject, subject sues contractor-PI, institution, sponsor, IRB, etc.
  - Coverage for institution?
    - Sponsor’s products/clinical trials policy not likely to respond b/c the contractor-PI did not adhere to the study protocol
    - What about the institution’s med mal?
      » Perhaps, assuming the contractor-PI’s med mal was endorsed accordingly to cover activities at the trial site

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Hypotheticals

• Note: even with an endorsement evidencing contractor-PI’s med mal to practice at the research site (institution), it will not cover automatically clinical trial activities
  – PI → make sure the privilege endorsement for a particular site/institution includes med mal for the clinical trials
  – Institution/clinical site → do not ask merely for a cert evidencing “proper liability coverage” that will be primary, $ amount of limits, that the institution is additional insured, etc.
    • Ask that the cert evidence med mal for bodily injuries resulting from the clinical trials
• Sponsor-initiated trial – PI is a contractor
  – The contractor-PI follows protocol, the med mal is endorsed to reflect activities at the new site including the trial, and a test subject is injured by the study drug
    • Sponsor’s products/clinical trials policy should cover this bodily injury

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Considerations

- Importance of CTA provisions
- ICF and IC process
- Communication between IRB and PI
- Type of trials (sponsor- or PI-initiated)
  - PI-initiated → additional responsibilities to PI → exposure to institution
- PI status as employee or contractor
- PI credentials/staff training
  - Careful with delegation
  - Caseload monitoring
- Institution’s insurance program
  - e.g., scope of medical malpractice, its own products-work hazard, E&O for financial loss
- Single carrier to ensure incentives are aligned and reduce gaps in coverage
- Exposure not just to damages → exposure to legal costs also