Clinical Trial Agreement Provisions – The Nits

Idaho State Bar Association
Health Law Section

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Michael C. Roach, JD, MHSA, MA, CHRC, CIP
mroach@aegis-compliance.com

Overview

- Subject Injury
- Indemnification
- Confidential Information
- Survival
- Independent Review
- Intellectual Property
- Access to EHR
- Use of Study Results
- Publication
- Debarred Individuals
- CRO a Party

Subject Injury

- Typical sponsor template:
  - "If subject suffers injury from any procedure done as party of the Study that the subject would not have had if he/she was not in the Study, Sponsor shall reimburse Institution the cost of medical services provided by the Institution to treat the injury."

- Problems?

Subject Injury

- "If subject suffers an injury from any procedure done as part of the Study that the subject would not have had if he/she was not in the Study, Sponsor shall reimburse Institution the cost of medical services provided by Institution to treat the injury."

Possible Alternative

- "If a subject suffers a Research-Related Injury (as defined below), the subject may seek medical care from any health care provider. Sponsor shall pay Institution, Principal Investigator, and the health care provider, as applicable, its usual and customary fee for reasonable diagnostic procedures and medical/surgical treatment provided by them that is necessary to treat a Research-Related Injury."

- Substitute "X % of Medicare Rates" for "usual and customary fee"?

Define "Research-Related Injury"

- "A 'Research-Related Injury' is a complication, injury or illness caused directly by the Study Drug or a procedure administered in accordance with the Protocol, as determined by the data safety monitoring board for the Study, if any."

Research-Related Injury

"Research-Related Injuries do not include: known complications or risks as documented in the informed consent form signed by the subject; the natural progression of an underlying or preexisting condition; injuries that would have been expected from the standard treatment using currently approved therapies for the subject's condition; injuries that are attributable to the negligence or misconduct of the Institution or any Institution Indemnitee; or injuries that are attributable to the failure of the Institution or Institution Indemnitees to perform the Study in accordance with the Protocol or written instructions provided by Sponsor or its designee, excluding deviations from the Protocol that arise out of medical necessity and deviations that are immaterial to the injury."

AEGIS COMPLIANCE & ETHICS

Indemnification

- Sponsor indemnifies for physical injury or death from study drug or device
  - Add:
    - breach of CTA
    - Sponsor negligence
    - Improper use of subject individually identifiable information by Sponsor
- Expand to cover actions by Sponsor or its affiliates, directors, etc.?

Confidential Information

- Very broad definition of sponsor's "CI"
  - Always includes study data/results
- Rarely reciprocal
  - What about site pricing info?
- Prohibits use and disclosure except as permitted in the CI section
  - What about publication; use for teaching and non-commercial research
- Does not allow for disclosure to Institution's attorneys, accountants, or consultants
  - Claims audits
  - Tax analysis

AEGIS COMPLIANCE & ETHICS

Survival

- Two approaches
  - General
    - "Provisions of this Agreement which by their nature are intended to continue in force after termination of this Agreement or which expressly require performance after termination of this Agreement, shall survive such termination."
  - List specific sections
    - Sponsors rarely include "payment" section
      - Hold backs

Independent Review

- Want statement that each party has had a chance to review the agreement and have it reviewed by its counsel

- If 3-way agreement, statement that lawyer for site does not represent PI

Intellectual Property

- Institution, PI and research personnel giving up all interest in any IP developed as result of the conduct of study
  - Bayh-Dole Act implications
- Tax-exempt entity giving something of value to for-profit entity
- Add provision that site can amend or terminate if its advisors conclude agreement threatens tax-exempt status.

Access to EHR

- Sponsor/CRO needs access to monitor
- How to limit?
  - Confidentiality agreement signed by monitors
  - Chaperone
  - Technological fix
- Be sure to address in CTA

Right to Use Results

- Want (need?) right to use results internally for education and non-commercial research
- Confidentiality provisions may preclude internal use
  - Need specific permission to use results internally

License to Use Results

- "Notwithstanding anything herein to the contrary, Institution and Investigator are each hereby granted a perpetual, non-exclusive, non-royalty bearing license to use Study Data generated and contributed by Institution and/or Investigator (i) for internal, non-commercial research and educational purposes, subject to the confidentiality provisions herein, and (ii) for preparation of publications and presentations as provided for herein."

Publication Rights

- When can you publish?
  - Completion of study
  - Final database lock
    - This is more clearly defined than "completion of study"
- Waiting period for multi-center study
- Sponsor review period
- Patent protection period
- Do you have a combined maximum delay you will allow?
  - 30 days for sponsor review and
  - 60 days for patent filing

Publication Rights

- Need express carve-out in confidentiality section
- Sponsor right to require changes?
- Beware publication committees
  - And language that protocol controls

Debarred Individuals

- Not reciprocal
- Typically requires Institution to speak for PI and sub-investigators
- Make reciprocal
  - Site needs to know as much as sponsor does
  - Expect push back!

CRO as Party

- Sponsor has rights and obligations in CTA
- Sponsor not a party
- Need rep and warrant from CRO that it has authority to bind the sponsor

Questions and Discussion