Differences Between Industry-Sponsored, Industry-Supported and PI-Initiated Studies

Frederick M. Frankhauser, JD, MBA, RPh

Director, Grants and Contracts

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Different Types of Agreements

- Confidentiality Agreements-
- Clinical Trial Agreements
  - Corporate Sponsor
  - Non-Corporate Sponsor
    - *Federal (NIH), State, non-profits and foundations*
- Sponsored Research Agreements
- Bench Science License Agreements
- Material Transfer Agreements
- Consulting Agreements
- Software Agreements
- Purchase Agreements
- Service Agreements

Types of Studies

- Investigator initiated
- Sponsor initiated
- Jointly initiated

Funding: What is covered and What is not

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Industry funded clinical research projects

- IDC rate
- IRB fees
  - Initial review
  - Annual maintenance fee
  - WIRB fees
- MCA
- Pharmacy Fee
  - Annual maintenance fee
  - Injections or infusions

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What about?

- Shipping costs
  - Dry ice
  - Delivery
- Start up costs
- Inflation
- Early termination
- Record retention
- Insurance
- Subject Travel expenses
  - Parking
  - hotel
- Advertising/Recruitment
- Biostatistics
- Labs

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Academia's Mission

- Generate and disseminate knowledge
  - Research
  - Education
  - Patient Care

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Industry's Mission

- Preservation of its investment in its assets
- Assuring integrity of the data as the study Sponsor
- Sponsor must ensure its regulatory responsibilities are met
- Commercialization of drug developed

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Contractual Terms

- Names of Parties/Signature
- Recitals
- Scope of Services
- Notices
- **Publication**
- **Confidentiality**
- Data
- **Intellectual Property**
- Insurance
- **Indemnification**
- **Subject Injury**
- Term and Termination
- Use of Name/Publicity
- Governing Law/Venue
- Other terms
- Terminology

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Intellectual Property

- Who owns the Idea
- What are restrictions, if any, to publications?

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Scenario #1

- Publication or presentation of the methods and/or results of the Study by the Institution or Investigator is not permitted.

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Publication

- Primary goal of academia
- Dissemination of unbiased information for public good.
- Means by which investigator achieves recognition in the field.
- Means by with the Institution achieves prominence.
- If no publication, why would academia be involved in the conduct of a study?

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Publication

- What does the Sponsor want?
  - Protect its confidential information and complete the study
  - Prevent unfavorable or neutral results
- What might the Sponsor want?
  - Limit the publication of negative data
  - Suppress or minimize negative results
- Who can publish; what and when
  - Define institution's right to publish results arising from its participation
  - Define sponsors right of review and comment
  - Define time frames for submission to sponsor for review and comment
    - *Delay – not to exceed on average 90 days*
    - *Multi center delay not to exceed 12 months*

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Scenario #2

- It is understood that this Study is part of a multi-center study Institution and Principal Investigator agree to use best efforts to not disclose the publicly unavailable results of the Study to any third parties, until the multi-center results of the Study are submitted for publication in accordance with this Section. Thereafter, Principal Investigator shall be free to publish the results of the Study subject only to the provisions of Section X regarding Sponsor's Confidential Information. The Principal Investigator shall furnish Sponsor with a copy of any proposed publication for review and approval prior to submission for publication, at least ninety (90) days prior to submission for manuscripts. At the expiration of such ninety (90) day period, Principal Investigator may proceed with submission for publication; provided however, that upon notice by Sponsor that Sponsor reasonably believes a patent application claiming an Invention (as defined in Section Y) should be filed prior to such publication, such submission shall be delayed until any patent application or applications have been filed.

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Scenario #2

- It is understood that this Study is part of a multi-center study and a publication of results from all sites is expected. Institution and Principal Investigator agree to use reasonable efforts to not disclose the publicly unavailable results of the Study to any third parties, except other clinical sites in the Study or as otherwise provided under this Agreement or agreed in writing by Sponsor, until the multi-center results of the Study are submitted for publication in accordance with this Section, or until notification that a submission of the multi-center results is no longer planned, or for twelve (12) months after termination of the Study at all sites, whichever shall first occur. Thereafter, Principal Investigator shall be free to publish the results of the Study subject only to the provisions of Section X regarding Sponsor's Confidential Information. The Principal Investigator shall furnish Sponsor with a copy of any proposed publication for review and comment prior to submission for publication, at least thirty (30) days prior to submission for manuscripts and at least seven (7) days prior to submission for abstracts. At the expiration of such thirty (30) day or seven (7) day period, Principal Investigator may proceed with submission for publication; provided however, that upon notice by Sponsor that Sponsor reasonably believes a patent application claiming an Invention (as defined in Section Y) should be filed prior to such publication, such submission shall be delayed for an additional sixty (60) days or until any patent application or applications have been filed, whichever shall first occur.

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Confidentiality

- Define confidential information
  - Inclusion/exclusion
- Sponsor wants broad definition
  - All information disclosed to the study and generated by the study
  - Study results confidential?
- Institution wants narrow definition
  - Decrease risk of exposure
  - Disclosed in writing and marked confidential
- Information must be identified in writing
  - If verbal, reduce to writing (10 days)
- Will Institution be disclosing confidential information?
  - Protected Health Information ("PHI")

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Confidentiality

- Return of Confidential Information
  - Copy for non-commercial, archival, educational purposes
- What are the time restrictions?
  - Ensure a reasonable time period (3, , 7 or 10 years)
  - What about PHI?
- Exceptions
  - Third party disclosure
  - Publication
  - Independently developed
  - Was known prior to the date of disclosure
  - Required by law, advance notice, and opportunity for sponsor to limit or narrow exposure

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Scenario #3

- “Institution and Investigator agree that the Protocol, Study Drug, CRFs, and any and all information, data, reports or documents of any kind learned, disclosed to or generated by Institution or Investigator regarding any phase of the work to be performed under this Agreement or otherwise provided to Institution or Investigator to which relates to the Study (“Confidential Information”) shall not be disclosed by Institution or Investigator to any third party or be used for any purpose other than the performance of the Agreement without the prior written consent of Sponsor, during or at any time after the termination of the performance of the Agreement provided, however, that such obligations of confidentiality shall not apply to:….”

Scenario #3

- “Confidential Information” refers to information of any kind which is disclosed by Sponsor to a
and which, by appropriate marking, is identified as confidential and proprietary at the time of disclosure. In the event that Confidential Information must be provided visually or orally, obligations of confidence shall attach only to that information that is confirmed by Sponsor in writing within ten (10) working days as being confidential.

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Scenario #3

- Each Recipient shall use Sponsor's Confidential Information solely for the purposes of conducting the Study, obtaining any required review of the Study or its conduct, or ensuring proper medical treatment of any patient or subject. Each Recipient agrees to make Confidential Information available only to those employees and students of Institution who require access to it in the performance of this Study and to inform them of the confidential nature of such information.

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Scenario #3

- For a period of three (3) years after the Effective Date of this Agreement, each Recipient agrees to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received from Sponsor and accepted by that Recipient only in accordance with this Section Z.

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Scenario #3

- Exceptions
  - it is publicly available prior to the date of the Agreement or becomes publicly available thereafter through no wrongful act of any Recipient;
  - it was known to any Recipient prior to the date of disclosure or becomes known to any Recipient thereafter from a third party having an apparent bona fide right to disclose the information;
  - it is disclosed by any Recipient in accordance with the terms of Sponsor's prior written approval;
  - it is disclosed by Sponsor without restriction on further disclosure;
  - it is independently developed by any Recipient; or,
  - any Recipient is obligated to produce it pursuant to an order of a court of competent jurisdiction or a facially valid administrative, Congressional or other subpoena, provided that the Recipient subject to the order or subpoena (A) promptly notifies Sponsor and (B) cooperates reasonably with Sponsor's efforts to contest or limit the scope of such order.

Intellectual Property

- Sponsor ownership – direct performance of the Study as outlined in the Protocol
  - Phase of the Study
  - Single center v. multi-center
  - Who developed the protocol? Sponsor initiated v. PI initiated
  - Non-exclusive, non-transferable, royalty-free license for internal research, educational, and patient care purposes
- Institution ownership – outside the Protocol
  - Expenses, who pays?
  - Provide sponsor six (6) month opportunity to negotiate exclusive, royalty bearing license
- What about a new use?

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Indemnification

- Indemnify
  - To reimburse a loss that someone has suffered because of another's act or default.
- Defend
  - One party agrees to defend by retaining counsel and paying for the costs of the defense
- Hold harmless
  - To absolve from any responsibility for damage or other liability arising from the transaction

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Indemnification

- Institution wants Sponsor to indemnify, defend and hold harmless: (very broad)
  - arising out of any side effect, adverse reaction, illness, or injury occurring to any person as a result of his or her involvement in the Study .
- Who are the parties?
  - Institution and their trustees, officers, medical and professional staff, employees, and agents and their respective successors, heirs and assigns
- What happens if a CRO is involved?
  - Letter of Indemnification from Sponsor

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Exceptions to Indemnification?

- Sponsor's indemnification shall not apply to any liability, damage, loss or expense to the extent that it is directly attributable to:
  - (i) the negligent activities, reckless misconduct or intentional misconduct of the Indemnitees; or
  - (ii) failure of the Indemnitees to adhere to the terms of the protocol for the Study, provided, however that emergency medical care shall not be deemed a violation of the protocol.

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Conditions for Indemnification

- Provide Sponsor with notice of claim within reasonable time after Institution receives such notice.
- Allow Sponsor to conduct defense unless request to do own defense at own expense.
- Assist Sponsor in providing defense, at Sponsor's expense.

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Cross Indemnification

- Can/Should the Institution provide?
- For Institution's negligence or willful malfeasance
- For claim caused by failure to follow the Protocol

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Subject Injury

- Sponsor responsible for injuries resulting from patients participation in the study
  - Cover the broadest of potential injuries and expenses
- Will institution accept third party billing?
- Define limitations
  - No underlying illness, negligence, deviation, subject not adhering to instructions
- Sponsor will reimburse what party?
  - Institution
  - Research subject

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Conflict of Interest

- IRB COI
- Institutional Policies
  - NIH
  - Interactions with Industry

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Questions

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Contact Info

- Fred Frankhauser, JD, MBA, RPh
  - Director of Grants and Contracts
  - ffrankhauser@tuftsmedicalcenter.org
  - 617-636-2892

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