



Friendly Reminder



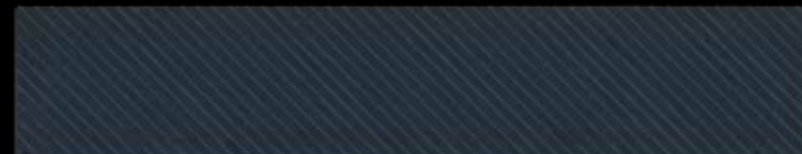
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Jeffrey Warner

NEGOTIATING CLINICAL TRIAL AGREEMENTS -- SELECTED ISSUES



Presented by

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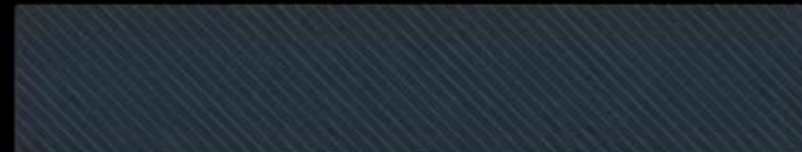
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DEFINITION OF A CLINICAL TRIAL

- Experiment, involving patients, designed to find the most appropriate treatment of future patients with a given medical condition
- Essential characteristic: results from a limited sample of patients are used to determine treatment in the general population



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FDA CLINICAL TRIAL PHASES

Testing in Humans				
	Number of Patients	Length	Purpose	% of Drugs Successfully Tested
Phase 1	20 – 100	Several Months	Mainly safety	70%
Phase 2	Up to several hundred	Several months to 2 years	Some short-term safety, but mainly effectiveness	33%
Phase 3	Several hundred to several thousand	1 – 4 years	Safety, effectiveness, dosage	25% – 30%

For example, of 100 drugs for which investigational new drug applications are submitted to FDA, about 70% will successfully complete Phase 1 and go to phase 2; about 33% of the original 100 will complete phase 2 and go to phase 3; about 20-30% of the original 100 will clear phase 3 (and, on average, about 20 of the original 100 will ultimately be approved for marketing).



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IMPORTANT ISSUES IN NEGOTIATING THE CLINICAL TRIAL AGREEMENT (2)

- Parties
 - Change of PI
- Records
- Confidentiality
- Publication
- Subject injury and Indemnification
- Disputes and State law



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CLINICAL RESEARCH AGREEMENT: Records

- Records
- Definitions – SOURCE DOCUMENTS
 - Time for retention
 - Completion or termination of the Study
 - Marketing application approval
 - Discontinuation of the IND
- Maintenance of Study records for the period

(continued)



CLINICAL RESEARCH AGREEMENT: Records (2)

- Transfer of Study records
- Ownership of documents
 - *Health Insurance Portability and Accountability Act of 1996 (HIPAA) and State laws on Patient Records*
- Disposition of documents



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CLINICAL RESEARCH AGREEMENT: ISSUES RELATED TO CONFIDENTIALITY

- Use of name of Sponsor/Institution
- Use of PI's name
- Trademarks
- Publicity
- Advertisement for patients
- Press releases
- Inquiries from media and financial analysts



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CLINICAL RESEARCH AGREEMENT: Publications and Scientific Communications

- Right to publish the results of the Study
 - Multi-Center publication
- Other rights to discuss Study (e.g., conferences – where and when)
- Notification to Sponsor
 - Prior to submission

(continued)



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CLINICAL RESEARCH AGREEMENT: Indemnification

- Who indemnifies and who is indemnified?
- From what?
- Expenses of claims and suits related to what injuries?
- Caused by – IN WHOLE OR IN PART?
- By any substance studied or any procedure performed in accordance with the provisions of the protocol

(continued)



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CLINICAL RESEARCH AGREEMENT: Indemnification (2)

And

- Sponsor's violation of 3rd party IP and privacy rights
- For use by Sponsor of the results of the Study
- Product liability
- Indemnification without prior payment by Institution

(continued)



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CLINICAL RESEARCH AGREEMENT: Indemnification (3)

- Exclusions from obligation to indemnify
 - Failure of the Institution to comply with any applicable governmental requirements or to adhere to the terms of the protocol?
 - Negligence of the Institution, officers, agent or employee, subcontractors?
- Some states will not allow indemnification of negligence or failure to comply with law



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CLINICAL RESEARCH AGREEMENT: Conditions to Indemnification

- Notice of any claim or lawsuit
 - Right to defend the lawsuit
 - Subject to Institution's right to retain the counsel of its choice?
- Right to settle the claim
- Right to require the indemnified party to cooperate fully in the investigation and with defense of any such claim or lawsuit



CLINICAL RESEARCH AGREEMENT: Additional Indemnification Issues

- Costs of extra unanticipated tests, treatments, and hospitalizations of patients required as a result of adverse events
- Costs covered by the Subject's or patient's medical or hospital insurance or by governmental programs providing such coverage

(continued)



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CLINICAL RESEARCH AGREEMENT: Additional Indemnification Issues (2)

- Non-medical indemnification (e.g., worker's compensation, third-party injuries, public health costs)
- Insurance



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CLINICAL RESEARCH AGREEMENT: Additional Sources of Information

- www.clinicaltrials.gov
- <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/good-clinical-practice-educational-materials>
- www.utsystem.edu/OGC/ University of Texas Office of General Counsel
- <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/websites-information-about-clinical-trials>
- <https://www.aamc.org/what-we-do/mission-areas/medical-research/clinical-trials> Association of American Medical Colleges site

QUESTIONS AND ANSWERS





**Florida Research
Administration Conference**



UCF
Office of Research

Break Time!

*Next Session begins
at 2:30pm*

*411 on NSF: National
Science Foundation as
a Sponsor*