

Clinical Trial Agreements

Course Syllabus



All lectures are 60 minutes with a 15 minute Q&A session.
All lectures begin at 12 pm CT/1 pm ET.

December 1

Lecture 1: The Basic Parts of the Clinical Trial Agreement & Focus on the Parties

- Overview of course and parts of a Clinical Trial Agreement
- Why are Clinical Trial Agreements important from a compliance perspective? (including non-billing importance)
- Who are the potential parties to a Clinical Trial Agreement?
- Models for parties:
 - » Academic medical community model
 - » Community hospital models
- Options for Hospitals and Physician Practices:
 - » Three-party agreements
 - » Site-agreements
 - » Master agreements between hospital and physician groups
 - » Material Transfer Agreements
- Stark Law Implications to Parties of Clinical Trial Agreements
 - » Potential financial relationships

- Payment for CRFs and other data collection
- Compliance monitoring of compensation provisions

December 10

Lecture 4: Intellectual Property/Inventions Provisions

- Rights to inventions
- Use of proprietary information
- Tax-exempt entities involved in Clinical Trial Agreements; Rev Proc 97-14

December 15

Lecture 5: Indemnification Provisions

- Balancing risks
- Transferring risks
- Research-related injuries
- Hidden compliance and operational risks in indemnification provisions
- Patients as third-party beneficiaries

December 3

Lecture 2: "Compliance with Law" Provisions

- Regulatory obligations under clinical trial agreements
- Federal laws accepted when federal grants involved
- Accepting jurisdiction of government agencies
- Acceptance of foreign laws through Clinical Trial Agreements

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Lecture 6: Compliance Considerations in Drafting, Negotiating & Executing Clinical Trial Agreements

- Using templates
- Master agreements
- Drafts that come from sponsors
- State law considerations
- Compliance monitoring of Clinical Trial Agreements
- Use of databases

December 8

Lecture 3: Compensation Section & Negotiations

- Language of compensation section
- Ways compensation is addressed in Clinical Trial Agreements
- Payment for clinical services and non-clinical services
- Documentation of fair market value