

## **Model Clinical Trial Agreement Outline**

Version 1.03 – March 1, 2007

- 0. Parties & Recitals
- 1. Definitions
- 2. Study Governance
  - 2.1. Protocol & Amendments
  - 2.2. Study {Drug/Device/Biologic} and Materials
  - 2.3. Sponsor Monitoring
  - 2.4. Sponsor-supplied Equipment
  - 2.5. CROs
  - 2.6. Audits
  - 2.7. Inspections
  - 2.8. Other Sponsor Duties
- 3. Duties of Site and Investigator
  - 3.1. Conduct of Study; Protocol
  - 3.2. GCP; Compliance with Laws and Regulations
  - 3.3. Debarment and Disqualification
  - 3.4. Financial Disclosure
  - 3.5. Conflict of Interest
  - 3.6. Investigator
  - 3.7. Subinvestigators and other Personnel
  - 3.8. Delegation of Investigator Duties
  - 3.9. Facilities
  - 3.10. IRB/IEC
  - 3.11. Study Documents
  - 3.12. Reporting and Meetings
  - 3.13. Record Retention & Destruction
  - 3.14. Enrollment
  - 3.15. Adverse Events
  - 3.16. Protocol Violations & Deviations
  - 3.17. Informed Consent
  - 3.18. Study {Drug/Device}
  - 3.19. Specimens; Shipment of Hazardous Materials
  - 3.20. Electronic Data and Signatures
  - 3.21. Data Clarification Queries
  - 3.22. Communication of Results to Subjects
  - 3.23. Return of Study Materials

- 3.24. Disaster Preparedness
- 4. Compensation
  - 4.1. Budget
  - 4.2. Initial Payment
  - 4.3. Advance Payment
  - 4.4. IRB/IEC Fees
  - 4.5. Subject Recruiting
  - 4.6. Payment for Study Visits & Milestones
  - 4.7. Screen Failures
  - 4.8. Incomplete Subjects
  - 4.9. Third-party Costs
  - 4.10. Hold-back & Final Payment
  - 4.11. Change Orders & Unanticipated Costs
  - 4.12. Payment Schedule
  - 4.13. Study Cancellation, Suspension or Early Termination
  - 4.14. Charges to Third-parties
  - 4.15. Payment Accounting & Discrepancies
  - 4.16. Overpayment
  - 4.17. Invoices
  - 4.18. Budget Adjustments
  - 4.19. Contingent Fees
  - 4.20. Payee
  - 4.21. Taxes
- 5. Confidential Information
  - 5.1. Confidential Information
  - 5.2. Confidentiality Obligations
  - 5.3. Disclosures
- 6. Protected Health Information and Use of Data
- 7. Intellectual Property
  - 7.1. Separate Property
  - 7.2. Site Authority
  - 7.3. Disclosure
  - 7.4. Data Ownership
  - 7.5. Ownership of Inventions
  - 7.6. License
  - 7.7. Filings
  - 7.8. License to Site
  - 7.9. Other Funding
- 8. Publication
  - 8.1. General
  - 8.2. Multicenter Articles

- 8.3. Multicenter Data
- 8.4. Confidentiality
- 8.5. Copyright
- 8.6. Authorship
- 8.7. Statement of Support
- 8.8. Communication
- 8.9. Registry
- 8.10. Acknowledgement
- 8.11. Publications Committee
- 9. Subject Injury
- 10. Indemnification
  - 10.1. Indemnification by Sponsor
  - 10.2. Indemnification by Site
- 11. Insurance & Liability
  - 11.1. Site Insurance
  - 11.2. Sponsor Insurance
  - 11.3. Limit of Liability
- 12. Effective Date, Term and Termination
  - 12.1. Effective Date
  - 12.2. Term
  - 12.3. Termination
  - 12.4. Compensation
  - 12.5. Survival
- 13. Notice
  - 13.1. Provision and Time of Notice
  - 13.2. Notification Parties and Addresses
- 14. General
  - 14.1. Governing Law & Jurisdiction
  - 14.2. Publicity and Use of Names
  - 14.3. Entire Agreement; Modifications
  - 14.4. Counterparts
  - 14.5. Freedom to Contract
  - 14.6. Authorized Representatives
  - 14.7. Assignment
  - 14.8. Delegation
  - 14.9. Relationship of the Parties
  - 14.10. Third-party Rights
  - 14.11. Severability
  - 14.12. Remedies and Waivers
  - 14.13. Conflict between Agreement and Protocol
  - 14.14. Force Majeure

- 14.15. Geographic Exclusivity
- 14.16. Non-solicitation of Employees
- 14.17. Language
- 14.18. Currency
- 14.19. Alternative Dispute Resolution
- 14.20. Miscellaneous

90. Signatures

99. Process

Exhibit 1. Budget

Exhibit 2. Protocol [Attachment]

Exhibit 3. Informed Consent Document [Attachment]

Exhibit 4. Sponsor-supplied Equipment [Optional Attachment]

Exhibit 5. Fee schedule Optional [Optional Attachment]

Exhibit 6. Site Indemnitees [Optional Attachment]

Exhibit 7. Sponsor Indemnitees [Optional Attachment]