

Research Contracts

Stephen G. Wohleb
Director, Legal & Litigation Services
Seton Family of Hospitals
512-324-5914
Fax: 512-380-7516
swohleb@seton.org

Heather J. Gipson, JD, MA, CIM
Director, Human Subjects Protections and
Research Services
Seton Family of Hospitals
512) 324-7000 Ext. 88310
(512) 324-7992 fax
hjgipson@seton.org

December 7, 2009

Overview

- Contract initiation and negotiation
- Key provisions for success and risk mitigation
- Ethical and safety considerations
- Protocol feasibility and resource needs

Relevant Seton Policies

- ***Approving and Conducting Clinical Research Studies (1000.30)***

“Execution of a Study Contract is required prior to commencement of any Study procedures”

- ***Contract Initiation and Administration (1000.26)***

– Currently undergoing revision

- ***Research Contracting***

– *under development*

Recurring Issues

- Who are the parties to the agreement?
- How many agreements are there?
- Indemnification
- Intellectual Property
- Payment for study articles
- Payment for study services
- Standard of care versus study-related
- Subject injury clause
- Publication
- Termination

Types of Contracts

- Sometimes Sponsor has a separate contract with PI
- Sometimes will only have indemnification letter instead of contract with Sponsor
- Type of contract is not as important as accomplishing major purposes of:
 - Risk-shifting (indemnification)
 - Clarity of rights/roles/responsibilities
 - Payment terms
 - IP rights

Types of Contracts

- May have more than one contract for a research study
- Types of contracts
 - Three way contract
 - Seton, PI, Sponsor
 - Four way contract
 - Seton, PI, Sponsor, CRO
 - Two way contract
 - Seton and PI
 - Subaward agreement (NIH-funded studies)
- Investigator-initiated study vs. Sponsored study

Threshold Issue

- *Who are the parties?*
 - Institution and Sponsor
 - Institution and Investigator
 - Investigator and Sponsor
- May depend on
 - purpose of agreement
 - who is running the study

Standard Provisions

- Payment for research
- Intellectual Property
- Confidentiality
- Termination
- Indemnification
- Subject Injury Clause
- Regulatory Compliance
- Audit/Inspection Rights
- Publication Rights

Standard Provisions

- Payment for research
 - Agreement must address payment to and from all parties
 - amount of payment
 - procedures for payment
 - Should address study-related versus standard of care services
 - If possible, agree (in writing, in advance) on services considered “routine costs” or “standard of care” vs. services provided solely for trial
 - Should address payment denials by third-party payors
 - IDE or Medicare coverage does not guarantee payment by commercial payors

Standard Provisions

- Intellectual Property
 - Patent rights and inventions
 - provisions allocating rights in inventions made during the trial
 - Copyrightable material and publication rights
 - Agreement should address who has the right to publish, licenses to copy and distribute, copyright of study-related documents
 - Trademark/service marks
 - Agreement should address whether parties are permitted use other party's name in any announcements, etc.

Standard Provisions

- Confidentiality
 - Industry-sponsored studies often have strict confidentiality provisions that apply to
 - The contract itself
 - Any sponsor-related information, study data, etc.
 - Will often require return of confidential information at conclusion of study
 - Use of names/trademarks
 - What about compelled disclosure?

Standard Provisions

- Term and Termination
 - Need to decide if agreement will be for fixed term versus an endpoint related to study
 - Sponsor will want agreement to coincide with duration of study
 - Institution may want fixed endpoint
 - Termination for safety concerns, breach, insolvency, non-payment

Standard Provisions

Indemnification

- Necessary to protect against costs or risks related to the study
- Extent of indemnification obligation will depend on type of study
 - FDA approved device vs. investigational
 - Clinical trial versus investigator-initiated, retrospective review, etc.
- Make sure investigator's employer is bound even if not subject to any other provisions of the agreement

Standard Provisions

Indemnification

- Public entities have minimal ability to indemnify
 - “To the extent permitted by Texas law,....”
- Minimum insurance requirements coincide with indemnification clause
 - Tip: Make sure allows for self-insurance

Standard Provisions

Subject Injury and Payment Denial Clauses

- Who pays if subject is injured?
- What do they pay for?
- What is the basis for amount to be paid?
 - E.g., full charges?
- What triggers payment obligation?
 - E.g., investigator-identified SAE
- Payment denials
 - What obligation will Sponsor have if payment is denied by third-party payor?

Standard Provisions

Regulatory compliance

- FDA filings
- HIPAA
- Human-subjects protections/IRB issues
- Good Clinical Practices

Standard Provisions

Publication Rights

- Who has the right to publish results of study
- Can institution be identified in publication
- “Sneak peek” rights
- Comment or editorial rights

Standard Provisions

Audit/Inspection Clauses

- Sponsor will want right to inspect
- Will require access by FDA
- What are terms/conditions of audits/inspections
 - Upon advance notice
 - During normal business hours
 - By mutual agreement
 - Who pays for copies
 - Least disruptive manner possible
 - Compliance with institution's policies while on-site

Standard Provisions

Miscellaneous Clauses

- Governing Law
- Venue for disputes and alternative dispute resolution
- Third-party beneficiaries
- Amendments, notices, entirety/merger clause, assignment
- Terms, conditions, certifications and assurances for government-funded research - ***DON'T OVERLOOK THESE***

Other Considerations

- **Stark and Anti-kickback Laws**
 - Ensure FMV of payments to investigators for services
- Payments or services provided to physician by hospital constitute remuneration and must meet Stark law exception
 - should also conform to anti-kickback safe harbor

Other Considerations

- **Private Use**

- Applies to premises financed with tax-exempt bonds (original construction or renovation)
- most Seton facilities are bond-financed
- bond-financed space must be used in furtherance of tax-exempt purpose, not in furtherance of private business interests
- contracts have to be structured to avoid private use issues
 - no exclusive or superior right to conduct research over other hospital activities
 - No basic research

Process - Where to start

- **Major Players**

- Contract Owner
- Office of Research Administration
- Seton Network Contracting Services
- Seton Legal Services
- Other parties to the contract
 - Investigator
 - Sponsor
 - CRO
 - contracted vendors providing research-related services

- **Other Players**

- Seton Finance
- Pricing
- Supply Chain
- Laboratory
- Pharmacy
- Nursing/Medical Units
- Surgery
- Imaging
- Risk Management
- Other Seton departments

Roles

- **Contract Owner**
 - Identifies need for written agreement
 - ♦ Is it research?
 - ♦ Does it involve an outside party?
 - ♦ If answer to both is “yes,” need a contract
 - Enters information into Seton Contracts Management System (“Determine”)
 - Develops and negotiates business terms, including budget
 - Works with affected departments to ensure operational feasibility, contractual compliance
 - Cooperates with NCS and Legal during review, negotiation, and finalization of contract

Roles

- ***Office of Research Administration***
 - May serve as the contract owner
 - Facilitates “internal” negotiations
 - Assists in budget development, pricing
 - Provides support for contract compliance

Roles

- ***Network Contracting Services***
 - Reviews Determine entry for completeness and accuracy
 - May generate initial draft of contract with input from contract owner
 - When Determine entry is complete and all pre-approvals obtained, notifies Legal Services that contract is ready for review
 - Routes contract for signature upon conclusion of negotiations
 - Maintains contracts in Determine
 - Sends reminders related to expiration, termination

Roles

- ***Legal Services***

- Consults on “pre-contracting” issues, e.g.
 - whether a contract is needed
 - what type of contract is required
- Generates (or begins reviewing) draft when notified by NCS
- Works with contract owner to ensure all necessary provisions are included in agreement
- Resolves legal issues with contract owner and other parties
- May assist in negotiating business terms
- Gives legal approval for contract to be executed

Roles

- ***Other Parties***
 - May present initial draft or template of agreement
 - Participates in negotiations
 - Executes contract before commencing study at Seton

Roles

Depends on protocol and resource needs

- *Seton Finance and Pricing*
 - consults on pricing, budgeting
- *Supply Chain*
 - advises on procurement issues
- *Laboratory, Pharmacy, Imaging, Nursing/Medical Units, Surgery, Emergency Department*
 - consult on feasibility and operational issues
 - approve study-related responsibilities of their department
- *Risk Management*
 - consults on risk issues, provides insurance certificates
- *Other Seton departments*

Process

- Identify a Seton contract owner
 - In most case, must be a Seton employee
- Enter contract into Determine
 - Prior to entering contract, consult with NCS or Legal to determine:
 - whether contract is needed
 - may already be a contract in place, e.g., Medical Director
 - may not need a contract if no external investigator
 - what type of contract(s) is/are needed
 - who will generate drafts of agreements
 - Enter contract when submit study to Steering Committee
- Monitor contract in Determine
- Remain involved and responsive during negotiations

Process

- When negotiations are completed, Legal notifies NCS that contract is ready to be finalized
- NCS routes contracts for signatures
- NCS provides fully executed agreements to contract owner, Legal, other parties
- Contract owner manages relationship
- Contract owner monitors compliance with contractual provisions by Seton, other party

Process

Practical Tips

- ☑ *Start think about contracting process early*
 - what type of contract is needed
 - who will generate the draft
 - what are the general terms of the agreement
- ☑ *Include all pertinent information in the Determine entry*
 - NCS now generating some initial drafts
- ☑ *Upload editable version of contract when contract is entered*

Process

Practical Tips

- ☑ *Read it*
- ☑ *Understand it*
- ☑ *Identify and raise issues in draft early*
 - can be done even before contract is entered intoDetermine
- ☑ *Be responsive to requests for information from others involved in the process*

THANK YOU!

Questions?

Stephen G. Wohleb

Director, Legal & Litigation Services

Seton Family of Hospitals

512-324-5914

512-380-7516

swohleb@seton.org

Heather J. Gipson, JD, MA, CIM

Director, Human Subjects Protections and Research Services

Seton Family of Hospitals

512) 324-7000 Ext. 88310

(512) 324-7992 fax

hjgipson@seton.org