

Research Contracting Process

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Research Contracting Process

Overview

- Relevant Policies
- Roles/Responsibilities
- Process
- Types of Contracts
- Contractual Provisions and Other Considerations

Relevant 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)***
 - requires research contracts to be in writing, regardless of amount of payment
- ***Responsibility and Authority Policy (1000.02)***
 - identifies who can sign contracts at Seton

Roles

- **Major Players**

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

- **Other Players**

- Seton Clinical Research
- Seton Finance
- 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

- ***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

- *Seton Clinical Research*
 - May facilitate contracting process if contract owner is from another department
- *Seton Finance*
 - consults on pricing, budgeting
- *Supply Chain*
 - advises on procurement issues

Roles

- *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
- ☑ *Get the contract into Determine early*
 - can start on contract at the time the study is submitted to the Clinical Research Steering Committee
- ☑ *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 into Determine
- ☑ *Be responsive to requests for information from others involved in the process*
- ☑ *Know whose court the ball is in*

Types of Contracts

- Often will 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
- Sometimes Sponsor has a separate contract with PI
- Sometimes will only have indemnification letter instead of contract with Sponsor

Types of Contracts

- Type of contract is not as important as accomplishing major purposes of:
 - Risk-shifting (indemnification)
 - Clarity of rights/roles/responsibilities
 - Payment terms
 - IP rights

Standard Provisions

- Payment for research
- Intellectual Property
- Confidentiality
- Termination
- Indemnification
- Subject Injury Clause

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

- Term and Termination
 - Need to decide if agreement will be for fixed term versus an endpoint related to study
- Indemnification
 - Necessary to protect against costs or risks related to the study
 - Insurance and subject injury clauses are related concepts

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

THANK YOU!

Questions?

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