Agreements 101

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How can OSR help?

What does OSR do?
Role of OSR in Contract Negotiations

• OSR Research Administration (including Industry Contracting) has the responsibility of negotiating agreements for sponsored projects on behalf of the University
  – Signature authority

• Contract negotiation requires collaboration with Principal Investigators and departments
What are the different types of agreements?

I know I need an agreement, but don’t know what type.
Types of Agreements

• Confidential Disclosure Agreement (CDA)/Non-Disclosure Agreement (NDA)
  – **Activity**: to share information confidential in nature for a particular purpose BEFORE any other relationship occurs
  – **Purpose**: to protect confidential information being shared
  – **Example**: a pharma company wants to share a clinical trial protocol with a PI so she can determine if she wants to participate in the trial
  – **Note**: these terms are normally embedded in other agreements
Types of Agreements

• Data Use Agreement (DUA) (also Data Transfer Agreement/Data Sharing Agreement)
  – **Activity**: to share data collected from another source for a particular purpose
  – **Purpose**: to protect the information being shared and outline the terms and conditions of the transfer
  – **Example**: a PI wishes to receive data from outside of UNC to conduct an analysis as part of a research project
  – **Note**: these terms can be embedded in other agreements
• **Material Transfer Agreement (MTA)**
  
  – **Activity**: acquisition or sharing of biological and research materials
  
  – **Purpose**: govern the use of the shared materials
  
  – **Example**: a PI wishes to receive research materials from outside of UNC to conduct research
  
  – **Notes**:
    
    • these terms can be embedded in other agreements
    
    • With or without funding
Types of Agreements

• Clinical Trial Agreement (CTA)
  – **Activity**: to conduct a clinical trial testing an investigational drug or device
  – **Purpose**: manages the relationship between the sponsor and the site
  – **Example**: a PI is conducting an industry sponsored clinical trial on an investigational cancer drug
Types of Agreements

• Sponsored Research Agreement (SRA)
  – **Activity**: to conduct a specified research project during a defined timeframe
  – **Purpose**: to govern the terms of the research project, such as publication, deliverables, intellectual property, funding, etc.
  – **Example**: a PI develops a research plan and a sponsor wants to fund the project
  – **Notes**: this research does not usually involve human subjects, but can
Types of Agreements

• Research Services Agreement
  – **Activity**: to conduct a specified task or service related to research
  – **Purpose**: to govern the deliverables and payment
  – **Example**: a sponsor wants a PI to perform particular testing services
  – **Notes**:
    • unlikely to result in the creation of new IP
    • Core/recharge center agreements fall under this category
Types of Agreements

- Federal contracts
  - **Activity:** to support research in areas of significant scientific interest, to further scientific knowledge, or to achieve a specific research goal
  - **Purpose:** to allow a federal agency to acquire goods or services for the direct benefit or use for the government
  - **Example:** DOD has a research idea and procures the services of an academic partner
  - **Notes:**
    - Difference between federal contract and a federal grant
      - Federal contracts designed to comply with the provisions of the Federal Acquisition Regulation (FAR)
Types of Agreements

• Subcontracts, subawards, site agreements
  – **Activity:** to engage with a subcontractor to perform a portion of a research plan or protocol
  – **Purpose:** to flow down the terms and conditions of the prime agreement
  – **Example:** a UNC PI wishes to have another researcher at another university assist in the analysis for their research project
  – **Notes:**
    • It is best to note the use of subs when we are negotiating the prime award or submitting the proposal
Types of Agreements

- Collaboration Agreements
  - **Activity**: to conduct a research program with two or more organizations
  - **Purpose**: to describe the actions that each organization has agreed to undertake and defines the obligations of each party
  - **Example**: a researcher has developed a research protocol with an outside organization and each party is performing a portion of the research and funding the project internally
  - **Notes**: typically no transfer of funds
Types of Agreements

• Teaming agreements
  – **Activity:** binds one or more organizations that are joining to propose a research program to a prime sponsor in response to a request for a proposal (RFP)
  – **Purpose:** to specify the objectives of each member and the actions and deliverables required from each party
  – **Example:** a PI is collaborating with an outside entity to submit a proposal to NIH
  – **Notes:**
    • specific to a collaboration to submit a proposal
    • May limit the University or key personnel to not compete with the RFP
Types of Agreements

• Miscellaneous
  – Memorandums of Understanding (MOUs)
  – Fellowships/training agreements
  – Master agreements
  – Consortium agreements
  – Gifts
## Where to submit?

<table>
<thead>
<tr>
<th>Type</th>
<th>System</th>
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<tbody>
<tr>
<td>CDA – Clinical</td>
<td>CRMS</td>
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<tr>
<td>CDA – Non-clinical</td>
<td>ALICE</td>
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<tr>
<td>DUA</td>
<td>ALICE</td>
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<tr>
<td>MTA – without funding</td>
<td>BLUE (OTC)</td>
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<tr>
<td>MTA – with funding</td>
<td>RAMSeS</td>
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<tr>
<td>CTA*</td>
<td>CRMS and RAMSeS</td>
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<tr>
<td>SRA/Research Services Agreements</td>
<td>RAMSeS</td>
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<td>Federal contracts</td>
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<td>Subcontracts/subawards/site agreements</td>
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<td>Collaboration agreements</td>
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<td>Teaming agreements</td>
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What documents need to be submitted for a complete review?

Why does OSR keep asking for additional documentation?
• Whether submitting in CRMS, ALICE, or RAMSeS, the following documents are required:
  – Scope of work/protocol/research plan
  – Budget and budget justification
    • Must include appropriate F&A rate
  – Draft agreement (if available)
  – Contact information for sponsor/external entity for negotiation
What are the responsibilities of the PI and/or department?

Why do I care about the agreement?
PI Responsibilities

- PI is the subject matter expert on the research project
- Also has other contractual obligations
PI Responsibilities

• Statement of Work/Research Plan/Protocol
  – Feasibility
  – Timeline
    • Personnel actions (hiring specific expertise)
    • IRB/IACUC approvals
    • Ancillary agreements (MTAs, CDAs, etc.)
    • Subaward/subcontract/site agreements
  – Deliverables/outcomes
• Project Resources
  – Staffing plan – Do I have the necessary people for the study and the timeframe?
    • Staff allocation
    • Training/certification
  – Budget/Payment terms
    • Burn rate – sometimes used as a method of program progress
    • Deliverable based payments – Are they reasonable?
    • Required purchases and/or travel
    • Cost share or matching requirements – Where are the funds coming from?
PI Responsibilities

• Reporting Requirements
  – When are the reports due? Am I able to meet the deadlines?
  – Am I required to have weekly/monthly conference calls or provide monthly status reports?
    • Can I comply?
  – Are the reporting deliverables reasonable?
• Other responsibilities to consider:
  – Confidentiality obligations
  – Site visits – Are there scheduled site visits?
  – Contingency plans
    • What happens if I do not accomplish all the required deliverables or meet enrollment goals?
    • Personnel actions – What are the impacts on timeline?
  – Communicate and coordinate with department business managers and OSR if any changes need to be made to the contract (amendments, etc.)
What can hold up negotiations?

Why is my agreement taking so long?
Common Sticking Points in a Contract

• Indemnification
• Governing Law
• Publication
• IP
• Payment terms
• FAR clauses in a federal contract

More discussion in Agreements 102
Questions?