What Goes on During Grant and Contract Negotiations?

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• Who has the power?
• What do you need to know?
• How do you prepare?
Institutional Approvals

- Who can negotiate?
- Who can sign?
- What is your role?
  - Initial document review
  - Initial contact
  - Advising the signatory
- When do you go to counsel?
Common Types of Awards

• Grant
• Cooperative Agreement
• Contract
• Subcontract (both issued and received)
Funder Intent

- Federal or Federal Pass Through Assistance or Procurement
- State & Local Government
- Private Not-for-Profit
- Private for-Profit/Commercial
Types of Contracts

- Research
- Service or Instruction
- Clinical Trial
- Master/Task Order Agreements
• When will the project be done?
What is to be done?

- Scope of Work
- Role of PI
- Concerns/policies/practices of your institution
How much will it cost?

Types of Budget

Fixed price

Cost Reimbursable
How much will it cost?

Payment Schedule

Time based
Deliverable based
Pay attention to

If Fixed Price:
- Requirement for audit? (no)
- Residuals (yes)

If Cost Reimburseable:
- Expenditure rate and timeline

If Fee for Service or Patient Based:
- Appropriate costing
- Billing compliance
- Patient care costs

All:
- F&A
- Invoice and payment intervals
Standard Agreements

• What is a standard agreement?
• When do you use it?
TYPICAL ELEMENTS OF NEGOTIATED AGREEMENTS
INSTITUTIONAL KEY

CONTRACTUAL

TERMS / ISSUES

Dispute Resolution

Indemnification

Governing Law
Dispute Resolution

- Arbitration and mediation
- Court of law
Four Types of Indemnification

- Use of Results
- Sponsor Negligence
- Product Liability
- Full Indemnity
## Indemnification

<table>
<thead>
<tr>
<th>Sponsor Concern</th>
<th>Institution’s Concern</th>
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<td>• Does not want to be on the hook for everything</td>
<td>• Does not want to carry any costs of the sponsor’s study</td>
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<td>• State universities may not be able to indemnify or may have statutory caps</td>
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Governing Law

- Your law and jurisdiction
- Sponsor’s law and jurisdiction
- Some other law and jurisdiction
- Silent
INVESTIGATOR KEY CONTRACTUAL TERMS / ISSUES

- Intellectual Property
- Data Use and Ownership
- Publication
Institutional IP Preferences

- Patents – protect new and useful ideas
  - Generally ownership should follow inventorship
  - Do you accept “work for hire” language
  - Bayh-Dole Act (37 CFR 401)
- Copyrights – protect original expression
- Trademark – protects name/logos used to identify goods
- Trade secret – protects secret as long as it is kept a secret – *Many research institutions do not keep trade secrets!*
# Intellectual Property

<table>
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<th>Sponsor Interests</th>
<th>Institutional Interests</th>
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<td>• Commercialize inventions</td>
<td>• Dissemination of new knowledge</td>
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<td>• Protect IP and financial interests in product development</td>
<td>• Preservation of pre-existing rights</td>
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<tr>
<td>• Ensure access to background IP</td>
<td>• Unanticipated results from project interpreted with patent law</td>
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<tr>
<td>• Ensure study sites adhere strictly to protocol – “Work for Hire”</td>
<td>• Defined time to exercise option for licensure</td>
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<td>• Partnership with Sponsor in research</td>
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Commercialization and Publication

**COMMERCIALIZATION**

**Sponsor Interests**
- Data generation
- Protect IP
- Market share
- Validate scientific results
- Investors
- Accuracy of publications

**PUBLICATION**

**Institutional Interests**
- Advancing knowledge
- Professional development
- Scholarly dissemination
- Maintenance of tax exempt status
- Copyright retention
- Fundamental research exemption
Publication

• Many allow sponsor to review (and comment on) publication prior to submission for 30-60 days
• Many allow sponsor to remove sponsor-disclosed confidential information (not results)
• Many allow publication delay for 60-90 days for sponsor or institution to protect IP rights (e.g., file provisional patent on a new discovery)
In federal contracting, be aware of

- FAR 252.204-7000 Disclosure of Information.
- The Contractor shall not release to anyone outside the Contractor's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this contract or any program related to this contract, unless—
  - (1) The Contracting Officer has given prior written approval; or
  - (2) The information is otherwise in the public domain before the date of release.
Data Use and Ownership

- Institutional Policy
- Confidentiality
- Management and Retention Requirements
- Data Sharing
Other Negotiation Issues
Early Termination for Cause or Convenience

- Coverage for expenditures and non-cancellable financial commitments
- Notifications
- Account suspension
- Reconciliation of accounts
- Settlements and repayment to sponsor if necessary
Federal Regulatory Compliance

- Human Subjects
- Animal Subjects
- Conflict of Interest
- Biosafety, Radiation, etc.
- Export Controls
- Other risks to PI, department/division, institution
Issuing Subawards

• Use **subaward** if:
  • Designated PI at recipient institution
  • Scope of work is substantial
  • Evaluation for recipient’s scope
  • Will be co-authorship
  • Shared IP

• Use a **vendor agreement** if:
  • Scope is only a portion of the work
  • Service is provided as part of vendor’s normal business activity
Issuing Subawards

• Request from recipient
  • Institutional authorization and contact information
  • Programmatic information including budget
• Audit documentation
• Debarment & suspension certification
• F&A rate agreement
Issuing Subawards

- Review at award acceptance
  - Was the budget reduced? For prime or all?
- Flow down of terms
- Are terms acceptable for recipient or do you need to convert them?
- Payment structure
- Match clauses to recipient
Issuing Subawards

- Must provide recipient
- CFDA # and title if applicable
- Award name
- Award number
- Award year
- Agency name
- Applicable laws and regulations
Non-cash agreements

MTA’s

MOU’s

MOA’s
Special Situations
International Agreements

- Communication
- Culture
- Basis of law
- Monetary unit fluctuation
- Business practices
Inexperienced Funder

• Also known as the “new attorney” syndrome
Inexperienced PI’s

• Ohmygod they negotiated it
• Ohmygod they signed it
• Ohmygod they gave away the farm
• And YOU have to tell them it’s worthless and clean up the mess
CONTRACT REVIEW EXERCISE
Questions?
RESEARCH AGREEMENT

TRUMPED UP CORP. ("Sponsor") and PUTATIVE UNIVERSITY ("PU") agree to the following terms and conditions.

Scope of Work. PU will use reasonable efforts to perform the experiments and studies described in the research proposal dated April 1, 2010 to Trumped Up Corp. The Research Project may be modified by mutual agreement in a duly executed amendment to this Agreement.

Term. The term of this Agreement is October 1, 2010 through November 30, 2011.

Reports. Upon completion of the research or termination of the Agreement, PU will submit a written study report. This report will be due 60 days after termination of this Agreement.

Costs and Billings. Sponsor agrees to pay PU $300,000 for the Research Project. PU will issue one invoice to Sponsor upon project completion.

Publications. PU agrees that any proposed publication or presentation relating to the Research Project conducted under this Agreement will be submitted to Sponsor for review and approval 30 days prior to submission for publication or presentation.

Intellectual Property. PU will promptly disclose to the Sponsor all creative ideas, developments and inventions whether or not patentable, conceived or first reduced to practice as a result of the Research Project ("Inventions"). All inventions conceived or first reduced to practice during the project period will be jointly owned by PU and Sponsor.

Termination. Either party may terminate this Agreement for convenience, with 30 days written notice to the other party. Sponsor’s financial obligations cease upon notification of project termination.

Indemnity. PU will indemnify, defend, and hold harmless Sponsor, and its officers, employees, agents, and subcontractors and their employees from any suit, action, claim, demand, judgment, and expense arising out of the performance of this Agreement.

Governing Law. The construction and enforcement of this Agreement will be governed by the laws of the State of Confusion, United States of America.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement signed by their respective officers duly authorized as of the date and year written.

PUTATIVE UNIVERSITY

BY: ________________________________            BY:_______________________________
NAME:                                                                      NAME:
TITLE: Project Director                                           TITLE:
DATE: _____________________________            DATE:___________________________

TRUMPED UP CORP.