



# Working with Industry

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# Research Type

- ▶ Industry funded research
  - ▶ Pfizer, GlaxoSmithKline, etc.
- ▶ No direct Federal Funding

# We Will Not Be Discussing

- ▶ Contract Language
- ▶ Clinical Trials
- ▶ Professional Service Agreements
- ▶ Private funded research
  - ▶ American Heart, Komen, etc.

# Definitions

- ▶ CDA /NDA = Confidentiality Disclosure Agreement
- ▶ CRA = Clinical Research Agreement
- ▶ IDC / F&A / Overhead = Indirect costs
- ▶ IDC Waiver = Administrative approval to accept a reduced rate of IDC lower than Federal Rate
- ▶ IP = Intellectual Property
- ▶ ORA = Office of Research Administration
- ▶ PI = Principal Investigator
- ▶ SOW = Statement of Work

# Know Your Sponsor

- ▶ PI Expertise
- ▶ University
- ▶ Cost at Minimum
- ▶ Own IP
- ▶ Need to publish
- ▶ Student involvement
- ▶ Indirect Costs
- ▶ Results Focused
- ▶ Timely
- ▶ Start-up
- ▶ Golden Rule

# Workflow

- ▶ PI identifies funding
- ▶ PI prepares the proposal/SOW
- ▶ ORA Reviews Proposal and Budget
- ▶ Agreement negotiation
- ▶ Award
- ▶ Award reporting and close-out

# Review Process



- ▶ Research Agreement
- ▶ SOW
- ▶ Budget
- ▶ Sponsor's written guidelines
- ▶ Intellectual Property
- ▶ Sponsor contact information

# What's Needed

- ▶ Required Institutional Paperwork
- ▶ Copy of Guidelines
- ▶ Statement of Work (SOW)
- ▶ Budget
- ▶ Research Agreement
- ▶ Review guidelines



# Required Institutional Paperwork

- ▶ Routing form
- ▶ Cost Share Approval
- ▶ COI forms
- ▶ IDC Exceptions
- ▶ IACUC/IRB

# Agreement Components



- ▶ Description of work being performed (SOW)
- ▶ Location
- ▶ Period of performance
- ▶ Publication
- ▶ Invention
- ▶ Budget

# SOW Bad Example

- ▶ I will be reviewing square pieces of glass containing some goo. I will report to the guy in charge of the results.

# SOW Good Example


- ▶ EGG NOG expert pathology reviewers are assigned to active EGG NOG study protocols for confirming institutional diagnoses, to assess relevant enrollment criteria, for assigning subtypes of tumors to the appropriate protocol arms, and for validating the suitability of tumor tissues for biology-based studies. Reviewers will assess materials provided to them and return their reviews in a timely fashion to the EGG NOG Biopathology Center.

# Budget


- ▶ Industry or Private Funding
- ▶ Simple or Detailed
- ▶ Fixed Price or Cost Reimbursable

# Fixed Price vs. Cost Reimbursable

- ▶ Fixed Price operate under an established price that cannot be revised.
- ▶ Cost-Reimbursable sponsored projects allow costs to be expended up to a set amount.

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- ▶ Cost Reimbursable Advantages
    - ▶ No incentive to cut corners
    - ▶ Quality vs. time
    - ▶ Less risk
  - ▶ Cost Reimbursable Disadvantages
    - ▶ Sponsor requires more financial reporting
    - ▶ Refund unused funds
    - ▶ Less incentive to be efficient

<http://gowwin.com/knowledge/cost-reimbursement>

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- ▶ Fixed Price Advantages
    - ▶ Know total price upfront
    - ▶ Best interest to Control Cost
      - ▶ Leftover money to PI/Department
  
  - ▶ Fixed Price Disadvantages
    - ▶ No Price Adjustments
    - ▶ Maximum risk



# Do I need Contract/Budget? Why?

- ▶ A contract establishes a legally enforceable agreement
- ▶ Creates binding obligations, rights and duties for each party
  - ▶ Payment of money
- ▶ Institution has a legal obligation to protect its personnel, assets and resources
- ▶ Institution must ensure that it limits its liability
- ▶ Comply with the terms in the contract

# Do I need Contract/Budget? Why?

- ▶ Comply with state and federal laws and regulations
- ▶ Contracts submitted for Institutional Approval
  - ▶ Office of Research Administration
  - ▶ Legal Office
  - ▶ Office of Technology Development
  - ▶ IACUC
  - ▶ IRB
  - ▶ Department
  - ▶ Risk Management



# Questions?

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