

# Working with Industry

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# Learning Objectives

Define roles and responsibilities

Describe how working with industry differs from other sponsors

Identify important contract provisions in industry agreements



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# Disclaimer



- We are discussing non-clinical (non-interventional) sponsored research, which includes:
  - Work that is parallel, or complimentary, to the faculty member's regular work, including federally funded work
  - A commercial application or extension of previously funded work
- NOT discussing:
  - Consulting
  - SBIR/STTR (follows federal guidelines)



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# Roles and Responsibilities



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# POLL #1

# Roles of Central Offices - UDO

## Industry Relations Team

- Unit in the University Development Office (UDO)
- Team of 2 leading industry research partnerships
- Works with other UNC offices
- Leads/supports life cycle of research business development:
  - Single point of contact to industry partners
  - Engagement strategy development
  - Closely work with faculty and staff on industry proposals
  - Communication of corporate priorities and interests to university constituents



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# Roles of Central Offices – OSR

## Research Administration Contracting

- Part of the Research Administration unit within the Office of Sponsored Research (OSR)
- 4 teams:
  - Industry clinical
  - Industry non-clinical
  - Non-industry (*new*)
  - Subaward/subcontracting
- The industry teams lead all industry contract negotiations for:
  - Sponsored research agreements, data sharing agreements (DUAs), non-disclosure/confidentiality agreements (CDAs), clinical trial agreements, service agreements



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# Role of Principal Investigator (PI)

- Working with industry sponsor to develop a project
- Partnering with departmental research administrators or business officers to develop the budget and administrative documents
  - Working with the scientific liaison at the industry partner
    - Divulging accurate compliance disclosures
- Reviewing intellectual property, commercialization, and export control submissions in the RAMSeS IPF
  - Providing input on the research agreement where necessary



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# Key Differences



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# Communication

- Relationship management
  - University Development Office (UDO) – Industry Relations
  - Unit development offices
- Managing expectations



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# Funding Overlap

- What other types of funding does the PI have?
  - Federal
  - State and local gov't
  - Foreign
  - Industry
  - Non-profit
  - Donors



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# Intellectual Property (IP) and Data Ownership

- IP
  - Is there background IP?
    - Sponsor IP
    - UNC IP
  - Does the PI have invention disclosures filed with the Office of Technology Commercialization (OTC)?
  - Is IP expected to be generated during the course of performance?
- Data
  - Are we receiving data?
    - Management of data
    - Future use
  - Who will own data generated during the project?



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# Endorsements/Use of Names

- Is UNC receiving and/or testing an industry product?
- Is the industry partner asking the PI to endorse a product?
- Is the industry partner asking to use our logos or the name of the PI?



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# Proposal

- Not a “traditional” proposal
- Usually relatively short and contains less detail compared to grant proposals
- Unless there is an RFP (which is rare), there are rarely guidelines and formatting requirements



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# POLL #2

# Budget and Billing

- Budget format
  - Detailed v. total
- Billing mechanism
  - Fixed price v. cost reimbursable
- F&A



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# Gifts

- Comes with:
  - “no strings attached” – no quid pro quo
  - No deliverables/milestones/restrictions
  - No F&A applicable
- Most flexible/least restrictive
- May be more efficient
- University Development Office processes
  - Industry Relations
  - Unit Foundations (e.g. Health Foundation, Pharmacy Foundation, and more)



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# Gifts, cont.

- General purpose may be specified (donor intent)
  - But, a “restricted gift” from a company may constitute a “grant”
- Is it a sponsored research agreement disguised as a gift?
  - Industry partner wants to give a PI a gift, but wants a report on the research
  - Research gift
  - Certain gifts may trigger COI review
  - <https://research.unc.edu/2017/05/12/gift-vs-sponsored-project/>
- There can be both sponsored research funding and a gift
  - Ex: sponsored research agreement for a specific project and a gift for a professorship to be decided by the dean



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# F&A

- F&A covers the cost of doing business and conducting research
  - Expenses not directly attributable to a project such as utilities, salaries & wages of research support staff, and office supplies/computer equipment
- F&A should be included in Industry Agreements
  - Good business practice
  - Cannot subsidize private firms with public resources
    - Any F&A expense not covered by sponsor (i.e. “under-recovered”) must be covered by the university



# F&A Rates

## Indirect Cost Information

[Facilities and Administrative Rate Agreement](#) – Dated 11/23/2016

COGNIZANT FEDERAL AGENCY FOR NEGOTIATED RATES:

Department of Health and Human Services (DHHS) – Division of Cost Allocation – Attn: Darryl Mayes, (202) 401-2808

Negotiated Rates - Effective 07/01/2017 and remain provisional until new rates approved	On-Campus	Off-Campus < 10-mile	Off-Campus ≥ 10-mile
ORGANIZED RESEARCH	55.50%	28.00%	26.00%
<ul style="list-style-type: none"><li>Clinical trials conducted in hospital owned facilities within a 10 mile radius apply the 28% Off-Campus rate</li><li>Clinical trials conducted in University owned facilities apply the full 55.5% On-Campus rate</li></ul>			
INSTRUCTION	50.00%	28.00%	26.00%
OTHER SPONSORED ACTIVITIES	36.00%	28.00%	26.00%

- **Organized Research** – most projects fit into this category
  - Includes clinical trials - if the clinical trial is conducted in hospital facilities, the OR – Off-Campus within 10-mi Radius rate (28%) would apply; if the clinical trial is conducted in university owned facilities, the OR – On-Campus rate (55.5%) would apply.
- **Instruction**
- **Other Sponsored Activities**
  - Includes research services, such as sample testing with no analysis or interpretation of results



# Important Contract Provisions



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# POLL #3

# Important Provisions in an Agreement

- Data and IP
  - Deciding who owns what
- Publication
  - University must reserve the right to publish but can allow for a review period
- Confidentiality
- Scope of work
  - Detailed description of the project
- Indemnification
- Warranties
- Governing law



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# Quick Update on COVID-19 Impacts



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# COVID-19 Impacts on Research

- Hiring
  - The temporary suspension by the UNC System office is still in effect and all non-essential HR actions are on pause
    - Exception may be granted
      - Grant funded actions can move forward if fully funded by external funding
- Confidentiality
  - Maintain confidentiality of all confidential information belonging to UNC and third parties
    - Care in use of personal devices, accounts
- Cybersecurity
  - Virtual Private Network (VPN)
  - Security with data sharing/clouds



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# Recap – Key Takeaways & Resources



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# POLL #4

# Key Takeaways

- Working with central offices when discussions with industry partner begin can help avoid downstream issues
  - OSR and UDO can work together to structure the deal appropriately and can advise on the appropriate F&A rate and budget presentation
  - Do not share budgets too early in project development
- Choose the most appropriate F&A rate (usually 55.5%)
- A gift can be part of the sponsored research discussion



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# Resources

- University-wide contracting website
  - <https://contracts.unc.edu/>
- Updated OSR website with industry information
  - <https://research.unc.edu/sponsored-research/resources/industry-contracting>
- Industry playbook
  - <https://research.unc.edu/sponsored-research/resources/osr-research-playbooks/>
- Industry Relations website – new design coming soon!
  - [industry.unc.edu](https://industry.unc.edu)



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# Contact Info

Contacts:

## OSR

Liz Powell, Assistant Director of Contracting – [lizthornberrymoore@unc.edu](mailto:lizthornberrymoore@unc.edu)

## UDO – Industry Relations

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