#### Contracts in a Nutshell

Contract Liaisons
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# Introduction: Industry Contracting Team

- Created in November 2012
- Collaborate with industry sponsors and negotiate research-related agreements
- Roles expanded to include non-monetary agreements with both public and private sponsors
- Angela Smolik
- Diane Koltz

#### Why do we need an agreement?

- To protect UNC's rights, and by extension, the rights of researcher as a UNC employee
- To protect publication rights
- To protect intellectual property rights
- To make sure both parties do what they have agreed to and remedies for breach of contract provisions

# Types of Agreements Covered

- Industry-funded agreements
  - Sponsored Research Agreements
  - Master Agreements and associated Task Orders
  - Service Agreements
  - Testing Agreements
  - Amendments
- Non-monetary agreements
  - Confidential Disclosure Agreements (CDA)
  - Data Use Agreements (DUA)
  - Collaboration Agreements/Collaborative Research Agreements
  - Combinations
  - Amendments

## Common Acronyms

- **CI** Confidential Information
  - Information which a party defines as proprietary
- **CL** Contract Liaison
  - The team, currently of two, that reviews industry sponsored and unfunded agreements for UNC
- COI Conflict of Interest
- Deliverable End product of a research project; what the sponsor is paying for, e.g., report
- IACUC Institutional Animal Care and Use Committee
  - Oversees the University's animal care and use program and is responsible for reviewing all animal care applications using vertebrate animals, ensuring compliance with federal animal welfare regulations, inspecting animal facilities and investigator laboratories, investigating animal concerns, and overseeing training and educational programs.
- IRB Institutional Review Board
  - Responsible for ethical and regulatory oversight of research that involves human subjects.

# Common Acronyms

- **IP** Intellectual Property
  - A product of human intellect; a work a work or invention that is a result of creativity, such as a manuscript, design, or method, to which one has rights and for which one may apply for a patent, copyright, trademark, etc.
- OCT Office of Clinical Trials
  - Performs all administrative, legal, and pre-award budgetary functions for clinical trials
- OSA Other Sponsored Activities
  - Programs and projects which involve performance other than instruction and organized research, e.g., community services, manual development
- **OSR** Office of Sponsored Research
  - Provide the faculty and staff assistance in all aspects of the research administration of their externally funded research
- OTD Office of Technology Development
  - Evaluating, patenting, licensing and assisting faculty in obtaining research support from corporate sponsors
- **OUC** Office of University Counsel

## Common Acronyms

- PI Primary Investigator/Principal Investigator
  - Full time EPA employee who is overseeing or leading the project
- RCP Research Compliance Program
  - Committed to advancing the highest standards of ethics, integrity and honesty, and to compliance with all applicable laws, regulations and policies governing research, privacy and conflict of interest.
- **SOP** Standard Operating Procedure
- **SO** Signing Official
  - An authorized official signatory for the University. For the agreements covered in this presentation, the SO would be one of the CLs, NOT a PI, a department chair, or your program administrator, or grant specialist.
- **SOW** Statement/Scope of Work
  - Description of work/services to be performed; timelines for performance

### Agreement Acronyms

- CDA (NDA) Confidentiality/Nondisclosure Agreement
  - Used to cover exchange of CI; usually entered into when discussions regarding a project are initiated
  - Signed by both parties; acknowledged by PI
- **DUA** Data Use/Sharing/Transfer Agreement
  - Defines terms under which data for a research project is sent or received
  - Signed by both parties; acknowledged by PI
- SRA Sponsored Research Agreement
  - Agreement setting forth terms and conditions for one particular project
  - Signed by both parties; acknowledged by PI
- PO Purchase Order
  - A document sometimes issued by a sponsor outlining the pricing for the deliverables
  - Typically not signed; issued by sponsor to UNC
- **SA** Service Agreement
  - Agreement for non-research-related deliverables (OSA)
  - Signed by both parties; acknowledged by PI
- **TA** Testing Agreement
  - Agreement for testing services
  - No IP or publication contemplated
  - Signed by both parties; acknowledged by PI
- MTA Material Transfer Agreement
  - Covers the transfer of physical research materials out of or into the University
  - Handled by OTD

## Agreement Acronyms

- MSRA Master Sponsored Research Agreement
  - A broad agreement designed to cover multiple projects
  - Contains common terms and conditions to govern all projects
  - Projects are contracted under the MSRA as Task Orders
  - Signed by both parties only
- TO Task Order
  - Attached to a MSRA and incorporates the terms of the MSRA
  - Short document describing the SOW, deliverables, project dates, and any terms differing from the MSRA
  - Signed by both parties; acknowledged by PI

# Template Agreements

- Always easier to start with UNC's
- Rely on precedent; prior agreements with same entity
- If entity approaches UNC, use ours

#### **Contract Terms**

#### **UNC Priorities**

- Confidentiality
- Publication
- IP/Ownership of Results
- Liability, Indemnification
- Governing Law
- PI Signature

#### **Industry Priorities**

- Confidentiality
  - Trade Secrets
- Publication
- IP/Ownership of Results
- Meeting Milestones
  - Strict timelines
- Deliverables
- Budgets
  - 'Biggest bang for the buck'

# Contracting With Industry: What To Expect

- Longer contract process
- Provisions and obligations must be strictly followed
- Prior review of publications, delayed publication
- Firm deadlines for reports/deliverables
- Agreement must be in place before work can begin
- IP considerations
- Delays could mean loss of funds

### Process: Funded Agreements

- Overall process for funded projects:
   IPF→Grant Specialists→ CLs→Program Administrators
- CLs
  - Review Form
  - Confirm COI (and IRB, IACUC) is approved
  - Provide UNC template
  - Review terms in agreement
  - Negotiate terms with company contracts person
  - Signatures (PI, UNC official, Sponsor)

#### **IPF**

#### IPF

- Budget including F&A and effort ?Justification?
- Statement/Scope of Work
- Draft Contract if provided
- Any related agreements (CDA/MTA/Amendments)
- Agreement Request Form fully completed and signed by PI
- IRB and IACUC approvals

# Grants Specialists Pre-Award

- Review and approve budgets
- Notify CLs of budget approval by email

#### **CLs**

- Review the Request Form
- Negotiate terms and conditions if necessary directly with sponsor
- When terms are agreed upon, coordinate signature of agreement
- Forward to Post-Award for account set-up

#### **Post-Award**

- Set up accounts
- Invoicing
- Accounting functions in financial system

# Process: Non-Monetary Agreements

- Email sent to CL Box OSR-CL@unc.edu, to include:
  - Subject line to include: PI, Type of Agreement,
     Contracting Party
  - What type of agreement we are to provide
  - Draft agreement if provided
  - Completed and signed request form
- We then review the agreement, negotiate if necessary, and obtain signatures

#### **CL Email Box**

- If sent to us individually, we will have you resend to the CL Box
  - Please DO NOT send an email to the box and to one or both of us individually (delays, confusion)

#### **Contract Liaisons**

#### Request Form

- Now required for all new contracts processed by CLs
- One page to be completed and signed by PI
- List of questions required in order for CLs to begin reviewing the agreement
- Required for the CLs to properly review the terms of the agreement appropriately given your responses, taking into consideration existing IP, related agreements, whether students will be involved, whether other offices have been involved, etc.
- Should be uploaded with the IPF at the Pre-Award stage for funded research projects

New Agreement Request Form

To be completed and signed by the PI when requesting a new Service, Sponsored Research, Data Use, or Confidentiality Agreement Email completed form to: OSR-CL@unc.edu with PI name and Entity in subject line

Materials or Data used for the pro	ject under this agre	ement:			
Obtained or created under a spons	ored project, licens	e agreement,	or materials transfer agr	reement?	Yes No
(List the associated proposal or agr	reement numbers al	oove)			
Related to IP, license agreement, p	atent, or invention	disclosed to C	office of Technology Deve	elopment?	
(List the associated numbers above	?)			_	
Are there hazardous materials that	EHS needs to be av	ware of?			
Are there any export control conce	erns?				
Intent and Goal of this project:					
Will any research be performed?					
Is the creation of Intellectual Prope	erty (IP) likely?				
Do you intend to use any IP develo	ped?				
Do you intend to publish on the re-	sults?				
Do you intend to publish on the me	ethods or enhancer	nents thereof	?		
Do you intend to use the results ag	gain or for another p	project?			
What is the timeline for start of pro	oject?				
Have you worked with this entity b	efore?				
Do you intend to engage with this	entity again?				
Additional Information:					
Have you been in contact with any	other group or per	son on campu	s relating to this agreem	ent or project?**	
** (If yes, list the office(s) and name	e(s) of the person(s)	you have con	tacted)		
What is the nature of the project/r	esearch/services yo	u will be perf	orming? (Please describe	on line below)	
Are there any other agreements as	sociated with this p	roject? *(If ye	s, attach to email)		
Will any students be working on th	is project?				
Will a Recharge Center be used for	any activities in thi	s project?			
Is there anything else we need to k	now? (If yes, please	describe in e	mail)		
Does the PI wish to be cc'd on corn	espondence and ha	ve prior revie	w of contract?		
Name of other Entity (Company, U	niversity, Hospital, I	tc.; NOT UNC	-CH)		_
Contact Information:					
Other Entity Contracts Person:		Principal Inv	estigator:	Other UNC Cont	act:
(entity name)		(name)		(name)	
(name)		(email)		(email)	
(email)		(phone)		(phone)	
(phone)		. h ! f	in annual and		- !
As the Principal Investigator, I ack the agreement process and cause		above inform	ation is correct, and any	missing or incomplete	: information will finder
Printed Name	Signature		Date	_	
a reasonable transferance					
Please complete the above form in When finished, please email this fo			not be reviewed until a OSR-CL@unc.edu		een received. d entity in subject line

#### **New Agreement Request Form**

To be completed and signed by the PI when requesting a new Service, Sponsored Research, Data Use, or Confidentiality Agreement Email completed form to: **OSR-CL@unc.edu** with PI name and Entity in subject line

Materials or Data used for the project under this agreement:	10	1
	Yes	No
Obtained or created under a sponsored project, license agreement, or materials transfer agreement?		,
(List the associated proposal or agreement numbers above)		
Andrewskie sologistssenskipping andrewskie selection objection state to k		
Related to IP, license agreement, patent, or invention disclosed to Office of Technology Development?	n.	
(List the associated numbers above)		
Are there hazardous materials that EHS needs to be aware of?		
Are there any export control concerns?		
Intent and Goal of this project:	9	
Will any research be performed?		
Is the creation of Intellectual Property (IP) likely?		
Do you intend to use any IP developed?		i i
Do you intend to publish on the results?		
Do you intend to publish on the methods or enhancements thereof?		
Do you intend to use the results again or for another project?		
What is the timeline for start of project?		
Have you worked with this entity before?		
Do you intend to engage with this entity again?		

Additional Information:				
Have you been in contact wi	th any other group or person or	campus relating to this agre	eement or project?**	
** (If yes, list the office(s) an	d name(s) of the person(s) you h	ave contacted)		
What is the nature of the pro	oject/research/services you will	be performing? ( <i>Please descr</i>	ribe on line below)	
Are there any other agreeme	ents associated with this project	? *(If yes, attach to email)		
Will any students be working	g on this project?			
Will a Recharge Center be us	sed for any activities in this proje	ect?		
Is there anything else we nee	ed to know? (If yes, please descr	ibe in email)		
Does the PI wish to be cc'd o	on correspondence and have price	or review of contract?		
Name of other Entity (Compa	any, University, Hospital, Etc.; N	OT UNC-CH)		
Contact Information:				
Other Entity Contracts Perso	on: Prin	cipal Investigator:	Other UNC Contact:	
(entity name)	(nan	ne)	(name)	
(name)	(em	ail)	(email)	
(email)	(pho	ne)	(phone)	
(phone)				
As the Principal Investigator	, I acknowledge that the above	information is correct, and a	any missing or incomplete information wi	ill hinde
the agreement process and	All Handler (Marie)	*		
	,			
Printed Name	Signature	Date	2	
	orm in its entirety. Your agreen this form to the Contract Liaison		til a completed form has been received.  with PI name and entity in subject	ct line

## Pl's Responsibilities

- Accurately complete IPF
- Complete and sign request form
- Certify IPF
- Meet COI requirements
- Obtain IACUC or IRB approvals as necessary
- Understanding terms and conditions in contract (if unsure, ask)
- Signing contract as acknowledgement of obligations
- Not begin work until a contract is in place.
- Notify us of ANY changes in the budget or statement of work
- Respond timely to requests for information, approval of language and/or clarification of obligations

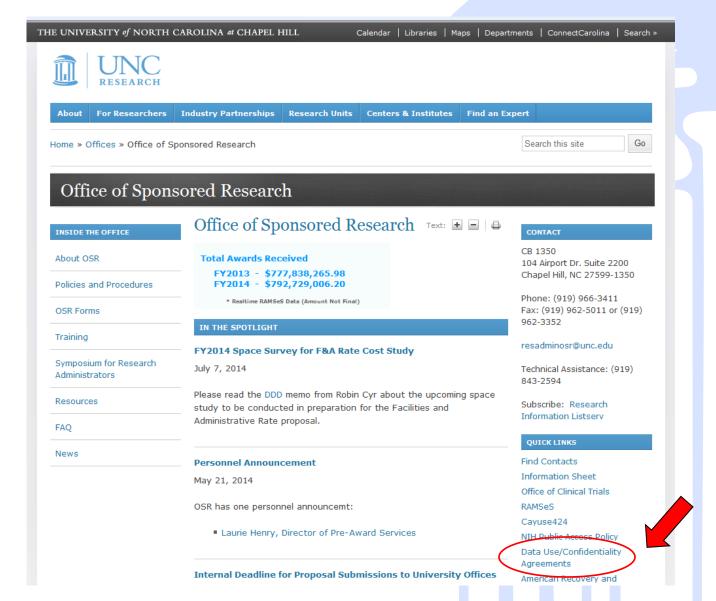
## Consequences

- Giving away IP rights
- Giving away publication rights
- Delays
- Liability risks increase
- Nonpayment
- Loss of sponsor funds

# Contract Liaisons: Behind the Scenes

- Two CLs
- Receive 70 new agreements each month (ave.)
- Complete 53 agreements each month (ave.)
- Over 1,080 agreements total\*
- 75-85 agreements in each CL's queue

# Contract Help: osr.unc.edu



#### **Contract Liaisons**

# OSR-CL@unc.edu

Office of Sponsored Research 104 Airport Drive, Suite 2200 CB#1350