“Partnering with the Office for Sponsored Research”

CRC Meeting
September 8th, 2015
Agenda

• Meet the Corporate Team
  – Senior Grant and Contract Officers
  – Coordinators
• Industry-Sponsored Projects?
  – Definition, examples
• Industry-Sponsored Project Requirements and Submission Processes
  – InfoEd
  – ESPR
• Common Questions
• Test Yourself!
• Q&As
Senior Contract and Grant Officers
(aka Agreement Negotiators)

Chrissy Barua
• CTAs, other Research-Related Agreements, CDAs, Amendments, Subcontracts

Pam Euring
• CTAs, other Research-Related Agreements

Sean Perry
• CTAs, other Research-Related Agreements

Manny Robert
• CTAs, other Research-Related Agreements, CDAs, Amendments, Subcontracts

Anne Grace
• Non-funded MTAs, DUAs and CDAs that are both industry and non-industry related
Coordinators

Art Miranda
• Coordinator Administration and Grants

David Adduci
• Coordinator Administration and Grants

Shehan Peiris
• Coordinator Administration and Grants
• Material Transfer Agreements (MTAs) and Data Use Agreements (DUAs)
An “Industry-Sponsored Project” means:

- A **for-profit** entity is providing the funding or material support for NU to conduct a specific line of scholarly or scientific inquiry, typically documented by a statement of work.

- A specific commitment is made by NU regarding the level of personnel effort, deliverables, and reports, and all project activities are budgeted and tracked.
Examples of Industry-Sponsored Project Agreements

• Clinical Trial Agreements
• Clinical Research Agreements
  – Registries, Chart History Reviews
• Basic Research Agreements
• Material Transfer Agreements
• Confidentiality Disclosure Agreements
• Subcontracts
• Amendments
• Other
  – Data Use Agreements, Outgoing Consultant Agreements, Collaborative Research Agreements, Fellowship Agreements, non-CME Agreements
Does OSR review **ALL** Industry-Related Agreements?
No.

**OSR cannot** review agreements for engagements involving an industry entity where:

1. the nature of the work is not research related;
   and/or
2. there is no data to publish.
Examples of Industry-Sponsored Project Agreements OSR does not review:

- Incoming Consulting Agreements
- For-profit speaking engagement agreements
- Gifts
- Purchasing Agreements
- Most Vendor/Service Agreements
How does OSR determine if an agreement should be processed by OSR?

The nature of the work contemplated by the agreement must meet these **three criteria**:

- directly related to a sponsored project here at NU,
- falls within the PI’s scope of work as an employee of Northwestern University (his/her 100% employment)
- if funded, an account needs to be set up through OSR (with the full overhead or indirects applied).

**Note:** This is due to potential conflict of interest issues as well as resource allocation issues. Depending on the agreement type, for some agreements not reviewed by OSR, PIs should discuss with John Calkins in OGC and/or they may be encouraged to seek outside legal counsel prior to executing the agreement.
Submission Process: Industry-Sponsored Project Agreements that use InfoEd

- Clinical Trial Agreements
- Clinical Research Agreements
- Registries, Chart History Reviews
- Basic Research Agreements
- Confidentiality Disclosure Agreements
- Other
  - Outgoing Consultant Agreements, Collaborative Research Agreements, Fellowship Agreements, non-CME Agreements
Create a Proposal Development (PD) record
Materials to submit: Industry-Sponsored Clinical Trials and Clinical Research

- Conflict of Interest (COI) Disclosures need to be up to date for all key personnel
- Draft Agreement
- Draft Budget
- Draft Informed Consent Form
- Copy of Clinical Protocol

Note:
- Documents, particularly agreements, sent to Senior Grant and Contract Officers must be in editable format NOT PDF.
Budget Tips: Industry-Sponsored Clinical Trials and Clinical Research

- Institutional Review Board (IRB) fee
- IRB Annual Review fee
- Regulatory/Start-Up fee

**Note:**
- Any IRB Fee’s should all go under ‘Protocol Development Fee’ Category
- Any other cost for Clinical Trial would go under ‘Clinical Direct Cost’

(More information can be found via the IRB website - http://irb.northwestern.edu/)
Facilities & Administrative (F&A) Rates:
Industry-Sponsored Clinical Trials and Clinical Research

- Clinical Trial and Clinical Research study - 30%
- Total Direct Costs (TDC)
  - TDC minus IRB fees
Pre-spending accounts: Industry-Sponsored Clinical Trials and Clinical Research

• A pre-spending account is established once all documents and required signatures have been received

DISCLAIMER

You are hereby advised that appropriate pre-spending on clinical trial accounts is authorized only at the sole risk of the applicable department, division, or center. Clinical trial pre-spending accounts are opened for one year. If no contract is executed for the clinical trial, or the award is otherwise not forthcoming, all charges on the account during the pre-spending period will be promptly and automatically transferred to the applicable non-sponsored guarantee account.

Furthermore, please be advised that the creation of a pre-spending account (including the issuing of a chart string number) for any clinical trial does not create, and shall not be interpreted as creating, any obligation or commitment on the part of Northwestern University or the Office for Research with regard to the endorsement or approval of any clinical trial contract, and does not affect other requirements imposed by Northwestern University and external authorities prior to the commencement of any clinical trial.
Pre-spending accounts: Industry-Sponsored Clinical Trials and Clinical Research

• Pre-spending is changed to an active award when agreement is fully executed and other documents have been received.
Materials to submit: Industry-Sponsored Basic Research

• Draft Agreement

• Draft Budget

• Copy of Statement of Work/Protocol

• Use Electronic Sponsored Project Request (ESPR) to request a pre-spending account, if desired

• Use ESPR (award process)

• Copy of Approval Letter from IRB or Institutional Animal Care and Use Committee (IACUC) before OSR can endorse project involving human or animal subjects
Materials to submit: Industry-Sponsored Fellowship and Educational Grants

- Draft Agreement
- Draft Budget
- Copy of Statement of Work/Protocol
- Use ESPR (award process)
- Copy of Approval Letter from IRB or IACUC before OSR can endorse project involving human or animal subjects
- Copy of approval email from Feinberg School of Medicine (FSM) Regulatory Affairs
Facilities & Administrative (F&A) Rates: Industry-Sponsored Basic Research, Fellowship and Educational Grants

- **Basic Research** – 64.4% on campus MTDC (modified total direct costs)

- **Fellowship and Educational Grants** - mechanism used to provide the funding will determine the F&A rate. Consult with OSR.
What Does OSR Need prior to Contract Execution?

• Confirmation of COI approval

• Final budget negotiated by the PI/department

• IRB approval with consent or IACUC approval, if applicable, with correct study title and sponsor name

• Completed InfoEd/PD submission with all approvals
Training Materials: Proposal Development in InfoEd

- Finance Facilities and Research Administration (FFRA) website:
  http://ffra.northwestern.edu/training/curriculum.html
  - Grants - FMS507 & FMS502 Training Guides

- OSR website:
  http://osr.northwestern.edu/resources
Submission Process: Industry-Sponsored Projects Agreements that use ESPR

- Both Material Transfer Agreement (MTA) and a Data Use Agreement (DUA) will be processed using an Electronic Sponsored Project Request (ESPR)
- Subcontracts
- Amendments
Create an ESPR
Training Materials:
Request Submission in ESPR

• OSR website:
http://osr.northwestern.edu/resources
Common OSR Transaction Questions

• InfoEd Approvals are not completed, but the question is ‘where is my chart string?’
  – **Answer**: You need the InfoEd Approvals before the chart string can be created.

• IRB approvals and COI have not been completed. But the question is ‘Has the contract been signed?’
  – **Answer**: The IRB approvals and COI need to be completed before the contract can be signed.
Yes or No

• The Department sends the Contract Officer the Clinical Trial Agreement in PDF form. Can OSR work with this effectively?
  – **Answer:** No, because OSR needs an editable Clinical Trial Agreement in order to begin negotiations/edit language

• Company A is listed as ‘Joe’s Crab Shack, Inc.’, is it ok for RA to choose ‘Joe’s Crab Shack, LLC’ instead?
  – **Answer:** No, because the name has to be exactly how it appears in the agreement, you would have to submit a new sponsor request for it to be added to the system. *Make sure to contact Mike Green (Info Team) if you have additional questions*
True or False (continued)

• A clinical trial is an example of an Industry related agreement.
  – **Answer:** True. Remember, OSR will review these agreements.

• The PI can sign an MTA as both the Investigator and Authorized Official because it is an unfunded agreement.
  – **Answer:** False. MTAs need to be approved and signed by an NU Authorized Official in OSR.

• MTAs and DUAs can be requested through ESPR.
  – **Answer:** True. Instructions for processing MTAs and DUAs can be found on the OSR website.
Audience Questions...

• What can a CRC do to help make a new sponsored research chart string move faster/more efficiently?
  – Checklist of things that a CRC can do before a chart string is generated, PD record needs to be set-up

• What can a CRC do to help make/annually renewing subcontracts move faster/move efficiently?
  – Complete the ESPR as soon as the budget period is set-up and double check your work

• Helpful hints for filling out InfoEd
  – Review the OSR website
  – Review InfoEd guides and training via FFRA website
  – Attend the FFRA/Info Team Open Lab
  – Ask Sara Krentz (Info Team)
Questions?