Pre-Award Overview

Josh Richards
Assistant Grants Officer
Office for Sponsored Research
Evanston Campus
What is a Sponsored Project Proposal?

An act of putting forward or stating something for consideration

A sponsored project may be considered a transaction in which there is a specified statement of work with a related, reciprocal transfer of something of value
Why Do Faculty Submit Proposals?

• Faculty put forth proposals to external sponsors requesting support for a number of University activities, including the following:

- Research
- Training
- Instruction
- Public Service
- Construction
How do sponsors solicit proposals?

• Sponsors make known their intentions to award funding in a general or specific area (typically as a result of a competition) by providing a solicitation for proposals.

• Referred to in a variety of ways:
  o Program Announcement (PA)
  o Funding Opportunity Announcement (FOA)
  o Request for Applications (RFA)
  o Request for Proposals (RFP)

• Contains vital information for successful administration of proposals, serves as the roadmap for proposal development.
How are Proposals submitted?

Note: all proposals, regardless of how they are submitted, require an InfoEd record.

There are two general submission types:
- System to System: Submitted directly to grants.gov through InfoEd
- Non-System to System: Submitted outside of InfoEd (e.g. over email, or an external submission platform like FastLane for NSF).
How are Proposals Submitted?

For hands-on system-related assistance, attend the OSR InfoTeam/FFRA Open Labs:

Mondays: 10:30a - 12:30p in Mudd Library
Tuesdays: 2:30p – 4:30p in Tarry 1-731

For Additional Information:  
http://osr.northwestern.edu/
Elements of a Proposal

- **Summary/Abstract**
  - Briefly describe what you are proposing.

- **Need/Impact**
  - Why is this work important?

- **Objectives**
  - What exactly do you plan to accomplish?

- **Research Plan**
  - How do you plan to accomplish these objectives?

- **Resources/Environment**
  - What resources, facilities, and support are available to the researcher?

- **Budget and Justification**
  - How much funding will be required to complete this work?
  - How will the funding be used to complete the project?

- **Biosketches**
  - Brief CVs demonstrating relevant expertise and qualifications.

- **Apendices**
  - Other materials as required/allowed by the sponsor.
Briefly, what are you proposing?

We propose to establish the Northwestern University Center for Advancing Equity in Clinical Preventive Services. The overall goal is to expand and accelerate the development, testing, and dissemination of innovative, practical, effective, generalizable interventions to increase equity of clinical preventive services. Our Steering Committee (SC) will include leaders from academic departments, our practice-based research networks, and our partner networks of community health centers (CHCs). The SC will create a vision and strategic plan for expanding our research program and allocate funds for pilot projects to implement that plan. Our Core Administration will provide support for research development, research methods and analysis, dissemination, and research training. We aim to generate multiple new grants over the 3-year funding period, at least one of which will be an implementation and dissemination grant across our large practice networks. Funds are requested for 3 initial projects to address important disparities. Project 1 addresses disparities in colorectal cancer screening. We will conduct a randomized controlled trial to determine whether a multifaceted intervention at a CHC serving a poor, predominantly Latino population can increase rates of repeat fecal occult blood testing (FOBT). Project 2 addresses disparities in cardiovascular disease prevention. We will conduct a randomized trial at 3 CHCs serving very diverse, underserved populations and compare usual care to a system of population health management that will a) use health IT to identify patients with no known cardiac history but high 10-year risk of cardiac events (Framingham Risk Score) who are not currently prescribed a statin, and b) perform outreach to educate patients about their risks, the benefits of treatment, and facilitate the treatment of eligible and appropriate patients with statin therapy. Project 3 seeks to understand and address the high rate of refusal of pneumococcal vaccine among African-Americans in one of our clinics. This project will interview patients to understand reasons for refusals and develop a multimedia program to show patients in examination rooms to explain the risks and benefits of pneumococcal vaccination. A pilot study will assess feasibility and patient and staff acceptance.
Need

Why is this work important?

Disparities exist for use of clinical preventive services by race/ethnicity, language, socioeconomic status, gender, age, and sexual orientation, and national organizations have set goals of reducing disparities. This center will combine our expertise in health literacy/health communication, quality improvement methods, and health information technology to develop and test interventions to achieve equity in preventive services.
Objectives
What exactly do you plan to accomplish?

Objectives should:
• Be measurable
• Be end-oriented
• Be realistic
• Address the stated need
• Correspond to a timeline

A. SPECIFIC AIMS
We propose to establish the Northwestern University Center for Advancing Equity in Clinical Preventive Services. Our overall goal will be to expand and accelerate the development, testing, and dissemination of innovative, practical, effective, generalizable interventions and delivery system redesigns to increase equity of access to and use of clinical preventive services. We will leverage our multidisciplinary faculty, research infrastructure, AHRQ-funded T32 post-doctoral fellowship, and practice-based research networks (including safety-net practices). The Leadership and Management of the Center will be through a Steering Committee composed of all partners. This will allow us to create a shared vision for developing our research agenda in health equity for clinical preventive services and achieve coordination, efficiency, and synergy across academic departments, training programs, and clinical practices/research networks. The Administration will be led by the outstanding grant administration team for the Division of General Internal Medicine and Institute for Healthcare Studies, which will also support other divisions/departments as needed for submitting new grants. The Research Development Core will help departments, divisions, clinical centers, and individual investigators vet initial ideas; create concrete, feasible study aims; establish collaborative and multidisciplinary research teams; and develop pilot projects and formal research proposals. The Research Methods and Analytic Core will provide methodological and technical support for our three initial projects, pilot projects endorsed by the Steering Committee, and preparation of future grant applications. The Dissemination Core activities will be multifaceted, including disseminating our findings, methods, and tools through publications, web sites, and workshops at national meetings; turning initial efficacy studies into effectiveness and implementation and dissemination studies; and working with our provider network to implement interventions that have been developed and shown to be effective. The Research Education and Training Core will work to train the next generation of investigators by providing research experience opportunities for medical students, residents, and post-doctoral fellows. Evaluation of the Center will be based on defined metrics and timelines as outlined. Our external advisory committee provides an overall evaluation of the Center and suggestions for improvement. In addition, we will actively work in collaboration with other Centers, as led by our Principal Investigator and Collaborative Scientific Lead, who will share the teams’ expertise in health information technology, health literacy, and practical clinical trials.

We propose 3 initial projects that span a range of clinical preventive services and exemplify the multi-component strategies needed to address these complex problems:

Project 1: Improving Rates of Repeat Colorectal Cancer Screening. The specific aims are: Aim 1: Test if a multifaceted intervention at a federally qualified health center (FQHC) increases repeat FOBT testing adherence over a 30-month period; Aim 2: Explore perceived barriers to screening among patients who received the intervention but did not complete repeat FOBT testing within 18 months; and Aim 3: Assess costs of the intervention and costs per additional repeat screening compared to patients who received usual care.

Project 2: Reducing Disabilities in Primary Prevention of Cardiovascular Disease. Aim 1: To conduct a randomized controlled trial among individuals cared for at three FQHCs who have a 10-year risk for myocardial infarction or coronary death of 10% or higher (i.e., Framingham Risk Score) to determine if our population health management intervention protocol (a) higher rates of documented statin treatment discussions within 7 days of discharge compared to usual care patients.
Research Plan

How do you plan to accomplish these objectives?

B. RESEARCH STRATEGY

B.1 INTRODUCTION

The overall goal of our proposed Center of Excellence is to expand and accelerate the development, testing, and dissemination of innovative, practical, effective, generalizable interventions and delivery system redesigns to increase equity of access to and use of clinical preventive services. We are uniquely well positioned to accomplish this goal because of our a) clinical and research experience across the spectrum of clinical preventive services, b) understanding of disparities in these services, c) methodological expertise in areas needed to design interventions to improve care and reduce disparities (i.e., health literacy, electronic health records [EHR] and health information technology [HIT], and care redesign), d) our strong academic-community partnerships, and e) our resources for research development, support, and training. This introduction briefly describes our conceptual framework for understanding and addressing disparities in clinical preventive services, our relevant research experience, and the resources and expertise of our clinical partnerships that serve to generate ideas and provide opportunities to test interventions in the real world.

**Complex Problems Require Multifaceted Solutions**

General quality improvement interventions have had limited success reducing disparities. This is not surprising because the root causes of disparities are complex and require multifaceted solutions. For example, even when patients understand the need for preventive services, many have difficulty accessing care because of lack of insurance, high out of pocket costs, or transportation barriers. Thus, solutions require policy and practice changes that enable access to preventive services without a provider visit, such as mailing home fecal occult blood tests (FOBT) to screen for colorectal cancer (CRC) and automatically notifying patients when they are due for screening (see Project 1). Some patients have negative attitudes or little knowledge about the need for preventive services, such as being unaware that they are at high risk for heart disease. Others may seek care mostly for acute problems so providers do not address prevention. These problems can be addressed by using HIT to identify high risk patients who have not received treatment. But, to be maximally effective, such an intervention would also need to clearly explain to patients their risk and the benefits of treatment using approaches and communication tools to overcome potential literacy, language, and cultural barriers that contribute to disparities (see Project 2). Thus, to maximally improve care and achieve equity, we must design interventions that address barriers to care, inform and activate patients, use information technology, and point of care reminders to identify patients who need services, and use team-based care to optimize effectiveness and efficiency. This approach was originally articulated as the "Designing and Testing Multifaceted Solutions Requires Multidisciplinary Approach.

Our research community includes clinician-investigators and Ph.D.s in health policy, clinical psychology, health services research, sociology, and anthropology. We use clinical and methodological areas needed to address disparities in clinical preventive services:

- **Clinical preventive services**: cancer screening, immunizations, counseling (weight management, physical activity, smoking cessation, primary prevention, sun protection, dietary therapy, alcohol and drug abuse screening), and counseling on managing health disparities.
- **Vulnerable populations and disparities** by race/ethnicity, language barriers, socioeconomic status, culture, and lack of adequate health insurance coverage.
- **Methods to measure disparities and design interventions to achieve equity**: race/ethnicity and language, survey research, qualitative research, health literacy.
Resources/Environment

What resources, facilities, and support are available to the researcher?

RESOURCES

Follow the 398 application instructions in Part I. 4.7 Resources.

FEINBERG SCHOOL OF MEDICINE, NORTHWESTERN UNIVERSITY
We believe we are exceptionally well-positioned to succeed with the proposed Center of Excellence because of our diverse and experienced faculty, our belief in the strength of multidisciplinary teams, our strong research administration, our practice based research networks, and our extensive partnerships with other local and national networks (see Figure B.1 in section B, Research Strategy).

The Center will be based at the Feinberg School of Medicine, Northwestern University. The Core Administration will be within the Division of General Internal Medicine. The Steering Committee will include multiple departments in the School of Medicine, and we will work to expand collaborations with other departments and schools at Northwestern University.

The General Internal Medicine Research Environment

The faculty of the Division General Internal Medicine (GIM) has experience studying medical and surgical patient outcomes, quality of care, patient safety, technology assessment, practice guidelines, health communications, health disparities, survey research and medical informatics research. The four major research themes include: 1) Health Communication, 2) Quality Improvement and Patient Safety in Primary Care, 3) Reducing Disparities for Vulnerable Populations, and 4) Clinical Epidemiology. GIM is the home of the Health Literacy and Learning Program (HeLP). HeLP's mission is to advance the study of health literacy and interventions to improve individuals' ability to obtain, process, and understand basic information needed to make appropriate health decisions. Northwestern is the first institution in the country to link the fields of medicine and education to improve how health systems educate patients and families on their health.

The GIM research program occupies approximately 17,000 square feet of contiguous space. It is adjacent to the 12,000 square feet of space for the faculty and staff of the Institute for Healthcare Studies (see below). There are 15 MD and PhD research faculty and approximately 75 staff who work in this space. There are weekly Work in Progress conferences and a weekly health services research seminar series for faculty to present their work. Faculty from across Northwestern present at these conferences, in addition to invited local and national speakers. This helps create a collaborative environment in which people work to develop and refine each others ideas.

Health Communication Multimedia Lab – GIM has unique resources for developing health communication materials. These include state-of-the-art digital video and multimedia production capabilities coupled with high

NORTHWESTERN UNIVERSITY
Evaluation

B.2.7 EVALUATION PLAN
Table B.2.7 lists the goals and milestones for the Center that correspond to the aims listed above.

<table>
<thead>
<tr>
<th>Aim</th>
<th>Goal (and assessment method, if not evident from goal)</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim 1</td>
<td>Submit follow-up grants for each of the 3 initial center projects</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: (3)</td>
</tr>
<tr>
<td>Aim 2</td>
<td>Develop and fund 3 pilot projects</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td></td>
<td>Develop and submit at least 2 projects in new research areas</td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: x</td>
</tr>
<tr>
<td>Aim 3,4</td>
<td>Provide support for new and established investigators (number of consultations &amp; pilot projects supported; co-authorship on papers; survey to assess satisfaction with Core)</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: x</td>
</tr>
<tr>
<td>Aim 5</td>
<td>Create e-news registry, web site</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td>Aim 6</td>
<td>Present at national meetings (number of presentations); create policy briefs (number)</td>
<td>Yr 1: x</td>
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<tr>
<td></td>
<td></td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: x</td>
</tr>
<tr>
<td>Aim 7a</td>
<td>Submit at least one implementation and dissemination grant with NU partners &amp; AHRQ</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td>Aim 7b</td>
<td>Develop summer research fellowship (number of fellows participating)</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td>Aim 8</td>
<td>Expand mentoring program for residents (number of residents participating)</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: x</td>
</tr>
<tr>
<td>Aim 9</td>
<td>Recruit and train at least 1 post-doctoral fellow (number; research career)</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: x</td>
</tr>
<tr>
<td></td>
<td>Conduct webinars for community-clinicians (number; attendance; satisfaction)</td>
<td>Yr 1: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 2: x</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yr 3: x</td>
</tr>
</tbody>
</table>

External Advisory Committee: This committee will meet annually to review our strategic plans for expanding health equity research for clinical preventive services, discuss proposed pilot projects, evaluate whether we are achieving our aims/metrics, and make suggestions for changes or additions to achieve the Center's goal of becoming the premier research center in the country in this area. Members will include [name], Commissioner of the Chicago Department of Public Health, a Family Physician, and a former medical director for a community health center; [name], President of The Aetna Foundation, a Pediatrician, and a national expert in disparities; and [name], a General Internist, Chief of the Division of General Internal Medicine and Director of the Medical Practice and Prevention Research at the Sheps Center for Health Services Research, University of North Carolina-Chapel Hill, and an expert on disparities, clinical preventive services, medical decision-making, and economic analyses. (See letters of support).
Budget

How much funding will be required to complete this work? How will the funding be used to complete the project?

- Realistic request of estimated cost to complete the project
- A large part of the budget will be devoted to personnel costs for most projects
- Other costs might include supplies, services, consulting costs, travel, subawards, etc
- For most administrators, the bulk of their time is spent on the creation of the budget and budget justification
Budget Justification

How much will all this cost and how will the funds be used?

- Use lay terminology
- Use categories developed by agency
- Relate line items to program objectives
- Ensure level of detail meets sponsor requirements
- Follow sponsor formatting guidelines
- Provide any required backup documentation
Budget Activity

• Budget development: communicating with the PI

  Brainstorm Questions to ask PI
  • Can you provide a draft statement of work?
  • How much time do you anticipate spending on the project?
  • Will there be a subcontract? If so, who are the participants?

What will your action items be when you hear back?
Budgeting for Faculty Effort

• Personnel costs proposed must connect to effort
• Budgeted for individuals working on project
• Importance of the integrity of the institutional base salary when calculating personnel costs
• Budget justification should demonstrate level of effort in line with salary request as it connects to the individual’s appointment period
• Calculated monthly on a percentage of effort basis
  – 9 month vs. 12 month appointments
  – E.g., 1.00 academic month, 0.50 summer month – what’s the effort percentage?
Budget: Fringe Benefits

1. Identify the appropriate fringe rate based on employment type
2. Identify the start date and corresponding composite rate
3. Multiply the fringe rate by the applicable salary amount

For Additional Information:
http://osr.northwestern.edu/proposals/budget-fringe-rates
General Statements on Chicago Campus

For NU/NM PIs without VA appointments
• Dr. ____________ has an appointment with Northwestern University (NU) and with the affiliated Northwestern Medical clinical practice plan (NM). The institutional base salary used in this application represents the combined salary from both NU and NM, which is paid by NU under a common paymaster. The number of person months in this application represents NU effort on the proposed project in relation to professional effort encompassed by the dual NU and NM appointments.

For NU/NM PIs with VA Appointments
• Dr. ____________ has an appointment with Northwestern University (NU) and with the affiliated Northwestern Medical clinical practice plan (NM), and with the Veterans Administration (VA). This arrangement is defined in a formal NU-VA Joint Appointment Memorandum of Understanding. The institutional base salary used in this application represents the combined salary from both NU and NM, which is paid by NU under a common paymaster system; it does not include salary from the VA appointment. The number of person months in this application represents NU effort on the proposed project in relation to professional effort for the dual NU and NM appointments.
Budget: Consultants

Categorized as a vendor-type relationship, where an individual or company is retained to provide professional advice or services on a project for a fee.

- Consultants cannot be NU employees
- Include in proposal regardless of whether or not they are paid
- List names and institutional affiliations
- Describe services being performed in budget justification
Budget: Consultants

- Consultants should provide a letter detailing, at minimum, the following:
  - Rate of pay
  - Number of hours to be worked
  - Work to be performed

- Additional consultant information required as needed:
  - Travel
  - Per diem
  - Other related costs

- For NIH and NSF, there is no maximum daily rate but the fees must meet the test of reasonableness*
Budget: Other Direct Costs

- Capital Equipment
- Computer Charges (server use, cloud computing, supercomputer time)
- Rental/lease charges
- Animal care
- Patient travel
- Human subjects payments
- Publication costs
- Equipment maintenance and service contracts
- Tuition
Budget: Research Assistance Scholarships (RAS)

- Allow graduate student RAs supported by sponsored projects to have a portion of their tuition charged directly to projects

- The Graduate School covers the balance of tuition via a RAS only if the sponsored project carries full F&A rate

- Minimum stipend level to receive a RAS scholarship is $2,491/month for 2015-16

- Tuition is not charged F&A
Budget: RAS

• Maximum amount awarded by NIH for support of graduate student is equal to the zero level National Research Service Award (NRSA) Postdoctoral fellow stipend in effect at the time the award is issued
  – Amount provided includes salary, fringe benefits, and tuition remission
  – Current stipend amounts can be found at: http://grants2.nih.gov/training/nrsa.htm
## Academic year 2015-16 Tuition Charges to Sponsored Projects

<table>
<thead>
<tr>
<th>Student Type</th>
<th>Cost per Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full registration (3-4 units)</td>
<td>$3,354</td>
</tr>
<tr>
<td>Advanced rate (500)</td>
<td>$3,354</td>
</tr>
</tbody>
</table>
Budget: Subawards

- Subcontractor organization must be identified in the budget justification
- Work to be performed must be described in Statement of Work
- Subcontractor’s OSR must provide an approved detailed and multi-year budget
- Subcontracts from NU-affiliated organizations must also be detailed in this manner
- First $25k of each subaward is included in F&A base for NU
- Subcontract F&A is not included in the NIH direct costs but is included in the NU MTDC calculations
Budget: Facilities and Administrative Costs (F&A)
Budget: Direct Costs vs. F&A

- **Direct Costs**: Clearly assigned to a specific research activity
  - PI & research staff salaries & benefits
  - Supplies
  - Equipment
  - Contractual services
  - Travel*

- **F&A**: Not clearly assigned to a particular research activity
  - Incurred by the institution as a consequence of conducting research
    - Building maintenance & utilities
    - Libraries
    - Centralized administrative costs
Budget: Modified Total Direct Cost (MTDC) vs. Total Direct Cost (TDC)

**Modified Total Direct Cost**
- Used for federal awards that provide F&A at our full overhead rate
- Also used if legislatively mandated by a federal agency or specific program
- Modify our base
- Remove items that are excluded from F&A

**Total Direct Cost**
- Used for industry clinical trial awards and other non-federal sponsors that limit their rate of F&A recovery
- No exclusions from the base
- F&A applied to full base
Budget: Modified Total Direct Costs (MTDC) is result of Exclusions to Total Direct Costs (TDC)

<table>
<thead>
<tr>
<th>Expense Acct.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>75335</td>
<td>Fabricated equipment</td>
</tr>
<tr>
<td>75490</td>
<td>Space rental</td>
</tr>
<tr>
<td>75720</td>
<td>Hospital medical expenses</td>
</tr>
<tr>
<td>76910-76960</td>
<td>Telecom/ network expenses</td>
</tr>
<tr>
<td>77510-77599</td>
<td>Capital equipment</td>
</tr>
<tr>
<td>78010-78080</td>
<td>Tuition and stipends</td>
</tr>
<tr>
<td>78650*</td>
<td>Subawards in excess of the first $25,000</td>
</tr>
</tbody>
</table>

For Additional Information: [http://www.it.northwestern.edu/telephone/converge/index.html](http://www.it.northwestern.edu/telephone/converge/index.html)

*For expense account 76950, only international and off-campus calling cards are allowed per Converged Communication Policy*
## Budget: F&A Rate Calculation

### Sponsored Research F&A Rate Statements to Add to All Proposal Budget Justifications

<table>
<thead>
<tr>
<th>Federal Awards*</th>
<th>Non-Federal Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>- F&amp;A has been calculated based on the following DHHS approved rates:</td>
<td>- F&amp;A has been calculated based on the following rates:</td>
</tr>
<tr>
<td>- 54.5% MTDC 09/01/14 – 8/31/15</td>
<td>- 64.4% MTDC 09/01/14 – 8/31/15</td>
</tr>
<tr>
<td>- 54.5% MTDC 09/01/15 – 8/31/16 and thereafter (provisional)</td>
<td>- 64.4% MTDC 09/01/15 – 8/31/16 and thereafter (provisional)</td>
</tr>
</tbody>
</table>

### On the NIH checklist page, check the following boxes:

| ✓ | DHHS Agreement Dated: 09/15/2015 |
| ✓ | Modified total direct cost base |

For Additional Information: F&A Rate Resour [http://osr.northwestern.edu/proposals/budget-FA-rates](http://osr.northwestern.edu/proposals/budget-FA-rates)
Budget: F&A Calculation

Calculate MTDC

MTDC = Direct costs minus exclusions

For example:
- Equipment: $10k
- Supplies: $10k
- Tuition: $10k
- Travel: $10k

MTDC = $20k

Identify the appropriate F&A rate

Review OSR website for help determining rate

Rate will depend on sponsor, where the work is occurring, and what work is being performed

Multiply MTDC by F&A Rate

To determine F&A costs, multiply the F&A base (MTDC) by applicable rate

For example:
- MTDC = $20k
- Rate = 54.5%
- F&A request: $10.9k
Appendix

• Most sponsors have limits & restrictions about what can be added

• May be used to highlight upcoming publications

• May include a copy of the planned survey
Questions?
Working with Industry
## Northwestern vs. Industry Goals

<table>
<thead>
<tr>
<th>Goal</th>
<th>Northwestern</th>
<th>Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Objective</td>
<td>• Expand knowledge through teaching, research, and public service</td>
<td>• Develop and commercialize a product, process, and/or service</td>
</tr>
<tr>
<td>Knowledge Dissemination</td>
<td>• Ability to publish with only limited time delay for review of patent rights</td>
<td>• Keep information proprietary and away from competitors</td>
</tr>
<tr>
<td>Knowledge Ownership</td>
<td>• Ownership of intellectual property developed by NU*</td>
<td>• Ownership and control of intellectual property developed by NU</td>
</tr>
<tr>
<td>Funding</td>
<td>• Full F&amp;A recovery&lt;br&gt;• Reasonable payment terms, such as timing and frequency</td>
<td>• Reduce costs wherever possible</td>
</tr>
</tbody>
</table>

*Clinical Trials*
Clinical Trial Agreements (CTA)

- Establish terms & conditions under which corporate research funding is accepted and conducted by NU

- Help protect NU, faculty, staff & subjects from liability

- Resolve intellectual property issues

- Preserve publication rights and NU data access
Key Risk Areas on Industry Projects

- Pre-spending
- Payment
- Budgets
- Unallowable Costs
- Final Report
- Fixed Price Projects
CTA Negotiation

• Negotiation takes time:
  – Completeness of submission to OSR
  – Negotiating terms of agreements
  – External review when required
  – IRB and budget approval

• Outcome:
  – Contract fully negotiated
  – IRB approval
  – Budget negotiated & approved
  – COI clearance

• Any Updates - Please Contact OSR!
Best Practices

• To expedite negotiations:
  
  – Email CTAs with draft consent to your Senior Contract and Grant Officer and cc the Administrative Coordinator

  – Don't forget to include the InfoEd # created in PD

For Additional Information:
http://osr.northwestern.edu/clinical-research/industry
Want to Learn More about CTA?

• Contact OSR Corporate Team Administrative Coordinators for one-on-one training:

• More information on broad principles applicable to research agreements between NU and industry:

• Watch for OSR Brown Bags announced on OSR listserv

For Additional Information:
http://osr.northwestern.edu/contact/contact
http://osr.northwestern.edu/clinical-research/industry
Questions?