InfoEd and ESPR for the Clinical Researcher: An Introduction to Northwestern’s Electronic Research Administration Systems

Kim Griffin, Director, OSR-Electronic Research Administration

Melissa Mizwa, Project Administrator Office for Sponsored Research-Info Team

ACCR Lecture
November 20, 2015
Topics of Discussion

• InfoEd
• ESPR
• Related Systems & Resources
• Q&A
InfoEd

• What is InfoEd?
  – Northwestern’s enterprise electronic research administration tool for proposal development/submission and tracking
  – Training opportunities offered by FFRA (NUIT):
    • FMS507 Clinical Trials Proposals in InfoEd PD – Classroom (click here to register)
    • FMS507 Online recording
    • Clinical Trials Presentation
    • Clinical Trials Training Guide
InfoEd

- Clinical Trials and other industry-sponsored projects are entered into the InfoEd Proposal Development module
  - Allows for electronic routing and approval within Northwestern
  - Allows for interfacing to NUFinancials when awarded
- For non S2S proposals, complete:
  - New Proposal Questionnaire and Set-Up Questions,
  - Proposal demographics
  - personnel and effort
  - total direct budget, approvals, the Proposal Routing Form and other appropriate supporting documentation.
Industry-Sponsored Project Agreements in 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
Materials to Submit to OSR via InfoEd

<table>
<thead>
<tr>
<th>Required Materials</th>
<th>Clinical Trials and Clinical Research</th>
<th>Basic Research</th>
<th>Fellowship and Educational Grants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Agreement</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Draft Budget</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Draft Informed Consent Form</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Protocol or SOW</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>IRB or IACUC Approval Letter</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Feinberg Sch. Medicine Regulatory Affairs Approval</td>
<td></td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

• Notes:
  – Draft documents, particularly agreements, sent to OSR must be in editable format, NOT PDF.
  – For pre-spend and award/post-award actions, use ESPR
Monitoring Negotiation Status

• Cognos canned report exists to provide information on agreement negotiations:
  – GM055 - Negotiation Status Report

• Request reporting access on page 4 of this form: http://ffra.northwestern.edu/documents/security/FFRAGeneralSecurityForm.pdf
Industry-Sponsored Project Agreements initiated via ESPR

- Data Use Agreement (DUA)
- Material Transfer Agreement (MTA)
- Non-Disclosure Agreements (*other than Clinical Trial CDA’s*)
- Subcontracts
- Subcontract Amendments
ESPR
ESPR

• ESPR = Electronic Sponsored Projects Request
• Facilitates the processing of post-submission and post-award changes by eliminating paper forms and enabling electronic routing of requests throughout the University.
• Information transfer tool
• https://www.espr.northwestern.edu/
ESPR Request Types

- Award Relinquishment / Transfer
- Budget
  - Carry-forward of Unobligated Balance
  - Open New Budget Categories
  - Revised Budget for an Award
  - Revised Budget for Submitted Proposal
- Data Use Agreements
- Fabricated Equipment
- Material Transfer Agreements
- No Cost Extension
- Non-Disclosure Agreements *(other than Clinical Trial CDA’s)*
- Personnel
  - Effort Change for PI or Other Key Personnel
  - Extended Absence of PI
  - PI or Co-I Change
  - Change of Department
- Prespending
  - Original Award
  - Continuation Year
- Subcontracts
  - Request to Issue New Subaward
  - Subaward Amendment
- Withdraw Proposal
Welcome to Electronic Sponsored Projects Request (ESPR) System

The ESPR application is designed to make completion of post-submission and post-award requests easier, and also to allow electronic routing of the request throughout the University.

ESPR Help & User Guide

Login

University NetID: 
NU-NetID-Based Password:

Login

Northwestern University | Northwestern Calendar: Plan-It Purple | Northwestern Search World Wide Web Disclaimer and University Policy Statements
© 2013 Northwestern University

Developed by: Office for Research Information Systems
Create Request: Choose Type

<table>
<thead>
<tr>
<th>Request Type:</th>
<th>Please Select Value</th>
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</thead>
<tbody>
<tr>
<td>InfoEd Proposal #</td>
<td>Award Reassignment</td>
</tr>
<tr>
<td></td>
<td>Budget</td>
</tr>
<tr>
<td></td>
<td>Data Use Agreement</td>
</tr>
<tr>
<td></td>
<td>Fabricated Equipment</td>
</tr>
<tr>
<td></td>
<td>Material Transfer Agreement</td>
</tr>
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<td></td>
<td>No-cost Extension</td>
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<td></td>
<td>Non-Disclosure Agreement</td>
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<td></td>
<td>Personnel</td>
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<td></td>
<td>Prespending</td>
</tr>
<tr>
<td></td>
<td>Subcontract</td>
</tr>
<tr>
<td></td>
<td>Withdraw Proposal</td>
</tr>
</tbody>
</table>

- **Proposal Title:**
  - Max limit of 800 characters.
  - For a DUA, MTA, or NDA without a proposal title, enter "N/A".

- **Principal Investigator:**
  - NetID: [ ]
  - Name: [ ]

- **Department/Center:**
  - Please Select Value

- **Originating Sponsor:**
  - [ ]
  - For a DUA, MTA, or NDA without a sponsor, enter "N/A."

- **Sponsor:**
  - [ ]
  - For a DUA, MTA, or NDA without a sponsor, enter "N/A."
Create Request: Enter Project Info

Electronic Sponsored Projects Request System
Office for Sponsored Research

Create Request

<table>
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<tr>
<th>Request Type:</th>
<th>Data Use Agreement</th>
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<tbody>
<tr>
<td>InfoEd Proposal #:</td>
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<td>Proposal Title:</td>
<td>Sample DUA</td>
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<tr>
<td>Principal Investigator:</td>
<td>NetID: mkm489 Name:</td>
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<tr>
<td>Department/Center:</td>
<td>OSR TEST</td>
</tr>
<tr>
<td>Originating Sponsor:</td>
<td>N/A</td>
</tr>
<tr>
<td>Sponsor:</td>
<td></td>
</tr>
</tbody>
</table>

For Data Use Agreements (DUA), Material Transfer Agreements (MTA), Non-Disclosure Agreements (NDA), and/or if no Proposal # exists, enter "N/A".

If you need to request a new agreement (i.e. DUA, MTA, NDA, or subcontract) but are unsure as to the correct type to request, please reference: [http://osr.northwestern.edu/agreements/types](http://osr.northwestern.edu/agreements/types)
# Complete Request Details

## Request: Data Use Agreement

<table>
<thead>
<tr>
<th><strong>Tracking #</strong></th>
<th>235</th>
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<tr>
<td><strong>Institution #</strong></td>
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<td><strong>Principal investigator:</strong></td>
<td>Melissa Mizwa</td>
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<td><strong>Proposal title:</strong></td>
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<td><strong>Originating sponsor:</strong></td>
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<td><strong>Sponsor:</strong></td>
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<td><strong>Request type:</strong></td>
<td>Data Use Agreement</td>
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<td><strong>Request created by:</strong></td>
<td>Melissa Mizwa</td>
</tr>
<tr>
<td><strong>Other Institution or Company name:</strong></td>
<td>Butterball, LLC</td>
</tr>
<tr>
<td><strong>Other Institution contact name:</strong></td>
<td>Fred Gobbler</td>
</tr>
<tr>
<td><strong>Other Institution contact e-mail:</strong></td>
<td><a href="mailto:fred_gobbler@butterball.com">fred_gobbler@butterball.com</a></td>
</tr>
<tr>
<td><strong>Will you be providing/ receiving any confidential (non-published) information OTHER THAN the data itself?</strong></td>
<td>Yes  ☐ No  ☐</td>
</tr>
<tr>
<td><strong>Describe the confidential info:</strong></td>
<td>A recipe for out-of-this-world sweet potatoes. 454 characters remaining out of the max limit of 500 characters.</td>
</tr>
<tr>
<td><strong>Will you be providing/ receiving any information that may be subject to export controls (e.g. data from/to another country)?</strong></td>
<td>Yes  ☐ No  ☐ Don't know</td>
</tr>
<tr>
<td><strong>What is the direction of this data transfer?</strong></td>
<td>Inbound (data coming into Northwestern)  ☐ Outbound (sending data out of Northwestern)  ☐ Two-way transfer (data exchanged both ways)</td>
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# Complete Request Details

## Outbound Transfers

<table>
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<tr>
<th>Question</th>
<th>Options</th>
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<tbody>
<tr>
<td>Describe data set (e.g. EEG data from patients with Alzheimer's, Cook County traffic pattern data, etc.)</td>
<td>Taste-test data on best turkey-sides pairings. 454 characters remaining out of the max limit of 500 characters.</td>
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<tr>
<td>Is the data related to people (e.g. clinical trials, consumer data, survey responses, and other research involving human subjects)?</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Describe the nature of the data set (if related to human subjects)</td>
<td>Confidential, non-health personal data (includes non-health survey data and consumer information)</td>
</tr>
<tr>
<td>If you're unsure which description applies, please consult with NU's IRB</td>
<td>Complately de-identified data (i.e. includes NO personal identifiers)</td>
</tr>
<tr>
<td>IRB status [If approved, exempt, or determined not human subjects research, include official IRB letter or determination. See &quot;Other Information &amp; Uploads&quot; below.]</td>
<td>Approved  Exempt  In Process  Determined not human subjects research</td>
</tr>
<tr>
<td>How will you be providing the data (e.g. secure file transfer, hard drive, remote server access, etc)?</td>
<td>Secure file transfer</td>
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<tr>
<td>Was this data generated as a result of research sponsored by the federal government, a foundation, or a company?</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Please identify the funding source, project title, and SP# (if known):</td>
<td>The Thanksgiving Institute, &quot;Turkey for me, Turkey for you&quot;</td>
</tr>
<tr>
<td>Is there a collaborator or organization outside of Northwestern University who contributed to the generation of the data who may need to approve the DUA?</td>
<td>Yes  No</td>
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# Upload Documents

## Other Information & Uploads

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<th>Brief description of research (required):</th>
<th>Investigation of genetically-engineering turkeys that taste best with out-of-this world sweet potatoes. 897 characters remaining out of the max limit of 1000 characters.</th>
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<tbody>
<tr>
<td>The Provider’s DUA, if they sent one to you</td>
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<tr>
<td>Additional info for OSR (optional):</td>
<td>1000 characters remaining out of the max limit of 1000 characters.</td>
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<tr>
<td>Upload additional info for OSR (optional):</td>
<td><img src="#" alt="Delete" /> <code>IRB Approval_12345.pdf</code> <img src="#" alt="Delete" /> <code>IRB Approval #12345</code></td>
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[Save Details] [Save & Submit for Routing] [Cancel & Back to Menu]
### ESPR Request Status

#### Electronic Sponsored Projects Request System
Office for Sponsored Research

<table>
<thead>
<tr>
<th>Edit</th>
<th>View</th>
<th>Status</th>
<th>Tracking#</th>
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<th>Principal Investigator</th>
<th>Award Department</th>
<th>Routing Started On</th>
<th>Sent Back On</th>
<th>Title</th>
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<tbody>
<tr>
<td></td>
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<td>Sample DUA</td>
<td>N/A</td>
<td>Data Use Agreement</td>
<td>Melissa Mizwa</td>
<td>OSR TEST</td>
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<td>tht346 - EPA-OITA-2011-005</td>
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<td>Fabricated Equipment</td>
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<td>tht346 - EPA-OITA-2011-005</td>
<td>231</td>
<td>KIM-001</td>
<td>Budget: Open New Budget Categories</td>
<td>Kimberly Griffin</td>
<td>Admin Services</td>
<td>11/10/2015</td>
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</table>
OnBase
InfoEd-OnBase Data Transfer

DEPARTMENT
USERS

SUBMITTED!

Overnight
data transfer

ONBASE

OSR & ASRSP
Info-Ed-OnBase: Access & Functions

• Link to OnBase on InfoEd PT Proposal Summary page

• Security is based on NetID / InfoEd credentials

• InfoEd Users are able to View, Save, Print documents in OnBase associated with a given SP# record
InfoEd Internal Documents: Uploads & Exported Documents

• Upload Menu: Streamlined document type list

• Documents in Internal Documents are exported EXCEPT Proposal Routing Form
Exports: Proposal Types

- All EXCEPT Industry-sponsored clinical trials (OSR uploads these directly to OnBase)
The OnBase Interface
Resources
Training Resources

- Finance Facilities and Research Administration (FFRA) website: http://ffra.northwestern.edu/training/curriculum.html

- OSR website: http://osr.northwestern.edu/
FEDERALLY SPONSORED CLINICAL RESEARCH

CLINICAL TRIALS DEFINITION
Clinical trials are one of the two main types of clinical studies (the other being observational studies). In October 2014, in order to more clearly distinguish between clinical trials and clinical research studies, the National Institutes of Health (NIH) revised its definition of a clinical trial as follows: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. This revised definition will apply to competing grant applications and contract proposals that are submitted to NIH on or after January 25, 2015.

For more information about the NIH clinical trials definition, including a decision tree and case studies, visit the NIH page on clinical trials. For more information on clinical studies in general or to search for a clinical study, visit ClinicalTrials.gov.

SUBMITTING PROPOSALS
All federally-sponsored clinical trial proposals must be processed through OSR. Procedures for OSR processing include completing an InfoEd Proposal Development (PD) record, which includes obtaining administrative approvals and satisfying all other compliance requirements. Review by the department chair and administrative personnel is essential to ensuring that the University can provide the space and resources needed to conduct the project. No study subject related activity can be initiated until appropriate IRB approval has been obtained and either a Notice of Grant Award is received or a subcontract agreement has been executed by OSR.
AGREEMENTS

NEGOTIATING AND ACCEPTING AGREEMENTS

Authority to review, negotiate, and endorse sponsored agreements has been delegated to Office for Sponsored Research. Individual investigators, chairs, or deans are not authorized to negotiate or endorse sponsored agreements on behalf of the Institution.

Sponsored agreements routinely include information about level of funding, period of performance, the mechanism for receiving funds, and reporting requirements. In many cases, sponsors incorporate a standard set of terms and conditions in their agreements (FDP sponsors, for example), but may also include additional project-specific requirements.

Many sponsors issue unilateral agreements that do not require institutional counter signatures. In these cases, OSR is expected to notify the sponsor if there are terms and conditions that are not acceptable to the Institution or the investigator. Some sponsors issue bilateral agreements, requiring an institutional countesignature. Often, it is necessary for OSR to negotiate changes to sponsor terms and conditions. Intellectual property rights, rights to publish, confidentiality, termination, and indemnification language often require negotiation in order to ensure appropriate protections for the investigator and the Institution.
INFOED

WHAT IS INFOED?
InfoEd is Electronic Research Administration support software that provides two major functionalities for the Northwestern sponsored research community: storing CSR's proposal and award data (Proposal Tracking module) and providing system-to-system proposal submission under many federal programs (Proposal Development module).

SUBMISSION REQUIREMENTS BY SPONSOR AND PROPOSAL TYPE
InfoEd Proposal Development (PD) is required for the internal routing and approval of all sponsored research projects (grants and contracts). Most grant proposals that used to be prepared using Adobe forms and submitted via Grants.gov must be prepared, routed, and submitted using PD (no Adobe forms necessary) in accordance with OSR submission deadlines. The chart below details types of proposals and the tools required for their preparation and submission.

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>PROPOSAL TYPE</th>
<th>PREPARED IN/SUBMITTED FROM</th>
<th>ROUTED/APPROVED IN</th>
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</thead>
<tbody>
<tr>
<td>All Federal sponsors not explicitly listed below*</td>
<td>New / Competing Renewal</td>
<td>PD</td>
<td>PD</td>
</tr>
<tr>
<td>NSF</td>
<td>New / Competing Renewal</td>
<td>Fastlane</td>
<td>PD</td>
</tr>
<tr>
<td>NEH</td>
<td>New / Competing Renewal</td>
<td>Grants.gov</td>
<td>PD</td>
</tr>
<tr>
<td>Complex Federal proposal types that cannot be submitted via Grants.gov</td>
<td>New / Competing Renewal</td>
<td>Paper</td>
<td>PD</td>
</tr>
<tr>
<td>Non-federal proposals</td>
<td>New / Competing Renewal</td>
<td>Per sponsor guidelines</td>
<td>PD</td>
</tr>
</tbody>
</table>
OSR Web: Training

PRESENTATIONS

UPCOMING PRESENTATIONS
For a list of presentations and other research administration-related events, visit the [OSR Events Page](#).

To receive notifications from OSR about relevant news and events, subscribe to the [OSR listserv](#).

PRESENTATION ARCHIVE

<table>
<thead>
<tr>
<th>TOPIC</th>
<th>CAMPUS</th>
<th>PRESENTER</th>
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<tbody>
<tr>
<td>NSF Update: Revised OFS &amp; Other Topics</td>
<td>Evanston</td>
<td>Chip Rehlinger, Kelly Morrison</td>
</tr>
<tr>
<td>OSR-Evanston Brown Bag: Uniform Guidance Briefing</td>
<td>Evanston</td>
<td>Elizabeth Adam, Michael Daniels, Kelly Morrison, Jane Roy-Sinof</td>
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<td>OSR-Chicago Monthly Meeting: OME Uniform Guidance</td>
<td>Chicago</td>
<td>David Lynch, Michael Daniels</td>
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<td>OSR-Chicago Monthly Meeting: Post-Award Management</td>
<td>Chicago</td>
<td>Kathy Mustea</td>
</tr>
</tbody>
</table>
OSR Web: Contacts

CONTACT

OSR Evanston Office
1801 Maple Street
2nd Floor, Suite 2410
Evanston, IL 60201-3149
Phone: (847) 461-3003
Fax: (847) 451-4006
Email: OSR-Evanston@northwestern.edu
Hours: 8:30am - 5:00pm

Find OSR Evanston Staff

OSR Chicago Office
760 N. Lake Shore Dr., 7th Floor
Rubloff Building
Chicago, IL 60611-4570
Phone: (312) 580-7955
Fax: (312) 503-2234
Email: OSR-Chicago@northwestern.edu
Hours: 8:30am - 5:00pm

Find OSR Chicago Staff

Find My Grants Officer
Constituency Lists for Chicago and Evanston campuses (last updated 11/8/2016)
Note: Both grants team and industry/clinical team contacts are included

Send OSR your feedback
Fill out a 3-question survey and tell OSR about your experience with the website.
Questions