OSR Monthly Meeting

February 19, 2019 (Evanston)
&
February 21, 2019 (Chicago)
AGENDA

• Announcements
• IRB: eIRB+ and Common Rule Changes
• DocuSign Pilot
• Dead-stops: Things that will kill a proposal
OSR Announcements

• OSR Subcontracts Team now has a unified email: OSR-Subk@northwestern.edu

• OSR Early Office Closure (Staff Retreat): Friday, February 22, 12:00-5:00

• OSR Corporate Contracts Team:
  – Welcome Kirk Samson as our newest CGO (Starts next Monday)
  – Associate CO, focused on MTA/DUA (Announcement Expected Soon!)
IRB: eIRB+ and Common Rule Changes
eIRB+/InfoEd Funding Matching
These changes don’t affect department-funded studies, or studies supported by affiliates’ grants (NMHC, Lurie, etc).

Answer ‘No’ to this new question, and the research team will add funding information as before.
Answer ‘Yes’ and they will be prompted to directly select the InfoEd grant.
By default, grants with the study’s PI will automatically be listed
Use the search functionality to search for other grants, for example, if the grant is not in the study PI’s name.
The research team can filter the results in several ways. Here, we’ve pulled 155 records where Abbvie is a sponsor, but we can also filter them down to two records by looking for a specific PI.
Select a grant and the study preparer will be prompted to attest to the match between the grant and the study.
Details are pulled automatically from the InfoEd record, minimizing errors and pulling correct information into approval letters. In the future, OSR will be able to automatically retrieve these letters.
The match is made in InfoEd, and we capture the Approval ID, the NetID of the person making the match/attestation, and if applicable, the person who ‘unlinked’ the record, in case a funding source is removed at Continuing Review, or in case a Modification to the study is made.
Changes to the 45 CFR 46 Protection of Humans in Research “Common Rule”
Introduction to terms

• 45CFR46: Subpart A: “Common Rule”
• 2018 Rule: “Revised rule”, in effect Jan. 21, 2019
• Pre-2018 rule: Current rule, projects approved prior to Jan. 21, 2019

Burden reducing provisions:
1. Activities which are not HR
2. No continuing review
3. No grant congruency review
Clinical trial means 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 the interventions on biomedical or behavioral health related outcomes.

NIH examples of interventions:

- drugs/small molecules/compounds, biologics, devices
- procedures (e.g., surgical techniques)
- delivery systems (e.g., telemedicine, face-to-face interviews)
- strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits)
- treatment strategies; prevention strategies; and, diagnostic strategies
Actual transition: Pragmatics first

• All new projects are subject immediately to the revised rule that goes into effect on January 21, 2019

• All projects that are closed to enrollment and in data analysis only
  – may never need to be transitioned to the revised rule
  OR
  – may be transitioned simply to remove some of the pre-2018 requirements such as continuing review

• All other projects approved under the pre-2018 rule will be rolled into the revised rule when it makes sense
New projects

1. Must be reviewed under the 2018 rule
2. Must use the currently IRB approved templates for protocol and consent found on the website
3. Typically, minimal risk, non exempt, non FDA and non-DOD or Department of Energy studies will not have an expiration date
No Continuing Review (CR)

• Most expedited studies will not require continuing review
• Reasons for maintaining the continuing review requirement:
  1. The project is regulated by the FDA or by another sponsor that requires continuing review
  2. The project involves additional regulatory oversight, such as a conflict of interest (COI) management plan
  3. The research will be conducted internationally or at non-NU sites and the NU IRB decides an annual review will be in everyone’s best interest
  4. A modification or incident report (RNI) reveals new information that requires additional oversight
  5. The investigator has previous serious non-compliance or a pattern of non-compliance that is of concern
  6. Something else the reviewer finds warrants review
Currently approved projects: Removal of the CR

• We started in August 2018 transitioning minimal risk studies to no-CR at the point of the submission of the regularly occurring CR

• Starting January 21, 2019, we can begin to consider removing or approving the expiration date on projects that:
  – Are in data analysis only, including analysis of identifiable private information or identifiable bio specimens; or
  – Are only accessing follow-up clinical data from procedures the participants would undergo as part of clinical care
New processes related to no CR

• The watermark: “….on or after [approval date]”

• System generated and reminders in letters regarding: “Reminder of study team responsibilities and project closure”

• Still obligated to submit modifications, RNIs and to close their study when it is completed
Changes to exempt research

1. There are some tweaky changes to Category 1, 2, 5 and 6, but those categories are largely the same.

2. Old category 3 removed and replaced with a new Category 3 which allows for:
   - “benign behavioral interventions” which are brief, harmless, not likely to have a significant lasting impact, and the researcher has no reason to think participants will find the interventions offensive or embarrassing

3. Category 4 will now allow for prospective data not just existing data.

4. Category 7 and 8 refer to secondary research with regard to the use and storage of identifiable private information or identifiable biospecimens. Both of these exempt categories require limited IRB review.
Limited IRB Review

• Some exemptions, specifically Category 2 if identifiers are retained and Categories 3, 7 and 8, will require “limited IRB review” as a condition of exemption.

• Limited IRB review will be required to ensure there are adequate confidentiality safeguards for potentially identifiable information.

• Limited IRB review, while similar to expedited review, will only be focused on the data management and data security plan.
Use of sIRB (single Institutional Review Board)

- sIRB requirement that U.S. institutions engaged in multi-site research rely on a single IRB for that portion of the research that:
  - Takes place within the United States
  - The same protocol will be used

- NIH requirement went into effect January 25, 2018
- Other federal agencies sIRB will go into effect January 20, 2020
- Contact IRBReliance@northwestern.edu for assistance
QUESTIONS?
DocuSign Pilot for Unfunded Agreements
FY 2019 Pilot

• We hope to show that DocuSign expedites a key part of the process of obtaining an executed agreement, while saving resources.

Begins Monday, 2/25

• Formal roll-out on Monday
• Beta testing (of sorts) through then
DocuSign: What’s Affected

- CDAs / NDAs
- DUAs
- Outgoing MTAs
DocuSign: How it Works

1. PI Clicks Link in Email
   (RA Receives Copy by Email)

2. PI Follows the DocuSign Tabs and Signs Electronically

3. PI Clicks Finish, Sending Document to Next Signer

4. Once the Last Signature is Applied, DocuSign Automatically Sends Everyone in the Cycle the Executed Agreement

5. You’re Ready to Proceed with the Data, Material, or Information Transfer or Exchange!
DocuSign: Why Are We Doing This?

CDA / NDA: Signature Times
(Purple Line = 10 days; Blue = 20)

Gray = Days Pending PI Signature

Red = Days Pending Sponsor Execution

CDAs Executed Nov/Dec 2018
How does the DocuSign Pilot Affect Research Administrators?

- OSR will provide Job Aids and Tips
- In the “Additional Info” Section of the Non-Funded Negotiations Request (NFN):
  - Please list the name and email address of the person (whether the PI’s assistant, research administrator, or lab manager) who can follow up with the PI to ensure the PI reviews and signs the agreement when it’s sent through DocuSign to the PI’s email address.
  - For PIs with more than one NU/NMHC email address, please also include the preferred PI email address.
  - NOTE: If you don’t provide that information OSR will copy the RA or person submitting the NFN, and use the PI’s address in the system.
DocuSign: Benefits
(aka What do we hope to see from the DocuSign Pilot?)

Secure
Legally-binding, secure signatures, with all steps tracked from send to full execution

Fast / Efficient
Electronic delivery and the ability to sign from smart phones and devices should speed execution: We'll be comparing execution times pre-pilot to pilot.

Convenient
24-hour availability and access
Avoid manual printing, scanning, and signing

Sustainable
Using less paper, we anticipate a reduced environmental impact and costs (e.g., mailing, storage, copier maintenance)
Proposal Dead-Stops
High risk proposal submission

- Adding International subawards
- Award terms and conditions at proposal stage
- Industry and Federal (especially DoD) contracts
- Representations and certifications
International Subs

• NU review process-this includes offices outside OSR and requires coordination
  – Department enters request into online form
  – Debarment check (Export Control Office)
  – Legal entity status (OSR)
  – COI (NUCOI)
Award Terms & Conditions

• At proposal stage T&C sometime negates our ability to negotiate when we get the award

• May need to connect with several offices across NU for review or approval
  – INVO
  – Export control
  – NUCOI
  – Risk Management
Contracts

• Contract proposals are more complicated than grant proposals, clear SOW should be provided
• Solicitations or RFP’s may have proposal requirements throughout the document, not just in the proposal development guidelines
• May require complex certifications or approvals from several offices across campus
  – INVO (IP terms)
  – Export Control (TRL, foreign national or publication restrictions)
  – NUCOI (Organizational COI review and management plan)
  – Risk Management (Insurance requirements)
Representations & Certifications

• Often need to connect with several offices to confirm accurate response or certification
  – Office of Equity
  – COI
  – Risk Management
  – Facilities
  – And many more
Consequences

- Proposal rejection
- NU withdrawal of non compliant proposal
- NU unable to accept an award
- Delayed award setup
Final Comments

• It should not be assumed that OSR can always fix any issues at award stage
• Submit your proposal in a timely manner to put out the best possible product
• A solid proposal also allows award setup to be more efficient
Thank you for joining us!

Find monthly meeting presentations on the OSR website at:
https://osr.northwestern.edu/training/presentations