

Research Administrator Meeting

Tuesday, January 23, 2018

10:00-12:00

Illinois Room (348), IMU

Agenda:

1. GAO Announcements
2. Costing Considerations
3. Quick Reference Guide – Overview
4. DSP General Announcements
5. NIH Updates
6. NSF Updates
7. Outgoing Subawards
8. Research Tracker Demo and Tips
9. ClinicalTrials.gov

January 23, 2018

Research Administrator Meeting

Agenda

- GAO Announcements (Audra Haddy)
- Costing Considerations (Audra Haddy)
- Quick Reference Guide – Overview (Audra Haddy)
- NCURA Webinars (Audra Haddy)
- DSP General Announcements (Wendy Beaver)
- NIH Updates (Lynn Hudachek)
- NSF Updates (Paul Below)
- Outgoing Subawards (Erin Brothers)
- Research Tracker Demo and Tips (Nate Cook)
- ClinicalTrials.gov (Brian Brotzman)

GAO Announcements

- FY17 Single Audit
- WhoKey Administration Application – Funds 500/510
 - New – PI Dept Research Admin, Co-I & Co-I Dept Research Admin Roles can assign WhoKey Reviewers
 - Coming Soon – Automatically carry over WhoKey Reviewers for new BRs

Costing Considerations

Costs charged to a Federal award must be **allowable**, **reasonable** and **allocable**.

Costs must be supported by “adequate” documentation.

Any credits for costs charged to a Federal award must be credited back to the award or refunded to the sponsor.

<https://gao.fo.uiowa.edu/managing-grants-contracts/costing-considerations-%E2%80%93-guidelines-charging-externally-sponsored-projects>

Costing Considerations

What makes a cost **allowable**?

- It is necessary for the project
- It is not specifically restricted
- It is treated consistently

Costing Considerations

What makes a cost **reasonable**?

- The type of the goods or services acquired and amount does not exceed that which would be incurred by a prudent person under similar circumstances

Costing Considerations

What makes a cost **allocable**?

- Goods or services involved are chargeable or assignable to that Federal award in accordance with the benefits received.

Costing Considerations

“Adequate” documentation includes the following elements:

- What was purchased
- Where/from who it was purchased
- When it was purchased
- Explains why it was purchased
- Who authorized purchase

Quick Reference Guide – Overview

- [UI Accounting Code Manual](#) provides general information about expenditure classifications (IACTs)
- [Quick Reference Guide](#) provides additional information of allowability and other considerations when charging to sponsored projects
 - Also includes IACTs, Descriptions, FMS Categories

NCURA Webinars

Coming Soon – New Training Opportunity

Life Cycle Series:

- Pre-Award/Budgeting (3 parts/90 mins each)
- Proposal Development (3 parts/90 mins each)
- Award Negotiation and Acceptance (3 parts/ 90 mins each)
- Award Monitoring/Management (2 parts/2 hrs each)
- Compliance (2 parts/2 hrs each)

DSP Updates

Research Administrators Meeting
January 23, 2018

DSP Updates

- DSP Announcements - Wendy Beaver
- NIH Updates – Lynn Hudachek
- NSF Updates – Paul Below
- Outgoing Subawards – Erin Brothers
- DSP Research Tracker Demo and Tips – Nate Cook
- ClinicalTrials.gov – Brian Brotzman

DSP Announcements

- DSP Staffing: Adwin Hesseltine, Contract Negotiator
- PIs leaving the UI and Grant Transfers
 - Notify DSP upon learning of PI transfers in or out
 - [DSP Grant Transfer Form](#)

DSP Announcements

- Patient Centered Outcomes Research Institute (PCORI)
 - Patient-engaged research
 - LOI for several [funding opportunities](#) due Feb. 13, 2018
 - Click on "Open" and "Upcoming" tabs
 - Contact Mary Blackwood in DSP with questions

The screenshot shows the PCORI website. At the top, there is a navigation bar with links: BLOG, NEWSROOM, HELP CENTER, SUBSCRIBE, CAREERS, and CONTACT. Below this is the PCORI logo and the text "Patient-Centered Outcomes Research Institute". To the right of the logo is a search bar with a magnifying glass icon and the word "Search". Below the navigation bar is a teal-colored menu bar with links: ABOUT US, RESEARCH & RESULTS, ENGAGEMENT, FUNDING OPPORTUNITIES (which is highlighted), and MEETINGS & EVENTS. Below the menu bar, the page is titled "Funding Opportunities". On the left side, there is a sidebar with links: What & Who We Fund, What You Need To Know To Apply, Applicant Training, and Merit Review Process. In the center, there are three tabs: Open, Upcoming, and Closed. The "Open" tab is selected. Below the tabs, the section is titled "Open Opportunities". The text below the title reads: "All open funding opportunities can be found below. If this is your first experience applying to PCORI for funding, we recommend that you begin on the [What You Need to Know to Apply](#) page. Please note each

DSP Announcements

- EU General Data Protection Regulation (GDPR)
 - Effective May 25, 2018
 - Protects certain data related to EU persons
 - Anticipate limited impact on UI human subjects research with EU-based sponsors and collaborators
 - Notify DSP if you learn of applicability
 - UI working group will develop a more standardized approach

DSP Announcements

- [DSP website](#) updates are coming
- Outreach:
 - [Lunch series for faculty: Research at the University of Iowa](#)
 - Sponsored by University of Iowa Office of Research and Economic Development
 - Register in advance
 - Running a compliant research program; Feb. 7, 11:30 a.m. - 1:00 p.m. 1289 CBRB
 - Intellectual Property, licensing, and new ventures; Feb. 28, 11:30 a.m. - 1:00 p.m. 2520D UCC
 - UIDP “Working at the University-Industry Interface: Effective Strategies for Active Researchers”; Date and time TBD
 - Outgoing Subawards; Date and time TBD
- Contact DSP to meet with your group on selected topics of interest

Doing Human Subjects Research?

Changing NIH Policies May Impact You



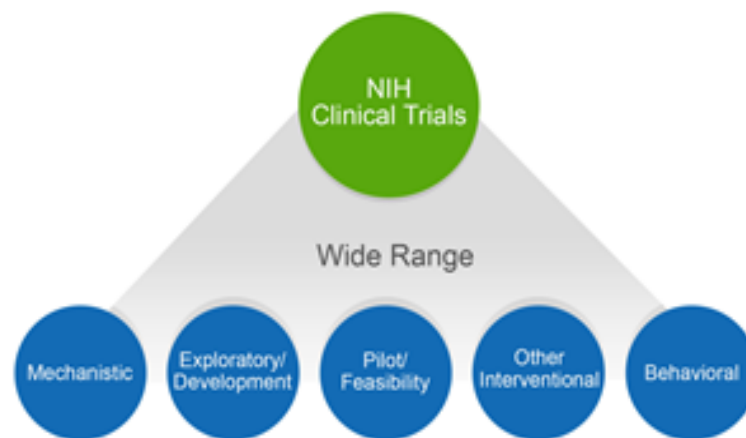
NIH Updates

NIH Might Consider Your Human Subjects Research to be a Clinical Trial

Does your study...

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect of intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome**?

If “yes” to **ALL** of these questions, your study is considered a clinical trial



Unsure how to answer the questions? We have a tool that can help! <https://grants.nih.gov/ct-decision/>

NIH Updates

Whether NIH Considers Your Study to be a Clinical Trial impacts whether you need to:

- Respond to a **clinical trial-specific FOA**
- Address additional **review criteria** specific for clinical trials
- **Register and report** your clinical trial in [ClinicalTrials.gov](https://clinicaltrials.gov)

NIH Updates

Identifying the Right Funding Opportunity Announcement (FOA) is Key

Due Dates on or after
January 25, 2018

All clinical trial applications **MUST** be submitted to an FOA that allows clinical trials

How to determine if an FOA accepts clinical trials?

1. Refer to Section II. Award Information
2. Indicated in FOA title (new FOAs only)

Tip: Check your FOA at least 30 days before the due date for any updates

NIH Updates

New Application Packages (FORMS-E)

Due Dates on or after
January 25, 2018

FORMS-E Application Packages is **REQUIRED** (including new Human Subjects and Clinical Trials form)

PHS Human Subjects and Clinical Trials Information Form

- ✓ Consolidates human subjects & clinical trial information from multiple forms into one
- ✓ Expands information required for studies meeting NIH CT definition
- ✓ Collects information at the study-level
- ✓ Aligns with CT.gov

See <https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm>

NIH Updates

Become Familiar with new HS/CT Form

Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0041
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☒ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

Information populated from R&R Other Project Information form.

If No to Human Subjects

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Required if Yes to human specimens/data question. Add Attachment Delete Attachment View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment Delete Attachment View Attachment

Check Application Guide and opportunity instructions to determine if attachment is needed.

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1 Add Attachment Delete Attachment View Attachment

[Review Annotated Form Set for NIH Grant Applications - FORMS-E Series](#)

NIH Updates

Changes to the Appendix Policy

Due Dates on or after
January 25, 2018

Since the new Human Subjects and Clinical Trials Information form collects key elements from the protocol, the **optional protocol submission will be removed from the Appendix Policy.**

Parent FOAs

- ✓ Will **NEVER** allow inclusion of the protocol in the application
- ✓ If the protocol is included, the application will be sent back

IC issued FOAs

- ✓ Protocols and other materials allowed only when specified as required in the FOA

See NIH Guide Notice: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html>

NIH Updates

Single Institutional Review Board (sIRB) Policy for Multi-site Research

Domestic multi-site non-exempt human subjects research studies will require a single IRB of record

Key Dates

- **Grants:** Applications due on or after January 25, 2018
- **Contracts:** Solicitations published starting January 25, 2018

Exceptions

- Career Development (K), Research Training (T), or Fellowship (F)
- Foreign sites
- Sites where review by sIRB is prohibited by federal, tribal, or state law, regulation, or policy
- When there is a compelling justification (very rare)

See <https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>

NIH Updates

Applications/Proposals

- **Plan ahead! Meet with the HSO as soon as you decide to pursue funding.**
- **In Single IRB plan, include:**
 - Name of the sIRB (if known)
 - Indicate that, if funded:
 - All sites, including any added after award, agree to rely on sIRB
 - Sites will sign reliance agreement and who will maintain records of this agreement
 - HSO recommends using the SMARTIRB Reliance Model
 - IRB Fee structure
 - Communication plan

NIH Updates

Updated SF424 (R&R) Guide – Version E

Use for due dates on and after January 25, 2018

<https://grants.nih.gov/grants/how-to-apply-application-guide.html>

May also access the NIH annotated Form Sets – See under Related Resources

NIH Updates

Updated Certificates of Confidentiality (CoC) Policy

Effective October 1, 2017 - CoCs will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016

- Eliminates the need for NIH funded investigators to apply for a CoC
- Enhances the privacy protections of individuals participating in NIH-funded research
- Requires investigators to only disclose information under specific circumstances
- Applies to NIH awards funded wholly, or in part, by NIH
- Disclosure restrictions also apply to anyone who receives a copy of identifiable sensitive information protected by the policy, even if they are not funded by NIH
- CoC is issued as a term and condition of award (no physical certificate)

Learn more at <https://humansubjects.nih.gov/coc/index>

NIH Updates

Training Resources - NIH Clinical Trial Policies

<https://grants.nih.gov/policy/clinical-trials/training-resources.htm>

(FAQS, slides, videos, podcasts, webinars...)

NIH Updates

Who to Contact?

Division of Sponsored Programs (DSP) – #319-335-2123 or niH@uiowa.edu

- FORMS-E
- Program Announcement/FOAs

Human Subjects Office (HSO) – <https://hso.research.uiowa.edu/>

General or CoC Questions: 319-335-6564 or irb@uiowa.edu

For External IRB or sIRB Questions: uirb-external@uiowa.edu

For Clinical Trials.gov questions: Ct-gov@uiowa.edu



NSF Updates

- PAPPG 18-1 changes effective 1/29/2018
 - Collaborators & Other Affiliations must use the COA excel template
 - Project Description must now also include a section titled Intellectual Merit
 - Budget Justification page limit increased to 5 pages
 - Budget Justification must include UI's definition of a "year" for PI and Senior Personnel effort not to exceed 2 months of NSF funding in one year.
 - UI uses a calendar year for this purpose

NSF Updates

- Proposal Submission Modernization
 - Some FOA's will allow you to submit through research.gov this spring. Feel free to use this option when it is available
 - https://www.nsf.gov/bfa/dias/policy/era_forum.jsp

Outgoing Subawards

Updates and Reminders

- Conflict of Interest Policy includes NSF research along with PHS research
- FDP Expanded Clearinghouse
- Fixed Price Subawards and the Uniform Guidance
 - Fixed price subawards *require prior approval* from the prime sponsor before issuance
 - Exception: when the fixed price subaward is specified and detailed in the proposal application
- Automatic Carryover Policy
 - The prime sponsor is federal grant funding
 - Iowa is the prime recipient of the federal grant funds
 - The subrecipient is a US educational institution
 - The prime award allows automatic carryover
 - The BR does not flip

Outgoing Subawards

Updates and Reminders

– Website Updates

– [Form I](#)

- Required for NEW subawards
- To be completed before subaward is requested through the Preq system, not at the proposal application stage

Outgoing Subawards

eDSP Subaward Module

- Subaward requests via the Research Tracker and Project View
- Will no longer use the Preq system for an outgoing subaward
- The module includes a wizard for the system to determine when a new subaward or amendment is required
- Target release date later this spring
- Watch for training times and opportunities

DSP Research Tracker Demo and Tips

Division of Sponsored Programs

Division of Sponsored Programs

2 Gilmore Hall

Phone: 335-2123



Email: dsp@uiowa.edu (General)

nih@uiowa.edu (DHHS related emails)

era@uiowa.edu (other federal and non-federal grant emails)

dsp-contracts@uiowa.edu (contract emails)



ClinicalTrials.gov Working Group and Departmental Liaisons

<https://hso.research.uiowa.edu/clinicaltrials.gov-working-group>

PURPOSE

The ClinicalTrials.gov Network will:

- Inform the UI IRB Compliance Program and UI Human Research Protection Program of researcher community needs regarding regulatory requirements specified by Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), ClinicalTrials.gov, and the Protocol Registration and Results System (PRS).
- Identify opportunities for continuous quality improvement in facilitating the UI research community's compliance with ClinicalTrials.gov requirements, as well as requirements from other entities, including but not limited to the International Committee of Medical Journal Editors (ICMJE), the European Medicines Agency (EMA), and the National Institutes of Health.
- Develop an in-house network of researchers who can serve as a resource to others in navigating regulatory and institutional requirements related to clinical trials and identifying best practices.

RESPONSIBILITIES

Members of the CT.gov Network will:

- Collaborate with the IRB Compliance Program and the Human Research Protections Program in the development and maintenance of policy and procedures that will improve compliance with regulations surrounding clinical trials;
- Serve on "ad hoc" working groups that evaluate specific issues and recommend potential improvements to the Network for adoption by the IRB Compliance Program and/or UI Human Research Protections Program, as well as participating in educational activities related to ClinicalTrials.gov;
- Raise potential issues within their respective division/area that are obstacles to complying with FDAAA 801 and requirements from other entities; and
- Serve as a resource to other researchers in completing the ClinicalTrials.gov records.

MEMBERSHIP

Specific individuals and departments have been identified and were approached regarding membership to the network/working group. Approval was gained from the respective DEOs for the members' participation as part of the working group.

COMMITMENT

Approximately 2-3 hours per week within your department, and a monthly 1-hour Working Group meeting. Initial activities will include onboarding (approximately 2 months), and continuing education during the implementation phase (first 6 months).

Presented by Brian Brotzman, UI Human Subjects Office