CLEAR Meeting

Hosted by Sponsored Research
October 12, 2021
Today’s Agenda

• Announcements
  – NSF PAPPG & System Updates
• Research Imaging Collaboration Office
• Subcontracts vs. Subprojects
• Subcontracts: Requests, Subrecipient Monitoring, and Research Compliance
Sponsored Research Staffing: Open Positions

• Contracts & Negotiations
  – Associate Contracts Officer (new FTE posting soon)
  – Contracts & Negotiations Manager (interviews in progress)

• Proposals & Awards Acceptance
  – Coordinator Sponsored Research (new FTE posting soon)

• Awards Management
  – Awards Management Associate (interviews in progress)
<table>
<thead>
<tr>
<th>Due Date</th>
<th>Description</th>
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</table>
| November 5  | • R01 Research Grants  
              renewal, resubmission, revision  
• U01 Research Grants - Cooperative Agreements  
              renewal, resubmission, revision |
| November 12 | • K Series Research Career Development  
              renewal, resubmission, revision |
| November 16 | • Other Research Grants and Cooperative Agreements  
              (R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3,  
              UH2/UH3) renewal, resubmission, revision |
| December 8  | • F Series Fellowships Individual National Research Service Awards (including F31 Diversity)  
              new, renewal, resubmission |
NSF PAPPG & System Updates

• Proposal & Award Policies & Procedures Guide (PAPPG) (NSF 22-1) effective for proposals submitted or due on or after October 4, 2021, included
  – Significant changes to NSF-approved biographical sketch and current and pending support formats
  – Two new "Other Types of Proposals":
    • Planning Proposals: must be prepared and submitted in Research.gov
    • Career-Life Balance (CLB) Supplemental Funding Requests: must be prepared and submitted in FastLane

• NSF also made a number of system updates for proposals submitted in Research.gov, FastLane, and Grants.gov related to new PAPPG
NSF Updates: Biosketches & Current and Pending Support

- Biographical sketch format updates include increasing the page limit from two to three pages.
- Current and pending support format updates include new sections for information on objectives and overlap.
- Trimming Service Implemented:
  - Research.gov, FastLane, and Grants.gov will remove any pages which do not contain data entered by users (i.e., blank pages) from NSF-approved current and pending support fillable PDF.
  - Only applies to the NSF-approved current and pending support fillable PDF and not to any other uploaded PDFs.
  - Triggered during document upload and during proposal submission in Grants.gov.
NSF Updates: Research.gov

• The Grant Opportunities for Academic Liaison with Industry (GOALI) and Planning proposal types and the Letter of Intent submission type now available for submission in Research.gov

• New automated compliance checks and associated error and warning messages for the enabled proposal and submission types
  – Error messages will prohibit proposal submission to NSF; warning messages still permit proposal submission.

• All supported proposal and submission types and compliance checks are also enabled in the Research.gov Proposal Preparation Demo Site.
NSF Updates: Resources

- NSF Proposal and Award Policy Update (presented at Fall 2021 Federal Demonstration Partnership (FDP) Meeting)
- NSF 22-1: Significant Changes and Clarifications to the PAPPG
- NSF Biographical Sketch and Current/Pending Support Updates Summary
- Research.gov System Updates Summary
Research Imaging Collaboration Office

Jessica Anaya Agosto & Crystal Santillanes
Research Operations: Clinical Trials & Imaging Studies

**Current State**

1. Researcher
2. Northwestern IRB
3. Office for Sponsored Research (OSR)
4. Outside department
5. Northwestern OSR & IRB

**Future State**

1. Researcher
2. Radiology Clinical Trials Support Core
3. Northwestern OSR & IRB
4. Outside department

RICO
Research Imaging Collaboration Office
## Administrative Fee Schedule

<table>
<thead>
<tr>
<th>Level of Support</th>
<th>Modality Services Included</th>
<th>Price</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1: Simple</td>
<td>Single Modality: X-Ray, DEXA, Ultrasound</td>
<td>$1,200</td>
<td>One-time fee billed at study startup</td>
</tr>
<tr>
<td>Tier 2: Moderate</td>
<td>Single Modality: CT, Nuclear Medicine, PET-CT</td>
<td>$1,800</td>
<td>Billed as needed during the lifecycle of the study</td>
</tr>
<tr>
<td>Tier 3: Complex</td>
<td>Single Modality: IR, MRI ALL MULTI-MODALITY STUDIES</td>
<td>$2,500</td>
<td>Billed as needed during the lifecycle of the study</td>
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</tbody>
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**Tier 3 includes the following:**
- Imaging Proposal Review by Medical Imaging Research Committee
- Completion of site surveys/questionnaires specific to each modality
- Site Initiation Visit
- Attendance in training, meetings and conferences (on-site, teleconferences, webinars) by research administrator
- Imaging Budget Development
- Study Specific Project Map Development
- Specific Research Order Development
- Review and confirmation of appropriate billing with Revenue Integrity
- Guidance with coordination and scheduling of services
- Imaging Query Resolution

### Amendment Fee

| All Tiers | $750.00 | Billed as needed during the lifecycle of the study |

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## Additional Support Services

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
<th>Price</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging Protocol Build</td>
<td>Creating custom acquisition, analyses or data-manipulation, protocol optimization that may be non-standard and time-intensive, and/or study-related analysis software or oversight of minor equipment installation.</td>
<td>$630 per scan</td>
<td></td>
</tr>
<tr>
<td>Technologist Training</td>
<td>Some industry studies require training of Medical Imaging personnel for study initiation. This can be completed by quiz, webinar, on-site training. Charges are based on modality and category of training.</td>
<td>$110 per hour</td>
<td></td>
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<tr>
<td>Research Analysis Report</td>
<td>Provides additional information regarding a research-related scan that is required for the research study or clinical trial but is not normally found in a standard radiologist report. This might include specialized interpretation requirements as well as consistent comparisons between baseline and follow-up scans.</td>
<td>$240 per hour</td>
<td></td>
</tr>
<tr>
<td>Phantom Scan</td>
<td>Some studies require phantom scans that must be performed for QA/QC purposes before a study is activated or continuously throughout the study cycle.</td>
<td>$390 per scan</td>
<td></td>
</tr>
<tr>
<td>Raw Data/QA/QC Collection</td>
<td>Some studies have additional requirements related to raw data/QA/QC copying. Estimates will be provided at study start up depending on study needs.</td>
<td>$110 per hour</td>
<td></td>
</tr>
</tbody>
</table>

**Additional Support Services**

**Additional Support Services will be billed as needed during the lifecycle of the study.**

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**Additional Support Services as detailed in your study budget issued with the Letter of Support Agreement.**
Standardized Study Intake Process

1. New study intake
2. Intake review
3. Rapid committee review
4. Approval & study budget
5. Feedback to outside department
6. Training & protocol setup
7. Start of study
8. Study progress & completion

**Intake, review & approval phase**

**Clinical study phase**

- Applicable to Industry-Sponsored studies only.
- Letter of Support will be issued 5-10 business days, after completion of study intake.
- For study intake to be considered complete, initial study intake survey must be submitted and additional queries must be addressed.

**Letter of support & detailed study budget for Radiology**

- Administrative fee - NU
- Imaging test (CPT codes) - NM
- Additional services - NU & NM
Research Imaging Collaboration Office

Jessica Anaya Agosto: jessica-anaya@northwestern.edu
Crystal Santillanes: crystal.santillanes1@northwestern.edu
Subcontracts vs. Subprojects
Subcontract, aka…

• Subaward
• Subk
• Subgrant
• Subsite

• Mechanisms:
  – External collaborator
  – Agreement executed with other entity
  – Paid via invoices on PO
Subproject, aka…

- Multiple chartstrings (projects)
  - Main/first chartstring is primary project
- Internal (to Northwestern) collaborator
- Set up for many reasons:
  - Multi-PI
  - Different departments
  - Different F&A rates
  - Supplements
  - Separate Components (projects and cores) on complicated award mechanisms (ex: NIH Ps)
Subcontracts: Requests, Subrecipient Monitoring, and Research Compliance
Subrecipient Monitoring

Sponsored Research relies on **subcontract requests** provided by the PI/department to include timely and accurate information.

- Subrecipient Monitoring: the process by which a pass-through entity (PTE) reviews subrecipient performance to ensure proper accountability and compliance with program requirements and achievement of project goals.

- As PTE for outgoing subcontracts on its sponsored awards, Northwestern is required to monitor subrecipients.

- Subrecipient monitoring needs are:
  - Determined during subrecipient risk assessment.
  - Communicated and outlined in the subcontract agreement, which includes appropriate required flow-down terms of award terms and conditions, required reporting and certifications, and additional terms or restrictions as needed.
Areas to Watch

• Progress and technical reporting

• Financial reporting, invoicing, and burn rate
  – ASRSP and department concurrence on sub site spending rate
  – Plan to accelerate the work
  – Consider authorizing No-Cost Extension

• Carry forward (carry over) considerations
  – Request sponsor approval when restricted
  – ASRSP and department concurrence with sub site unobligated balance
  – Redirect unobligated balances
Research Compliance

Required research compliance elements should be in place prior to routing subcontract requests and must be in place prior to subcontract issuance.
Research Compliance Specifics

• NUCOI: When prime sponsor is NSF or PHS agency, special attention must be given when engaging sub sites that will follow NUCOI policy

• IRB: when human subjects research contemplated at sub site,
  – Ensure sub site FWA is active
  – Be mindful of the exceptions list and special handling for the following: (DoD prime sponsoring agency, foreign sub site, reliance (IAA or sIRB)
  – Reliance agreement needs to be taken care of BEFORE subcontract is issued

• IACUC: Ensure NU’s ACUC has conducted review of animal subjects project contemplated at sub site and have secured NU acknowledgement and MOU
Join us for the next CLEAR Meeting on Tuesday, December 14, 10:00am