CLEAR Meeting
February 2022

Hosted by Sponsored Research
February 8, 2022
Today’s Agenda

• Announcements
• Research Imaging Collaboration Office (RICO) Updates
• Clinical Trial Agreement Best Practices
Sponsored Research Staffing

• **Award Management**
  – Awards Management Associate (#43207)*

• **Contracts & Negotiations**
  – Sr. Assoc. Director, Res. Contracts (#42408)
  – Contracts & Negotiations Manager (#43089)
  – Contracts Officer (#42847)*
  – Associate Contracts Officer (#43130)

• **Proposals & Award Acceptance**
  – Sponsored Research Officer (#43292)
  – Assistant Sponsored Res. Officer (#43468)
  – Sponsored Research Coordinator (#42403)

* Multiple positions available
<table>
<thead>
<tr>
<th>Due Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 5*</td>
<td>• R01 Research Grants</td>
</tr>
<tr>
<td>(Saturday)</td>
<td>• U01 Research Grants - Cooperative Agreements</td>
</tr>
<tr>
<td></td>
<td>renewal, resubmission, revision</td>
</tr>
<tr>
<td>March 12*</td>
<td>• K Series Research Career Development</td>
</tr>
<tr>
<td>(Saturday)</td>
<td>renewal, resubmission, revision</td>
</tr>
<tr>
<td>March 16</td>
<td>• Other Research Grants and Cooperative Agreements (R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3) renewal, resubmission, revision</td>
</tr>
<tr>
<td>April 8</td>
<td>• F Series Fellowships <em>Individual NRSAs</em></td>
</tr>
<tr>
<td></td>
<td>(including F31 Diversity) new, renewal, resubmission</td>
</tr>
<tr>
<td>April 12</td>
<td>• R13, U13 Conference Grants &amp; Cooperative Agreements</td>
</tr>
<tr>
<td></td>
<td>All - new, renewal, resubmission, revision</td>
</tr>
</tbody>
</table>

*Deadline pushed to next business day (Monday) in each case
SRA Transformation Program

- **SRA Transformation Program Updates**

- Key milestones upcoming
  - Onboarding wrapping up mid-March
  - First iteration: Award SmartForm/Award Modifications/Integration to NUFinancials
Training / Resource Updates

• Revised subcontractor commitment forms coming soon
• Updated “getting started” info for CTA’s based on today’s presentation
• Sponsored project “in-person”/virtual training sessions March 8, 9, 15, 16
  – More info and registration links on SR website
Outdated Process vs. RICO Process
Research Operations: Outdated Process vs. RICO Process

Outdated Process

1. **Northwestern IRB**
2. **RADIOLOGY DEPARTMENT**
   - CT
   - MRI
   - Nuclear medicine
   - Ultrasound
3. **Sponsored Research (SR)**
4. **Outside department**

RICO Process

1. **Research Imaging Collaboration Office**
2. **Radiology Clinical Trials Support Core**
   - CT
   - Nuclear medicine
   - MRI
   - Ultrasound
3. **Northwestern SR & IRB**
4. **Outside department**
Standardized Study Intake Process

1. New study intake
2. Intake review
3. Rapid committee review
4. Approval & study budget
5. Letter of support & detailed study budget for Radiology
6. Training & protocol setup
7. Start of study
8. Study progress & completion

Outside department

Intake, review & approval phase

- Applicable to Industry-Sponsored studies only.
- Letter of Support will be issued 10-15 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.

Clinical study phase
Research Imaging Collaboration Office

Roll-Out & Implementation

Northwestern Medicine
Feinberg School of Medicine
Department of Radiology
RICO Memo:
Issued
Nov 10th, 2021
Implemented
January 15th, 2022

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### Administration Fees

<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 3</td>
<td>Single Modality: MRI, PET, Ultrasound</td>
<td>$5,200</td>
<td>1 data set per clinical study</td>
</tr>
<tr>
<td>Tier 2</td>
<td>Single Modality: CT, Nuclear Medicine, PET-CT</td>
<td>$2,000</td>
<td>1 data set per clinical study</td>
</tr>
<tr>
<td>Tier 1</td>
<td>Multi-Modality: MRI, PET, Ultrasound, CT, Nuclear Medicine, PET-CT</td>
<td>$2,500</td>
<td>1 data set per clinical study</td>
</tr>
<tr>
<td>Amendment Fee</td>
<td>Multi-Modality: MRI, PET, Ultrasound, CT, Nuclear Medicine, PET-CT</td>
<td>$750.00</td>
<td>1 data set per clinical study</td>
</tr>
</tbody>
</table>

### Additional Support Services

<table>
<thead>
<tr>
<th>Activity</th>
<th>Price</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging Protocol Development</td>
<td>$500 per study</td>
<td></td>
</tr>
<tr>
<td>Technologist Training</td>
<td>$150 per hour</td>
<td></td>
</tr>
<tr>
<td>Research Assistant Support</td>
<td>$250 per hour</td>
<td>as needed during the lifetime of the study</td>
</tr>
<tr>
<td>Phantom Scan</td>
<td>$300 per scan</td>
<td></td>
</tr>
<tr>
<td>Raw Data/QL/OC Collection</td>
<td>$500 per set</td>
<td></td>
</tr>
</tbody>
</table>

All service fees will be updated annually to reflect varying hospital costs. All costs of care imaging will continue to be billed through the hospital through RICO billing codes.

More information about these changes, including access to the study intake form and a detailed fee schedule, are available on the Research Imaging Collaboration Office (RICO) website: [www.northwesternmedicine.com/researchimaging/collaborationoffice](http://www.northwesternmedicine.com/researchimaging/collaborationoffice)

Our team is excited to become part of your team.
# Fee Schedule: Administrative Fees

<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></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>
</tr>
<tr>
<td>Amendment Fee</td>
<td>major protocol or budget changes All Tiers</td>
<td>$750.00</td>
<td></td>
</tr>
</tbody>
</table>

All Tiers include the following:

- Imaging Proposal Review by Medical Imaging Research Committee
- Equipment software and hardware information provided upon request
- Site Initiation Visit attendance upon request
- Imaging Budget Development
- Specific Research Order Development
- Review and confirmation of appropriate billing with Revenue Integrity
- Guidance with coordination and scheduling of services
Fee Schedule: Additional Support Services

<table>
<thead>
<tr>
<th>Activity</th>
<th>Price</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging Protocol Build</td>
<td>$630 per study</td>
<td></td>
</tr>
<tr>
<td>Technologist Training</td>
<td>$110 per hour</td>
<td></td>
</tr>
<tr>
<td>Research Analysis Report</td>
<td>$240 per hour</td>
<td></td>
</tr>
<tr>
<td>Phantom Scan</td>
<td>$590 per scan</td>
<td></td>
</tr>
<tr>
<td>Raw Data/QA/QC Collection</td>
<td>$110 per hour</td>
<td>Additional support services will be billed as needed during the lifecycle of the study.</td>
</tr>
</tbody>
</table>
Do I have to use RICO services?
Do I have to use RICO Services?

- Industry-Sponsored
- Utilizing Radiology Services

RICO Intake

If your Contract, IRB, Budget, were approved prior to 1/15/2022 and you are just starting enrollment, RICO process still applies. Studies starting prior to implementation date are exempt from RICO fees.
Research Imaging Collaboration Office

RICO Process

Northwestern Medicine
Feinberg School of Medicine
Department of Radiology
During intake you will be asked standard questions regarding your study, detailed protocol information, and an upload of all available protocol documents.

*This is where the finance contact information can be entered*
RICO Process- Review

- Study Intake
- Radiologist Review
- Financial Review
- Letter of Support
RICO Process- Letter of Support, Budget and Logistics

Research Imaging Collaboration Office
Letter of Support Agreement

Principal Investigator:
School/Unit:
STU:
Protocol:
Version:

The Research Imaging Collaboration Office has reviewed your submission documents and approved the imaging portion of the study. The study has undergone RICO committee review of study imaging procedures, services, and cost to confirm all studies utilizing radiology clinical imaging resources are feasible and technically appropriate. A study budget is included with this letter of support (please reference attachment).

Administrative Fees:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Price</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start-up Fee: Tit #</td>
<td>$</td>
<td>One-time fee billed at study startup</td>
</tr>
<tr>
<td>Imaging Protocol Build</td>
<td>$650</td>
<td>Billed as needed during the lifecycle of the study</td>
</tr>
<tr>
<td>Technologist Training</td>
<td>$130</td>
<td>Billed as needed during the lifecycle of the study</td>
</tr>
<tr>
<td>Research Analytic Report</td>
<td>$240</td>
<td>Billed as needed during the lifecycle of the study</td>
</tr>
<tr>
<td>Phantom Scan</td>
<td>$590</td>
<td>Billed as needed during the lifecycle of the study</td>
</tr>
<tr>
<td>Raw Data QA/QC Collection</td>
<td>$110</td>
<td>Billed as needed during the lifecycle of the study</td>
</tr>
</tbody>
</table>

Amendment Fee: All Thus
(major protocol or budget changes) $750.00 Billed as needed during the lifecycle of the study

Study Specific NMBH CPT Codes (Research account is required with NMBH to bill the following to the study):

<table>
<thead>
<tr>
<th>Description</th>
<th>CPT Code</th>
<th>Price</th>
</tr>
</thead>
</table>

*Please be aware pricing is based on fees associated with current fiscal year. We recommend budgeting for annual inflation for multi-year studies as prices are subject to change.

Once assigned, please forward your NU chart string number to RICO@northwestern.edu. Grants must have account codes 78765 AND 75000 open on the NU chart string.

If there are requested changes to the protocol after this letter of support has been issued, the study team will be responsible for resubmitting the study to the Research Imaging Collaboration Office for approval. The study team is responsible for sending any protocol updates, imaging manual updates, as well as inactivation documents to RICO. Please submit these documents to RICO@northwestern.edu.

We look forward to working with you on this research project.

Kind Regards,

Jessica A. Agosto
Sr. Research Administrator
Department of Radiology
Research Imaging Collaboration Office

RICO Committee Members

Jessica A. Agosto
Senior Research Administrator, Department of Radiology

Bradley Allen, MD, MS
Chief of Cardiovascular and Thoracic Imaging, Department of Radiology

Amir A. Borhani, MD
Associate Professor of Radiology (Body Imaging) and Surgery (Organ Transplantation)

Sarah Fopma
CT Technical Coordinator, Northwestern Medicine

Michael Markl, PhD
Vice Chair for Research, Department of Radiology

Crystal K. Santillanes, MS, CCRC
Research Operations Manager, Department of Radiology

Northwestern Medicine
Feinberg School of Medicine

Department of Radiology
Research Imaging Collaboration Office

Q&A.

For more information please visit our

RICO Web page:
https://www.radiology.northwestern.edu/research/research-imaging-collaboration-office-rico/index.html
Clinical Trial Agreements
Best Practices
What is a CTA?

CTA = Clinical Trial Agreement

• Binding contract

• Usually between university/academic medical center (AMC) and corporation

• Establishes:
  o Payment terms
  o Agreed-upon regulatory framework
  o Liability allocation
  o Responsibilities
  o What happen before, during, and after the trial
Negotiation Overview

• Some back-and-forth with sponsors is common. **Why?**
  - Different interests between the university and the industry sponsor
    - **University:** education of students and dissemination of knowledge for public good
    - **Industry:** shareholders, profitability, getting new products to market

• Negotiation by SR ensures agreement terms don’t expose Northwestern to unnecessary or unreasonable risks/demands
  - May involve Contract Research Organization (CRO)
  - Back and forth on terms involves email and phone calls
    - Sign-offs needed?
    - Regulatory Compliance
    - Patent Attorney
    - Conflict of Interest
    - Risk Management
CTA: Walk-Through

A Few Key Sections:

- Publication
- Indemnification, Liability, and Insurance
- Subject Injury
- Inventions/Intellectual Property
Publication

Why is this in the CTA?

- Most university and Academic Medical Centers (AMCs) require this
- Non-profit institutions: mission to disseminate information and educate (societal benefit → tax exempt status)

What it does:

- Outlines what can be published and when
- Allow for reasonable delay for review/comment—but never approval—and for patent applications
Indemnification, Liability, and Insurance

Why is this in the CTA?

• Both parties want to minimize risk and it is useful to appreciate what risks you are taking on when conducting or sponsoring a study

What it does:

• One party agrees to protect another against an anticipated loss or damage arising out of the trial

Sponsor-initiated studies: Sponsor should indemnify Northwestern against and insure for any loss or damage incurred as a result of conducting the study

  o Sponsor’s use of the study/date results
  o Third-party claims
  o Sponsor’s negligence or misconduct

Investigator-initiated studies: Each party normally indemnifies the other against any loss or damage the results from the indemnifying party’s negligence or misconduct.
Indemnification, Liability, and Insurance

- Northwestern has insurance requirements in all sponsor-initiated clinical trials
  - In the event a sponsor is unable to meet these requirements, the study may undergo a clinical/financial risk assessment
  - Party who stands to gain most financially should bear most risk, taking into account other considerations, such as for-profit status and so on

- **Both parties want to**: minimize costs and avoid risks
Subject Injury

Why is this in the CTA?
• Subject injury protection is important to Northwestern and study subject in clinical trials

What it does/how it works:
• Near-term mechanism for reimbursement of treatment costs related to illness or injuries
• CTA and Informed Consent language should be consistent, not the same
• Northwestern cannot accept language that requires it to bill a study subject’s insurance
• This is another “cost of doing business” related to sponsor-initiated clinical trials
Inventions/Intellectual Property

Why is this in the CTA?

• Each party wants to protect their intellectual property

What it does:

• Apportions rights to inventions that might arise out of the study
• Allows parties to protect their respective investments

Note: sponsor-initiated or investigator-initiated?
## Inventions/Intellectual Property

### Sponsor-Initiated

- Company typically has pre-existing IP rights, including patents on the study compound or device.
- Northwestern prefers to retain ownership of new uses for the compound/device not anticipated by Protocol (unlikely).

However, typically gives sponsor a time-limited option for an exclusive license with royalty rate.

### Investigator-Initiated

- Northwestern IP is embedded in the Investigator-written protocol.

But, use of Company funder’s proprietary product may diminish invention rights of Northwestern.
Negotiation Summary

Negotiation takes time

• Completeness of submission to SR
• Negotiating terms of agreements
• External review when required
• Budget approval

Outcomes

• Contract fully negotiated
• Budget negotiated & approved
• COI clearance & IRB approval
• Study startup/research project begins
• Ultimately, dissemination of knowledge
CTA Submission Process

Routing CTA from Department to Sponsored Research

- Submit CTA via InfoED
- Route CTA to the status: “Under OSR Clinical Trial Admin Review”
Creating the Record in PD

- Complete the Proposal Routing Form (PRF) in InfoED
  - All fields in the PRF must be completed
  - One important section that is often omitted: Sponsor’s Contact Information
    - The Sponsor or CRO contact name and email address are required for the negotiator to send an edited draft of the agreement
  - Project Title and Protocol Title must match
  - IRB/IACUC information must be included if the study involves either humans or animals
MS Word editable versions of supporting document must be included as **Attachments** in InfoEd

- ✓ Letter of Indemnification (LOI) if required
- ✓ Protocol (draft acceptable)
- ✓ Informed Consent Form (ICF) (draft acceptable)
- ✓ Budget (draft acceptable), and
- ✓ Any other supporting documentation
Routing the PD Record

- Route the PD record to receive all required department approvals

- Verify “Pre-Route Complete” record status

- Update record status to: “Under OSR Clinical Trial Admin Review”
Pre-Spend Accounts for Industry Funded Clinical Trial Agreements

- SR is standardizing the process for requesting pre-spend accounts

- Submit a Change Request in InfoEd if a pre-spend account is needed
  - *Time saver!* Requests related to industry clinical trials automatically route in InfoEd to the relevant staff; departments will not need to email outside the system for these requests
Questions?
Join us for the next CLEAR Meeting:

Tuesday, April 12, 10:00am