ORIENTATION FOR NEW CLINICAL RESEARCH COORDINATORS

Presented by

NC TraCS Institute
UNC Office of Clinical Trials
UNC Network of Clinical Research Professionals
Overall Agenda for Orientation

• **Module 1:**
  Introduction to Clinical Research, Education, and IRB

• **Module 2:**
  Informed Consent, Documentation and GCP, and Essential Documents

• **Module 3:**
  Contracting, Billing Coverage Analysis, ClinicalTrials.gov, Budgets and Accounting, Study Start-up

• **Module 4:**
  COI, Privacy/HIPAA, Recruitment, and IDS / Device Policy

• **Module 5:**
  NIH Public Access Policy, From CDA to Study Close Out
NIH COMPLIANCE POLICIES & YOU

Mary White, MS, MSHI, AHIP, EMT-B
TraCS Knowledge Management Librarian
NC TraCS & Health Sciences Library
mw@unc.edu
Your Funding? NIH Funded?
Research Funding @ UNC: Federal!

- Educational and Research Institutions: 7.01%
- Business and Industry: 5.94%
- Foundation: 5.93%
- State Government (NC): 3.87%
- Nonprofit Organization: 3.22%
- Association: 1.44%
- Others: 0.75%
- Federal: 71.85%
3 Take Home Points!


2. As a Clinical Research Professional, You Can Help!

3. Wait, what? Contact the UNC Health Sciences Library & NC TraCS!
NIH Biosketch: What & Why?

• Why is it important:
  • Biosketches are included in NIH & AHRQ research grant, pre & postdoctoral fellowship applications…$$$$!

• Why now?
  • New Policy! Effective 5/25/2015!

• Goal:
  • Explain “contributions to science”, allow for alternative references, full bibliography, automated CV

• How:
  • MyNCBI (MyBibliography) & SciENcv

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<td>Up to 24 selected refs</td>
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BIORAPHERICAL SKETCH

Provide the following information for the Senior/Key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:

DECEMBER COMMON USER NAME (credentialed, e.g., agency name):

POSITION/TITLE:

EDUCATION/TRAINING (Begin with bachelor’s or other initial professional education, such as nursing; include postdoctoral training and residency training if applicable. Add alterative text as necessary):

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<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
<th>COMPLETION DATE</th>
<th>FIELD OF STUDY</th>
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NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem, the central finding(s), the influence of the finding(s) on the progress of science or the application of these finding(s) to health or technology, and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products, patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or networks) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciEcnv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly [...]
The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

Division G, Title II, Section 218 of PL 110-161
Implemented by NIH Public Access Policy (11 Jan 2008)
Enacted as law by Omnibus Appropriations Act of 2009
NIH Public Access Policy Basics

• **Who: it affects**
  - NIH funding (investigators, grants, contracts, etc)
  - FY 2008 or later

• **What: it covers**
  - Peer-reviewed journal articles
  - Accepted for publication on or after April 7\textsuperscript{th}, 2008
NIH Public Access Policy Basics

• **When: to submit**
  - Submit upon acceptance for publication
  - Publically available within 12 months of publication
  - Retroactive submission if not in compliance

• **Where: to submit**
  - PubMed Central (PMC) via My NCBI
  - PubMed Central ≠ PubMed

• **Why: do this?**
  - ‘Advance science and improve human health’
  - Access for public and researchers
  - Consequences for non-compliance
Why: Changes in Policy Compliance

• As of July 1, 2013:
  – NIH will delay processing of an award if publications arising from it are not in compliance with the NIH public access policy.
How: to Comply

1. Preparing a manuscript
   - Address copyright
   - show me

2. Accepted for publication
   - Post it to PubMed Central and track it in My NCBI
   - show me

3. Reporting to NIH
   - Include PMCID in citations
   - show me
How: to Comply

1. Preparing a Manuscript: Copyright?
   – Make sure copyright agreement allows you to submit manuscript to PubMed Central

2. Accepted for Publication: Submit Paper
   – Find out what submission method to use
     • 4 methods, journal may do some or all of the work

3. Reporting to NIH: Cite PMCID(s)
   – In all progress reports, grant renewals, new grant applications, etc.
     • PMCID is used to show compliance
How: Can YOU Be Involved?  
Be a Delegate!

1. Preparing a Manuscript: Copyright?

2. Accepted for Publication: Submit Paper
   - Find out what submission method to use
     - 4 methods (A, B, C, D)
     - Journal may do some or all of the work
   - Method C: Author/Investigator/ Delegate may start the process
   - In all methods: Author/Investigator must approve submission and PMC-formatted manuscript (final steps)

3. Reporting to NIH: Cite PMCID}s
How: to manage compliance for Biosketch & Public Access Policies

– As of July 1, 2013: Investigators must use My NCBI to enter publications into progress reports for the Public Access Compliance.
How: to manage compliance for Biosketch & Public Access Policies

– What is My NCBI?

• My NCBI is a personalized account that allows you to manage your publications and track compliance
• eRA Commons to be linked to author/investigator’s My NCBI account
• Author/investigator adds you as a delegate in My NCBI
Managing Compliance: Delegates

• What is a delegate?
  • Person granted access to My Bibliography in My NCBI

• What can a delegate do?
  • Modify My Bibliography
  • Monitor compliance
  • Connect publications to grants/awards
  • Submit article via NIHMS with MyNCBI login info (Method C, task 1)
Where To Get Help

• Health Sciences Library guides:
  – The NIH Public Access Policy and You (http://guides.lib.unc.edu/compliance)
  – NIH Biosketch (http://guides.lib.unc.edu/nihbiosketch)

• Ask-a-Librarian
  – http://asklib.hsl.unc.edu/

• Classes! at HSL & NC TraCS

• Individual / Group Consults
3 Take Home Points!


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FROM CDA TO STUDY CLOSURE

Christine Nelson, Director, Office of Clinical Trials
Val Buchholz, Office of Clinical Trials
Objectives

• Review the steps for successful clinical trial implementation beginning with first sponsor contact through study closure
So it begins…

1. **Sponsor Sends Site Information Questionnaire/Protocol Synopsis**
   - Site Provides Sponsor with Information
   - Sponsor Accepts Site
   - Confidentiality Disclosure Agreement (CDA) Sent to Site
   - CDA Submitted to Office of Clinical Trials (OCT) via CRMS (Clinical Trials Management System)
   - OCT negotiates terms and executes CDA with sponsor

2. **Feasibility Assessment**
   - Sponsor Sends Protocol; Budget; Clinical Trial Agreement (CTA); and draft ICF

3. **IRB Submission**
   - Review Protocol for Uncommon procedures or requirements
   - Complete Billing Coverage Analysis in CRMS
   - IDS Submission CTRC Application Hospital Services
   - Negotiate Final Budget With Sponsor
   - Complete CTA Submission via CTRMS
   - CTA/Budget/ICF Finalized

4. **Local IRB or Central**
   - Receipt of IRB Approval Documents including ICF

5. **Conflict of Interest eForms Completed**

6. **Receipt of IRB Approval Documents including ICF**
Site Survey

• Site information form
• Site Qualification form
• Site Feasibility form
• Sponsors and CROs track turn around times
CDA

- CDA must be submitted via CRMS
- Cannot be signed by PI
- Quick turn around
- Not every CDA results in receiving a protocol
- Sponsors and CROs track turn around times
Confidentiality Disclosure Agreement (CDA) Submitted to Office of Clinical Trials (OCT) via CRMS (Clinical Trials Management System). OCT negotiates terms and executes CDA with sponsor.

Sponsor Sends Site Information Questionnaire/Protocol Synopsis

Site Provides Sponsor with Information

Sponsor Accepts Site

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IRB Submission

Review Protocol for Uncommon procedures or requirements

Complete Billing Coverage Analysis in CRMS

IDS Submission CTRC Application Hospital Services

Negotiate Final Budget With Sponsor

Complete CTA Submission via CTRMS

CTA/Budget/ICF Finalized

Conflict of Interest eForms Completed

Local IRB or Central

Receipt of IRB Approval Documents including ICF

Receipt of IRB Approval Documents including ICF
CRMS

• Protocol – final or draft?
  • May just send protocol until you are selected as a site
  • May send someone out to do site qualification visit
• Draft ICF
• Draft CTA
• Draft Budget
• Investigator brochure
• Pharmacy manual
• Lab manual
Feasibility

- Conduct a preliminary feasibility assessment
  - Read the draft ICF
  - Read the protocol
    - Potential enrollment
    - Study schedule (practical, reasonable)
    - Study duration
    - Non-routine care items
    - Imaging
    - Pharmacy
    - Lab/specimens
  - Resources (study coordinator, data manager, 24/7)
  - Adequate staffing
  - Training requirements
  - Special vendor requirements
Budget

- Billing Coverage Analysis
  - Spreadsheet from CRMS
  - Deemed and Qualified
  - Epic Billing calendar
- Funding source (federal or industry)
- Consistent approach
- Ensure start up fees are sufficient and invoiced
- Standardized fees
- Screen fails
- Monitoring visits
- Monthly invoicing
- IDS
- CTRC
CTA

- Submit CTA to OCT via CRMS
  - Complete review request form (RRF)
- Contract manager assigned
- Only the assigned contract manager negotiates the CTA
- Open communication with your contract manager
- The CTA can be negotiated while you negotiate your budget
- Once budget has been finalized with sponsor we can execute the CTA
IRB

- Submit when you are sure the PI wants to participate
- UNC local IRB or Central IRB
- ICF and contract must be consistent in respect to subject injury, stipends and what has been promised for free to the subjects
- CTA/ICF checked for Consistency
  - CTA Executed
    - Billing Calendar Built in Epic
      - CTA Executed
        - eIPF completed in Ramses
          - Conflict of Interest eForm completed
            - Account Number Assigned
              - Study Information is pushed to EPIC via CRMS
                - Site Initiation Visit
                  - Prepare for/Enroll Subjects
                    - Enrollment Complete
                      - Study Closure
CTA and IRB

- IRB Approval
- ICF and CTA must be consistent
- OCT will check
- If inconsistent the ICF will need to be revised
Ramses

- eIPF
- Internal budget
- Need an account
  - Set up by OCT
- COI
  - Individual
  - Institutional
Study Start Up

- When can I enroll! Its been months and I am already tired…
Study Start Up

• More to do!
  • SIV
  • Study supplies
  • CRMS
  • Epic
  • IDS
  • Subject binders
  • Source documents
  • Logs
  • Study visit checklist
Study Conduct

- Enroll your first subject
  - Inclusion/exclusion criteria
  - ICF
    - Documentation of the informed consent process
  - Complete screening
- Randomize
- IVRS
- CRMS
- Epic
- HIPAA form - HIM
Ongoing conduct of study

- Study visit checklists
- Case report forms
- Epic Billing review
- Investigational product accountability
- SAE/AE reporting
- Monitor Access
- Annual IRB renewal
- Amendments
- Modifications
- Deviations
Audits – FDA or Sponsor

• Who do you call?

• Hint – it’s not Ghost Busters!
Close-out

- All study subjects complete
- Data lock
- IRB closure
- Pack up the records
- Pat yourself on the back
Questions
Upcoming Training:

Friday, Feb 13, 2015
IRB Tips and Updates

Please contact @ if you have any questions or recommendations