Orientation for New Clinical Research PERSONNEL

Module 4

Presented by

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

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

• **Module 2:**
  Informed Consent, Documentation, GCP and Study start-up

• **Module 3:**
  Contracting, Billing Coverage Analysis, ClinicalTrials.gov, Budgets and Accounting, Essential Documents

• **Module 4:**
  COI, Preparing NIH Grant Budgets, and IDS / Device Policy, Epic & HIPAA Training

• **Module 5:**
  Recruitment, From CDA to Close Out
CONFLICT OF INTEREST

Joy Bryde, MSW
Conflict of Interest Officer
Conflict of Interest Program
jbryde@unc.edu
Who is Covered by the Policy on Individual Conflicts of Interest (COI) and Commitment?

Eight sections for Conflict of Interest, including Research
What is a COI?

Conflict of interest is a situation in which financial or other personal considerations:

- may compromise,
- may involve the potential for compromising, or
- may have the appearance of compromising

an employee’s (covered individual’s) objectivity in meeting University duties or responsibilities, including research activities.

UNC Board of Governors Policy Manual
Visualizing COI at UNC

- Actual Conflict of Interest
- Potential Conflict of Interest
- Appearance of a Conflict of Interest
What is a COI?
(continued)

The bias that such conflicts may impart can affect many University duties, including:
• decisions about personnel,
• the purchase of equipment and other supplies,
• the collection, analysis and interpretation of data,
• the sharing of research results,
• the choice of research protocols,
• the use of statistical methods,
• and the mentoring and judgment of student work.
Why the Conflict of Interest (COI) Process?

Comply with:
- UNC Board of Governors’ Policies and Regulations
- North Carolina State Statutes and Regulations
- Federal requirements (funding, human subjects)
- DHHS 42 CFR Part 50, 45 CFR Part 94  effective 08/24/ 2012
- NSF Grant and Administrative Guidelines January 2013

Mantra:
Disclose and Manage
Terms to know

- **COI**: Conflict of Interest

- **FCOI**: Financial Conflict of Interest means a Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

- **Disclosure**: to submit to the University the details of any interests, financial or personal, that might be a potential conflict of interest

- **Disclosure**: to share details of a conflict of interest with subjects, a research team or in presentations or publications as necessary
COI Snapshot

- FCOIs
- COIs
- COI Disclosure
- COI Training
How Does the Research COI Process Work?

- COI Training  coi-training.unc.edu
- Event-based Disclosure
  - Sponsored Research
  - IRB Protocols
- Evaluation and Review
- Management
- Report to Sponsor
- Update Disclosure Annually or on Change of Circumstances
Research COI Disclosures

IRB (IRBIS)
- Principal Investigator
- Co-investigator
- Faculty Advisor
- Project Manager or Study Coordinator

OSR (RAMSeS)
- Lead Principal Investigator
- Principal Investigator
- Investigator
- Postdoctoral Research Associate
- Clinical Research Coordinator
- Other Key Participant (UNC Faculty)
- Independent Consultant Investigator

Not trigger COI disclosures:
- Fellow, Graduate Research Assistant, Other Key Participant, Project Manager, Technical Staff, Undergraduate Student, Administrative Contact, Administrative Assistant

Not trigger COI disclosures:
- Research Assistant, Regulatory Associate, Other (Read Only Access)
Why is a Disclosure Required for Each Study and Reviewed for a “Known” Conflict?

- Federal regulation
- University Policy
- Each study is different even if the “conflict” appears to be the same
  - Different drugs
  - Different protocol
  - Different people
    - For human subjects research, informed consent text must be context specific
What Happens Next?

No conflicts indicated
• System filters every 10 minutes
• IRBIS/Ramses automatically updated

Potential conflicts indicated
• Initial Evaluation at COI Office, usually further information is needed
• Next Step
  • Expedited Review with Committee Chair(s) (Existing Management plans or <$10K) OR
  • Full Committee (New conflict, >10K)

NOTE: Five Standing COI Committees – Medicine, Public Health, Dentistry, Pharmacy and College of Arts & Sciences. Some committees meet 1x per month; others every 2-3 months.
What are Financial Interests?

**Tangible**
- Personal Income - real or potential value
- Equity/Stock/Options (mutual funds excluded)
- Royalties/licensing fees/copyrights
- Indirect – family member
- Gifts (for self or others)
What are Non-Financial Interests?

- Board membership
- Executive position
- Scientific or technical advisor
- Trustee
- Volunteer position
  - (such as fundraising)
Management Principles

**Principles**
- Transparency
- Honoring the Student/Trainee Experience
- Protection of the credibility of the individual doing the work
Management Tools

**Tools**

- Management Plans
  - Public Disclosure
  - Independent Review of Data
  - Change in Roles
  - Monitoring Committees
- Alternative Options for Trainees
- Alternative Administrative Routing

**NOTE:** Significant financial interests presumed not allowable in human subjects research, particularly for a principal investigator.
Federal Anti-Kickback Statute

**Purpose:** To protect patients and federal health care programs from fraud and abuse

**Summary:** Prohibits the solicitation, receipt, offer or payment of remuneration “in return for” or “to induce” the referral of program related business, arranging for, or recommending, the purchase, lease, or ordering of any item or service reimbursed by a federal healthcare program

**Penalties**
- Civil: Fines up to $50,000; Exclusion from federal health care programs
- Criminal: Felony; Up to five years in prison; Fines up to $25,000
Anti-Kickback: Clinical Trial Risks & Solutions

**Risks**
- Direct payments to investigators
- Incentives for investigators (exotic meeting locations)
- Unbudgeted payments
- Financial COI
- Study biases (site selection, prescribing)
- Excess funds
- Study merit

**Potential Solutions**
- Institutional financial management
- Institutional contracting
- Published and enforced COI policies
- IRB and training
- Published Policy on Excess Fund Disposition
- Internal review and approval
UNC-CH CONFLICT OF INTEREST POLICY IS STRICTER THAN FDA

- Stricter definition of significant financial interest
- Project-by-project disclosure of financial and other conflicts of interest
- Any changes to financial and other interests must be reported within 30 days.
- University rules regarding compensation from Sponsors
UNC Policy regarding Compensation from Sponsors

- University employees may not accept gifts, payments, or in-kind support (including but not limited to financial payments, gift certificates, books, conference attendance and payment of travel expenses)
  - as inducements for performance in a University project
  - except as expressly included in budgeted project costs in a contract between the University and the project sponsor.
FDA Investigator Financial Disclosure

• This disclosure requires that the Principal Investigator certifies that s/he does not have a significant financial holding in the company with which he wishes to contract.

• This helps to avoid conflict of interest situations in which the Investigator’s data may be called into question because of financial interest in the company.
Contact Information

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General Email for questions: coi@unc.edu
Websites: air.unc.edu coi-training.unc.edu
PREPARING & EXECUTING NIH GRANT BUDGETS FOR CLINICAL RESEARCH STUDIES

Cassandra J. Barnhart, MPH
Manager of Research Administration
UNC Ophthalmology
Objectives

• Learn the differences in budget preparation between NIH vs. Industry sponsored trials
• Identifying resources and tools to assist in preparing your budget
• Identifying reasonable / hidden costs to your department (the NIH won’t pay for WHAT?!)
Federal vs. Industry: What’s the Difference?

Industry
- Primary goal is FDA approval to market a new drug or device (or a new indication)
- More common disease indications (for example, Type II diabetes)

Federal
- Primary goal is to answer “best practice” medical questions (comparing current therapies). Ratio benefits / risks
- More likely to conduct research on less common indications (for example, Type I diabetes)
# Federal vs. Industry: What’s the Difference?

## Overhead

<table>
<thead>
<tr>
<th>Activity</th>
<th>On-Campus</th>
<th>Off-Campus* (Adjacent) (10-mile radius)</th>
<th>Off-Campus* (Remote)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organized Research</td>
<td>52.00%</td>
<td>28.00%</td>
<td>26.00%</td>
</tr>
<tr>
<td>Instruction</td>
<td>50.00%</td>
<td>28.00%</td>
<td>26.00%</td>
</tr>
<tr>
<td>Other Sponsored Activities</td>
<td>36.00%</td>
<td>28.00%</td>
<td>26.00%</td>
</tr>
<tr>
<td>Clinical Trials (Federal)*</td>
<td>52.00%</td>
<td>28.00%</td>
<td>26.00%</td>
</tr>
<tr>
<td>Clinical Trials (Non-Federal)**</td>
<td>28.00%</td>
<td>28.00%</td>
<td>26.00%</td>
</tr>
</tbody>
</table>
## Federal vs. Industry: Salaries

<table>
<thead>
<tr>
<th>Industry Sponsors</th>
<th>Federal Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No salary cap</td>
<td>• NIH salary cap of $185,100 (effective 1/1/16)</td>
</tr>
<tr>
<td>• Generally no direct salary support (paid on a per-visit basis)</td>
<td>• FTE for research staff allowed (within reason)</td>
</tr>
<tr>
<td>• Estimated hourly wage</td>
<td>• Estimated “Calendar Months (CM)”</td>
</tr>
</tbody>
</table>
Getting Started: Where to Begin?

• Funding Opportunity Announcement (FOA) on Grants.gov.
  • Search for grant opportunities
    • Newest
    • Category
    • Agency
    • Eligibility

• Learn Grants (Grants 101) – recommended if you’re new to grants

• Download application packet (or use Cayuse)
Getting Started: Where to Begin?

- **Cayuse 424**
  - UNC’s grants processing system
  - Able to create a new proposal with FOA number found on Grants.gov
  - Automatically loads required forms (less headache)
Getting Started: Where to Begin?

- Two types of NIH budgets

  - Modular
    - $25,000 increments (up to $250,000/year in direct costs)
    - No detailed budget required* (only Personnel Justification)
      *OSR still requires a detailed budget

  - Non-Modular
    - Typically available up to $500,000/year without prior approval (dependent on award mechanism)
    - Detailed budget required for each year requested
Getting Started – Items to Consider

• Salary & Fringe
  • Principal Investigator
    • Current salary cap is $185,100 (Per NIH - ask for full amount, but know that this is the max that will get funded – usually updated annually)
    • If clinical faculty, must use Supplemental Rate (27.962% plus medical insurance stipend of $7,703.92)
    • If basic researcher, use general rate of 22.883% plus medical insurance stipend of $5,659 (ask HR if unsure)
  • Coordinator
    • Fringe benefit rate is 22.883% plus medical insurance stipend of $5,659
  • Grad Student Research Assistant
    • Fringe benefit rate is 8.99% plus medical insurance stipend of $3,399
    • Tuition must also be covered, prorated to effort
    • Okay to increase by 3-5% annually

Updated fringe benefit rates can be found at: http://research.unc.edu/offices/sponsored-research/resources/data_res_osr_infosheet/
NIH Cost Principles
(NIH Grants Policy Section 7.2)

- Is it Reasonable and Necessary?
  - A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made.

- Is it Allocable?
  - A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant.
NIH Cost Principles
(NIH Grants Policy Section 7.2)

• Is it Consistent?
  • Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
Examples of Allowable Direct Costs
(NIH Grants Policy Section 7.9)

- Advertising and PR
  - Recruitment, program outreach
- Animals
  - Cost to purchase and maintain
- Child Care Costs
  - For research participants
- Consortium (Subcontract) Agreements
  - If subcontracting with another site to conduct study
- Study Drugs
  - Purchase costs
- Equipment
  - Specifically purchased for the study ($5,000 or more)
Examples of Allowable Direct Costs (NIH Grants Policy Section 7.9)

• Incentives
  • Research participant stipends

• Materials and Supplies
  • Specific to conduct of the study
  • May include computers

• Meals
  • For research participants (e.g. CTRC studies)
  • Okay if not already included in stipend

• Professional Services (Consultants)
  • Example is a Biostatistician not on salary at UNC
  • Flat rate, no fringe benefits

• Publication and Printing
  • Journal submissions of study results, etc.
Examples of Allowable Direct Costs
(NIH Grants Policy Section 7.9)

- Research Patient Care
  - Anything with a CPT code
  - Not to exceed Medicare Allowable (NOT the research fee)
  - Labs
  - Exams

- Travel
  - Meetings specific to study or presentation of results at research conference
  - Includes transportation, lodging, and per diem amounts
NIH Internal Budget Forms
(Initial Period)

RESEARCH & RELATED BUDGET - Budget Period 1

<table>
<thead>
<tr>
<th>ORGANIZATIONAL DUNS:</th>
<th>Enter name of Organization:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget Type:</td>
<td></td>
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<tr>
<td></td>
<td>Project</td>
</tr>
<tr>
<td>Budget Period:</td>
<td>1</td>
</tr>
</tbody>
</table>

A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First</th>
<th>Middle</th>
<th>Last</th>
<th>Suffix</th>
<th>Base Salary ($)</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</td>
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</tr>
<tr>
<td>Project Role:</td>
<td>PD/F1</td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

Additional Senior Key Persons: 

Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</td>
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<tr>
<td></td>
<td>Post Doctoral Associates</td>
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<tr>
<td></td>
<td>Graduate Students</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
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</tr>
</tbody>
</table>

| Total Number Other Personnel |
|                              |

Total Salary, Wages and Fringe Benefits (A+B)
### NIH Internal Budget Forms (Initial Period)

**C. Equipment Description**

List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
</table>

Additional Equipment:

- [Add Attachment]
- [Delete Attachment]
- [View Attachment]

Total funds requested for all equipment listed in the attached file

<table>
<thead>
<tr>
<th>Total Equipment</th>
</tr>
</thead>
</table>

**D. Travel**

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)
2. Foreign Travel Costs

Total Travel Cost

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
</table>

**E. Participant/Trainee Support Costs**

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other

Number of Participants/Trainees

<table>
<thead>
<tr>
<th>Total Participant/Trainee Support Costs</th>
</tr>
</thead>
</table>

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*Note: The image contains a table with fields for budget items and amounts, as well as buttons for adding, deleting, and viewing attachments.*
### NIH Internal Budget Forms (Initial Period)

#### F. Other Direct Costs

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Total Other Direct Costs

#### G. Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
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<td></td>
</tr>
</tbody>
</table>

Total Direct Costs (A thru F)

#### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Indirect Costs

#### I. Total Direct and Indirect Costs

Total Direct and Indirect Institutional Costs (G + H)

#### J. Fee

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### K. Budget Justification

(Only attach one file.)

[Add Attachment] [Delete Attachment] [View Attachment]
NIH Internal Budget Forms  (Initial Period)

RESEARCH & RELATED BUDGET - Cumulative Budget

<table>
<thead>
<tr>
<th>Section</th>
<th>Totals ($)</th>
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<tbody>
<tr>
<td>Section A, Senior/Key Person</td>
<td></td>
</tr>
<tr>
<td>Section B, Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
<td></td>
</tr>
<tr>
<td>Section C, Equipment</td>
<td></td>
</tr>
<tr>
<td>Section D, Travel</td>
<td></td>
</tr>
<tr>
<td>1. Domestic</td>
<td></td>
</tr>
<tr>
<td>2. Foreign</td>
<td></td>
</tr>
<tr>
<td>Section E, Participant/Trainee Support Costs</td>
<td></td>
</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
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</tr>
<tr>
<td>2. Stipends</td>
<td></td>
</tr>
<tr>
<td>3. Travel</td>
<td></td>
</tr>
<tr>
<td>4. Subsistence</td>
<td></td>
</tr>
<tr>
<td>5. Other</td>
<td></td>
</tr>
<tr>
<td>6. Number of Participants/Trainees</td>
<td></td>
</tr>
<tr>
<td>Section F, Other Direct Costs</td>
<td></td>
</tr>
<tr>
<td>1. Materials and Supplies</td>
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</tr>
<tr>
<td>2. Publication Costs</td>
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<td>3. Consultant Services</td>
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<td>4. ADP/Computer Services</td>
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<td>5. Subawards/Consortium/Contractual Costs</td>
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<td>6. Equipment or Facility Rental/User Fees</td>
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<tr>
<td>7. Alterations and Renovations</td>
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</tr>
<tr>
<td>8. Other 1</td>
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<td>9. Other 2</td>
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<tr>
<td>10. Other 3</td>
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<tr>
<td>Section G, Direct Costs (A thru F)</td>
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</tr>
<tr>
<td>Section H, Indirect Costs</td>
<td></td>
</tr>
<tr>
<td>Section I, Total Direct and Indirect Costs (G + H)</td>
<td></td>
</tr>
<tr>
<td>Section J, Fee</td>
<td></td>
</tr>
</tbody>
</table>
Indirect Costs

• Current Rate is 52% (unless otherwise indicated in grant announcement) of **most** allowable direct costs

• **Includes**: salary & fringe, materials & supplies, consultant fees, travel, publication costs, patient stipends, consortium costs up to $25,000 per entity

• **Does NOT include**: equipment, patient care costs, tuition, each consortium cost IN EXCESS OF $25,000 (total proposed period)
  • If any of these apply, specify Modified Total Direct Costs on grant application
### Example NIH Internal Budget

#### Grant Budget Worksheet Example

<table>
<thead>
<tr>
<th>PI non-MD</th>
<th>1st yr full salary</th>
<th>% fringe</th>
<th>% increase/yr</th>
<th>medical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>90,000</td>
<td>0.2288</td>
<td>5,659</td>
</tr>
<tr>
<td>2nd yr full salary</td>
<td>95,400</td>
<td></td>
<td></td>
<td>5,829</td>
</tr>
<tr>
<td>3rd yr full salary</td>
<td>98,262</td>
<td></td>
<td></td>
<td>6,004</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Y1 % salary</th>
<th>Y2 % salary</th>
<th>Y3 % salary</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.800</td>
<td>0.800</td>
<td>0.800</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>initial budget</th>
<th>2nd yr</th>
<th>3rd yr</th>
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</thead>
<tbody>
<tr>
<td>salary</td>
<td>72,000.00</td>
<td>76,320.00</td>
</tr>
<tr>
<td>fringe+medical</td>
<td>21,002.96</td>
<td>22,127.32</td>
</tr>
<tr>
<td>Total</td>
<td>93,003</td>
<td>98,447</td>
</tr>
</tbody>
</table>

#### PI MD

<table>
<thead>
<tr>
<th>PI MD</th>
<th>1st yr full salary</th>
<th>% fringe</th>
<th>% increase/yr</th>
<th>medical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>168,273</td>
<td>0.2796</td>
<td>0.030</td>
<td>7,704</td>
</tr>
<tr>
<td>2nd yr full salary</td>
<td>173,321</td>
<td></td>
<td></td>
<td>7,935</td>
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<tr>
<td>3rd yr full salary</td>
<td>178,521</td>
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<table>
<thead>
<tr>
<th>Y1 % salary</th>
<th>Y2 % salary</th>
<th>Y3 % salary</th>
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<tr>
<td>0.200</td>
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#### MD w/Salary Cap

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<th>MD w/Salary Cap</th>
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<tr>
<td></td>
<td>185,100</td>
<td>0.2796</td>
<td>0.030</td>
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<tr>
<td>2nd yr full salary</td>
<td>185,100</td>
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<td>3rd yr full salary</td>
<td>185,100</td>
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<table>
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<tbody>
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<th>3rd yr</th>
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<tbody>
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<td>salary</td>
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<td>18,510.00</td>
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### MD Faculty

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<th>Medical</th>
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<td>1st yr</td>
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<td>3rd yr</td>
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<table>
<thead>
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<th>Y1 % salary</th>
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<table>
<thead>
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<th>Year</th>
<th>Salary</th>
<th>Fringe+Medical</th>
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</thead>
<tbody>
<tr>
<td>1st yr</td>
<td>90,000.00</td>
<td>29,017.80</td>
<td>119,018</td>
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<td>2nd yr</td>
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<td>3rd yr</td>
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### PhD Faculty

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<th>Medical</th>
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<tbody>
<tr>
<td>1st yr</td>
<td>107,385</td>
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<tr>
<td>3rd yr</td>
<td>113,924</td>
<td>6,004</td>
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<table>
<thead>
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<th>Y1 % salary</th>
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<table>
<thead>
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<th>Total</th>
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</thead>
<tbody>
<tr>
<td>1st yr</td>
<td>10,739</td>
<td>812</td>
<td>11,550</td>
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<tr>
<td>2nd yr</td>
<td>5,530</td>
<td>355</td>
<td>5,885</td>
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<td>3rd yr</td>
<td>11,392</td>
<td>861</td>
<td>12,253</td>
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### Coordinator 1

<table>
<thead>
<tr>
<th>Year</th>
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<th>% fringe</th>
<th>% increase/yr</th>
<th>Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st yr</td>
<td>61,763</td>
<td>0.2288</td>
<td>0.030</td>
<td>5,659</td>
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<tr>
<td>2nd yr</td>
<td>63,616</td>
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<td></td>
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<tr>
<td>3rd yr</td>
<td>65,524</td>
<td>6,004</td>
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<table>
<thead>
<tr>
<th>Year</th>
<th>Y1 % salary</th>
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<tr>
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<td>2nd yr</td>
<td>15,904</td>
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<td>3rd yr</td>
<td>16,381</td>
<td>5,249</td>
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<table>
<thead>
<tr>
<th>Year</th>
<th>Salary</th>
<th>Fringe+Medical</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>0</td>
<td>0.0000</td>
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</table>

**Personnel total**: 313,022 318,153 329,626 0 0
## Example NIH Internal Budget

<table>
<thead>
<tr>
<th>Equipment</th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP/Heart Rate Monitors</td>
<td>10,860</td>
<td>37,180</td>
<td>37,180</td>
</tr>
<tr>
<td>Lenses</td>
<td>13,659</td>
<td>37,180</td>
<td>37,180</td>
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<tr>
<td>Publication Costs</td>
<td>1,500</td>
<td>3,000</td>
<td></td>
</tr>
<tr>
<td>Patient Stipend</td>
<td>10,000</td>
<td>10,000</td>
<td></td>
</tr>
<tr>
<td>Project Management</td>
<td>7,750</td>
<td>5,250</td>
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</tr>
<tr>
<td>Recorders</td>
<td>2,300</td>
<td>3,000</td>
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</tr>
<tr>
<td><strong>Other direct costs</strong></td>
<td>68,090</td>
<td>53,930</td>
<td>3,000</td>
</tr>
<tr>
<td><strong>Travel</strong></td>
<td>4000</td>
<td>3000</td>
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</tr>
<tr>
<td><strong>Total Direct costs</strong></td>
<td>394,771</td>
<td>376,083</td>
<td>335,626</td>
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<tr>
<td><strong>F&amp;A base</strong></td>
<td>381,112</td>
<td>376,083</td>
<td>335,626</td>
</tr>
<tr>
<td><strong>% for F&amp;A</strong></td>
<td>0.52</td>
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<tr>
<td><strong>F&amp;A</strong></td>
<td>198,178</td>
<td>195,563</td>
<td>174,525</td>
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<tr>
<td><strong>Total F&amp;A</strong></td>
<td>568,266.30</td>
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<tr>
<td><strong>Total costs</strong></td>
<td>592,949</td>
<td>571,645</td>
<td>510,151</td>
</tr>
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</table>

Note: This excel spreadsheet was made without the ROUNDUP function, therefore final values differ slightly from those in the NIH application.
Hidden Costs (The NIH won’t pay for What?!)

• Salary in excess of salary cap
  • Example: if a salary is $200,000 and the PI has 10% effort:
    10% of base salary = $20,000
    Minus 10% of salary cap = $18,510
  • Department cost share = $1,490

• IDS Pharmacy Costs
  • Per the Chief Grants Management Officer, this is an “institutional” expense, and not allowable
Important Resources to Remember

- OSR Toolkit: Developing a Budget
  - [http://research.unc.edu/offices/sponsored-research/resources/research-toolkits/developing-submitting-proposals/data_res_osr_proposalbudget/](http://research.unc.edu/offices/sponsored-research/resources/research-toolkits/developing-submitting-proposals/data_res_osr_proposalbudget/)

- OSR Information Sheet (updated fringe benefits, etc.):
  - [http://research.unc.edu/offices/sponsored-research/resources/data_res_osr_infosheet/](http://research.unc.edu/offices/sponsored-research/resources/data_res_osr_infosheet/)

- NIH Grants Policy Statement Section 7.2: Cost Principles:

- NIH Grants Policy Statement Section 7.9: Allowability of Costs/Activities:
Any Questions?

sandy_barnhart@med.unc.edu
919-843-0076
INVESTIGATIONAL DRUG SERVICE (IDS)

Sue Pope, Pharmacist
Manager, UNC IDS
IDS Operational Overview

- **IDS staff**
  - 3 Pharmacist and 4 Technician FTEs
- **Studies managed**
  - Over 330 total studies managed annually
- **IDS hours of operation**
  - 0730 to 1600 Monday through Friday
  - IDS closed on major hospital and university holidays
- **Locations**
  - 3rd floor Memorial Hospital - Prepares medications for protocols that contain IV products
  - Ground floor Neurosciences Hospital - Prepares medications for protocols that only contain oral, non-chemotherapy medications
  - 3rd floor North Carolina Cancer Hospital
IDS Staff

LEADERSHIP
• Sue Pope, RPh
  Manager, IDS
  Email: sue.pope@unchealth.unc.edu;
  Pager: 216-2450
  Office: 984-974-0040
• Lindsey Amerine, PharmD, MS
  Assistant Director, Oncology, IDS
  Pager: 919-216-6597

PHARMACISTS
• Linda Manor, RPh - linda.manor@unchealth.unc.edu
• William Zhao, PharmD, PhD
  yun.zhao@unchealth.unc.edu
• Elaine Vu, PharmD
  elaine.vu@unchealth.unc.edu

IN AN EMERGENCY:
• Outside of normal business hours
  – IDS maintains an on-call pager
• In an emergency, an IDS clinical
  pharmacist can be reached by
dialing 919-216-9727. They will
  provide assistance with:
  • Individual drug or research
    questions
  • The breaking of a treatment
    blind
  • Provide support for inpatient or
    IV room staff who may be
    unfamiliar with a particular
    research protocol
Investigational Drug Service

Memorial Hospital, 3rd Floor
- 984-974-6359 (fax for orders)
- Prepares medications for protocols that contain IV products

Neurosciences Hospital, Ground Floor
- 984-974-3471 (fax for orders)
- Prepares medications for protocols that only contain oral, non-chemotherapy medications
Do I need to use IDS for my research protocol?

- For research protocols within the Hospital system, the clinical and distributional services of IDS are required.
- IDS Pharmacy required to be involved with all investigational studies that use an agent/drug.
  - Joint Commission Medication Management standards.
- An agent/drug (including supplements) will be considered investigational, if following two criteria met:
  1. Administration of agent is part of protocol which requires IRB approval.
  2. A subject is required to sign an Informed Consent Form before receiving the agent.
- Study locations other than main Hospital (e.g. Southern Village, Carrboro Dialysis, UNC School of Dentistry, EPA, etc.).
How and when do I initiate a request for IDS services?

- Request for IDS services should be initiated simultaneously with Contract negotiation (OCT) and request for IRB approval
- IDS needs notification 6 to 8 weeks prior to 1st study subject enrollment
- Use Clinical Research Management System (CRMS) to submit protocol materials to IDS
- Or, email a completed IDS Request for Services (RFS) form, an Intensity Worksheet, and copy of protocol to the IDS manager.
What do the services of the IDS cost?

- Complexity of protocol determines extent of IDS services used and cost.
- Protocol Intensity Worksheet uses a fee for service pricing structure to determine budget for study.
  - Score the protocol with a point based system to determine the level of service
  - 4 levels of service - the level determines the start up and monthly fee.
  - One time start up fee, non-refundable, charged as soon as notebook is ready for dispensing.
- Once drug is received and on shelf in IDS, begin billing monthly fee.
- IDS ceases to bill when the drug has been removed from the pharmacy and a final pharmacy close out visit has been conducted.
- Need protocol intensity worksheet before IDS can process memo for IRB.
New IDS Billing Procedures

- Billing will now use the Vestigo Software system
- Billing will be monthly
- Bills will come from Support@McCreadiegroup
- Bills will be sent via email to the PI or any contact that is given to the IDS manager
- Payments will be remitted to General Accounting
- If your study is open any portion of the month you will be billed for that month.
- Notify study closings by the 25\textsuperscript{th} of the month to avoid further billing.
What types of products can be compounded by IDS?

- IDS can participate in treatment and placebo blinding for solid oral dosage forms
- More complex compounding (liquid formulations, suppositories, troches, patches, etc) are outsourced to a local compounding pharmacy
  - Compounding fees of the local pharmacy apply in addition to standard IDS fees
How are research protocols handled outside of normal business hours?

- Approximately 95% of research protocols are handled during normal business hours (M-F, 0730 to 1600)
- However, if a research protocol will require after hour dispensation, an assigned pharmacist can coordinate this with Hospital inpatient Pharmacy or IV room
- IDS pharmacist will coordinate delivery and storage of materials to the IV room/Inpatient Pharmacy as well as provide necessary in-services to the staff
Scheduling a Monitoring Visit

• In an effort to accommodate all sponsors, monitoring visits and site initiation visits must be coordinated in advance. Contact your assigned pharmacist or call IDS
  • Call 984-974-0469 or 984-974-3777 to schedule a monitoring visit
  • 2 monitoring visits allowed per day per IDS work area
  • Scheduled typically a month or more in advance
  • “Remote” monitoring visits are typically not supported by IDS
To whom and where can Clinical Trial Materials (CTM) be sent?

- After contacting IDS (984-974-0469) to make them aware of the incoming shipment as well as total volume of expected shipment, CTMs can be directed to the following address:

  Investigational Drug Services  
  3rd Floor, Room N3122  
  101 Manning Drive  
  Chapel Hill, NC 27514  
  Phone: 984-974-0469  
  Fax: 984-974-6359
How are Investigational Medications Dispensed?

IDS can begin preparing an investigational medication for your patient ONLY when:

1. Completed protocol orders are faxed to 3W IDS or NS IDS Pharmacy
2. Orders must be signed by provider listed on 1572 and IRB application (original signature, not a copy)
3. Coordinator must give IDS verbal confirmation that patient is available for treatment (if pertinent to protocol)
4. Coordinators must present an original signed prescription order when picking up an investigational medication in the IDS pharmacy.
UNC INVESTIGATIONAL DEVICE POLICY

Marie Rape, RN, BSN, CCRC
Associate Director, TraCS Regulatory Service
Overview

The University of North Carolina Health Care System must ensure compliance with regard to utilization of investigational devices.

- There is a policy that governs:

  - Administrative Procedures
  - Device Receipt
  - Device Storage
  - Device Use/Dispensing
  - Device Return
Administrative Procedures

Prior to use of an investigational device, the following has to occur:

• **IRB approval**

• **Final sponsor budget** will sponsor provide device free of cost or must UNC Hospitals purchase? (contact Hospital Purchasing)

• **Contract** must be fully executed (UNC Office of Clinical Trials)

• Must enter trial in CRMS and complete Billing Coverage Analysis (to obtain codes and charges from Integrated Billing Office)

• Notify **UNC HCS Reimbursement** of pending trial. They will coordinate with Medicare Fiscal Intermediary.
Receipt, Storage, Use/Dispensing, Return

- Device Receipt-
  - What Does Protocol say?
  - Request Sponsor to notify of shipment
  - Comply with Sponsor documentation requirements

- Device Storage-
  - Secure, segregated, clearly identified as investigational

- Device Use/Dispensing-
  - Record use/dispensing information

- Device Return-
  - Read clinical trial agreement to see if contract terms govern
  - Record information
  - Work with UNC Hospital Purchasing to return unused devices.
EPIC AND HIPAA TRAINING

Marie Rape, RN, BSN, CCRC
Associate Director, TraCS Regulatory Service
Epic, the Clinical Research Management System (CRMS), and OnCore
Epic is the Electronic Health Record System used by the UNC Health Care System.

Who will need access to Epic:

- If you work on a drug trial, device trial, or your study has any Hospital charges (one blood draw, x-ray, etc.)
- If you schedule visits in UNC Health Care System rooms
- If you review medical records / charts.
Research Workflow

Pre-Study

- IRBIS
- CRMS
- OnCore

Study approvals, request services from OCT & IDS, build initial budget, coverage analysis and reviews, enrolling patients or scheduling for CTRC

In Study

- Epic

Schedule visits, document encounters, place orders, review charges, get reports

Interface will transfer basic study info and patient association
In addition to the research-specific Epic@UNC training courses (Research Administration 100, Research Coordinator 200, and Research Coordinator 300), several Quick Reference guides have been developed to help you:

**Quick References:**
- What's Happening?
- Changes in the CTRC
- Using the CTRC Scheduler
- CTRC High Acuity & Inpatient Visits
- CTRC Flow Charts
- CRMS Records & Participants
- Learning Street Epic Training Materials
- Upcoming Procedures and Surgeries
- Finding Pended Orders
- Investigational Drug Services (revised)
- Ordering Imaging and Phlebotomy (revised)
- Linking Appointments to Research - For Scheduling Only
- Ordering for Research
- What to Expect on Day 1
- Frequently Asked Questions
- Research Training Tip Sheet (revised)
- Changing Providers
- Patient Timelines

**Epic Access Request Form for External Research Monitor**

**University Employee/Student Epic Access Request Form**

**Billing Coverage Analysis:**
- Billing Coverage Analysis Tutorials:
  - Internet Explorer users
  - Google Chrome users

**Research Town Hall Slides:**
- All Departments
- Oncology

**References for OnCore:**
- OnCore CPD New Study Entry Checklist
- OnCore NPO New Study Entry Checklist
For More Training:

Research Administration 100: OnCore, CRMS Records, and BCA Documentation
Register via Hospital’s LMS system

Upcoming dates:
Oct 11       Dec 13
Nov 8        Jan 10
Health Insurance Portability and Accountability Act – “HIPAA”

• HIPAA is a federal law aimed at protecting health information by establishing standards for the use and disclosure of individually identifiable health information (known as Protected Health Information or PHI) created, received or disclosed by a health care entity.
  • PHI is any information about health status, provision of health care, or payment for health care that can be linked to an individual. This is interpreted rather broadly and includes any part of a patient’s medical record or payment history.
  • When a covered entity discloses any PHI, it must make a reasonable effort to disclose only the minimum necessary information required to achieve its purpose.
HIPAA and Research

- HIPAA requires either a **patient authorization** or a **waiver of the authorization requirement** to use identifiable health information (PHI) for research.

- **IRB makes determination if HIPAA privacy laws apply.**

- Most research requires a signed HIPAA Authorization form if accessing a subject’s PHI from medical record.

- **IRB may waive authorization requirement** (signed form) for
  - retrospective chart reviews (how many blood clots in last 100 patients)
  - reviews preparatory to research
  - "de-identified" data sets
  - a limited waiver of HIPAA authorization may be granted by IRB to identify potential subjects for recruitment
HIPAA does not apply to de-identified data – all of the following must be removed:

- Names
- Geographic subdivisions smaller than a state (zipcode)
- All elements of dates (except for year) for birth, admission, discharge, and death
- All ages over 89, including year
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers
- Device identifiers
- URLs
- IP addresses
- Biometric identifiers, including fingerprints and voiceprints
- Full-face photographs
HIPAA - Research Training

- Topic of HIPAA included in the CITI Human Subject Protection (Ethics) training
- UNC SOM requires additional HIPAA training
- All SOM employees involved in human subject research are required to take HIPAA Training:
  - General Privacy and Information Security
  - Training conducted initially upon hire and renewed annually
- University requires online HIPAA training for new employees and requires annual renewal training, [http://www.unc.edu/hipaa/training.htm](http://www.unc.edu/hipaa/training.htm)
Recommended Reading:

**The Immortal Life of Henrietta Lacks**

*Doctors took her cells without asking.*
*Those cells never died.*
*They launched a medical revolution* and *a multimillion-dollar industry.*
*More than twenty years later, her children found out.*
*Their lives would never be the same.*

*Rebecca Skloot*