UNC THE NORTH CAROLINA TRANSLATIONAL & CLINICAL SCIENCES INSTITUTE

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL NRP Network for Research Professionals

UNC OFFICE OF CLINICAL TRIALS

ORIENTATION FOR NEW CLINICAL RESEARCH PERSONNEL

MODULE 4

Presented by

NC TraCS Institute

UNC Office of Clinical Trials

UNC Network for Research Professionals

Online Logistics

- I will be monitoring the chat window for questions and will ask those questions to the presenter at the end of each talk, or during breaks in the conversation when the presenter invites questions.

- Slides will be emailed to everyone after the presentation, along with the evaluation link and any announcements.

- If you would like a certificate for ACRP/SOCRA credit, please complete the evaluation at the end of the presentation and send me an email – marie_rape@med.unc.edu

- Feel free to reach out to me either in the chat window or by email, I'm happy to help with anything you need.

Overall Agenda for Orientation

- **Module 1:** Introduction, NRP/ Education, and Office of Clinical Trials
- **Module 2:** IRB Processes, Conflict of Interest
- **Module 3:** GCP, Documentation, Informed Consent, Research Monitor Access
- **Module 4:** Contracts, Clinical Trial Agreements, Planning/Accounting of Funds, NIH Budgets, Billing Coverage Analysis
- **Module 5:** Recruitment, Study Start-up, Roles of Research Personnel, UNC Investigational Drug Services, UNC Device Policy
- **Module 6:** Introduction to RedCap, Investigator-Initiated Study Process, ClinicalTrials.gov, Documenting AEs & SAEs, IND and IDE studies

CLINICAL TRIAL AGREEMENTS

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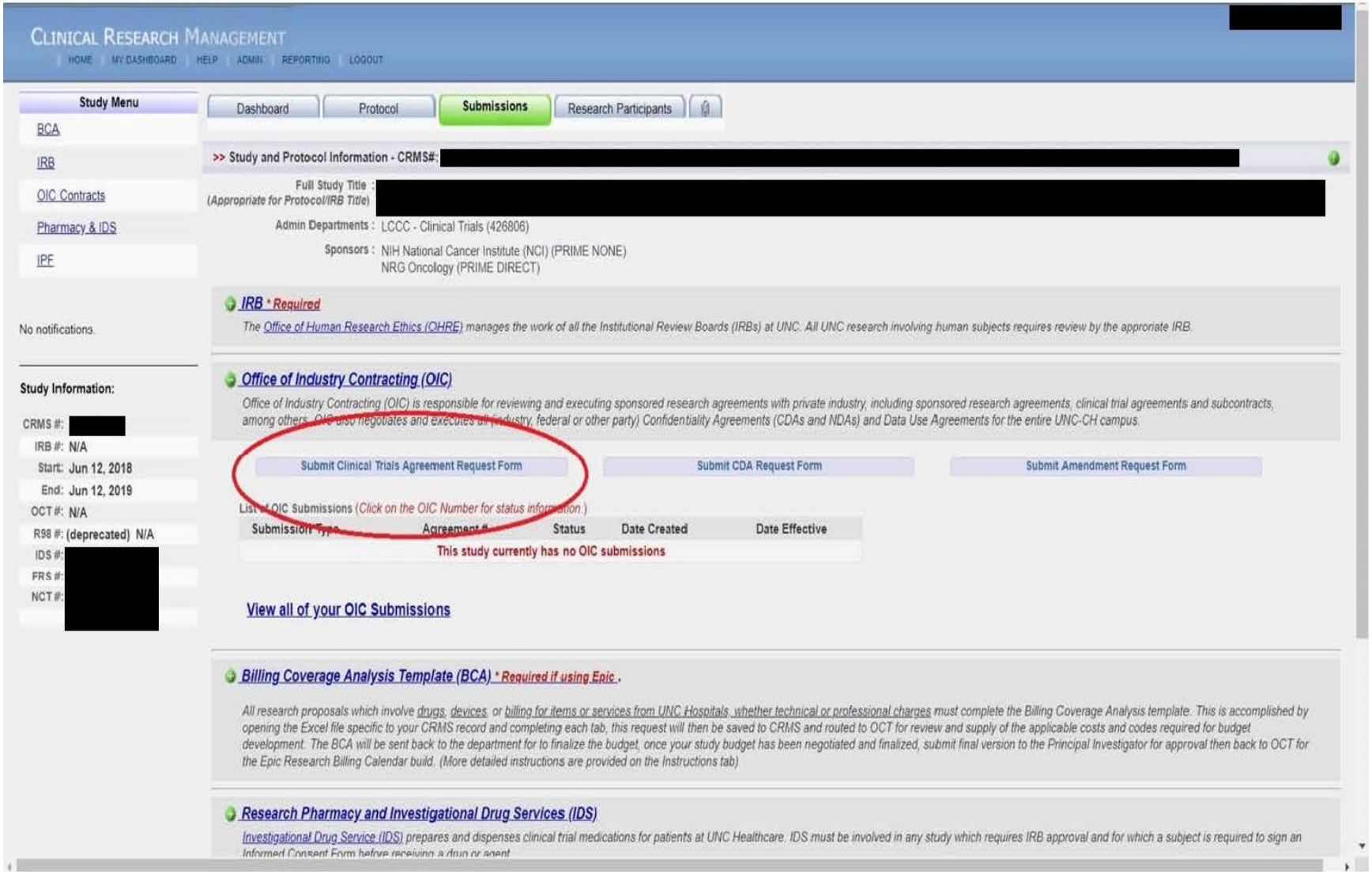
Learning Objectives

- Overview of Clinical Trial Agreements (CTA) negotiation processes at UNC
- Submitting a CTA for review
- Importance of the CTA to UNC and Investigator
- Critical CTA provisions

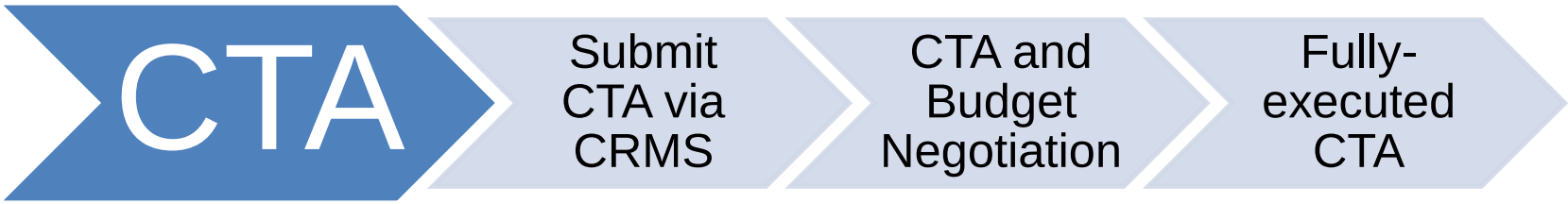
Research Contracts at UNC: Office Responsibilities*

Office of Technology Commercialization (OTC)	Industry Contracting Group-OSR	Office of Sponsored Research (OSR)
• MTAs (unfunded) • Licensing agreements not linked to sponsored projects	• CDAs • DUAs • Clinical Trial Agreements • MTAs (funded) • Contracts with "industry" SRA, Services, Testing, Start up, core/recharge *On rare occasions, OTC and OSR may evaluate assignments on a case-by-case basis	• Contracts and grants with federal, state, foreign government • Foundation & Non-profit grants/contracts • Proposals

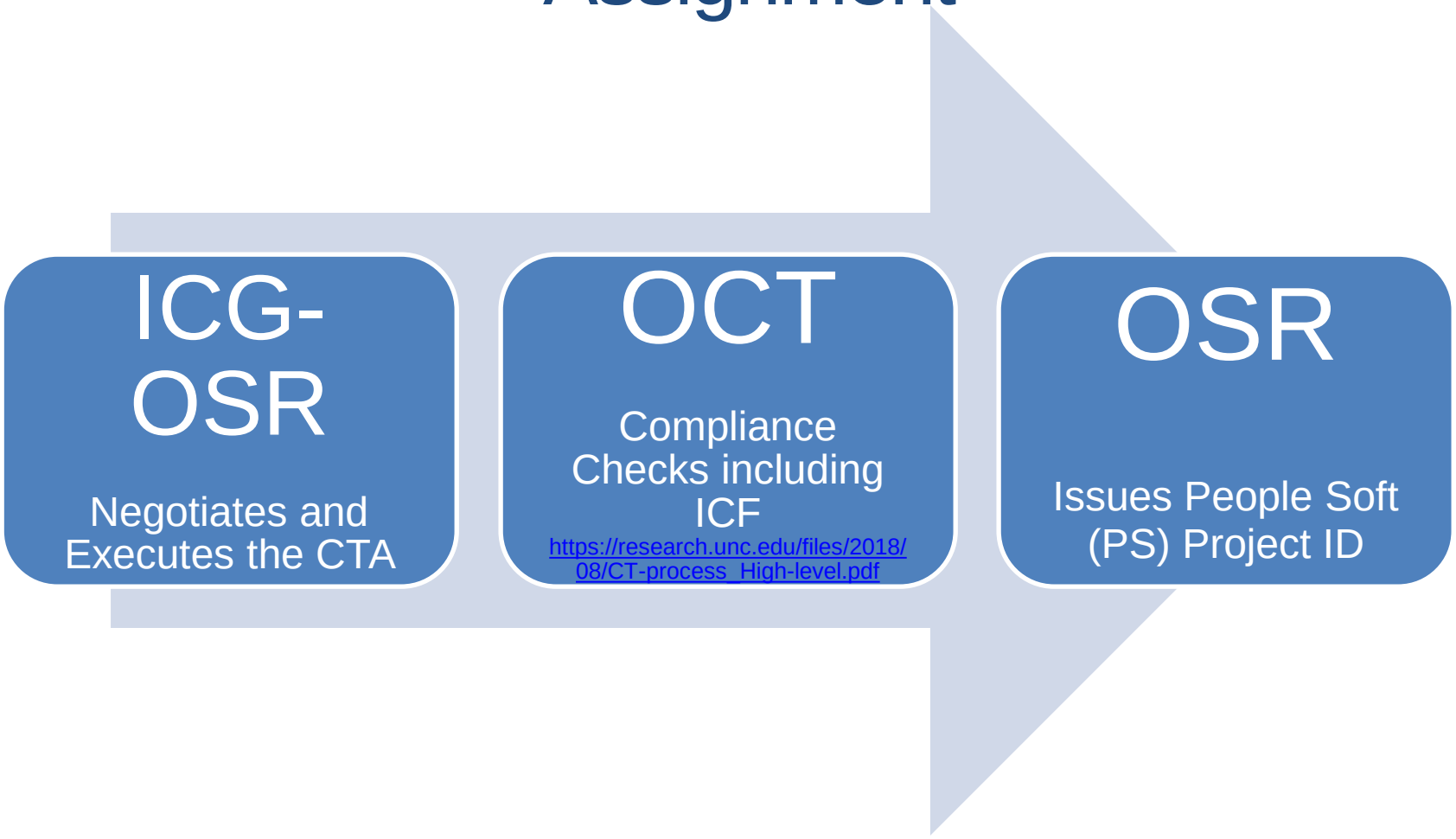
Submitting a CTA into CRMS



Life Cycle of a CTA



Clinical Trial Start Up Process: Submission of CTA though Account Assignment



Agreement Status

- Assignment to ICG Contract Manager (CM) contingent upon complete submission of:
  - CTA, ICF (including model consent), draft budget, other miscellaneous documents
  - External contact (phone & email)
  - Lead PI, and PI Certification
  - Try to be specific in listing department personnel (Regulatory, Budget, Coordinator)
- Agreements are assigned to CM on a rotating basis, notification email upon assignment

Negotiation Detail
(Department-facing)

Agreement Activity

Type	Status	Activity Date
ICF Subject Injury	Consent Comments Out	03/09/2017
Agreement Action	Routing in OIC » To Account Manager	03/08/2017
Agreement Status	Signature(s)-External » Signed by Sponsor	03/08/2017
Agreement Status	Signature(s)-External » To Sponsor for Signature	03/03/2017
Agreement Status	Signature(s)-Internal » Signed by UNC	03/03/2017
Agreement Status	Signature(s)-Internal » Signed by PI	03/03/2017
Agreement Status	Signature(s)-Internal » To PI for Signature	02/24/2017
Budget	Other	02/22/2017
Other	Other	02/20/2017
ICF Subject Injury	Consent Comments Out	02/20/2017
Other	Other	02/20/2017
Agreement Status	Terms Finalized	02/20/2017
Agreement Status	Under Negotiation » Response Out to Sponsor/Site	02/17/2017
Budget	Finalized	02/17/2017
Agreement Status	Under Negotiation » Response In from Sponsor/Site	02/15/2017
Agreement Status	Under Negotiation » Response Out to Sponsor/Site	02/11/2017
Agreement Status	Under Negotiation » Response In from Sponsor/Site	02/06/2017
Agreement Status	Under Negotiation » Contract Note	01/25/2017
Agreement Status	Under Negotiation » Follow-Up	01/25/2017
Agreement Status	Under Negotiation » Initial Comments to Sponsor/Site	01/05/2017
Agreement Action	Administrative » Assigned to CM	01/03/2017

Parties to the Contract

- Investigator is not a party, signs as “read and understood”
- No need for PI to sign CDA, *but be aware of obligations*
- CRO as a party = expect delays

What is a CRO?

- Contract Research Organization
- Hired by Sponsor to negotiate, manage and/or make payments for a study.
- Often hired by a Sponsor who does not have contracting or budget management expertise in house.
- CRO = Possible Delay
  - Negotiation practices are often CRO's preferred language not Sponsor's
  - After CRO approval, Sponsor still needs to approve of language.
  - CRO is often not willing to accept previously agreed upon terms.
  - If CRO is signing and not Sponsor, UNC will require a Letter of Indemnification (LOI) from Sponsor.

CTAs: Important Terms and Provisions

For UNC

- Liability (Indemnification)
- Subject Injury
- Publication, Policy & Waivers
- CRO involvement
- Subject Privacy (HIPAA)
- Subject Safety Reporting (AAHRPP)
- Intellectual Property
- Governing Law (Enforcement)
- Term and Termination
- Avoiding “Incentive” language
- Audits & Monitoring
- Equipment
- Confidential Information
- ACTA (Accelerated Clinical Trial Agreement)

For the department

- Budget/Payment Schedule Negotiation
- Billing and Invoicing Requirements
- Publication
- Data Capture requirements (CRFs)
- Record Retention
- Adverse Events Reporting
- Audits & Monitoring
- Return/Destruction of Study Materials
- Equipment
- Enrollment

Note: Depending on whether the protocol is Sponsor- vs. Investigator-initiated will impact terms and conditions

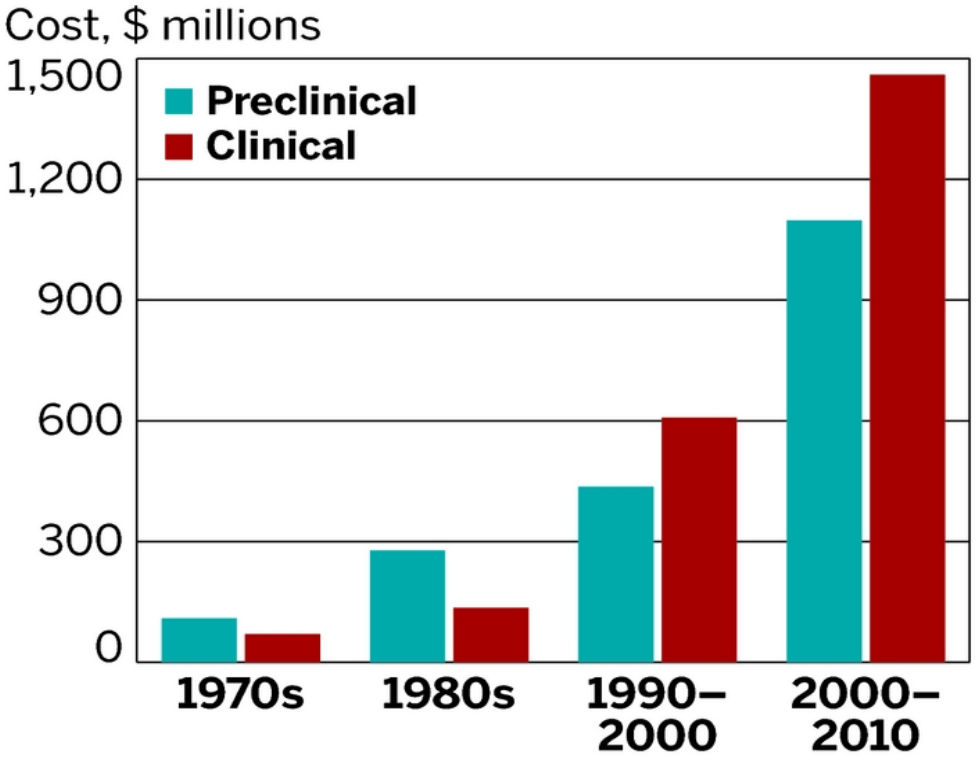
Budget and Payment Terms: Negotiation Tips

CM does not negotiate the budget BUT will provide guidance on payment terms upon request

Issue	Sponsor Proposed Language:	Request this instead:
Frequency of Payment	Sponsor will pay quarterly (a) Subject payments (b) Other invoices	Sponsor will pay monthly (how often are CRF's being submitted?)
Contingencies	Sponsor will pay if Institution performs the Protocol correctly.	Sponsor will not pay for visits in which a protocol violation occurred.
Hold Backs	Sponsor will pay 80% of the invoiced amounts. . .	Sponsor will pay 90% of the invoiced amounts. . . AVOID: Hold back until database lock
Forfeiture	Sponsor will pay for invoices submitted within 60 days of study close out.	Institution will submit invoices to Sponsor within 90 days of study closeout.
Disputed Payments	Sponsor will pay for undisputed & detailed invoices	Sponsor will promptly notify Institution of a disputed invoice, good faith effort to resolve not to exceed "x" days. (*alt: spell out what is required to be in the invoice)
Incentive Language	Sponsor will provide $500 additional dollars for each subject enrolled before July 1st.	Sponsor will provide an additional $1000 to support enhanced coordinator enrollment efforts prior to July 1st.

Confidential Information

- The cost to develop new pharmaceutical drug now exceeds 2.5 billion.
- Sponsor is motivated to protect their rights in their product: Confidential Information and Intellectual property.
- Typically 5-7 years confidential treatment.



Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B, Rick Mullen, Scientific American, Nov 24, 2014

Publication

- Publication required by Board of Governors policy, tax exempt status, export control law (Fundamental Research Exclusion)
- PI develops expertise and reputation in their field
- Registration requirements (International Committee of Medical Journal Editors or ICMJE)
- Delay Period: for Sponsor review, multi-center publication
  - Sponsor review for confidential information or intellectual property
- Association for the Accreditation of Human Research Protection Programs Or AAHRPP

BMJ 2016;352:i637

Ownership and Intellectual Property

- Ownership of Study Data/Results

  Data is primary “product”

- Intellectual Property may include:

  Patents

  Copyright

  Trademark

  Trade secret

- Sponsor will typically own IP, data/results

Please alert ICG-OSR if additional funding

for your study is coming from other sources

(e.g., Federal, Industry, Foundation)

because the other funders may have study-related IP rights!

Ownership and Intellectual Property - Defined

- Patent: Protected property right in invention/idea that excludes others from using, making, or selling for a period of time.
- Copyright: Protects published and unpublished original works, where copyright holder has exclusive rights to publish, reproduce, distribute copies, display or perform the work.
- Trademark: Protects words, phrases, symbols, logos (ex: UNC logo) from usage by other entities or competitors. Owner has exclusive use & can prevent others from using same or even similar mark that could confuse consumers. May extend perpetually.
- Trade secret: Protects valuable secret information & ideas (ex: Coca-Cola recipe) that must be kept confidential to maintain value. May extend perpetually.

Study Data and Study Records

- Data Capture: CRFs/eCRFs
- Mandatory progress reports to Sponsor: written or verbal
- Record Retention: Time
- Record Storage: Secure, on/off site
- Record Destruction: Notification, transfer to Sponsor, cost
- *Plan for storage, and ask for funding!*

Equipment and Study Materials

- “Materials” (Drug/Device) and Equipment: storage, maintenance, accounting
- Repair and replacement of loaned/leased equipment
- Equipment liability, UNC generally does not insure Sponsor’s equipment
- Return of equipment at study conclusion and sponsor’s expense

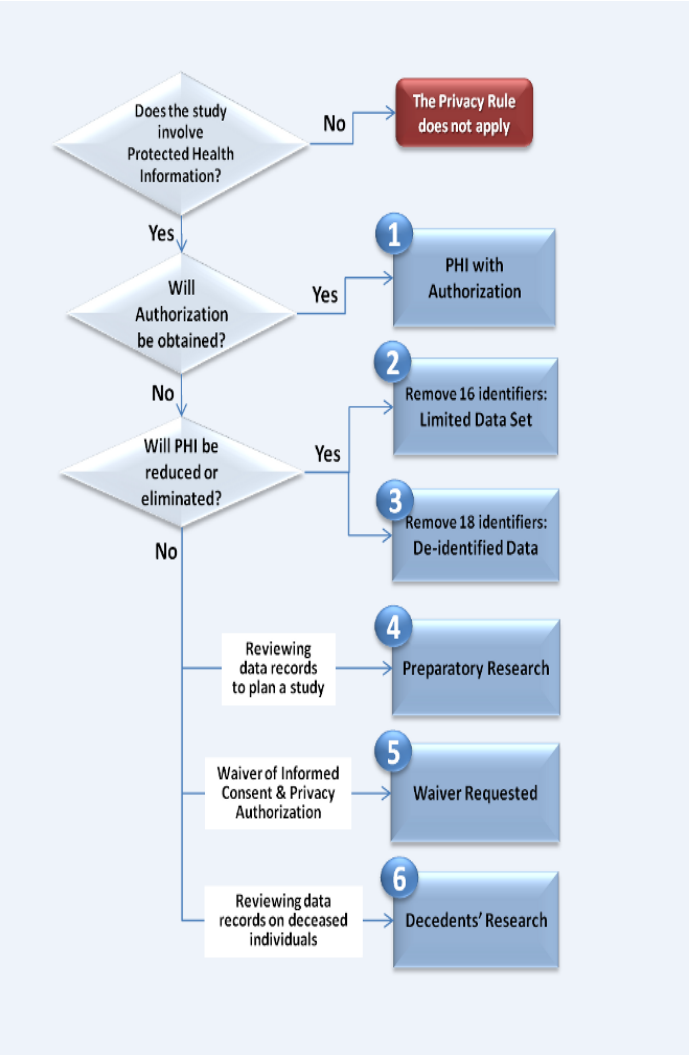
Sponsor Access to UNC

- Monitoring/Auditing access for Sponsor/CRO
- Sponsor presence at regulatory audits
- Privacy Concerns (Epic SOP*)
- Availability of study records, facilities, and personnel

Epic SOP and Research Monitor confidentiality statement
Available at Research Central

PRIVACY and HIPAA

- Even if research is intended to be de-identified, Sponsor/CRO may have access to individually identifiable information about subjects
- UNC has a regulatory responsibility to ensure that sponsors maintain confidentiality
- Contract may specify language to be included in the ICF/IRB application
- EU General Data Protection Regulation (GDPR) – considerations based on location of Sponsor



Source: Loma Linda Investigator's guide to HIPAA: http://researchaffairs.llu.edu/sites/researchaffairs.llu.edu/files/docs/hipaa-flowchart.pdf

Indemnification

- Indemnification is a contractual promise to protect the other party from 3rd party liability
- Related to subject injury provisions, but *not the same!*

Narrow	Intermediate	Broad
Sponsor indemnifies UNC for subject injury	Sponsor indemnifies UNC for subject injuries, Sponsor breach of agreement and law, Sponsor use of data and results	Sponsor indemnifies UNC for performance of the Protocol

Subject Injury Language

- Sponsors not required by U.S. law to pay
- Can be a contentious part of the negotiation
- ICF should be consistent with CTA

Sponsor preferred language	UNC preferred language
payment only after insurance denial, or billing differently – OCT position statement 5/3/2017	pay vs reimburse diagnosis *and* treatment
no payment for subject failure to follow instructions – IRB position statement 12/1/2016	injuries *and* illnesses
limits in time/value: SOL or dollar cap	drug/device *and* protocol procedures
payment solely for emergency, customary, “out of pocket” expenses	PI’s determination
	subject has right to seek treatment from any health care provider

Reasonable exceptions: UNC’s negligence, UNC’s failure to follow protocol, Subject’s underlying disease (unless exacerbated by drug)

Investigator-Initiated Protocols

- Sponsorship carries important regulatory requirements!
- Expect different timelines for CTAs vs. IITs.
- Let your CM know if you will have sub-sites
- Understand your regulatory requirements!

CTA: Industry Initiated	IIT: Investigator Initiated
Protocol written by company	Protocol developed by Investigator
Company is the Sponsor	UNC is the Sponsor*/Company, if funding, is “funding/product source”
UNC seeks broad indemnification	Company will offer limited indemnification
UNC requires broad subject injury	Often no subject injury
UNC may be one of many sites	UNC may have sub-sites to manage (check applicable box in CRMS submission)
Company has broad rights to study data, results, IP	UNC will own study data, results, and limit Company's IP rights appropriately
Company must register study, perform monitoring	UNC may be responsible for registration, monitoring
Publication often delayed/limited pending multi-center publication	Often no delay for publication
Company may seek a CDA before sharing protocol with UNC	Consider a CDA before sharing your protocol

BEFORE SIGNING THE AGREEMENT

REVIEW THE ENTIRE CONTRACT

Reminder of Important Terms & Provisions:

- Term and Termination
- Budget/Payment Schedule/Billing & Invoicing Requirements
- Enrollment
- Confidential Information
- Data Capture Requirements (CRFs)
- Subject Privacy (HIPAA)
- Adverse Events Reporting
- Subject Safety Reporting (AAHRPP)
- Audits & Monitoring
- Liability/Indemnification
- Subject Injury
- Publication
- Intellectual Property
- Governing Law
- Equipment
- Record Retention
- Return/Destruction of Study Materials

Questions and FAQs

- Does the Industry Contracting Group have a CTA or IIT template?
- Why is my CM asking me so many questions?
- Can we start the study before the contract is signed?
- My sponsor cancelled the study. Can we be reimbursed for start-up costs?
- Where is my PS Project ID?
- How long will my CTA take to be signed?

BILLING COVERAGE ANALYSIS (BCA)

Andrea Eiring, MSM, CCRA, CPHRM

Office of Clinical Trials

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Billing Coverage Analysis (BCA)

DEFINITION

A systematic review of research-related documents to determine the (Medicare) billing status of *both* the study itself and the items and services provided to the research subjects over the course of the study.

A.K.A. Medicare Coverage Analysis

- **MEDICARE?!?**

- Primary BCA objective -- to ensure that all clinical trial costs are billed to the *appropriate* payer (*i.e.* Sponsor, a third-party payer (including Medicare), or the patient).
- Almost every study has the potential to enroll Medicare/ Medicaid patients as participants.
- Medicare rules tend to set the trend for the payer industry.
- UNC follows Medicare rules for billing in the context of clinical research.

The Billing Coverage Analysis should:

- Lead budget development process:
  - to allow negotiators to identify which services can appropriately be billed to third party payers and which must be covered by the Sponsor
- Be completed:
  - before negotiating budget to ensure the Sponsor adequately covers study costs
  - prior to enrolling study subjects and performing clinical research procedures
- Be communicated:
  - to the charge capture and billing systems (Epic) in order to prevent inappropriate billing

Which Studies Require BCA and Which Require Submission of the BCA Workbook?

- A billing coverage analysis is required for ALL trials
- Completion of the BCA workbook in CRMS is required for any study involving any kind of Epic billing - even those studies wherein the Sponsor pays for everything, or everything is billed to the subject or third party

Current Medicare Clinical Trial Policy

- **National Coverage Determination (NCD) 310.1**
  "Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials."

- All other Medicare rules apply

Qualifying Clinical Trials

- **Determined by 2-step process:**
  - **Step 1**: Confirm that trial meets <u>all 3</u> of the following criteria:

1. Evaluates an item or service that falls within a benefit category - **AND** -
2. Study designed with therapeutic intent - **AND** -
3. Enrolls patients with diagnosed disease

Qualifying Clinical Trials

- **Step 2**: Determine if trial is "deemed" to meet the CMS 7 desirable characteristics of a trial through one of these criteria:
  - Is funded by or supported by centers or groups funded by NIH, CDC, AHRQ, CMS, DOD, VA **- OR -**
  - Is conducted under an IND **- OR -**
  - Has been determined IND-exempt according to FDA regulations

Unapproved Device Trials- IDE-Significant Risk

- Medicare pre-review required for Category A (experimental) and Category B (Nonexperimental/ investigational) IDE device protocols
- IDE holder responsible for submitting to CMS
- Cannot bill patient for routine costs or the device unless approved for billing by Medicare
- CMS website lists all approved IDE protocols
- Do not confuse FDA IDE approval with CMS billing approval

Unapproved Devices Trials- IDE-Non-Significant Risk

- Site responsible for submitting to Local Medicare Administrative Contractor (MAC) for review
- Cannot bill patient for routine costs or device unless the trial is approved for billing by MAC

Other Devices Trials

- Approved devices follow NCD 310.1 rules
- 510K-cleared devices follow NCD 310.1 rules
  - Be careful with 510K cleared devices-the trial must utilize the device exactly as permitted in the Instructions For Use on which the designation is based
  - If used otherwise, an IDE is required

Qualifying Clinical Trial-*NOT!*

- A trial that fails either part of the two-step test
- An IDE-SR trial that has not been approved by central CMS
- An IDE-NSR trial that has not been approved by local MAC

Is *NOT* a qualifying clinical trial and no items or services are billable to the patient, even if the item or service would be covered outside the trial.

Qualifying CT - What you CAN Bill to Subject

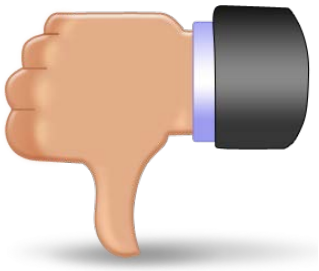
- If the study is a qualifying clinical trial, then **“routine costs”** in the trial can be billed to Medicare (and other payers), provided the item or service is not otherwise prohibited by Medicare.

- In simple terms, a “routine cost” is one of the following:
  - Conventional care (would receive if not in study)
  - Administration of the investigational item (research)
  - Detection or prevention of side effects (research)

*Exception to the rule: Treatment for complications arising from participation in <u>any</u> clinical trial - including non-qualifying trials - can be billed

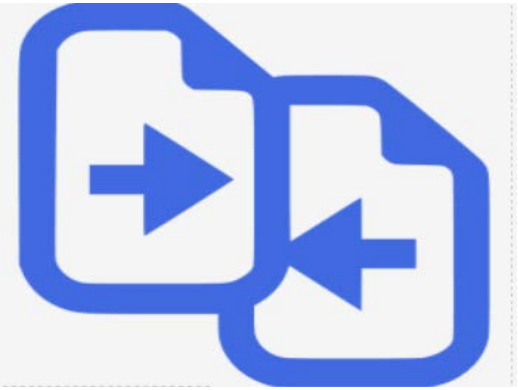
Qualifying CTs - What you Can't Bill to Subject

- **We cannot bill the patient for costs that:**
  - Are paid for by the Sponsor (double dipping)
  - Are promised free in the informed consent
  - Are not ordinarily covered by Medicare
  - Are research tests that do not meet CMS criteria, such as:
    - tests done solely to determine trial eligibility
    - baseline tests for monitoring side effects unless also part of conventional care
    - services performed more frequently than conventional care



Role of the Informed Consent Form

- Every research study must have a section in the Informed Consent Document that discloses added costs the subject may incur while participating in the trial.
- The Sponsor budget and Informed Consent Document must be consistent in items billed to patient or covered by Sponsor

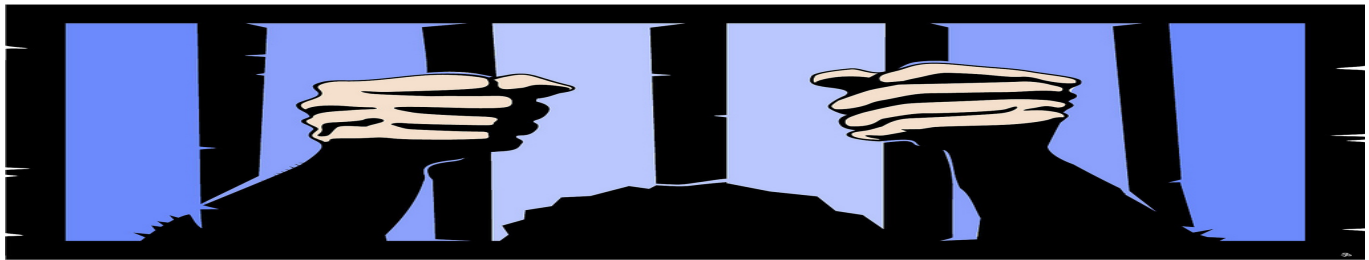


False Claims Act (31 USC §§3729-33)

- In regard to research billing, this law enacts liability against a person or entity who knowingly ignores CMS regulations (as demonstrated by "**reckless disregard**" or "**deliberate ignorance**") by:
  - Submitting a false claim
  - Using a false record or statement to get a claim paid or approved
  - Causing a 3rd party to do either of the above

False Claims Act - Consequences

- Civil penalties: $5K-$11K per submitted claim plus up to 3x damages incurred by government
- Possible exclusion from participation in Federal health care programs
- Regardless of the funding source (i.e., applies to Industry Sponsors and Federal grants alike)

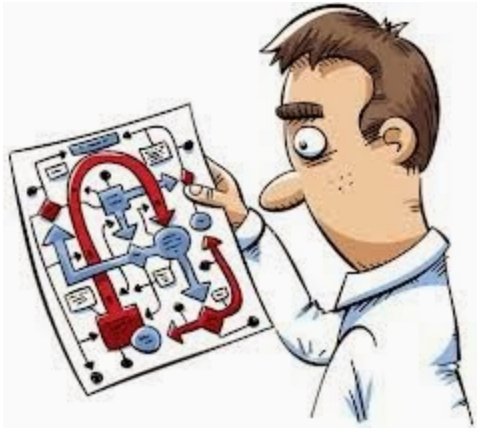


Non-Compliance or Improper Billing

- Failure to comply with applicable laws, regulations, and Informed Consent documents
  - Intentional or **un**intentional
  - Serious and “continuing” non-compliance is reportable to federal funding agencies and FDA (for studies subject to their authority)

Non-Compliance or Improper Billing

- Why does this happen?
  - Decentralization
  - Unfamiliar with the rules
  - Not paying attention
  - Lack of **C**oordination, **C**ollaboration, and **C**ommunication
  - It's everyone's responsibility



Risks of Non-Compliance

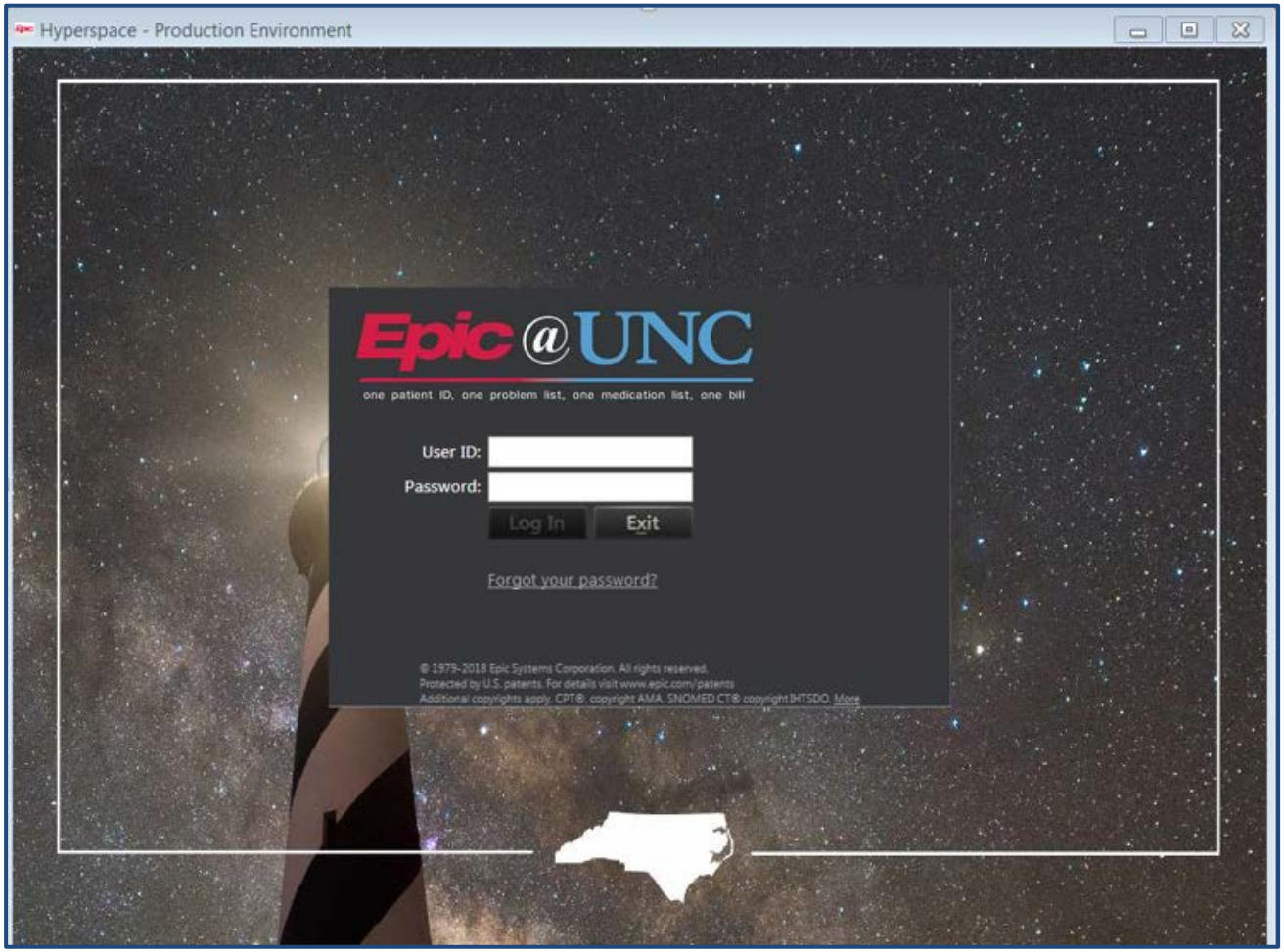
- Inappropriate Medicare billing is considered fraud and can lead to large fines.
- Financial harm to research subjects
  - Co-pays and deductibles billed in error
  - Charges sent to collection agency impact credit score
  - Affects patient satisfaction and continued participation in research

Risks of Non-Compliance

Systems & processes are needed to apply proper billing and provide due diligence to ensure charges are directed to the correct party and are not billed incorrectly or to multiple payers.

UNC Systems

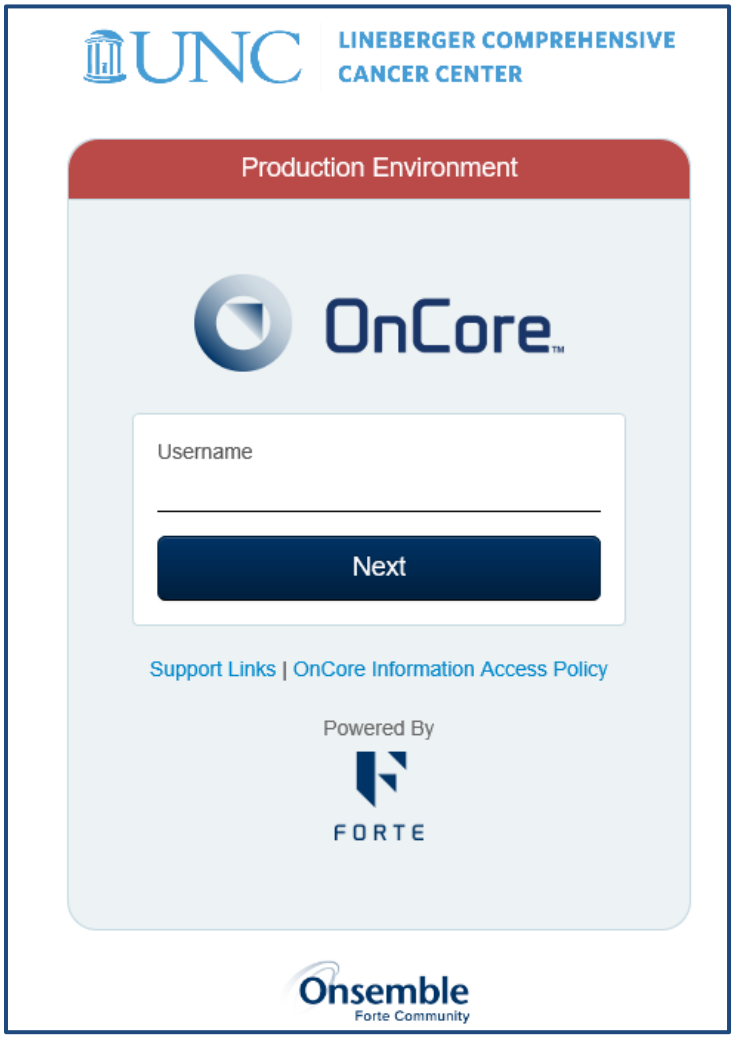
Epic is the Electronic Health Record System used by the UNC Health Care System.



You Will Need Access to Epic…

- If you schedule visits in UNC Health Care clinics
- If you link subjects to study visits and timelines
- If you perform charge review
- If you review medical records/charts
- If you document electronically
- If you enter orders

CRMS and OnCore are the Systems used by the University to Communicate with Epic



You Will Need Access to CRMS/OnCore…

- If you perform the coverage analysis
- If you need to request Investigational Drug Services
- If you need to request a confidentiality agreement or clinical trial agreement from OSR-Industry Contracting
- If you identify, consent, or enroll subjects (OnCore for LCCC)
- If you conduct study visits (OnCore for LCCC)
- If you need to create a CTRC visit profile
- If you schedule CTRC visits

Research Workflow

Pre-Study

- CRMS
- OnCore

Study activation, request services from OCT, OSR-IC & IDS, billing coverage analysis for calendar build; enroll patients, schedule CTRC visits

In Study

- Epic

Schedule visits (in hospital), link encounters, document encounters, place orders, review charges, get reports

Interface will transfer basic study info and patient association

Epic @ UNC

one patient ID, one problem list, one medication list, one bill

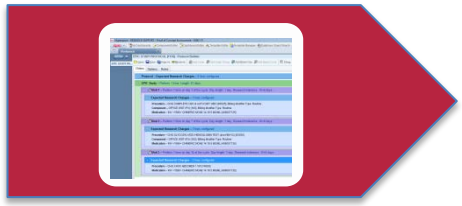
Pre-Study Financial Workflow: Current Process

Coordinator builds schedule of events in Excel template

BCA goes to OCT to check study billing status & workbook completeness

OCT supplies codes and research prices

Budget and contract finalized and confirmed by research staff and PI



Office of Clinical Trials or Lineberger CPO creates billing calendar for study in Epic

Coordinator/schegistrar links subject encounters to calendar.

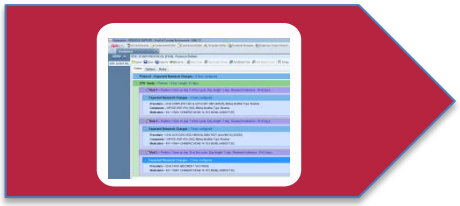
Pre-Study Financial Workflow: New Process Starting April 11, 2021

Coordinator creates CRMS record for new study

OCT performs a coverage review for all studies

OCT completes BCA for studies with Epic billables and reviews with study team

Budget and contract finalized



OCT or Lineberger CPO creates billing calendar for study in Epic; OCT verifies BCA matches final docs and activates study in Epic

Coordinator/schegistrar links subject encounters to calendar.

BCA Education and Training

- Who can benefit?
  - Financial administrators who develop budgets
  - Research staff who perform the coverage analysis
  - Regulatory staff who submit informed consents to the IRB
  - Research staff who perform charge review
  - Managers/investigators who want to understand the process
  - Anyone interested in research billing!!

BCA Training Opportunities

- Research Administration LMS course provides detailed CRMS system and coverage analysis information.
  - Required for Epic access (except for “read only”)
  - Pre-requisite to Study Management and Non-clinician orders & Documentation courses
- CITI training provides information on the evolution of the need for coverage analysis and includes sample scenarios in the questions.
  - Recommended for anyone performing the coverage analysis or negotiating budgets

Research Administration: OnCore, CRMS Records and BCA Documentation

Register via Hospital's LMS system

.....

Upcoming dates:

Apr 20

May 18

Jun 15

RESEARCH CENTRAL

https://irbis.research.unc.edu/crms/researchcentral/

Quick References:

For New Staff:

- Confidentiality Statement
- University Employee/Student Epic Access Request Form
- Registering for Research Training
- Request a Provider (SER) Record for RCs
- Research Administration
  - Research Administration Handout
  - CRMS & BCA Training
  - OnCore Training Slides

Coverage Analysis Assistance

- Schedule a Zoom meeting for one-on-one help
- Call or email OCT for help anytime!
  - BCA: Andrea Eiring aneiring@email.unc.edu 919-962-5865
  - CRMS: crms@unc.edu

New BCA Policy

FAQs in session handout

Be on the Lookout for a TOWN HALL

April 20, 2021

12:30-1:30 pm

Questions?

If you have further questions, please email me at

aneiring@email.unc.edu

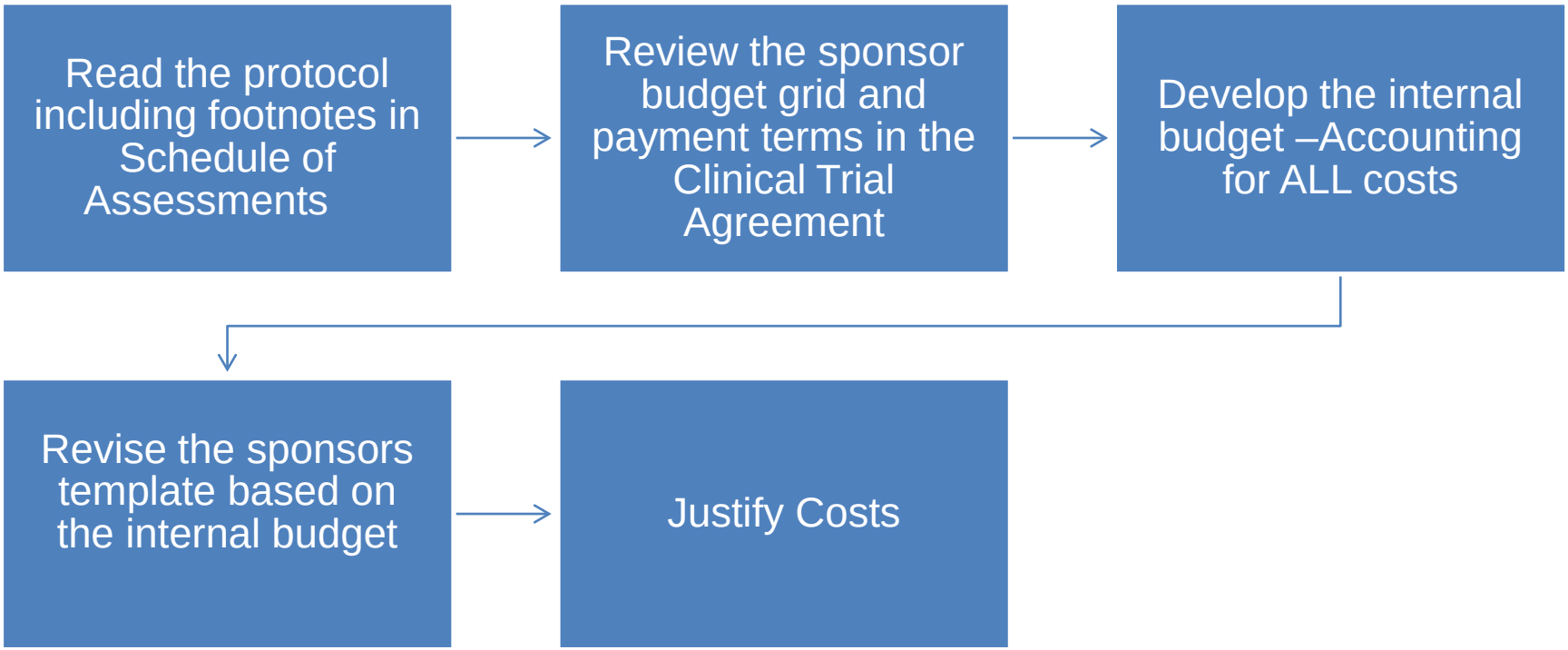
BUDGETING AND ACCOUNTING OF RESEARCH FUNDS

Jillyan Cunnup

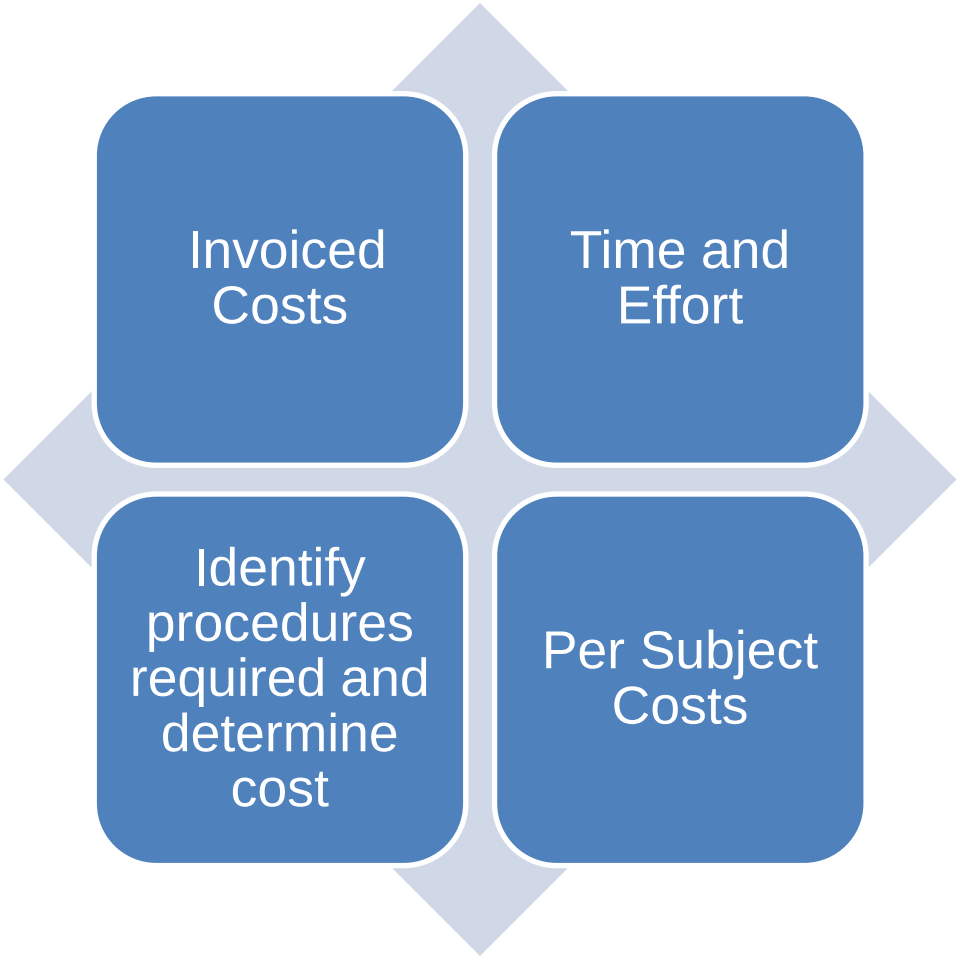
Administrator, Division of Endocrinology

The Financial Struggle

Budget Development Process



Industry Sponsored Budget Components



Facilities and Administration (F&A) Cost Rates

Activity	On-Campus	Off-Campus* (Adjacent) (10-mile radius)	Off-Campus* (Remote)
Organized Research	55.50%	28.00%	26.00%
Instruction	50.00%	28.00%	26.00%
Other Sponsored Activities	36.00%	28.00%	26.00%
Clinical Trials (Federal)**	55.50%	28.00%	26.00%
Clinical Trials (Non-Federal)***	28.00%	28.00%	26.00%

Billing Compliance and IRB Review Fees Invoiced by the Office of Clinical Trials

	Industry-Funded Studies using a Central IRB	Industry-Funded Studies using UNC's IRB
Initial IRB Review Fee	N/A	$3,000
Initial Preparation Fee	$1,000	Included in above
IRB Renewal Fee	N/A	$750

IRB Fees (not subject to F&A) *IRB fees invoiced by the Office of Clinical Trials.*

IRB review fees shall be incurred upon IRB review, even if a study contract has not yet been executed. The IRB review fees are assessments for a portion of the real costs associated with protocol review and related study requirements by the IRB. The actual costs of the review process are still incurred if subjects are never enrolled, if the study terminates before milestones are met, if expenditures exceed revenue, or if a contract is never finalized. The invoice is therefore due and payable upon receipt. *The investigator and/or department will be responsible for all costs not covered by the sponsor, specifically including the IRB (and BCA) review fees*

Billing Compliance Fees

- **Billing Compliance (for conduct of BCA) fee** (not subject to F&A)
  BCA fees invoiced by the Office of Clinical Trials

- **A fee of $2,000 will be charged to the sponsor as a Billing Compliance Fee** to cover the cost of conducting a BCA, and should be included in budgets submitted to the sponsor as of March 1, 2014. This fee is incurred upon conduct of the BCA, even if a study contract has not yet been executed.
- The purpose of the BCA is to determine deemed and qualifying status as well as which routine care costs may be billed to Medicare or other insurers and which costs must be paid by the sponsor. The Billing Coverage Analysis is required to be performed prior to the initiation of the clinical trial to ensure proper billing of services and financial feasibility.

Clinical Trial Agreement (CTA)

- Start up and Advance payment
  - When and How much?
- Payment Cycle
  - How often will they pay?
- Withholding %
  - How much are they going to hold back?
- Length of Storage
  - 10-20-30 years?
- Final Payment
  - Timing of Payment?

Initial & Ongoing Payment

- The Initial Payment- paid upon receipt and Sponsor acceptance of:
- (a) Initial IRB approval letter/notice;
- (b) Receipt of activation letter by Sponsor.

- Sponsor will pay Site for completed Subject visits in accordance with Section 3.E – Per Patient Costs. A completed visit or milestone includes the proper completion of all protocol activities and delivery to Sponsor of complete and accurate CRF data for that visit.

- The total amount of each payment will be determined by data entered into the Electronic Data Capture system (EDC). Payments are processed on a monthly basis, provided ten percent (10%) of each payment will be retained to be paid in accordance with the Final Payment as outlined.

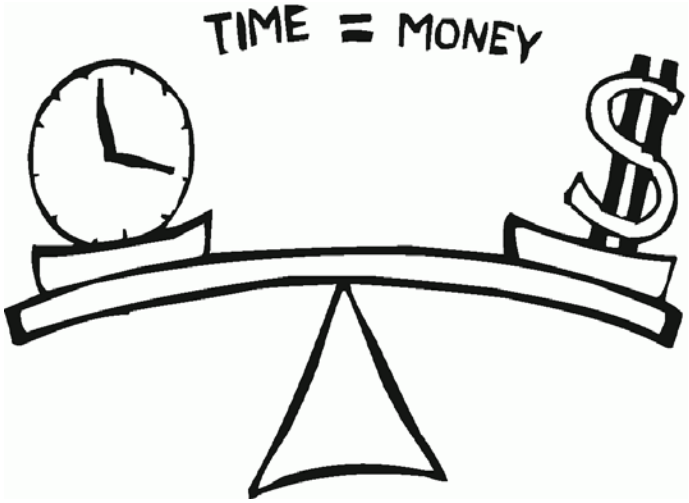
Final Payment

- The payments administrator shall reconcile and reimburse the Institution or other appropriate payee the balance of any retained monies and any remaining amounts upon:
  - Verification of completed subject visits;
  - Final acceptance by Sponsor of all CRF/eCRF pages;
  - Resolution of all data clarifications issued; and satisfaction of all other applicable conditions set forth in this Appendix and the Master Agreement related to this site only.

Per Subject Budget

Coordinator Costs

- Estimating Coordinator time
  - Informed Consent (estimated 3 hours)
  - Subject Recruitment & Pre-Screening
  - Scheduling
  - Inclusion/Exclusion Criteria & Medical History
  - Questionnaires
  - Assessments
  - Review of Labs
  - ECRFs (estimate for 1 hour spent with subject 1.5 hours of paperwork)
  - Regulatory Paperwork
  - Monitor Visits
    - What is the monitoring schedule
    - Remote monitoring still takes time (MAYBE EVEN MORE)



Remember: It always takes longer than you expect

Per Subject Budget

Coordinator Costs- Percent Effort

- Percent Effort must be allocated to visits and number of subjects
- Percent Effort Calculation
  - Salary + Benefits (estimated 35%)
- Be realistic on the number of anticipated subjects
  - If you base the calculation on more subjects then are actually enrolled then the study will likely end in a loss

Per Subject Budget

Physician Costs

- Estimating PI Time
  - Informed Consent
  - Physical Exams
    - Can be part of study or billed as 9920X
  - Review of Labs
  - Review of SAE's
  - Exams
  - Monitor Visits
  - Patient phone calls

Per Subject Budget

Procedure & Lab Costs

- CPT Codes
  - Account for both the technical fee and the professional fee
  - Take into account the location of the procedure
- Central Labs
  - Who will be processing/shipping samples
  - Include estimated staff time to collect/process/ship
- Local Lab
  - Price of lab and lab draw
  - CPT Code
  - Verify “panel’ labs are the same at your site

Per Subject Budget

Patient Stipend

- Is there a subject stipend? How much
  - Confirm amount matched informed consent
  - Is the amount offered acceptable for the ask
- Who is paying?
  - Direct pay from sponsor (preferred)
  - Gift Cards from sponsor
  - Gift Card/Check/ Cash from study site

**If site is paying make sure that indirect have been added to the budget.

Start Up Fee

- Regulatory
  - Interface with Study Team, Sponsor, CRO and IRB of record
  - Manage IRB submission including follow-up comments and or questions arising during approval process
  - Complete all FDA & Sponsor-required documents (1572s, FDFs, CVs,)
  - Create and Maintain regulatory binder
- Financial
  - Coordinate charges between all procedural departments
  - Gather budget costs and finalize an approved budget
  - Handle contract paperwork
- Study Coordination
  - Attend all required protocol training and investigator meetings
  - Assure all staff working on the study are trained
  - Prepare source documents
  - Organize SIV

Invoiced Items

- Start Up Fee
- Advertising
- Document Storage
- Rent
- Screen Fails
- Adverse Events
- FDA/Sponsor Audits
- IRB/BCA Fee
- IRB Renewal
- IDS
- Dry Ice
- Protocol Amendment
- Monitoring Visit
- Pharmacy
- Annual maintenance fee

Internal budget- What and Why?

- The internal budget is used to show a more specific detail of the external budget you have negotiated .

- **What**
  - Show the % of effort that you will be paying the study staff
  - Show the amount you will be paying for research labs and procedures
  - Show the amount paid to study subjects
  - Details about supplies needed.
  - Invoice costs

- **Why**
  - To ensure the funds are used appropriately
  - To provide an additional level of comfort in knowing costs are covered
  - Can be useful in reconciling the account especially to a business manager

Sample Budget

Initial Budget

Visit Schedule	Payment Per Patient Per Visit Completed
Visit 1 (Screening)	$1,372.00
Visit 2* (Randomization)	$1,139.67
Visit 3 – Phone visit	$245.25
Visit 4	$600.50
Visit 5 – Phone visit	$245.25
Visit 6	$729.17
Visit 7 – Phone visit	$245.25
Visit 8	$679.50
Visit 9 – Phone visit	$245.25
Visit 10	$649.17
Visit 11 – Phone visit	$215.25
Visit 12*	$901.17
Visit 13 – Phone visit	$310.75
Visit 14	$640.50
Visit 15 – Phone visit	$290.25
Visit 16	$698.17
Visit 17 – Phone visit	$290.25
Visit 18	$640.50
Visit 19 – Phone visit	$290.25
Visit 20	$1,028.17
Visit 21 – Phone visit	$315.25
Visit 22	$530.50
Visit 23 – Phone visit	$290.25
Visit 24* (EOT)	$1,424.67
Visit 25 (Follow-up)	$471.00
Per Patient Cost (inclusive of site overhead cost)	**$14,487.94**
Patients to be Enrolled/Randomized	7
PATIENT COSTS @ EXPECTED ENROLLMENT/RANDOMIZATION	**$101,415.58**

Final Budget

Visit Schedule	Payment Per Patient Per Visit Completed
Visit 1 (Screening)	$1,783.60
Visit 2* (Randomization)	$1,481.57
Visit 3 – Phone visit	$318.83
Visit 4	$780.65
Visit 5 – Phone visit	$318.83
Visit 6	$947.92
Visit 7 – Phone visit	$318.83
Visit 8	$883.35
Visit 9 – Phone visit	$318.83
Visit 10	$843.92
Visit 11 – Phone visit	$279.83
Visit 12*	$1,171.52
Visit 13 – Phone visit	$403.98
Visit 14	$832.65
Visit 15 – Phone visit	$377.33
Visit 16	$907.62
Visit 17 – Phone visit	$377.33
Visit 18	$832.65
Visit 19 – Phone visit	$377.33
Visit 20	$1,336.62
Visit 21 – Phone visit	$409.83
Visit 22	$689.65
Visit 23 – Phone visit	$377.33
Visit 24* (EOT)	$1,852.07
Visit 25 (Follow-up)	$612.30
Per Patient Cost (inclusive of site overhead cost)	**$18,834.37**
Patients to be Enrolled/Randomized	7
PATIENT COSTS @ EXPECTED ENROLLMENT/RANDOMIZATION	**$131,840.59**

Sample Invoiced Cost

Initial Budget

Initial Costs	***Amount***
Administrative Start Up Fee (Non-refundable)	$1,500.00
Total Initial Costs	***$1,500.00***
Site Costs	***Amount***
IRB Costs	Upon Invoice; See Section 3.C - IRB; payable upon receipt of proper documentation and approval of the appropriate Sponsor Trial Manager.
Advertising/Recruitment Costs: Sponsor agrees to reimburse Institution for Study-related advertisement and recruitment-related expenses if pre-approved by Sponsor in writing and, upon presentation of invoices and supporting documentation which may include IRB approval.	Up to $2,000.00; Institution may be eligible for additional reimbursement of advertising/recruitment expenses beyond the initial allotment of funds, if prior approval of advertisement plans/scope of work is obtained in writing from the appropriate Trial Manager before the spend occurs. Upon Invoice
SAEs and AEs requiring additional data collection (**NON-ADJUDICATED EVENTS**). Sponsor agrees to reimburse Institution for all Adverse Events of Special Interest requiring additional data collection (AESIs), Serious Adverse Events (SAEs).	$125.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each AESI/SAE event upon the Institution's completion of all follow-up information and Sponsor's acceptance of the documentation; Upon Invoice
SAEs & AEs requiring additional data collection (**ADJUDICATED EVENTS**). Sponsor agrees to reimburse Institution for all events requiring adjudication.	$150.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each adjudicated event upon the Institution's completion of all follow-up information and Sponsor's acceptance of the documentation; Upon Invoice
Unscheduled Visit - Reasonable and medically necessary Unscheduled visits (conducted onsite)	Up to $240.00 for reasonable and medically necessary unscheduled onsite visits; payable upon receipt of proper invoice and supporting documentation (source document and/or progress note of visit required to be submitted with invoice) as confirmation of work performed and subject to review and approval of the appropriate Sponsor Trial Manager. Upon Invoice
General Pass Through Expense	Up to $2,500.00; At normal/usual/customary reimbursement rates and receipt of proper documentation as confirmation of work performed. Upon Invoice

Final Budget

Initial Costs	***Amount***
Administrative Start Up Fee (Non-refundable)	$4,000.00
Pharmacy Start Up Fee (Non-refundable)	$1,000.00
Total Initial Costs	***$5,000.00***
Site Costs	***Amount***
IRB Costs	Upon Invoice; See Section 3.C - IRB; payable upon receipt of proper documentation and approval of the appropriate Sponsor Trial Manager.
Advertising/Recruitment Costs: Sponsor agrees to reimburse Institution for Study-related advertisement and recruitment-related expenses if pre-approved by Sponsor in writing and, upon presentation of invoices and supporting documentation which may include IRB approval.	Up to $2,000.00; Institution may be eligible for additional reimbursement of advertising/recruitment expenses beyond the initial allotment of funds, if prior approval of advertisement plans/scope of work is obtained in writing from the appropriate Trial Manager before the spend occurs. Upon Invoice
SAEs and AEs requiring additional data collection (**NON-ADJUDICATED EVENTS**). Sponsor agrees to reimburse Institution for all Adverse Events of Special Interest requiring additional data collection (AESIs), Serious Adverse Events (SAEs).	$175.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each AESI/SAE event upon the Institution's completion of all follow-up information and Sponsor's acceptance of the documentation; Upon Invoice
SAEs & AEs requiring additional data collection (**ADJUDICATED EVENTS**). Sponsor agrees to reimburse Institution for all events requiring adjudication.	$200.00 per reportable event. Payable upon verification of appropriate event recording and receipt of proper documentation. Payment will be issued for each adjudicated event upon the Institution's completion of all follow-up information and Sponsor's acceptance of the documentation; Upon Invoice
Unscheduled Visit - Reasonable and medically necessary Unscheduled visits (conducted onsite)	Up to $240.00 for reasonable and medically necessary unscheduled onsite visits; payable upon receipt of proper invoice and supporting documentation (source document and/or progress note of visit required to be submitted with invoice) as confirmation of work performed and subject to review and approval of the appropriate Sponsor Trial Manager. Upon Invoice
Re-Consenting Fee (per Consent)	$75.00; Upon invoice; payable upon receipt of proper documentation and approval of the appropriate Sponsor Trial Manager.
General Pass Through Expense	Up to $2,500.00; At normal/usual/customary reimbursement rates and receipt of proper documentation as confirmation of work performed. Upon Invoice


Wow this is a great budget they gave us. So much more money than we need.
Said no one ever.
someecards
user card

Accounting of Research Funds

- The tracking of research funds can make or break a research project. This is often done by various people in the department but is crucial to success

Visits

Payment

Expenses

Visit Tracking

- Industry Sponsored Trials
  - Log of completed, skipped or incomplete visits
  - Track when data entry is completed per visit
  - Keep a log of each visit completed by the subject and make note if certain parts of the visit were not completed or if a visit was skipped.
  - Track when subjects are re-consented.
  - Track Early- Terminations

Visit Log

Subject Name

Date of Birth

Subject	Subject Number	Visit Date	Visit #	Phone Visit #	Unscheduled Visit	CRF Complete	MESI/SAE	Subject Withdrawn	Research Labs Drawn?	
TAB	502-003	3/24/2017	Screening			x			yes	
TAB	502-003	4/12/2017	Randomization			x			yes	
TAB	502-003	4/24/2017		3		x			no	
TAB	502-003	5/8/2017	4			x			yes	consented to new ICF
TAB	502-003	6/7/2017	5			x			no	
TAB	502-003									
TAB	502-003									
TAB	502-003									
TAB	502-003									
TAB	502-003									
TAB	502-003									
TAB	502-003									
TAB	502-003									

Patient Data Invoicing- Why and How?

- Why should we invoice?
  - To ensure ACCURATE payment of completed work.
  - To ensure TIMELY payment of completed work
  - To ensure QUALITY reconciliation can occur

- How do we invoice?
  - Send invoice to the sponsor with visit data
  - Send invoice to managers with visit data

Payment and Expenses

- Checks
  - Ensure checks are sent in a timely manner based upon contract
  - Always verify that the amount of money received matched the amount of work completed.

- Expenses
  - Track procedure, patient payments, salary, supplies as well as other study related costs.

Closing of Account

- All money received?
  - Make sure all visits, invoiced items,
  - Always verify that the amount of money received matched the amount of work completed as well as the amount on the contract.

- Expenses
  - Verify IRB, IDS and other University expense have been paid. Often with UNC bills are delayed and it is your responsibility to check this before closing a study.

- Residual Funds
  - If you have money leftover you will be allowed to transfer the funds into a residual. Residual accounts are managed at the Department/Division level. You will need to be aware of what the policy is on spending and accountability. Federal funded grants will require written communication and approval from the NIH for carryover or no-cost extensions.

Financial Compliance

Effort Certification and Reporting Technology

- Effort is the portion of time spent on a given professional activity and expressed as a percentage of the total 100% professional activity for which an individual is employed by UNC.

- **Important points:**
  - The government recognized that it is a “reasonable estimate”
  - Total effort must equal 100%
  - Effort is not based on a standard (e.g 40-hour) work week, instead based on whatever was worked
  - 100% effort considers all professional activities related to the individual UNC appointment.
  - Effort does not include outside activities (external consulting etc)

- **Certifying Effort**
  - Effort is certified on a regular basis via ecrt.unc.edu
  - All employees paid from sponsored activities are required to certify the effort spent
  - Effort is calculated based on the information in the payroll system
  - The investigational item or service itself, unless otherwise covered outside the clinical trial

PREPARING & EXECUTING NIH GRANT BUDGETS FOR CLINICAL RESEARCH STUDIES

Cassandra J. Barnhart, MPH

Manager of Research Administration, Ophthalmology

Pre-Award Specialist, UNC Institute for Global Health and Infectious Disease

UNC THE NORTH CAROLINA TRANSLATIONAL & CLINICAL SCIENCES INSTITUTE

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL NRP Network for Research Professionals

UNC OFFICE OF CLINICAL TRIALS

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

Activity	UNC Facility	Non-UNC Facility (10-mile radius)	Non-UNC Facility (Remote)
Organized Research	55.50%	28.00%	26.00%
Instruction	50.00%	28.00%	26.00%
Other Sponsored Activities	36.00%	28.00%	26.00%
Clinical Trials (Federal)*	**55.50%**	28.00%	26.00%
Clinical Trials (Non-Federal)**	**28.00%**	28.00%	26.00%

Federal vs. Industry: Salaries

Industry Sponsors

- No salary cap
- Generally no direct salary support (paid on a per-visit basis)
- Estimated hourly wage

Federal Funding

- NIH salary cap of $199,300 (effective 1/3/21)
- FTE for research staff allowed (within reason)
- Estimated “Calendar Months (CM)”

Getting Started: Where to Begin?

- Cayuse 424 (https://unc.cayuse424.com/)
  - 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 $199,300 (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 (30.796% plus medical insurance stipend of $8515.16)
    - If basic researcher, use general rate of 25.889% plus medical insurance stipend of $6,512 (ask HR if unsure)
  - Coordinator
    - Fringe benefit rate is 25.889% plus medical insurance stipend of $6,512
  - Grad Student Research Assistant
    - Fringe benefit rate is 9.49% plus medical insurance stipend of $4,137.60
    - Tuition must also be covered, prorated to effort
  - Pre-escalate Y1 up to 5% to plan for future salary increases (annual increases now discouraged)

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 Allocable?
  - Allocable costs are those that directly benefit the project. If a cost can be shared by more than one project, it must be charged based on proportions that can be approximated, using reasonable methods, with a high degree of accuracy.

- Is it Reasonable and Necessary?
  - Costs that reflect what a prudent person would pay.

NIH Cost Principles
(NIH Grants Policy Section 7.2)

- Is it Consistent?
  - Costs must be consistently assigned to the same categories for similar actions regardless of the source of funding.

- Is it allowable?
  - Costs must be allowable under the terms and conditions of the award agreement and meet all Federal and University regulations.

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
- ClinicalTrials.gov
  - Registration and Results Reporting
- 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)

- ADP/Computer Fees – required if Biostats personnel are on the budget: Current rates are $6170/fte for faculty and staff and $3085/fte for students. Rates apply to each user and are charged based upon each person's salary distribution. Co-Investigator, __(enter faculty name)_____, __(X)__% effort of $6,170 = $_(XXX)____ annual.

  (email Monika Caruso at mcaruso@bios.unc.edu for current rates)

- 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

OMB Number: 4040-0001
Expiration Date: 6/30/2016

ORGANIZATIONAL DUNS: Enter name of Organization:

Budget Type: ☐ Project ☐ Subaward/Consortium Budget Period: 1 Start Date: End Date:

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)

Project Role: PD/PI

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

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

Total Senior/Key Person

B. Other Personnel

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

Total 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

Equipment item	Funds Requested ($)

Additional Equipment: [ ] Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	Total Participant/Trainee Support Costs

NIH Internal Budget Forms (Initial Period)

F. Other Direct Costs — Funds Requested ($)

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
8.
9.
10.

Total Other Direct Costs

G. Direct Costs — Funds Requested ($)

Total Direct Costs (A thru F)

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)

Total Indirect Costs

Cognizant Federal Agency (Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs — Funds Requested ($)

Total Direct and Indirect Institutional Costs (G + H)

J. Fee — Funds Requested ($)

K. Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

NIH Internal Budget Forms (Initial Period)

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section 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		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		

Indirect Costs

- Current Rate is 55.5% (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

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 = $19,930
    - **Department cost share = $70**

- IDS Pharmacy Costs
  - NIH considers this "overhead", and the costs have to come out study's bottom line.

  There is some good news; however: IRB and Billing Coverage Analysis fees do not apply to federal research projects

Internal Processing

- Proposal created in Cayuse
- Electronic Internal Processing Form (eIPF) entered into Ramses
  - Includes personnel (role and effort), research subjects, research materials, subcontract (as applicable), detailed budget, budget justification, export control, intellectual property, community engagement, research locations, and project abstract
  - Attachments required include internal budget and justification (budget totals must match Cayuse)
  - This is required for both federal AND industry budgets
- OSR or Sponsored Programs will review proposal and IPF to make sure all required elements are present
- OSR or Sponsored Programs Submits to Grants.gov

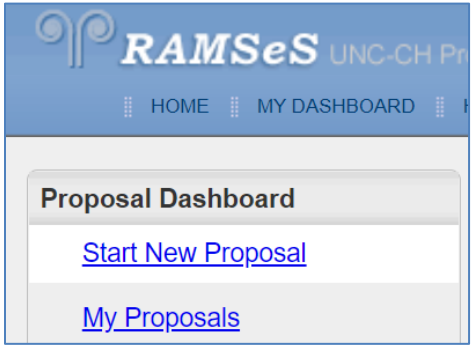
Internal Processing

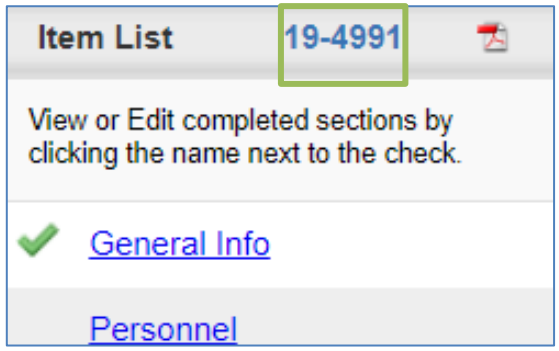
- Electronic Internal Processing Form (eIPF) entered into RAMSeS
  - Includes personnel (role and effort), research subjects, research materials, subcontract (as applicable), detailed budget, budget justification, export control, intellectual property, community engagement, research locations, and project abstract
  - Attachments required = internal budget & justification (totals must match Cayuse)
    - *This is required for both federal AND industry budgets*
- Office of Sponsored Research (OSR) or Sponsored Programs Office (SPO) review proposal and IPF to make sure all required elements are present
- OSR or SPO Submits to Grants.gov (or applicable sponsor portal)

Initiating an IPF - Overview

1. Login to RAMSeS- https://ramses.research.unc.edu/ramses/
2. From the Proposal Dashboard click "Start New Proposal"
3. Once the "General Info" screen has been completed and saved, the IPF number is generated by RAMSeS, along with a list of IPF screens

   FYI **The IPF number consists of the 2-digit Fiscal Year followed by 4 digits. IPF numbers are assigned in numeric order beginning on July 1st of the given fiscal year), e.g., the first IPF created in FY19 would be 19-4991, etc.*
4. Complete the IPF "General Info" screen
5. Click down the Item List and complete each IPF Screen





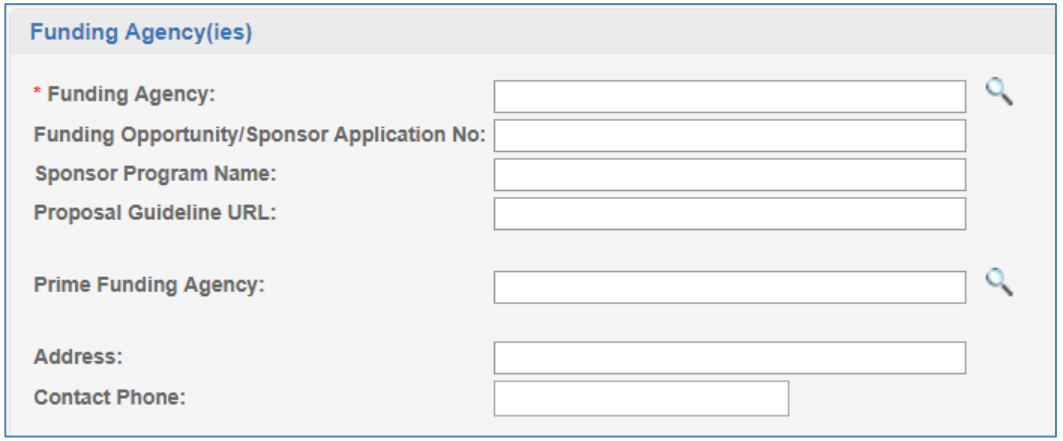
IMPORTANT! IPFs must be received in OSR/SPO/OCT at least five (5) business days prior to the application deadline. Please allow ample time for preparation, submission, and routing of the IPF to accommodate this requirement.

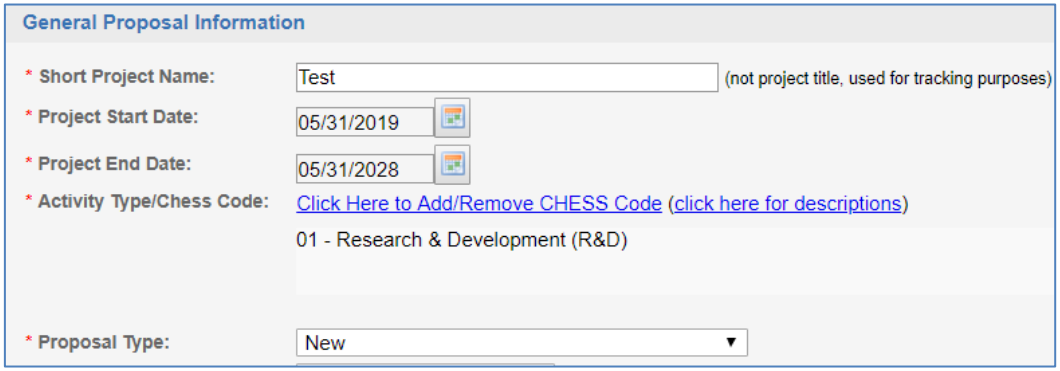
RAMSES IPF

General Info

→ Always indicate both the Funding Agency and the Prime Funding Agency (where applicable)
→ Indicate appropriate Proposal Type - New, Supplement, Non-Competing Continuation/Progress Report, Resubmission or Amendment, Renewal (competitive), Revision (competitive) or Recurring Contract

The "Primary Award Contact" (required field) is the individual designated to work with OSR on award setup at the time the proposal is funded



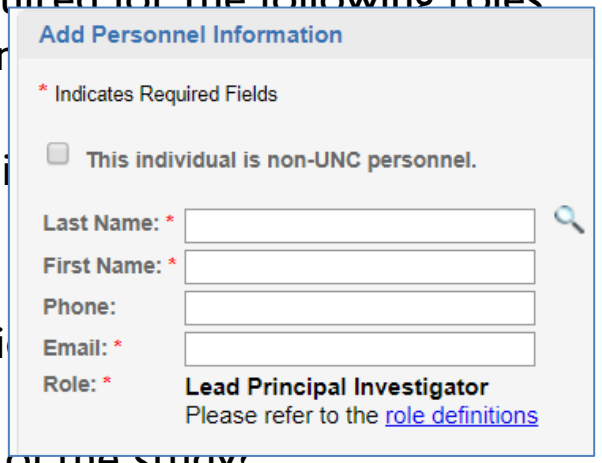


RAMSES IPF

Personnel

UNC personnel

→ completion of a COI disclosure and COI Training is required for the following roles: Lead PI, PI, Investigator, Postdoctoral Research Associate, ar
Coordinator
→ COI Training is required for all other roles, except Admi



Non-UNC Personnel

→ When adding non-UNC personnel, checking "This indivi
non-UNC personnel" triggers these questions:

☐ Does this person substantially contribute to the design of the study?
☐ Is this person conducting any experiments or activities?
☐ Is this person directly involved in/or have control over collection of data?
☐ Is this person involved in the analysis of the data?

→ Independent Contractors with any "Yes" responses are automatically assigned the role of "Independent Contractor (Investigator)" and will be required to complete a UNC-CH COI disclosure and UNC-Chapel Hill COI Training.

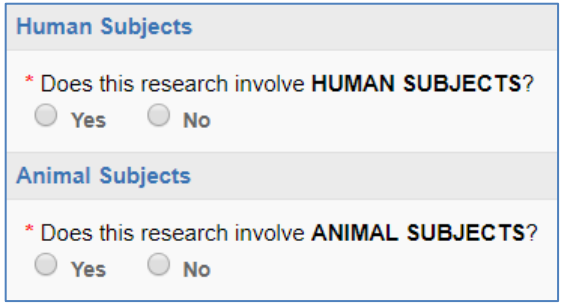
RAMSES IPF

Preparing IPF for Submission

3. "Research Subjects"

→ Indicate whether or not human/animal subjects involved with research.

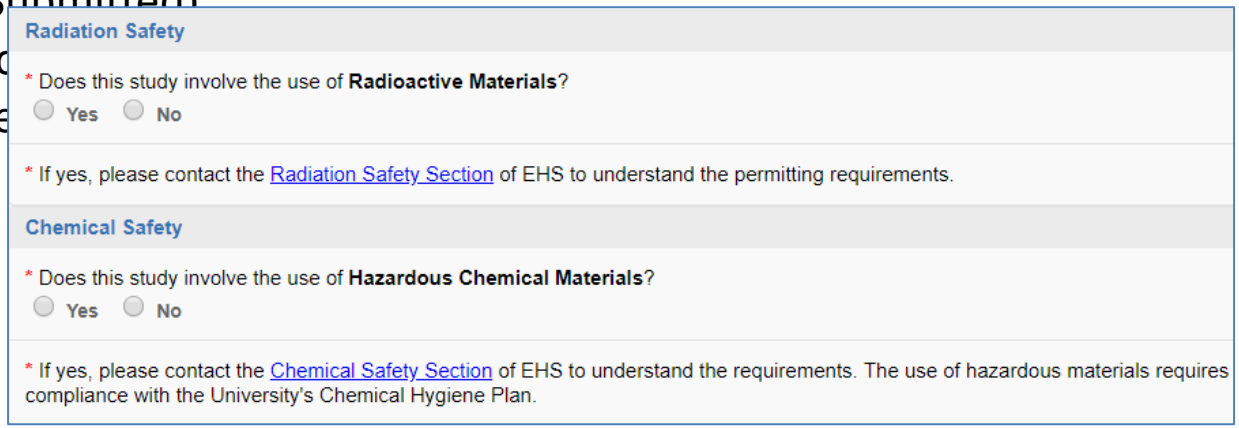
→ Indicate if human/animal research is being conducted at UNC-Chapel Hill – if yes, indicate IRB or IACUC protocol, or the reason the protocol has not yet been submitted for approval (JIT or Not Yet Submitted)



4. "Research Materials"

→ Indicate whether or no
research will be conducte

→ Indicate whether or not the study involves radioactive, hazardous chemical and/or biological research materials. "Yes" responses trigger additional questions to be answered.



RAMSES IPF

Subcontractors

→ When adding a proposed subcontractor, search for/enter the subcontractor name, indicate whether the subcontract will involve human and/or animal subjects, and indicate what (if any) research materials will be involved in the proposed subcontractor's scope of work.

→ If animal research is to be performed by the subcontractor, indicate (1) whether the subcontractor is a domestic or foreign institution, (2) if it is a subcontract, fee-for-service, or collaborating site, and (3) the animal species to be used.
For animal research performed at institutions other than UNC-Chapel Hill, for each ins

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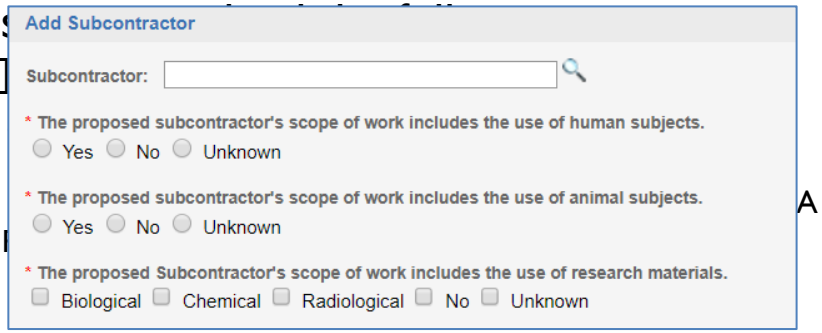


IMPORTANT: If the IPF is not subject to JIT, it is required to attach all of the above documentation at the time of the IPF submission.

→ For each subcontractor, the following must be attached via the IPF "Attachments" IPF screen:

☐ Statement of Work
☐ Budget Justification
☐ Letter of Intent (signed by an authorized official of the proposed

RAMSES IPF

Subcontractors

DHHS/NSF Sponsors only

When a DHHS or NSF sponsor has been indicated as either the Funding Agency or the Prime Funding Agency via the "General Info" IPF screen and a subcontractor is being added, an additional Yes/No response must be provided for each proposed subcontractor: "The proposed subcontractor has a Conflict of Interest (COI) policy that complies with Department of Health and Human Services (DHHS) or National Science Foundation (NSF) standards, as applicable to this sub-award."

IMPORTANT! It is recommended that the IPF Creator check with proposed subcontractors to verify that its conflict of interest policy is CFR-compliant. The following website is available to verify if the institution has reported that they are in compliance: http://sites.nationalacademies.org/PGA/fdp/PGA_070596. ***Delays may occur in the processing of an IPF if a CFR-compliant policy is not in place and/or cannot be verified.***

"Subcontractor Personnel" IPF screen (*DHHS/NSF IPFs only*)

❼ When adding a subcontractor to an IPF with a DHHS/NSF sponsor, a "No" response to the CFR-compliant COI policy question automatically triggers the addition of a "Subcontractor Personnel" screen to the IPF Item List.

RAMSES IPF

Subcontractors

→ Subcontractor personnel indicated with the following roles will be required to complete a UNC-Chapel Hill COI disclosure: PI, Investigator, Postdoctoral Research Associate, and Clinical Research Coordinator. (It is not possible for the Lead PI role to be assigned to subcontractor personnel.
→ Additional personnel added at time of award for subcontractors without a compliant COI policy will also be required to complete a UNC-Chapel Hill COI disclosure.

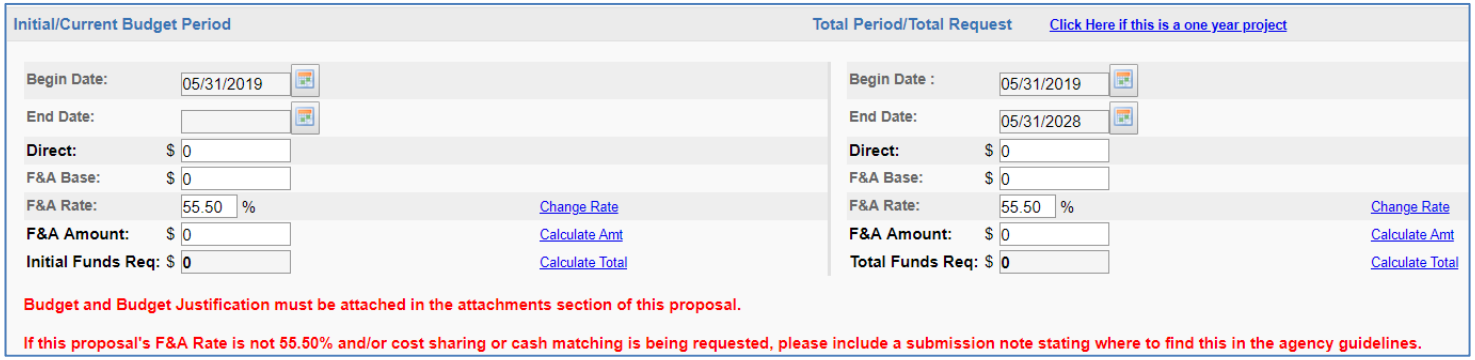
IMPORTANT! For COI disclosure and COI Training purposes, subcontractor personnel will be identified by the email address entered via the "Subcontractor Personnel" screen.

- The email address cannot be revised once it has been added and saved. The only way to revise an incorrectly added subcontractor personnel email address prior to IPF submission is to remove the individual via the Subcontractor List of Personnel, and re-add him/her with the correct email address.
- After the IPF has been submitted, subcontractor personnel added with incorrect email addresses will have to be removed and re-added by either the Proposal Specialist or the Program Administrator.

RAMSES IPF

Budget

Complete the Budget screen by entering both Initial and Total Budget Details



→ Enter Cost-Sharing/Cash-Matching information (as appropriate)

→ Personnel/Space/Equipment information (as appropriate)

→ If the IPF's F&A Rate is not 55.50% and/or cost sharing or cash matching is being requested, please include a note via "Submission Notes" IPF screen stating where to find this in the agency guidelines.

→ Budget and Budget Justification must be attached

*If "F&A Sharing" screen is triggered ONLY if Lead PI's department is different than the IPF's Admin Award department or if PIs/Investigators listed on the "Personnel" screen are from departments other than the Admin Award department. **FYI** F&A distribution indicated via the "F&A Sharing" screen represents the intention of the collaborating units to share F&A recoveries from a resulting award. It does not transfer any funds automatically - implementing F&A transfers remains the responsibility of the administering unit. If you have special circumstances, include it via "Submission Notes."*

IMPORTANT! If budget includes a reduction in F&A, an F&A waiver request (found on OSR Information Sheet) must be submitted/approved before IPF is approved.

RAMSES IPF

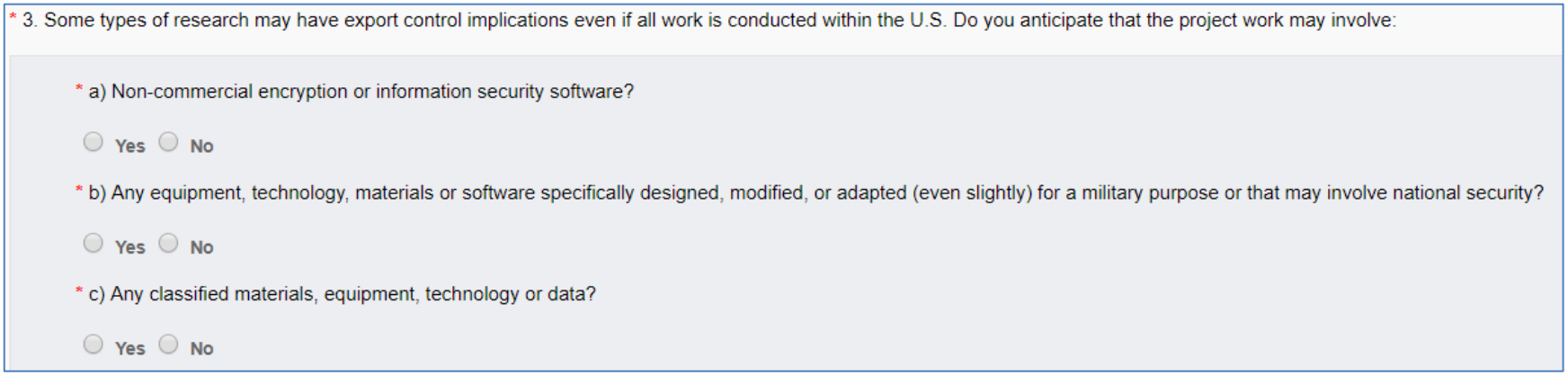
Export Control

→ Answer Export Control questions as directed

→ Questions may be directed to Judy Culhane Faubert (faubert@email.unc.edu) or visit one of the following export control websites:

☐ http://www.unc.edu/campus/Export_Control/

☐ http://www.unc.edu/depts/legal/newlinks.html

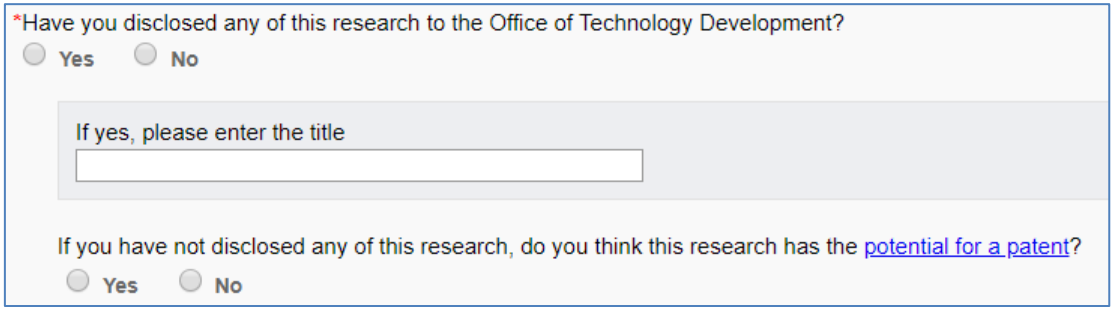


RAMSES IPF

Intellectual Property

→ Provide information re: Intellectual Property as indicated:

- ☐ research disclosed to the Office of Technology Development (OTD)
- ☐ filed or issued patents
- ☐ materials obtained from a third party under a transfer agreement granting ownership rights in inventions and/or data out of the use of the material
- ☐ Will this research use any material, patented or otherwise, which is owned by UNC-CH and licensed to a commercial entity?
- ☐ SBIR (Small Business Innovative Research Program)
- ☐ STTR (Small Business Technology Transfer Program)

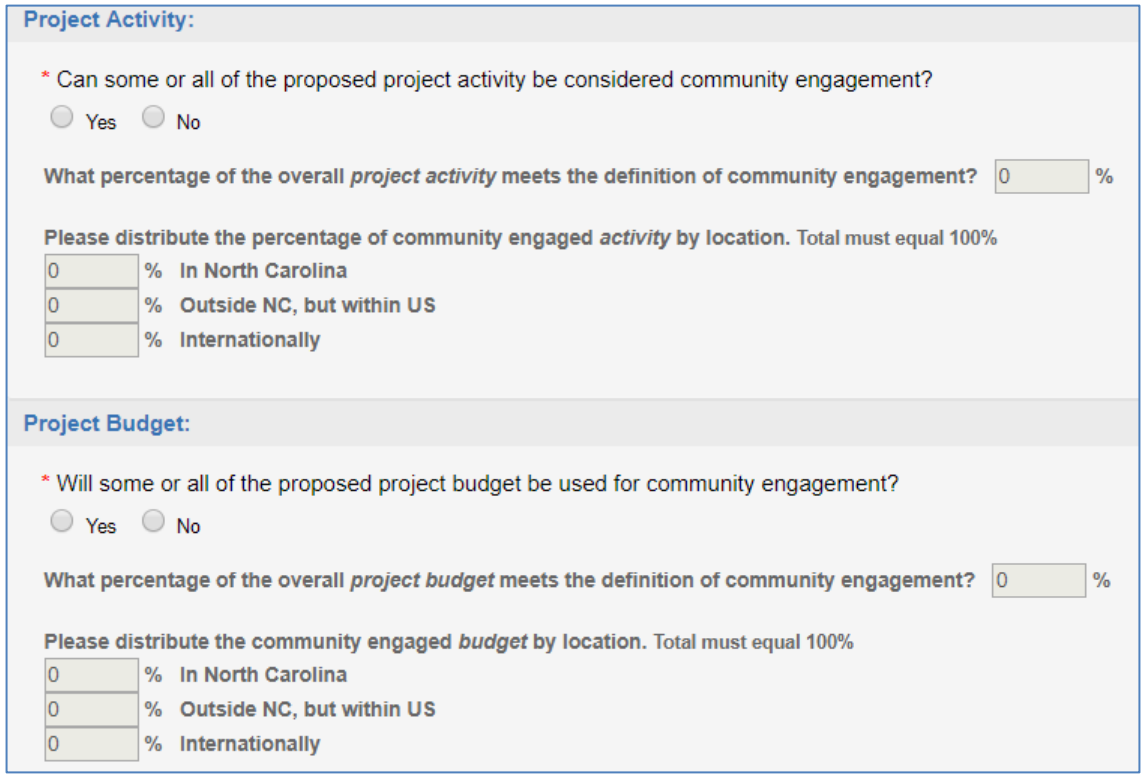


RAMSES IPF

Community Engagement

→ Indicate if some or all of the proposed project activity can be considered community engagement, and if yes, indicate what percentage, and distribution by location (in NC, outside NC but within the US, or internationally-must total 100%)

→ Indicate if some or all of the proposed project budget will be used for community engagement, and if yes, indicate what percentage, and distribution by location

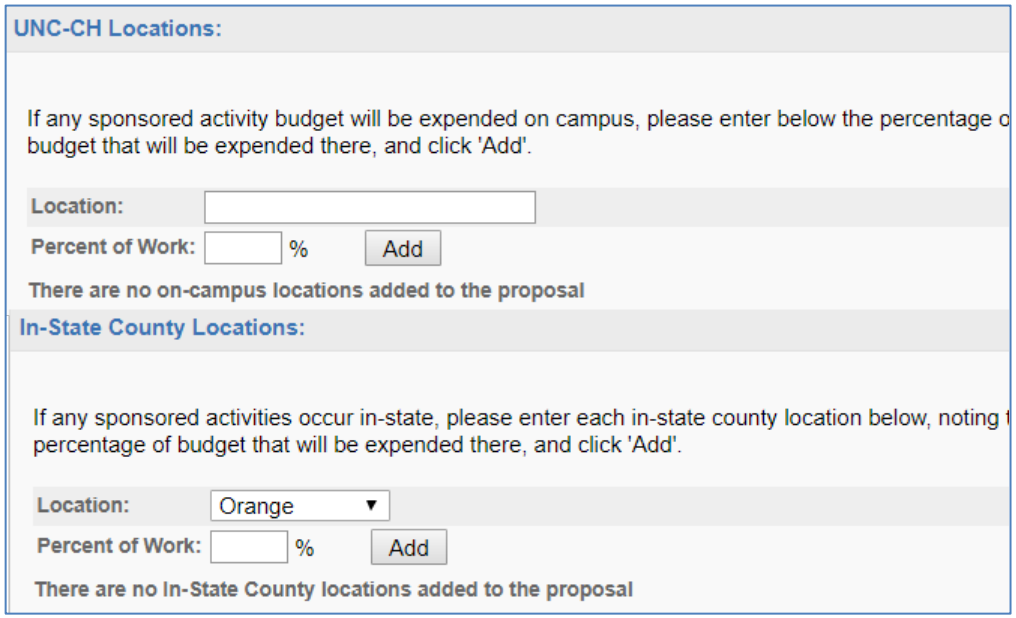


RAMSES IPF

Location of Budget Expenditures

→ Indicate the locations where the research budget will be expended (UNC-CH, In-State/County, Out-of-State and/or Internationally) and assign a percentage of the budget to be expended to each location.

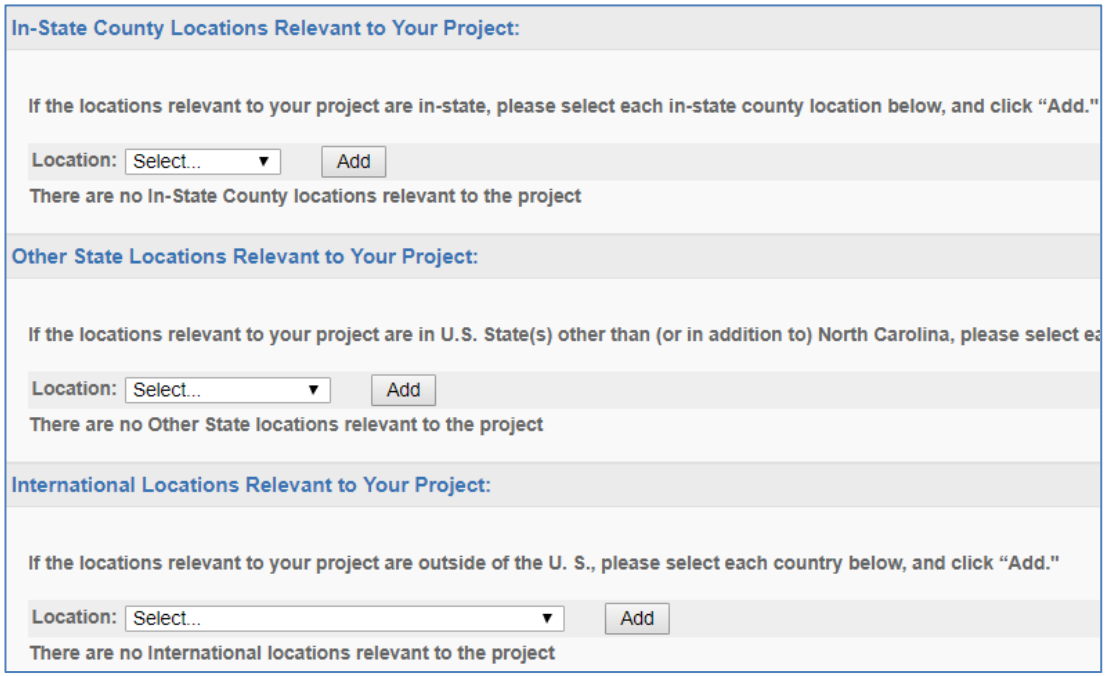
→ Percentages should reflect the portion of the total budget which would be expended in that location, and must total 100%



RAMSES IPF

Locations Relevant to Your Project

→ Many projects are associated with a particular geographic location. For example, for projects involving or affecting human or animal populations (collecting new data or analyzing existing data), these geographic locations would be where the humans or animals live. For environmental studies, these geographic locations would include the site(s) of the phenomenon under study.



→ Indicate geographic location(s) relevant to your project, ensuring that all pertinent locations are reflected.

RAMSES IPF

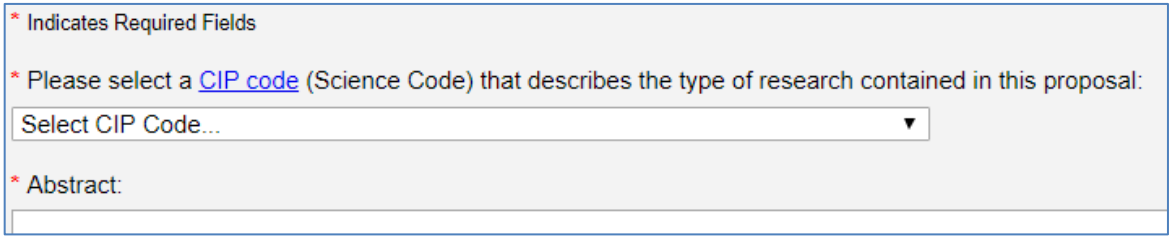
Application Abstract

→ Select a Classification of Instructional Programs (CIP) Code and enter Application Abstract. (More information is available at http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2002165

→ The abstract will be used for the UNC-CH Research Abstracts Database (RAD), a database designed to match faculty researchers with potential collaborators and funding resources and to help identify expertise and areas of research interests on the UNC-CH campus.

→ The abstract should be plainly written and in sufficient detail to summarize: (a) the purpose(s) or problem(s), (b) the hypothesis(es) or objective(s), and (c) the method(s) of the project(s).

→ All abstracts in the RAD will be available to the public, unless indicated otherwise via the "Application Abstract" IPF screen.

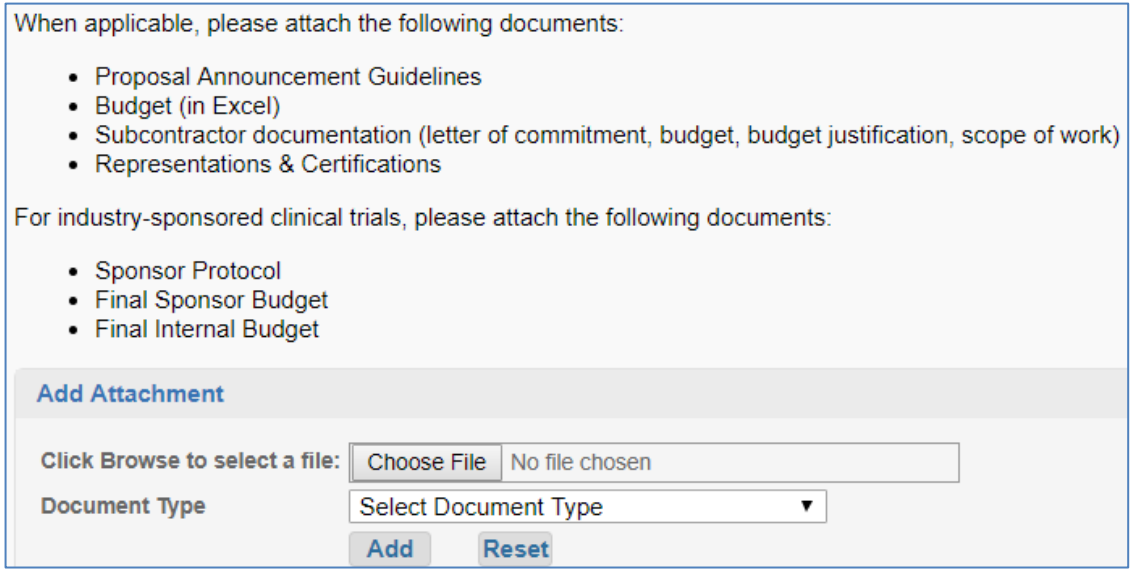


RAMSES IPF

Attachments

→ Proposal Announcement Guidelines
→ Budget (in Excel)
→ Subcontractor documentation (letter of commitment, budget, budget justification, scope of work)
→ Representations & Certifications (when applicable)
→ For industry-sponsored clinical trials, please attach the following documents:

- ☐ Sponsor Protocol
- ☐ Final Sponsor Budget
- ☐ Final Internal Budget



RAMSES IPF

Approving Departments

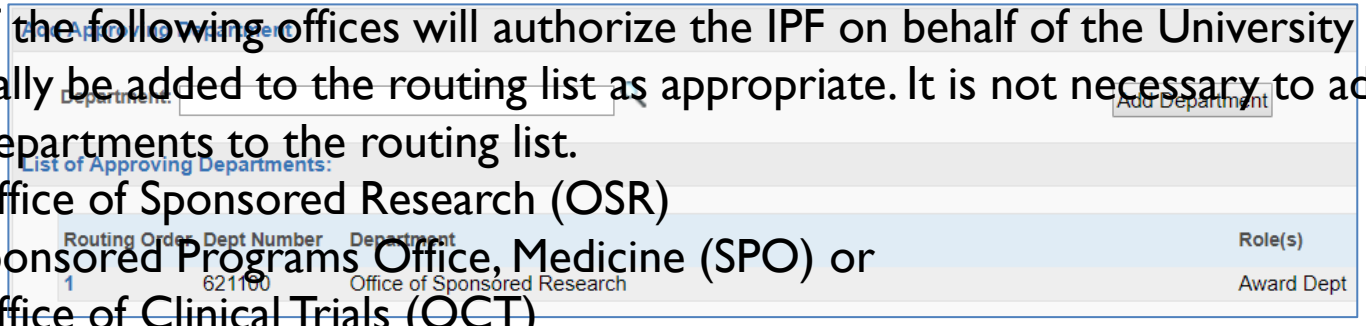
→ Departments required to review/approve the IPF are automatically added to the routing list (based on information provided on various IPF screens) and may be reviewed via the "Approving Depts" screen.

→ If desired, additional departments may be manually added to the routing list via "Add Approving Department"

→ The "Role" column (via "List of Approving Departments") indicates the reason each department has been added to the routing list, e.g., Award Dept, Lead PI, Rollup from sub-department, etc.

→ One of the following offices will authorize the IPF on behalf of the University and will automatically be added to the routing list as appropriate. It is not necessary to add one of these departments to the routing list.

- ☐ Office of Sponsored Research (OSR)
- ☐ Sponsored Programs Office, Medicine (SPO) or
- ☐ Office of Clinical Trials (OCT)



RAMSES IPF

Routing Order - Approving Departments

The Admin Award department is required to be first in the routing order and cannot be changed. Departmental routing of the IPF does not begin until the Admin Award department has signed off on IPF.

- Sequential Routing (1, 2, 3, etc.) is the default routing order – one department at a time reviews the IPF (in the order designated via the "List of Approving Departments"). Approval by the Admin Award department triggers the approval notification email to the second department on the routing list, approval by the second department on the routing list triggers an email to the third department, etc.

- Concurrent Routing – to expedite the review/approval process, the routing order for departments (other than the Admin Award department) may be designated to be reviewed/approved concurrently (at the same time). For example, indicating "2" for all departments after the Admin Award department will result in all "2" departments being notified at the same time to review/approve (upon approval by the Admin Award department). → When indicating Routing Order via "List of Approving Departments," ensure that sub-departments route ahead of their respective parent departments, and that Colleges/Schools are indicated last in the routing order.

RAMSES IPF

Submission Process

NOTE - Upon submission of the IPF, the actual routing order may vary somewhat, based on institutional routing requirements.

"Submission Notes" IPF screen

→ Add notes related to IPF screens i.e., F&A, cost sharing etc.

→ Indicate if proposal package was prepared in Cayuse

IPF Submission Confirmation / Submission

→ After completion of all screens on the IPF Item List (green check mark on each screen), the IPF may be submitted by clicking the "Submit" button located at the bottom of the IPF Item list.

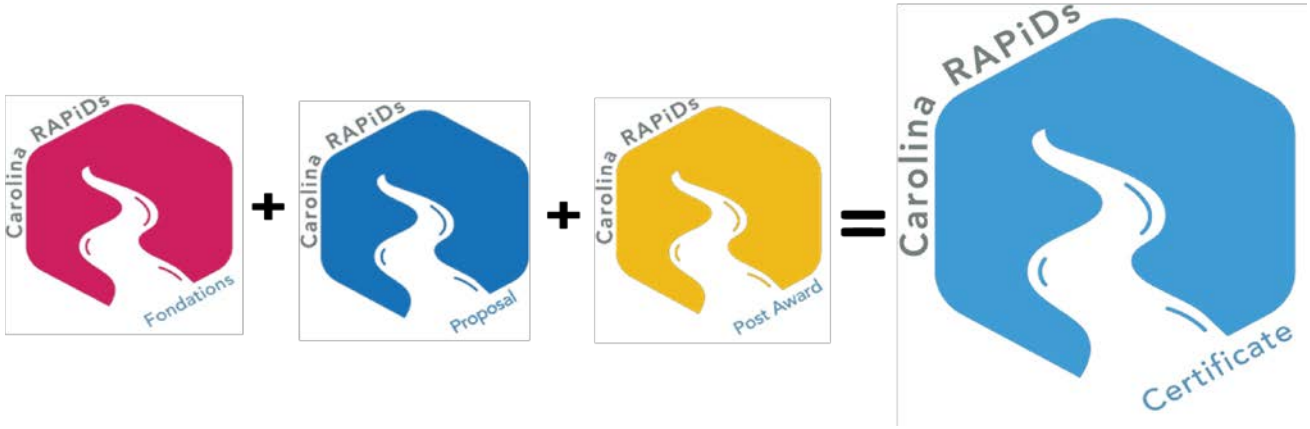
Important Resources to Remember

- OSR Toolkit: Developing a Budget
  - http://research.unc.edu/offices/sponsored-research/resources/research-toolkits/developing-submitting-proposals/data_res_osr_proposalbudget/
- OSR Information Sheet (updated fringe benefits, etc.):
  - http://research.unc.edu/offices/sponsored-research/resources/data_res_osr_infosheet/
- NIH Grants Policy Statement Section 7.2: Cost Principles:
  - http://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.2_the_cost_principles.htm
- NIH Grants Policy Statement Section 7.9: Allowability of Costs/Activities:
  - http://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.9_allowability_of_costs_activities.htm
- Ramses (Internal Processing Website)
  - https://ramses.research.unc.edu
  - https://research.unc.edu/sponsored-research/resources/faq/
- Cayuse (UNC Grant Software)
  - https://unc.cayuse424.com/305/login.do
- Sponsored Programs Office (SPO) for School of Medicine
  - https://www.med.unc.edu/spo/

Want More Training?

About RAPiDs

The Certificate in Research Certification is comprised of three initial Cores of study: the Foundations Core, Proposal Core, and Post-Award Core. Each core covers knowledge in their respective areas of research administration and after completing each core, users will earn a Certificate. Completion of these three initial Cores of study (or all three Certificates) garners the full Carolina RAPiDs Certification in Research Administration.



https://research.unc.edu/sponsored-research/train/rapids/

Any Questions?

sandy_barnhart@med.unc.edu

919-843-0076

Week 4
Evaluation Link:
https://go.unc.edu/orientwk4

OR

If you need a certificate of attendance, please email marie_rape@med.unc.edu after completing the evaluation survey.