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, NIH Public Access Policy, 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.
Visualizing COI at UNC

- External or Personal Interests
- Institutional (aka University) Duties

- 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
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
- 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
- Institutional financial management
- 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.
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General Email for questions: coi@unc.edu
Websites: air.unc.edu coi-training.unc.edu
NIH COMPLIANCE POLICIES & YOU

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

- Educational and Research Institutions: 7.01%
- Business and Industry: 5.94%
- Foundation: 5.93%
- State Government (NC): 3.87%
- Nonprofit Organization: 3.22%
- Association: 1.44%
- Others: 0.75%

Federal: 71.85%
3 Take Home Points!

1. Want NIH Funding? NIH Funded?
   Could be in jeopardy if you aren’t in compliance with NIH Policies (Biosketch & Public Access).

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

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

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

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

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

• How:
  • MyNCBI (MyBibliography) & SciENcv

<table>
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<tr>
<th>Old Format</th>
<th>New Format</th>
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<tr>
<td>4 page limit</td>
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<td>Personal Statement</td>
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<td>5 contributions to Science + 4 refs each</td>
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<td>15 selected refs</td>
<td>Up to 24 selected refs</td>
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Courtesy: David Carroll, NC TraCS
BIOPHICAL SKETCH

Provide the following information for the biographical sketch and other significant contributions. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:

skilled COMBOB LUMBER (pediatric, eg., agency name):

POSITION TITLE:

EDUCATION/TRAINING (Begin with date attended or other initial professional education, such as nursing, include postdoctorate training and residency training if applicable. Add other training as necessary):

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Commencement Date</th>
<th>FIELD OF STUDY</th>
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NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

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

B. Positions and Honors

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

C. Contribution to Science

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

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly

New page limit

Include up to four refs that highlight your experience and qualifications

NIH announced this provision in 2011 NOT-OD-11-045, but this is the first explicit mention in the biosketch

Describe up to 5 contributions to science

Include up to four refs supporting each Contribution

URL to entire bibliography

Courtesy: David Carroll, NC TraCS
The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.
NIH Public Access Policy Basics

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

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

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

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

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

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

1. Preparing a manuscript
   - Address copyright
   - show me

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

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

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

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

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

1. Preparing a Manuscript: Copyright?

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

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

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

- What is My NCBI?

  - My NCBI is a personalized account that allows you to manage your publications and track compliance
  - eRA Commons to be linked to author/investigator’s My NCBI account
  - Author/investigator adds you as a delegate in My NCBI
PMC is a free full-text archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health's National Library of Medicine (NIH/NLM).
Managing Compliance: Delegates

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

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

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

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

• Classes! at HSL & NC TraCS

• Individual / Group Consults
3 Take Home Points!


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

3. Wait, what? Contact the UNC Health Sciences Library & NC TraCS!
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@unchhealth.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@unchhealth.unc.edu
• William Zhao, PharmD, PhD
  yun.zhao@unchhealth.unc.edu
• Elaine Vu, PharmD
  elaine.vu@unchhealth.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
- 919-966-6359 (fax for orders)
- Prepares medications for protocols that contain IV products

Neurosciences Hospital, Ground Floor
- 919-966-8735 (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 25th 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 (966-1766) 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.
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 TRAINING, HIPAA, PRIVACY & CONFIDENTIALITY

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 (OnCore)
- Ordering Imaging and Phlebotomy (revised)
- Linking Appointments to Research - For Schedules 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

References for OnCore:
- OnCore CPQ New Study Entry Checklist
- OnCore NPO New Study Entry Checklist
- Oncore Staff Entry Checklist

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

Research Town Hall Slides:
- All Departments
- Oncology
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 (external)
- 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

References for OnCore:
- OnCore CPO New Study Entry Checklist
- OnCore NPO New Study Entry Checklist
- OnCore Staff Entry/Checklist

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

Research Town Hall Slides:
- All Departments
- Oncology
For More Training:

Research Administration 100
Register via Hospital’s LMS system

Upcoming dates:

- October 13
- November 17
- December 15
- January 12
"You spelled 'confidential' wrong."
Privacy

• The right to seclusion, isolation from others
• The right to be left alone
• Increasingly, the right to be forgotten
• Privacy typically refers to right to privacy of an individual

Confidentiality

• The obligation that those in a position of trust have to safeguard the private information of others
• Typically refers to maintaining confidentiality of data or information provided about an individual
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, cont’d

• 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
HIPAA, cont’d

- 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)
UNC Oversight Structure

- Privacy and Security Liaisons
- HIPAA Steering Committee
- Required training for use of PHI,
- Limiting access to systems containing sensitive information
When Things Go Wrong

• Breaches
  • Loss of laptop, flash drive, files, tissue, etc.
  • Improper disposal – shred, shred, shred
  • Intrusion
  • Access of information by person not authorized
  • E-mail: non secure transmission, subject lines w/ PHI

• Notification Requirements
  • Report to IRB and Privacy Office
  • Elements of Notice
    • Circumstances, what happened, when?
    • What steps to take to protect ones information
    • Where to go for more help
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
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