ORIENTATION FOR NEW CLINICAL RESEARCH COORDINATORS

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 and GCP, and Study Start up

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

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

• **Module 5:**
  Recruitment, From CDA to Study Close Out
RECRUITMENT SERVICES

Carol Brelan, MPH, RRT, AE-C
Research Recruitment Director
NC TraCS
NC TraCS Recruitment Services Goals
Accelerate Subject Recruitment across UNC!

- Improve UNC research studies internet presence
    - A simple research volunteer registration process
    - A easy to read studies listing geared to the general public
    - An online location for volunteers and UNC researchers to interface
    - Uses social media tools- Facebook, Twitter, etc.

- Disseminate research recruitment tools and methods
  - Recruitment planning consultations
  - Tool kit for recruitment campaigns
  - Researcher networking
  - E-recruitment methodologies
  - Best practices workshops and presentations

[https://tracs.unc.edu/index.php/services/recruitment-services](https://tracs.unc.edu/index.php/services/recruitment-services)
Recruitment Planning

A recruitment plan should be developed as soon development begins on the protocol or as soon as you receive it, whether investigator-initiated, industry-sponsored, NIH or other sponsor.

1. Start with a protocol review with a focus on recruitment
   - inclusion/exclusion criteria, study procedures and timelines
2. Develop a subject profile and identify barriers and benefits to participation
3. Use i2b2 to estimate available population cohort counts
4. List your recruitment strategies
5. For each strategy, list your tactics
6. Create a promotional campaign with timeline
7. Evaluate your plan for risks and develop contingencies
8. Develop a practical budget and estimate resource needs
9. Start slow, make adjustments and then increase your speed
10. Review your plan at least monthly or more often as needed
Barriers to Study Recruitment

- A recent poll was conducted by Zogby Analytics for Research America
- One question asked was “Fewer than 10% of Americans participate in clinical trials. Why don’t people take part in research studies?”
- Answers:
  - Not aware/lack of information = 53%
  - Lack of trust = 53%
  - Too risky = 51%
  - Adverse health outcomes = 44%
  - Little or no monetary compensation = 35%
  - Privacy Issues = 27%
  - Too much time = 27%
  - Not sure = 11%
Recruitment Tactics

Before you develop your promotional campaign materials, ask yourself: What message do you want to convey to potential volunteers about the study? Remember, IRB approval of all recruitment promotional materials is required!

Tactics to promote your study – each study requires a customized approach!

- Send a letter or call patients from approved registries or chart review
- Posters, Pamphlets, Mailings (Flyers, letters, post cards)
- Request identified data from the Carolina Data Warehouse
- Develop a friendly and informative phone screen/script
- Create social networking venues- Facebook, Twitter, Instagram
- Attend Community events (fairs, flea markets, senior center health events)
- Develop a UNC mass email
- Consider media advertising - TV, radio, print,
- Build a study-specific website using Wordpress or consider StudyPages/other vendor
Recruitment Tactics - continued

- Dear Doctor Letters – snail mail, fax or email to local providers

  Our UNC IRB requires review of doctor to doctor letters as part of your recruitment plan. These types of communications are not seen by patients but inform providers about your study.

  Note! Although our UNC IRB requires approval for doctor to doctor letters, FDA regulations are less stringent. UNC IRB will be revising their SOPs over the coming months and will take into consideration the FDA guidance. Learn more at

  http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

  Reminder! UNC IRB SOP 26.2 - “...prohibited are finder’s or referral fees to colleagues who may identify or refer eligible subjects to a research study (e.g., a general practitioner sending patients to a specialist conducting a study.)
Recruitment Tactics - continued

Tactics that don’t require IRB approval:

• List your IRB approved study in Join the Conquest
• Develop a system for identification of potential subjects
• Attend conferences
• Conduct informational lunch ‘n learns on the condition you are studying
• Arrange for presentations at departmental meetings
Coming Soon!

• Recruitment Services feedback surveys- let us know how we are doing and what your needs are

• Join the Conquest
  • For Volunteers:
    • homepage enhancements
    • opt-in study interest notifications
    • search by location/within x miles
    • satisfaction surveys
  • For Researchers:
    • website promotional campaign
    • improved study listing form
    • recruitment metrics
    • provider access portal
    • satisfaction surveys
Where Can I Learn More About Recruitment Services?

Visit NC TraCS Recruitment Services Website

http://tracs.unc.edu/index.php/plan-research/research-recruitment

Call or email NC TraCS at

nctracs@unc.edu  919 966-6022

Contact Carol Breland, MPH, RRT, AE-C

brelandc@email.unc.edu

919 966-6274
RECRUITMENT THROUGH THE CDW-H: IRB REQUIREMENTS
Carolina Data Warehouse (CDW-H)

• What is the CDW-H:
  • The CDW-H (CDW for short) is a central data repository containing clinical, research and administrative data sourced from the UNC Health Care system.
  • UNC Healthcare extended to Rex, Chatham, Pardee, etc. so with Epic introduced at these outlying hospitals, patient data flows into CDW

• What is included in the CDW:
  • All legacy Webcis data and now all Epic data
  • Includes medical, financial and other hospital data
  • For new hospitals now in UNC Healthcare (i.e., Rex Hospital), this means their patient data is also in the CDW, if they are using Epic.
CDW and Research Recruitment

- The CDW serves as a gatekeeper to providing research teams with EMR data on patients who meet eligibility for recruitment.
- If recruiting through CDW, recognize that patient info provided could be for patients at many locations.
- May want to narrow recruitment search to those in specific zip codes to avoid getting patients outside main UNC campus area (if so desired).
- If you want to recruit from other hospitals, consider whether there are other gatekeepers at outlying facilities who may need to be aware of your recruitment approach.
Recruitment Etiquette

• Old-fashioned courtesy is paramount!
• Review carefully the list of potential participants provided by CDW-H and exclude any that are not eligible
• Engage any known providers in recruitment early in the process- (Do you have patients that meet these criteria?)
• Request a PCP contact from participants and send a letter or email to alert them of trial participation
• Affiliate hospitals and clinics new to the UNC research mission require additional time to absorb recruitment methods developed for main campus- be patient!
• Promote trial opportunities as a benefit of being part of the UNCHCS provider network.
Indicating Use of CDW in IRB Application

- **A.9 Identifiers**: Mark all identifiers you will receive from CDW (names, telephone #s, dates or date of birth, zip code, email, medical record number). Needs to match CDW request form.

- **B.1 Methods of Recruiting**: Indicate use of a telephone script or letter to reach out to potential participants. IRB will require you submit the documents for approval.

- **B.2.1 Request a Limited Waiver of HIPAA** to identify potentially qualified subjects in order to contact them to elicit their interest in study.

- **B.3.4 Where are you studying subjects**: Indicate Healthcare setting and check places that apply (UNC medical center, Rex Hospital, Chatham Hospital, etc.) and specify where in the facility subjects will be studied (e.g., CTRC or ACC at UNC).

- **C.1 Data Sources**: Indicate use of UNC Health Care System Medical records, then check electronic medical records using CDW-H.
Recruitment Letters

Suggested language:

• Your records in the UNC Health Care System indicate you may be eligible to participate in our research study entitled “Xxxxxxxxxxx”. We are contacting people who have either an xxxx (lab value) or xxxxx (specific inclusion criteria) .......

• We are contacting people who are in the xx to xx age range who have been seen by the UNC Health Care System in the past year in order to tell them about a research program that we are doing.

• We are contacting you because you were seen by UNC Health Care or one of our affiliate hospitals or clinics in the past year......
Telephone/Email Scripts

Begin with something similar to the recruitment letters:

• Hello, my name is ____________. I am a (student/faculty member/staff member) from the University of North Carolina at Chapel Hill conducting a research study entitled XXXXXXXXXX. This study will test xxxxx in xxxxx patients. Your records in the UNC Health Care System indicate you may be eligible to participate in our research study OR based on your medical history, you may be eligible to participate in our study.

• If participant asks “How did you get my name/contact information?”
  • **Answer**: We received approval to access medical records of patients in the UNC Health Care System who meet our research study criteria. Based on your medical history, you appear eligible to participate in this study.

• If participant states, “but I am not a UNC Health Care patient, I go to Rex Hospital (or other hospital/clinic)”.
  • **Answer**: UNC Health Care System now includes several affiliate hospitals and clinics, including Rex (or other).
What to say… and not to say

• Language used in recruitment materials should only reference or describe medical records coming from the UNC Health Care System and Affiliate Hospitals / Clinics.

• Subjects do NOT actually sign up for the Carolina Data Warehouse for Health. The names of potential research participants are in the CDW by virtue of them having been seen by the UNC Health Care System (includes affiliate Hospitals and Clinics) in the last few years.

• One should NEVER say “We are contacting you because you signed up with the Carolina Data Warehouse for Health” as this is incorrect.

• Recruitment letters / telephone scripts should NOT make a reference or describe that patient data or records were provided by the Carolina Data Warehouse for Health.
Contact for more information

- Carol Breland, MPH, RRT Research Recruitment Director, NC TraCS  brelandc@email.unc.edu

- Marie Rape, RN, BSN, Associate Director of Regulatory, NC TraCS marie_rape@med.unc.edu

- Diane Towle, Quality Improvement Manager, UNC Institutional Review Board  towle@email.unc.edu
FROM CDA TO STUDY CLOSURE

Panel Members:

Christine Nelson
Val Buchholz
Objectives

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

1. **Sponsor Sends Site Information Questionnaire/Protocol Synopsis**
2. **Site Provides Sponsor with Information**
3. **Sponsor Accepts Site**
4. **Confidentiality Disclosure Agreement (CDA) Sent to Site**
5. **CDA Submitted to Office of Clinical Trials (OCT) via CRMS (Clinical Trials Management System)**
6. **OCT negotiates terms and executes CDA with sponsor**
7. **Sponsor Sends Protocol, Budget, Clinical Trial Agreement (CTA), and draft ICF**
8. **Feasibility Assessment**
9. **IRB Submission**
   - **Conflict of Interest eForms Completed**
   - **Local IRB or Central**
   - **Receipt of IRB Approval Documents Including ICF**
10. **Review Protocol for Uncommon procedures or requirements**
11. **Complete Billing Coverage Analysis in CRMS**
12. **IDS Submission CTRC Application Hospital Services**
13. **Negotiate Final Budget With Sponsor**
14. **Complete CTA Submission via CTRMS**
15. **CTA/Budget/ICF Finalized**
Site Survey

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

- CDA must be submitted via CRMS
- Cannot be signed by PI
- Quick turn around
- Not every CDA results in receiving a protocol
- Sponsors and CROs track turn around times
CRMS

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

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

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

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

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

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

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

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

• More to do!
  • SIV – Site Initiation Visit
  • Study supplies
  • CRMS – Clinical Research Management System
  • Epic
  • IDS – Investigational Drug Services at UNC Healthcare
  • Subject binders
  • Source documents
  • Logs
  • Study visit checklist
Study Information is pushed to EPIC via CRMS

Site Initiation Visit

Prepare for/Enroll Subjects → Enrollment Complete → Study Closure

Account Number Assigned

Conflict of Interest eForm completed

eIPF completed in Ramses

CTA Executed

CTA/ICF checked for Consistency

Billing Calendar Built in Epic
Study Conduct

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

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

• Who do you call?

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

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

Date and time

Please contact @ if you have any questions or recommendations