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 5

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

Week 5
Evaluation Link:
https://go.unc.edu/orientwk5

OR

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

STUDY TEAM RESPONSIBILITIES

Laura Viera, MA, CCRP

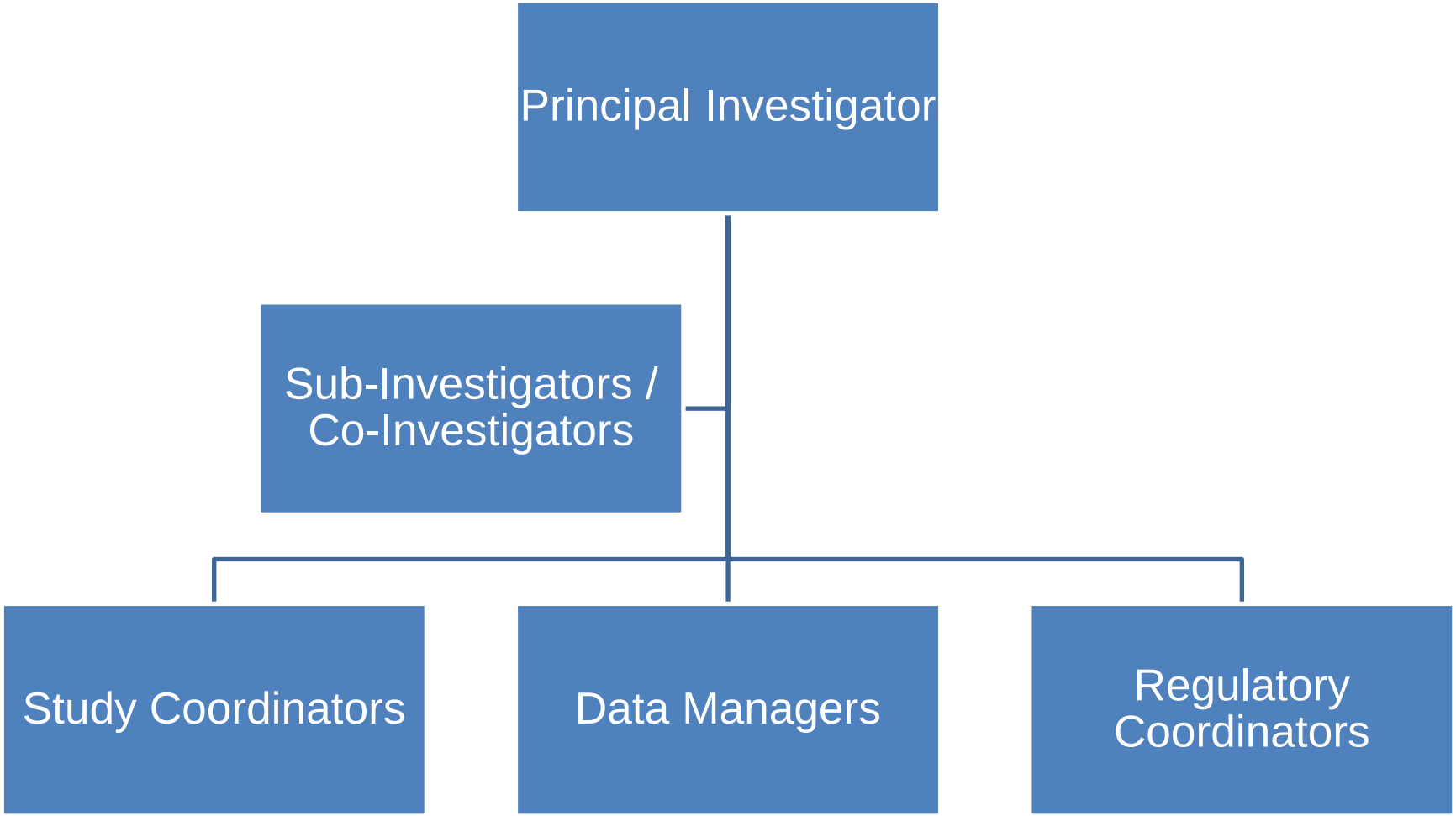
Director, Clinical Research Operations

The Research Team

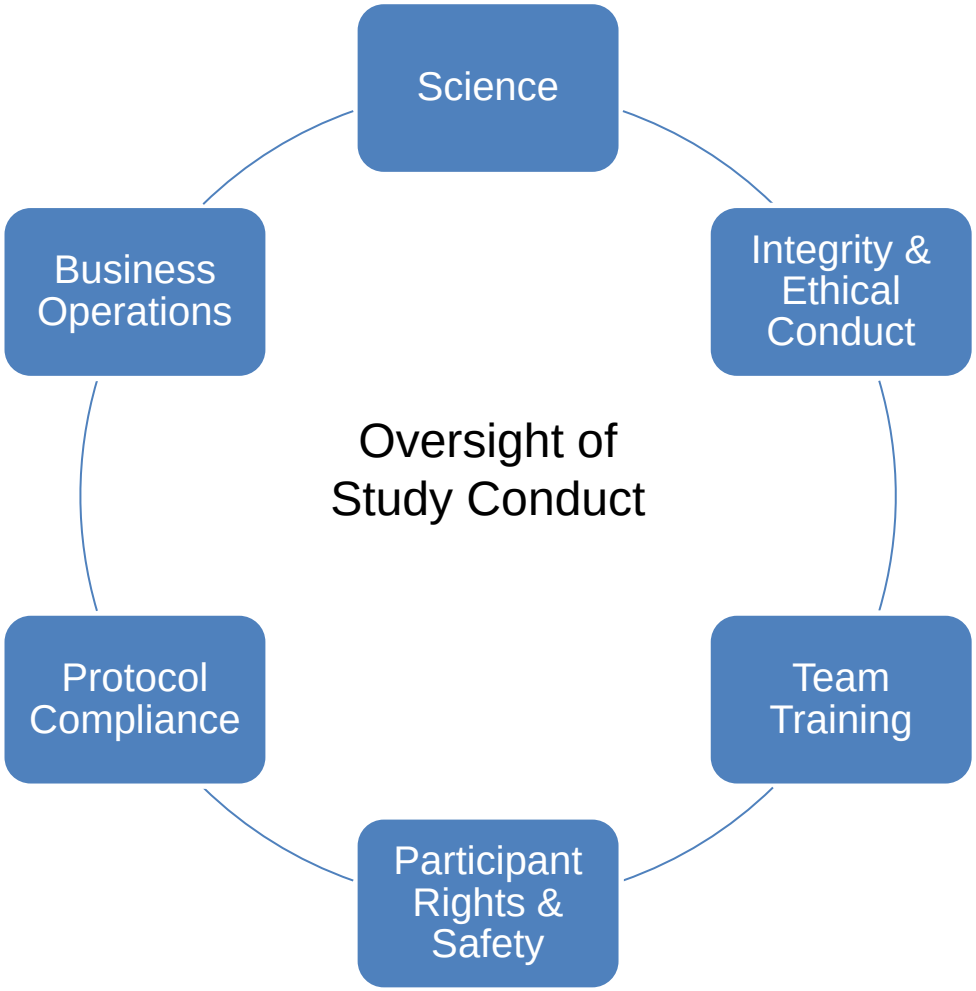
In order to efficiently and effectively perform clinical research, you need staff with sufficient

time, knowledge, skills and resources

Research Teams



Principal Investigator (PI)



PI Responsibilities from FDA 1572

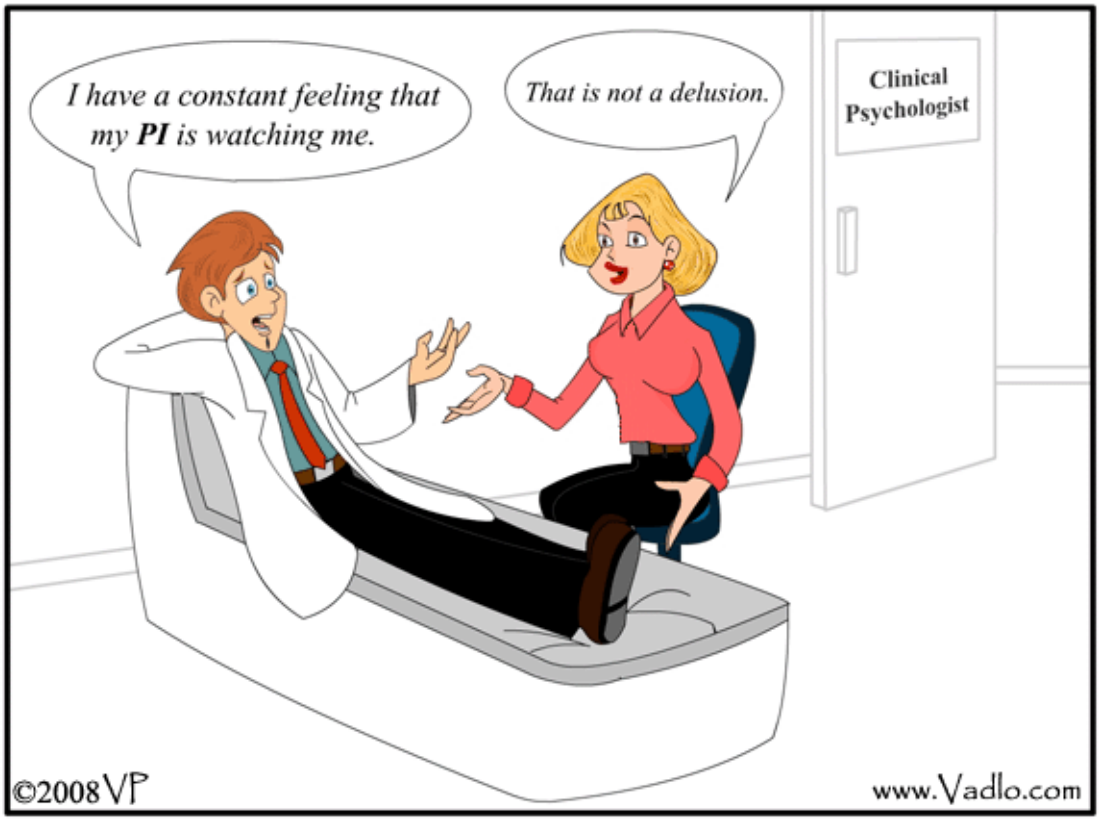
FDA 1572 is a legally binding document, in which the PI agrees to:

1. Conduct study in accordance with protocol
2. Personally conduct or supervise the study
3. Ensure proper informed consent is obtained
4. Report adverse events
5. Understand the information in the IB, including risks/side effects
6. Ensure all members of study team understand responsibilities
7. Maintain adequate and accurate records
8. Maintain compliance with IRB
9. Comply with all FDA regulations (21 CFR 312)

PI is also responsible for adhering to all local regulations!

Form FDA 1572 continued

"I agree to **personally conduct or supervise** the described investigation(s)."



Study Coordinator

Study Coordinator Role

- Manages and conducts day-to-day study activities in accordance with the protocol, regulations and requirements

- Per UNC, the role of a study coordinator is to ". . . ensure smooth, accurate progress of the project from the planning stage through study end (and often beyond) by acting as liaison to the investigator, the subject, the institution, and the company or government sponsor."

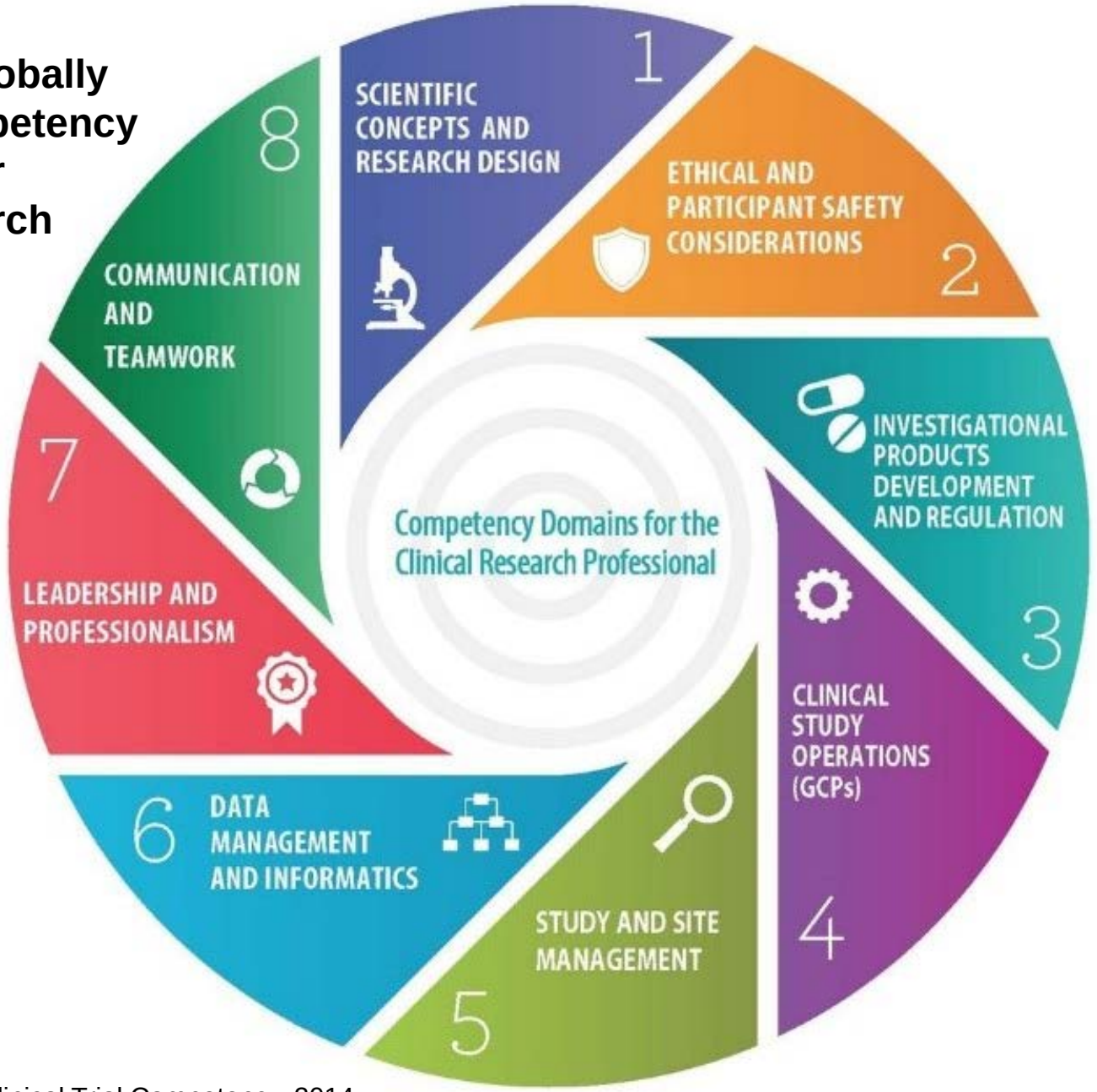
Study Coordinator Role, continued

Metaphors for 3 primary advocacy roles:

- Parent – patient welfare / patient advocate
- Lawyer – participant rights and welfare / providing neutral information
- Teacher / Policeman – understand value of protocol and defend it

(The Invisible Hand in Clinical Research: The study coordinator's critical role in human subjects protection (Davis et al., 2002))

Universally applicable, globally relevant competency framework for clinical research professionals



Joint Task Force for Clinical Trial Competency, 2014

The GREAT coordinator will have:

- Superior attention to detail
- Excellent communication skills
- Ability to build rapport and positive relationships
- Collaborative nature
- Ability to identify appropriate times for flexibility vs. rigidity
- Ability to work independently
- Strong organizational skills
- Positive and proactive approach
- Perseverance
- Leadership and professionalism
- Passion

Coordinator Responsibilities: Protocol Evaluation

- Confirm availability of appropriate: subjects/participants, personnel, equipment, facilities, testing capabilities
- Develop timelines, documentation standards, SOP's as needed
- Ensure protocol is thorough and clear and can be implemented as written
- Ensure protocol is consistent with all other materials (CRF's, IRB application, SOP's)
- Propose & negotiate alternatives to improve implementation

Coordinator Responsibilities: Financial

- Develop/negotiate study budget
- Submit billing coverage analysis
- Review hospital billing
- Submit invoices
- Track milestones
- Monitor budget and expenditures
- Obtain and disburse participant incentives
- Track and report participant incentives for tax reporting

Coordinator Responsibilities: Regulatory

- Collect and maintain regulatory documentation
- Prepare IRB applications
- Submit IRB modifications, renewals, closures
- Coordinate and participate in monitoring and/or audit visits
- Stay informed of regulations and policies
- Instate tools/methods/standards to maintain compliance

Coordinator Responsibilities: Documentation and Reporting

- Observe, document and report adverse events
- Maintain appropriate and sufficient documentation of study activities, including: data collection, protocol deviations or changes, dispensing drugs, disbursing funds, team training, etc.
- Over-documentation > under-documentation
- Over-reporting > under-reporting

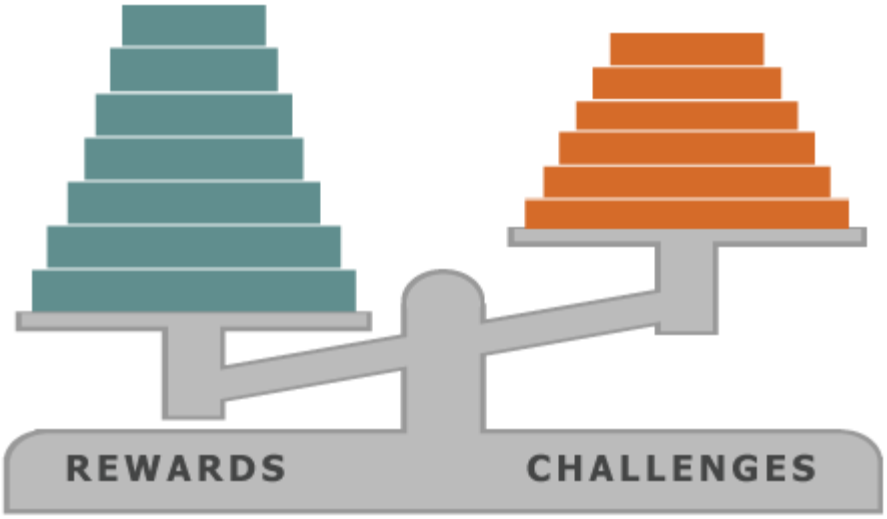
Coordinator Responsibilities: Study Visits and Participants

- Recruit study participants
- Track, document and project accrual
- Review and document participant eligibility
- Discuss study details
- Obtain informed consent
- Schedule and conduct study visits
- Ensure all study tests and visits are performed in accordance with the protocol
- Promote participant compliance by providing patient support and education
- Serve as primary point of contact for participants

Coordinator Responsibilities: Data Collection and Management

- Order, receive, log supplies
- Obtain, process and ship biological samples
- Conduct study procedures to collect data
- Complete data collection forms
- Review data for completeness and accuracy
- Enter data into database
- Maintain data security
- Respond to data queries

Challenges	Rewards
Demanding timelines and goals	Create positive relationships
Encountering barriers to recruitment and protocol execution	Meet and work with diverse groups of people
Tight budgets, Slow progress	Make significant, positive impact on the people we work with daily
Paperwork, paperwork, paperwork!	Produce science that will shape our future!



STUDY START-UP AND IMPLEMENTATION

Laura Viera, MA, CCRP

Director, Clinical Research Operations

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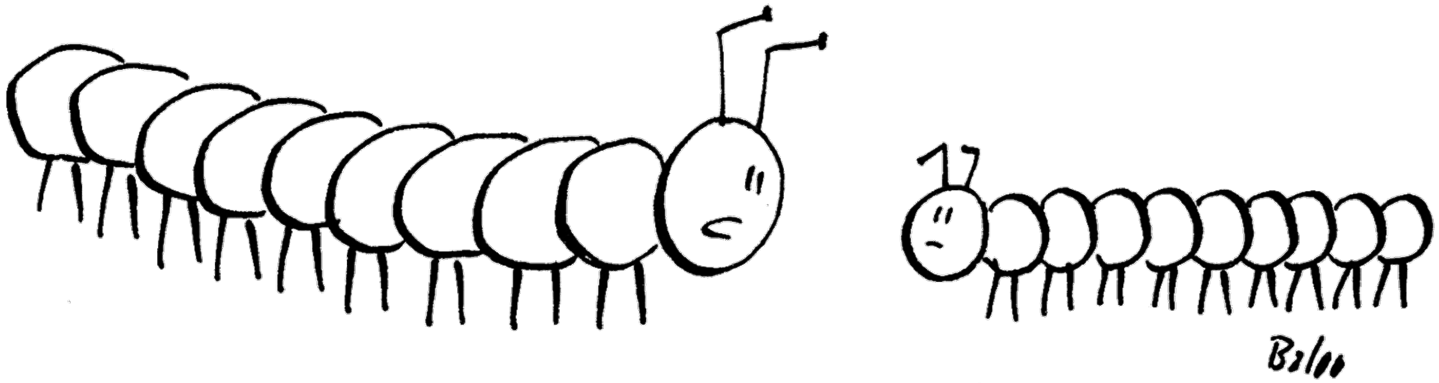
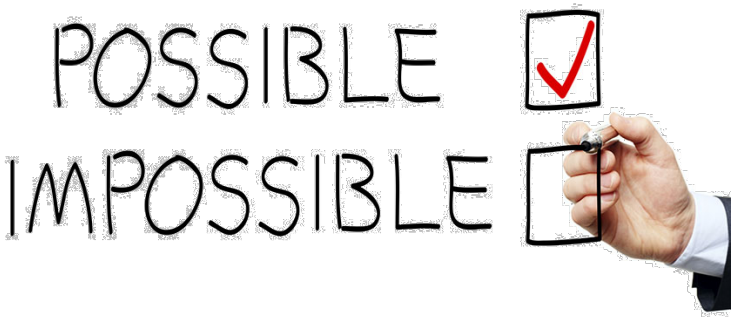
Protocol Implementation



"Strength and speed are useful, son, but coordination is *crucial!*"

We have a great idea or a proposal from a sponsor… now what?



Assess feasibility!

1. Is the protocol innovative?
2. Are there competing trials?
3. Is the risk to subjects acceptable?
4. Does the protocol address underserved populations?
5. Does the work build on prior UNC findings?
6. Is the inclusion/exclusion criteria reasonable and do we have access to participants?
7. Is the budget sufficient?
8. Is the schedule of events feasible?
9. Does our staff have capacity to do the work?
10. Does our team have appropriate training?
11. Do we have the necessary equipment?
12. Do we need to involve ancillary departments?

We are funded!! Now what?

Contracts, agreements, approvals, Oh, my!

1. Gather your team:
   - Team training (and documentation!)
   - Notify providers, nurses, clinic staff, etc. of upcoming research protocol
   - Consult your stakeholders and subject-matter experts
   - Hold a study start-up meeting

We are funded!! Now what?...cont.

2. Create/gather your materials:
   - Develop detailed protocol and/or SOP's
   - Finalize data management plan
   - Refine recruitment materials (eg. flyers, emails, tracking logs)
   - Create source documents
   - Create various study tracking logs (eg. accrual, AE's, protocol changes)
   - Organize regulatory materials
   - Obtain and organize other study materials (eg. specimen kits, order forms, study drug, participant materials)
   - Create visit checklists

Allow time to review all study materials for completeness and consistency!

We are funded!! Now what?...cont.

3. Practice, test, evaluate:
    - Perform mock informed consent discussions
    - Visit the facilities and observe clinical flow and procedures
    - Ensure everyone has appropriate access to buildings and systems
    - Perform dry-runs of study visits
    - Test equipment


... AND THIS IS THE FORM YOU SEND BACK TO CONFIRM YOU'VE SENT BACK ALL THE OTHER FORMS!
FORM

Recruitment & Retention Program

Emily Olsson, CCRP
Program Manager
NC TraCS

emolsson@unc.edu, 919-966-6274
tracs.unc.edu/consultation to request a consult

WHAT'S THE BIG DEAL?

- A 2015 analysis of registered trials revealed that 19% were closed or terminated early because they could not accrue enough participants
- As many as 86% of clinical trials do not reach recruitment targets within their specified time periods
- Data suggest that study timelines have potentially doubled beyond planned enrollment periods due to low recruitment rates
- Failures to meet recruitment goals has important scientific, financial, and ethical implications

*Huang, Grant D. et al. "Clinical trials recruitment planning: a proposed framework from the Clinical Trials Transformation Initiative". Contemporary Clinical Trials, vol 66, 74-79.

Barriers to Study Recruitment Success

- A 2017 poll on public perception of research asked:

"Fewer than 10% of Americans participate in clinical trials. Why don't people take part in research studies?"

- What do you think??

ANSWERS TO PUBLIC PERCEPTION SURVEY: 2017

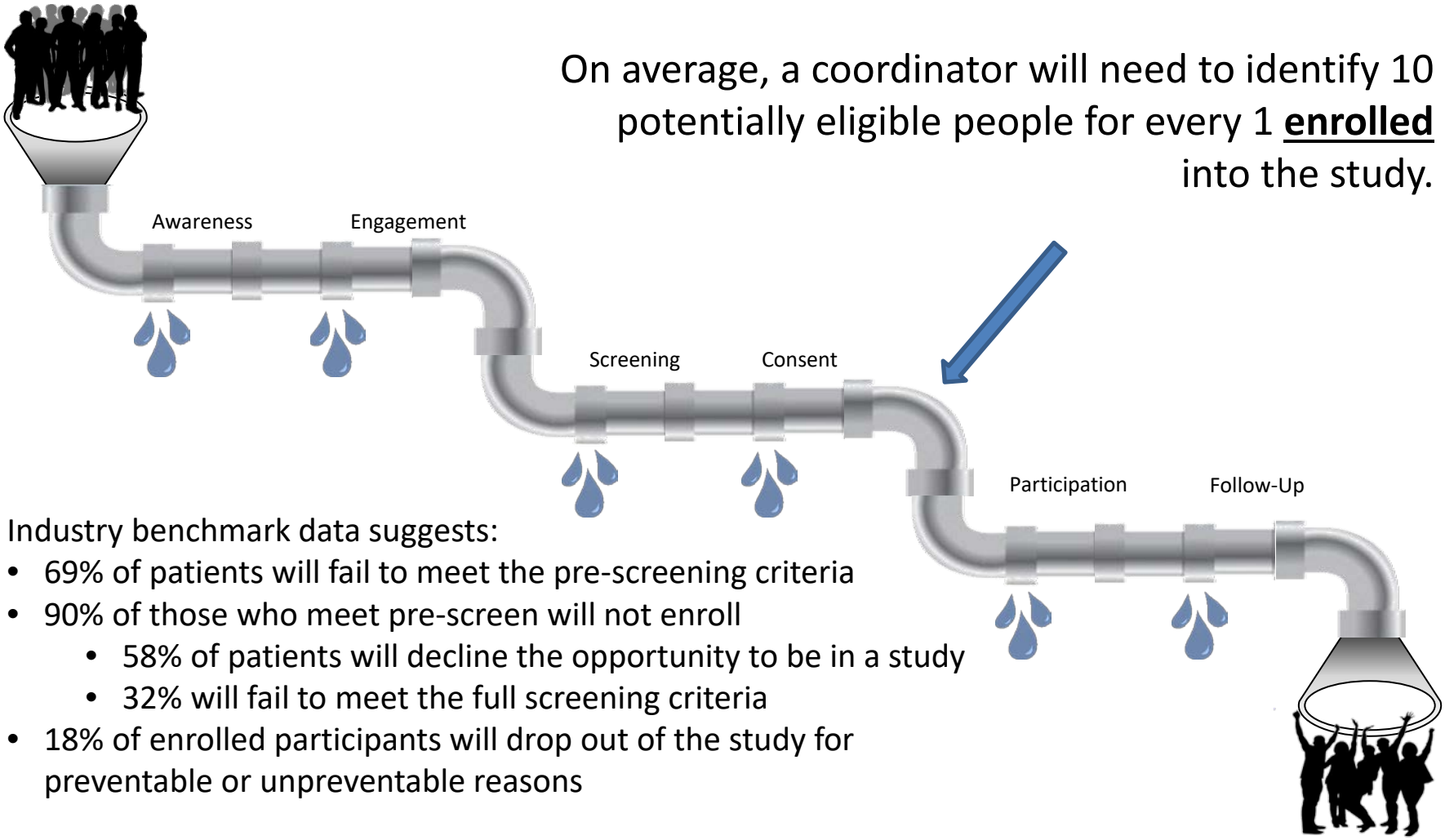
"Fewer than 10% of Americans participate in clinical trials. Why don't people take part in research studies?"

- 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%

*Research!America survey of U.S. adults conducted in partnership with Zogby Analytics in July 2017.

WHAT'S THE BIG DEAL?

On average, a coordinator will need to identify 10 potentially eligible people for every 1 **enrolled** into the study.



Industry benchmark data suggests:

- 69% of patients will fail to meet the pre-screening criteria
- 90% of those who meet pre-screen will not enroll
  - 58% of patients will decline the opportunity to be in a study
  - 32% will fail to meet the full screening criteria
- 18% of enrolled participants will drop out of the study for preventable or unpreventable reasons

*Clinical Performance Partners – Benchmark Data – CPP and PhESi 1998-2012

What's the big deal?

On average, a coordinator will need to
otentially eligible people for
to the study.

To complete 100 participants

You need to enroll 118

You need pitch the study to 1,180 potentially eligible

You need to screen/identify/reach 3,806 people

Industry ben
- 69% of patients
- 90% of those wh
  - 58% of patient
  - 32% will fail to meet the full s
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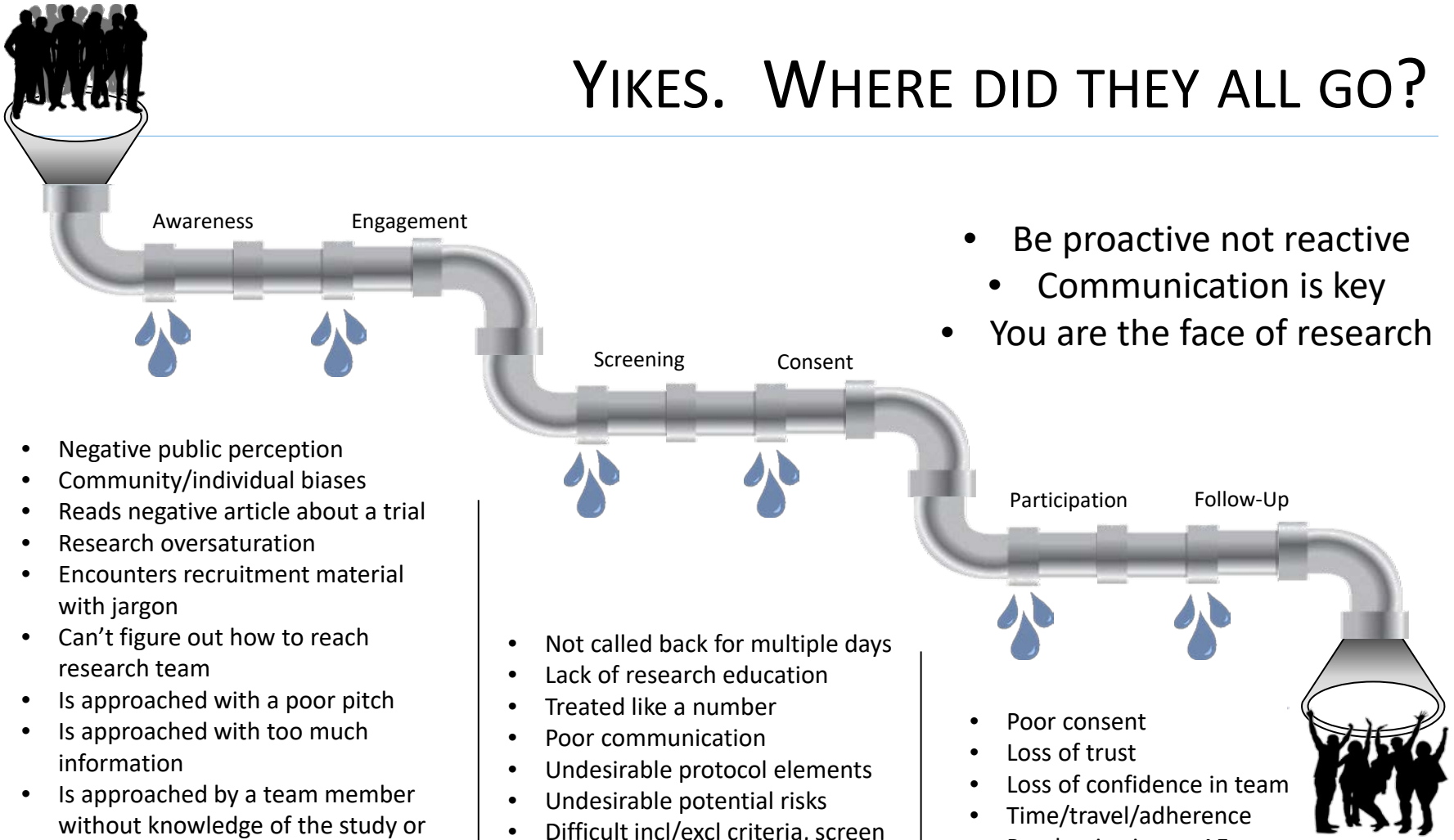
*Clinical Performance Partners – Benchmark Data – CPP and PhESi 1998-2012

YIKES. WHERE DID THEY ALL GO?



- Be proactive not reactive
- Communication is key
- You are the face of research

- Negative public perception
- Community/individual biases
- Reads negative article about a trial
- Research oversaturation
- Encounters recruitment material with jargon
- Can't figure out how to reach research team
- Is approached with a poor pitch
- Is approached with too much information
- Is approached by a team member without knowledge of the study or condition
- Team can't adequately pre-screen
- Ineligible during pre-screening
- Failure to assess population feasibility
- Use of wrong recruitment strategies

- Not called back for multiple days
- Lack of research education
- Treated like a number
- Poor communication
- Undesirable protocol elements
- Undesirable potential risks
- Difficult incl/excl criteria, screen fail
- Too many visits
- Too much time off of work
- Inconvenient times/locations
- Difficulty obtaining records

- Poor consent
- Loss of trust
- Loss of confidence in team
- Time/travel/adherence
- Randomization or AE
- Not enough incentive
- Confusion
- Poor communication
- Loss of interest/investment

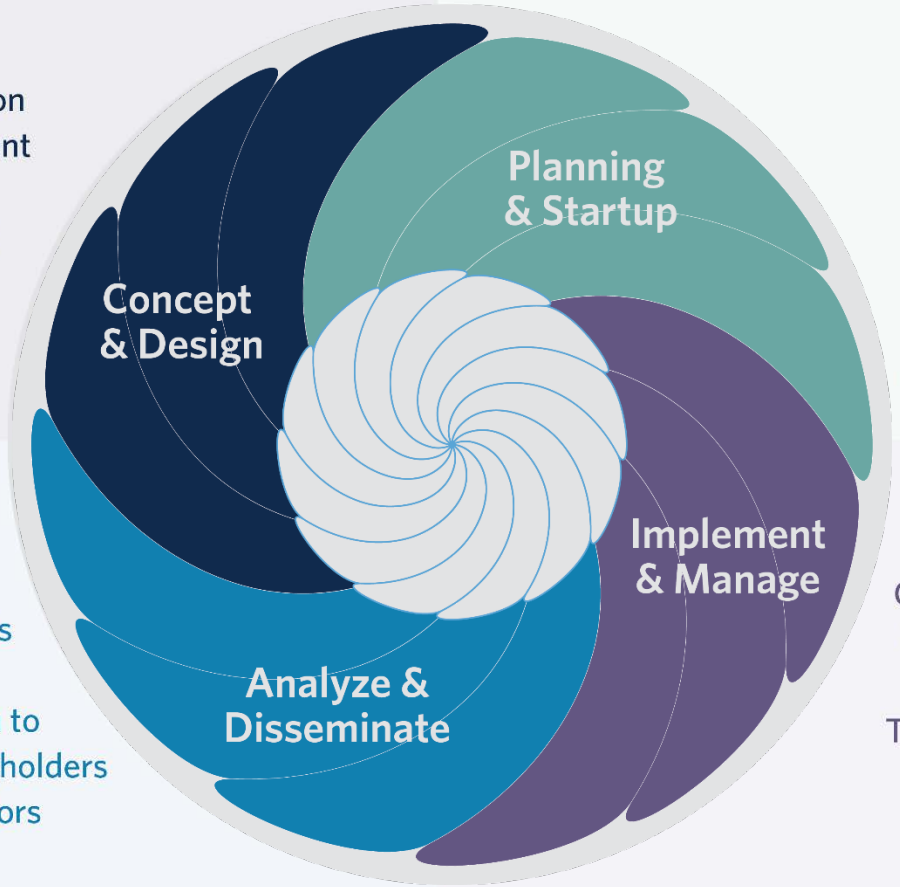
When should you be thinking about recruitment?

Foundation

Population Identification
Stakeholder Engagement
Study Design
Protocol Development
Grant-Writing

Framing

Budgeting
Resource Availibility
Site Selection
Staff Training
Feasibility Assessment
Recruitment Planning
Material Development
Messaging & Language



Curb Appeal

Interpretation of Results
Dissemination Plan
Relevant Dissemination to Participants and Stakeholders
Stakeholder Ambassadors

Systems and Upkeep

Outreach & Engagement Strategies & Campaigns
Screening & Consent
Tracking Effort & Accrual
Retention Optimization
Relationship-Building

Biggest impacts on recruitment and retention

- ❑ Protocol
- ❑ Capacity
- ❑ Facilitators and Barriers
- ❑ Approaches
- ❑ Communication
- ❑ YOU!

Protocol

Who, What, How, and Why

- Include stakeholders from your population in the planning!
- Select a research question that is relevant and impactful to your population
- Carefully consider inclusion and exclusion criteria
- Design a protocol that makes it easy for your population to join, participate, and that speaks to their motivations
- Be mindful of diversity inclusion and considerations for special populations

Capacity

Can and Should you do this study?

- Confirm availability and accessibility to population
- Confirm sample size and effort to achieve sample size
- Consider competition for participants time
- Think about realistic required resources
- Budget for realistic required resources
- Do you have appropriately trained staff
- Do you have appropriately invested sites
- Consider your timeline
- Recruitment Planning

Barriers and Facilitators

What will work for and against you?

- Know what you are up against, solve problems when you can, and highlight your strengths
- Potential Barriers
  - What would prevent participation?
  - Transportation issues, time commitment, fear, lack of trust, lack of credibility, study recruitment budget, lack of site investment, etc
- Potential Facilitators
  - What would encourage participation?
  - Appropriate compensation, perceived benefit, providing data/results, flexible appointment times, childcare, strong community relationships, etc

Approaches

How will I reach them, enroll them, and retain them?

REMEMBER: Your detailed recruitment plan and any patient-facing materials require IRB approval!

The promotion of each study requires a customized approach. Consider utilizing multiple strategies, messages, and materials. Be creative!

- Where will you recruit?
- How will you recruit?
- How will you describe the study?
- How will potential participants contact you?
- What resources do you have available?
- What tools will you use to keep participants invested and on track?

Approaches

How will I reach them, enroll them, and retain them?

- Active Recruitment
  - You identify and pursue individual potential participants
- Passive Recruitment
  - You rely on potential participants to contact you and express interest
- Word of Mouth and Participant Networks
  - Encourage participant ambassadors; create peer to peer networks, create registries, create advisory boards
- Effort Tracking to inform future studies

Approaches

Examples

- Research for Me @UNC Recruitment Listing– done via IRB application
- Cold contact – chart review or registries (letter, phone call, secure email)
- In-clinic recruitment (in-person)
- Carolina Data Warehouse eligible patient list
- Use ResearchMatch.org
- Advertising (print, TV, radio, buses)
- Social media campaigns
- Flyers, pamphlets, info cards
- UNC Mass Email
- Physician referral
- Websites and Screening Tools
- Lunch ‘n’ Learns
- In-services
- NRP listserv to learn from others
- Consult with patient advisory boards
- Plug into existing networks
- Community events and outreach

Note about Physician Referrals

- <u>"Dear Doctor" letters:</u>
  - Any written communication to local providers to ask for their assistance with recruitment for a study.
  - Not patient facing, but the UNC IRB does require review/approval of any "dear doctor" communication. The FDA guidance is less stringent, but you must follow local policy.
- <u>Finder's Fees:</u>
  - Sites may be provided with funds in support of the additional time and effort required by their staff to recruit for the study. This must be the same across sites.
  - This MAY NOT be tied to actual referral numbers.
  - 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.)*

Research for Me

@unc

The public-facing front door to research opportunities at UNC. An online resource introducing people to research and allowing them to search available studies presented in lay language.

Create a common resource to improve public transparency of, accessibility to, and familiarity with human subjects research done by UNC investigators and at UNC Health

Address barriers impacting public awareness of and willingness to engage with research

Provide a way for researchers to find collaborators and assess saturation

Components of Research for Me @UNC

Comprehensive, searchable directory of UNC research studies interacting with human subjects

Default view filters to studies that have elected to utilize the site as a recruitment tool. User may expand the search to view the full portfolio

Resources to learn about the research process, participation, and other engagement opportunities

Stories highlighting notable research and topics of interest.

Profiles sharing inspiration and experiences of study teams and participants

Research for Me @unc

Listing Options

Basic Listing

- Required
- Displays limited information about the study
- Members of the public unable to express interest; no study team contact information displayed
- Shorter submission form
- Manual entry due to different audience and relevant information

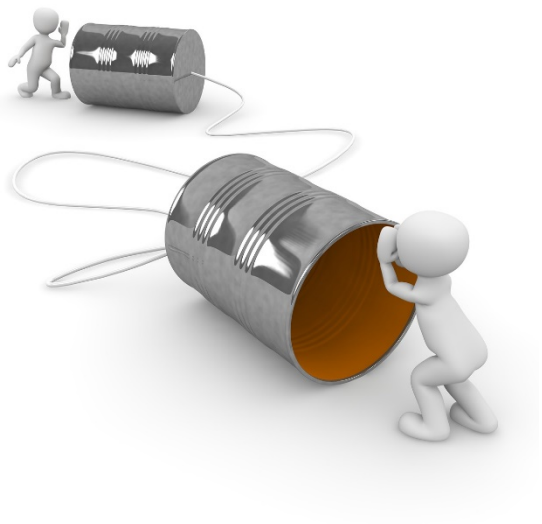
Recruitment Listing

- Optional
- Include extended information about study participation
- Potential participants can contact study team to express interest
- Unique URL – used as landing page for recruitment materials or social media
- Free

Communication and Transparency

How will you explain the study?

- Messaging in recruitment materials:
  - Will people understand what you're doing?
  - Why should they care?
  - Avoid coercion
  - Avoid too much information
  - 8th grade reading level
- Elevator pitches and screening scripts
  - Research in general
  - Your study
- Letters, emails, voicemail, and texting – considerations for privacy and language



Communication and Transparency

How will you explain the study?

- Responsiveness
- Staff knowledge and communication skills
- Be honest and give them enough information to make an informed decision, but
  - Avoid overwhelming them
  - Be sure to address any potential barriers – you don't want them to be surprised by something during consent
- Be patient
- Be flexible
- Develop a clear consent form and proper IC process!

YOU!

YOU ARE THE FACE OF RESEARCH FOR THE PARTICIPANT

- Think about everything from the perspective of a participant
- **Judgement**
  - is this a good candidate?
- **Relationship building**
  - Remember that they are a person, not a number
- **Competence**
  - know your stuff, your participant is likely an expert in their own condition
- **Honesty and Trust**
  - Don't guess and be up front about points of frustration
- **Informed consent process**
  - Make sure they understand
- **Tracking windows and communicating**
- **Tracking effort**

How can we help?

Consultations

Tools and Resources

Education and Training

- **Consultations and Services**
  - Recruitment planning prior to study launch
  - Troubleshoot an ongoing study
  - Review individual recruitment/retention components
  - Social Media guidance and plan development
  - Material development (flyers, scripts, consent aids, CDW-specific, logos, websites)
  - Staff training, communication, and elevator pitches

How can we help?

Consultations

Tools and Resources

Education and Training

- **Research for Me @UNC**
- **Recruitment Templates and Resources**
- **Recruitment and Retention LibGuide**
- **Screening and Enrollment Log Template**
- **Recruitment and Retention website**
- **Custom tool or resource development based on need**

How can we help?

Consultations

Tools and Resources

Education and Training

- **Seminars and Workshops**
  - How to Elevator Pitch Your Study
  - Creating Effective Recruitment Materials
  - Practicing Empathy in Participant Relationships
  - Use of Lay Language
  - Defining Value for the Participant
- **More to come!**
- **Customized/targeted trainings with individual study teams**

Where Can I Learn More?

- Visit NC TraCS Recruitment Program Website
  - https://tracs.unc.edu/index.php/services/recruitment-services
- Request a Consult with Recruitment Program
  - https://tracs.unc.edu, click “request a consult”
  - Use your ONYEN to register in the system
  - Submit a request and select “Recruitment Services”

Take Away

- ❑ You are the face of UNC research for any patient that you contact and any participant that you enroll
- ❑ Be professional, knowledgeable, kind, clear, and empathetic
- ❑ Participant experience with you will determine whether they decide to volunteer again and will impact their perception of UNC the research community.
- ❑ Make the experience for every participant positive, so that they become research ambassadors, share their positive experiences, and encourage others to explore Research for Me @UNC!

Resources

- Online study listing (can use in recruitment materials): https://researchforme.unc.edu
- Recruitment and Retention LibGuide: https://guides.lib.unc.edu/researchrecruitment
- Online Resource for Recruitment Research in Clinical Trials (ORRCA): http://www.orrca.org.uk/
- Learn more about TraCS services and tools: tracs.unc.edu
  - Community and Stakeholder Engagement
  - IDSci (i2b2, Emerse, CDW-H)
  - Inclusive Science Program
  - Research Coordination and Management Unit
  - Tools (REDCap, Semblie, etc)
- Trial Innovation Network Webinars: https://trialinnovationnetwork.org/elements/network-events/?category=archives
- IRB SOPs: https://ohresop.web.unc.edu/files/2018/05/Complete_Current_SOP.pdf
- HSL and health literacy librarians: https://guides.lib.unc.edu/healthliteracy
- Office of Research Support and Compliance (entities): ORSC@unchealth.unc.edu

Using the Carolina Data Warehouse for Study Recruitment

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tracs.unc.edu/consultation to request a consult

What is the CDW?

- The Carolina Data Warehouse for Health is a service of NC TraCS
- Central data repository which allows mining of UNCHCS data for the purposes of trial recruitment, retrospective analysis, inter-institutional sharing, and more
- Includes medical, financial, and other hospital data form 2004-present
- Includes data from the UNC Entities which are actively using Epic (Rex, Chatham, Nash, etc)
  - If you're interested in recruiting from an entity, contact the Office of Research Support and Compliance first (ORSC@unchealth.unc.edu)

When is it appropriate to use the CDW?

- When you need lists or datasets based on information available in the medical record
- When you are recruiting for a study with a population that has specific inclusion/exclusion criteria which can be determined in the medical record.
- Plan ahead for use – this isn't an overnight fix to recruitment issues.

CDW and Participant Recruitment

- The CDW serves as a gatekeeper for EMR data on patients that can be used for recruitment purposes
- If recruiting using the CDW, recognize that patient information provided could be for patients at many locations
- You may want to narrow recruitment search to those in specific zip codes to avoid getting patients outside main UNC campus area (if desired)
- **You must have CDW-specific recruitment materials IRB approved before you can receive your data**

Self-Service and Other Tools

- I2b2
  - Self-service tool to assess population availability and recruitment feasibility
- Emerse
  - Self-service tool. Works like a “Google” of free-text clinical notes
- RedCap
  - Customizable, secure study database. Can be used for CRF data points and questionnaires
- CDRNs
  - Carolina Data Research Networks

What kinds of things can I ask of CDW-H?

- Feasibility Determination
  - "I need to determine feasibility for an upcoming trial. Can you tell me how many patients between the ages of 18 and 55 have had more than five HbA1c values greater than 6.5 over the past three years?“
  - For more complicated queries than can be done easily in i2b2.

What kinds of things can I ask of CDW-H?

- Identifiable Recruitment Lists
  - "I am recruiting for a trial and would like a pool of potential participants to contact. Can you give me names and contact information for female patients who were newly diagnosed with Crohn's disease in the past year?"
    - Particularly useful for difficult to identify populations or for populations from a wide variety of clinics.
    - Particularly useful for large-scale studies
    - Can be done once or on a recurring basis
    - Required in order to recruit participants via MyChart

What kinds of things can I ask of CDW-H?

- Custom Services and Epic Builds
  - Notifications
    - "I would like to build custom Epic features, such as receiving a notification when there is an inpatient eligible for my study."
  - MyChart Recruitment messaging
    - "I would like to utilize messaging via MyChart to contact patients identified as potentially eligible by the CDW-H"
  - Flowsheets and questionnaires

MyChart Recruitment Options

myUNCChart™ Foundation

Use MyChart to find out whether potentially eligible patients are interested in participating in a study. When a patient is identified, details about the study appear in MyChart along with other studies the patient is or has been involved in. The patient indicates whether she's interested in participating, and an In Basket message is sent to users at your organization. These actions are tracked and reportable.

- The study team selects and send the interest message using Epic.

myUNCChart™ Message

Use MyChart to inform potentially eligible patients in bulk about participating in a study. When a patient is identified, details about the study are sent to MyChart as a Inbox message. Links may be included for patients to follow, but no other action is available. Reporting metrics are available from custom report created by NC TraCS.

- A NC TraCS analyst sends the bulk messages.

myUNCChart™ Integrate

Building off the *Message* functionality, links to REDCap are included in the MyChart message. REDCap is used to capture and record study interest. This option allows more complete cohort management and linkages between external study identifiers, the patient's medical record, and third-party study websites.

- A NC TraCS analyst sends the bulk messages.

Research Health Informatics with Epic@UNC

Thursday April 15th, 2021

12:00 PM – 1:00 PM

Speakers:
Stephanie Deen and Adam Lee, NC TraCS

Registration for this event is required

https://tinyurl.com/yhdf9zkg

Remote attendance is available. Please mute the line and do NOT put on HOLD.

Presentation Objectives:

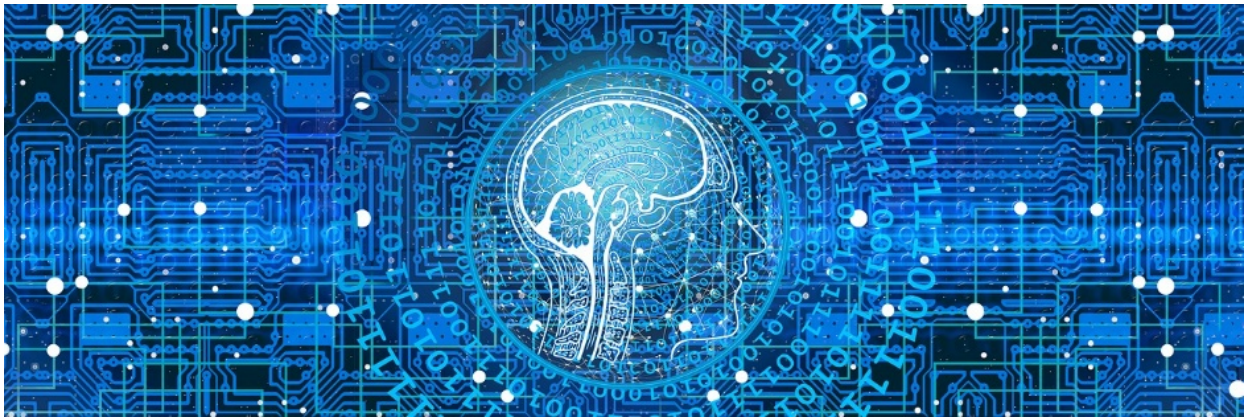
Adam Lee and Stephanie Deen from TraCS will be presenting on EPIC Updates and Health Informatics.

Objectives:

- Provide overview and success stories of using myUNCchart (myChart) for patient recruitment
- Provide overview and use cases for Best Practice Advisories within Epic for research studies
- Review of Epic@UNC security and feature updates and enhancements.

Sounds Great! How do I use the CDW-H?

- Budget for use
- Office hours and/or request a consultation
- Submit a data request
- Modify IRB application and develop CDW-specific recruitment materials



Meet with the CDW for a consultation

- Request a free consult from CDW through TraCS Central
  - tracs.unc.edu/consultation
  - Learn about how the CDW team can tailor your request to your needs
- Office Hours: no appointment necessary, walk-in to speak with a CDW analyst and ask questions related to datasets, i2b2, or other CDW "stuff"
  - 1st Wednesday and 3rd Thursday of each month: 1-5pm. TraCS, room 219
- FAQs:
  - tracs.unc.edu/index.php/services/informatics-and-data-science/cdw-h/cdw-h-faq

Submit a CDW data request

- After the above steps have been completed, visit https://tracs.unc.edu/request to request service from the CDW

- Register with TraCS, sign in with your ONYEN, select Informatics and Data Sciences, and follow prompts to provide information about your request.

Computable Phenotype

This helps both you and the analyst understand what you are looking for. An analyst can help you to refine this, but it will help if you come to the consultation with a general outline of this.

A computable phenotype is a very specific list of inclusion and exclusion criteria used to identify patients for a study. Below is an example of the type of criteria included in computable phenotypes:

> Can you pull data from the CDRN that will show me all patients between ages _____ and _____, who have been diagnosed with _____, but haven't had a _____ in the last 6 months, but have had ___ visits in the _____ clinic over the past year? I also need to know if they're taking _____, or have had any ___, ___, or ___ lab values over ___ mg/ml in the past year.

Computable phenotypes are important for any clinical data request, but they are especially important for CDRN requests. A strong computable phenotype will ensure you find expected and like populations across institutions.

Indicating CDW use in the 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). Must match CDW request form.
- **B.1 Methods of Recruiting:** Indicate use of a **CDW-specific** telephone script, recruitment letter, email, or MyChart message to reach out to potential participants. Indicate in recruitment methods how you will use the CDW data to recruit subjects. IRB will require you submit the documents for approval. CDW will ensure correct approved materials prior to data release.
- **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, ACC, Peds Clinic).
- **C.1 Data Sources:** Indicate use of UNC Health Care System Medical records, then check electronic medical records using CDW-H.

Time to Process a Request

- Consideration and approval process
  - Remember, you must have IRB approval for use of CDW and of CDW-specific recruitment materials before your request can be processed. To avoid delays, be sure to indicate all appropriate data points that will be received and submit CDW specific recruitment language
  - When your data is ready, you will be able to access it in a secure environment
- The amount of time to process your request will vary considerably depending on a number of factors:
  - Team preparedness (proper IRB indication and recruitment materials)
  - Current capacity of CDW-H analysts
  - Time sensitivity of the study and recruitment timeline itself
  - Complexity of the request

Recruiting Patients obtained from a CDW query

- ❑ You will receive a list of patients meeting your criteria along with their contact information.
- ❑ You can reach out to them as you've indicated in your IRB application
- ❑ The CDW is an internal tool – you should never reference it in your communication with patients
- ❑ As with any recruitment tactic, scale your outreach appropriately

CDW Recruitment Templates

- ❑ Revised templates for CDW recruitment materials were implemented in February 2021
- ❑ Templates for:
  - ✓ Mailings
  - ✓ Telephone scripts
  - ✓ Email recruitment
  - ✓ Guidelines and FAQs
- ❑ Meet with Recruitment and Retention for help with your materials

Recruitment Etiquette

- UNCHS is an academic medical institution with a research mission. We are very familiar with what research is, why it's important, and how it's conducted. Patients on the CDW list and their providers may not yet be familiar with the research process or opportunities that research can offer.
- Review carefully the list of potential participants provided by CDW and exclude any that are not eligible
- Be patient and courteous. Have a "research" pitch prepared. Be prepared for some patients to be defensive.
- If a patient enrolls as a participant, you may consider/need to send notice of their participation to their PCP for continuity of care. This should also be indicated in the consent form if part of your SOP for the study.

Suggested Language – CDW Letters and Mailings

Dear XXX:

- The UNC School/Department of <Insert school/department name> and UNC Health are dedicated to providing the very best care available for our patients; we are always learning more about the topics that are important to you to bring you the most current information. Research is one way that we do that. **As a patient, researchers will occasionally contact you to tell you about a new study, as below.**

OR

- The UNC School/Department of <Insert school name> and UNC Health are dedicated to providing the very best care available for our patients; we are always learning more about the topics that are important to you to bring you the most current information. Research is one way that we do that. **Your medical records indicate that you might be a good match for the study described below.**

Suggested Language – CDW Phone Scripts

Telephone scripts should begin with something similar to the recruitment letters:

Hello, may I speak with (patient's name)? (verify before proceeding)

My name is _____ and I am a researcher with the Department of ____ at UNC. We are currently conducting a study on _____ which we think you may be a good fit for. Do you have a few minutes for me to tell you more about what we are doing and see if you may be interested in participating?

If they say yes, THEN go into more detail.

If they say no or are too busy to talk, say "No problem, would it be alright if I mailed/emailed you some information instead?"

Come see me for more details on writing a phone script!

Suggested Language – CDW Email

General interest:

The UNC School of <Insert school name> and UNC Health are dedicated to providing the very best care available for our patients; we are always learning more about the topics that are important to you to bring you the most current information. Research is one way that we do that. As a patient, researchers will occasionally contact you to tell you about a new study, as below.

Research Opportunity: <insert simple, catchy title to pique patient interest>

Our team studies _____ and we are currently looking for _____. This research study will look at _____ to see if _____.

The study involves ___ visits to ___ over about _____. During the study, participants will be asked to _____. You might be able to take part in this study if you:

- List main inclusion/exclusion criteria in plain language

Please consider helping us to learn more about _____ and how it could _____. <Compensation is provided for your time and effort.>

Suggested Language – CDW Email

This is for you:

Dear <patient name>,

The UNC School of <Insert school name> and UNC Health are dedicated to providing the very best care available for our patients; we are always learning more about the topics that are important to you to bring you the most current information. Research is one way that we do that. Your medical records indicate that you might be a good match for a study that is currently looking for participants.

To learn more about this study and to see if you are a good fit, please visit <insert website or screening tool> or contact us at: <email> or <phone xxx-xxx-xxxx>.

If you or a family member is curious to learn about other research opportunities here at UNC, please visit ResearchForMe.unc.edu. Every person in every study makes a difference; it is thanks to participants like you that we are able to keep learning and discovering!

Special Considerations for Email

- Because email messaging may not be secure or an unintended person may receive a message or open an email message (spouse if joint email or boss if work email address), it is not acceptable to include sensitive information such as a medical condition, lab result, specific clinic or study title in an email message.

- As such, researchers should only include general statements like those listed in their email recruitment message. If one is able to infer from the information in the email the person's health condition, the PI may consider only including the recipient's first name and sending the email securely.

- Links and attachments may be permissible

PATIENT FAQS

- **"How did you get my name and contact information?"**
  - Answer: Part of the UNC Health Care mission is to support research. Since UNC is a teaching and research institution, it is part of the policy that your information may be shared with UNC researchers who are conducting studies that have been reviewd an approved by our IRB (which is the group on campus who protects the rights of research participants). This is all indicated in the Notice of Privacy that is provided to all patients when they check in for a UNCHCS appointment.
  - As a team member on an IRB-approved study, we have a limited HIPAA waiver and are able to review basic medical information to determine which patients may be eligible to participate in our research study.

Patient FAQs

- **"I told the last researcher that called me that I want to be taken off of the list – I don't want to be contacted about this"**
  - Answer: When you tell a researcher that you don't want to participate, we are not allowed to keep your contact information. This actually helps to protect your privacy since your information is not stored, but unfortunately, does mean that you may be contacted again by another researcher in the future.
  - The UNCHCS privacy policy that every patient signs at check-in does indicate that your name may be provided to researchers. If you wish to discuss that policy or if you have further questions, I'd be happy to provide you with the number to the UNC IRB, whose job it is to protect your rights.
    - UNC IRB: 919-966-3113 or IRB_subjects@unc.edu
    - UNCHC Privacy Office: 919-962-6332 or privacy@unc.edu

Patient FAQs

- **"Did my doctor refer me to this study?" or "Does my doctor know about this study?"**
  - Answer: The answer to this will depend a bit on the study.
  - Never mislead a patient into thinking that their PCP referred them to the study if they did not. You may provide them with a copy of the consent form which they make take to talk over with their doctor. Indicate that you are available to answer any questions that the doctor might have. You may also offer to contact the doctor with information
  - You can also indicate that although their doctor may not specifically be familiar with the study, it has been reviewed by a committee whose job it is to protect participant rights and safety. You may also indicate that the study is overseen by the PI, who is ultimately responsible (and qualified) for determining whether the patient is a good candidate for the study.

Patient FAQs

- **"But I am not a UNC Health Care patient. I go to Rex (or other) hospital"**
  - Answer: UNC Health Care System now includes several affiliate hospitals and clinics, including Rex (or name of other UNC hospital affiliate). So, even though you receive your care at Rex (or other name), your records are part of the UNC Health Care System.

WHAT **NOT** TO SAY…

- Be careful in describing how you received access to patient data – language in recruitment materials and conversations with patients should only describe medical records as coming from the UNC Health Care System and Affiliate Hospitals / Clinics.

- One should NEVER say “We are contacting you because you signed up with the Carolina Data Warehouse for Health” as this is incorrect. No reference to the CDW should be made in recruitment letters or scripts either.

- Subjects do NOT 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.

Take Away

- The CDW is an excellent tool that has a variety of applications. Carefully consider how it could best compliment your study and if you have the effort and capacity to utilize it.
  - If in doubt, talk to a CDW-H analyst to see if it's a good fit for you
- You are the face of UNC research for any patient that you contact and any participant that you enroll
- Be professional, knowledgeable, kind, clear, and empathetic
- Participant experience with you will determine whether they decide to volunteer again and will impact their perception of UNC the research community. Make the experience for every participant positive, so that they become research ambassadors, share their positive experiences, and encourage others to participate!

Questions/Discussion

Thank you!

https://tracs.unc.edu/index.php/services/informatics-and-data-science

INVESTIGATIONAL DRUG SERVICES (IDS): WHAT & WHY

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UNC Health
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UNC HEALTH℠

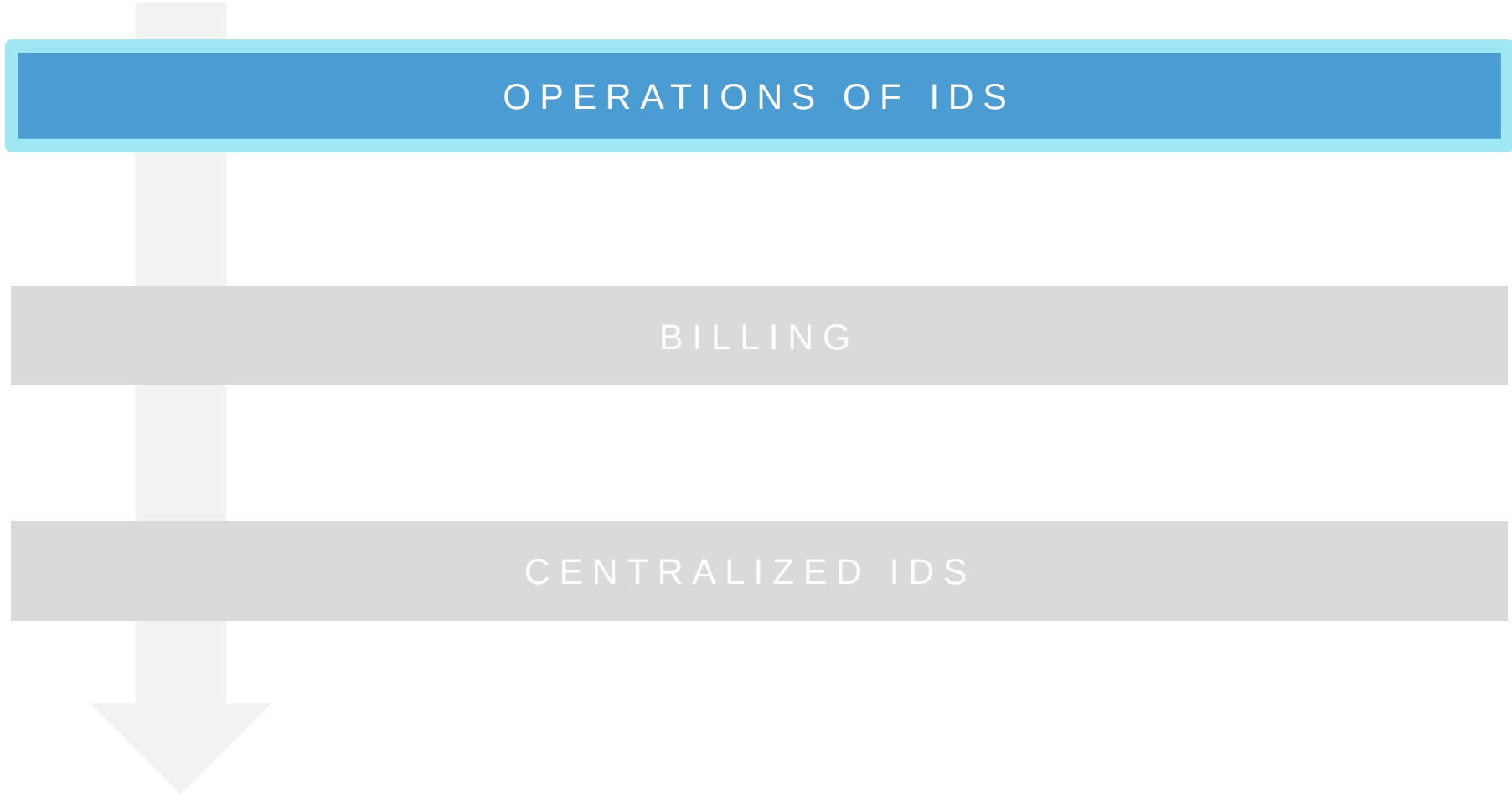
AGENDA

OPERATIONS OF IDS

BILLING

CENTRALIZED IDS

AGENDA



INVESTIGATOR RESPONSIBILITY FOR DRUG PRODUCT

ICH E6 GCP (Section 4.6)	• The investigator is responsible for product accountability at the study site
Investigators can delegate duties	• At UNC, the IDS Pharmacist is delegated this responsibility
Joint Commission Medication Management Standards	• MM.06.01.05 • "… written process for the use of investigational medications specifies that the pharmacy controls the storage, dispensing, labeling, and distribution of investigational medications."

IDS OPERATIONAL OVERVIEW

IDS STAFF

- 10.6 Pharmacist FTEs
- 9.0 Technician FTEs
- 1.0 Reimbursement analyst FTE

DISPENSING

- Nearly 600 studies
- 11,000 + dispenses for FY20

HOURS

- 0730 to 1600, M – F → General IDS
- 0800 to 1630, M – F → Cancer IDS
- Closed on major hospital and university holidays
- Weekly IDS meeting Thursdays 2:30 – 3:15pm

IDS OPERATIONAL OVERVIEW

Memorial Hospital, 3rd Floor

- Phone: 984-974-0469
  Fax: 984-974-6359
- Sterile compounding, general disease states

Neurosciences Hospital, Ground Floor

- Phone: 984-974-3777
  Fax: 984-974-3471
- No sterile compounding, general disease states

Cancer Hospital, 3rd Floor

- Phone: 984-974-8236
  Fax: 984-974-8560
- Cancer therapeutics, all formulations

IDS SHIPPING ADDRESSES

Do not include investigator's name

Do not raise shipments without first notifying IDS

UNC Healthcare
Investigational Drug Services
3rd Floor, Room N3122
101 Manning Drive
Chapel Hill, NC 27514

UNC Healthcare
Cancer Investigational Drug Services
NC Cancer Hospital Infusion Pharmacy, RM C3247-5
101 Manning Drive
Chapel Hill, NC 27514

WHAT DOES IDS DO? ALL IDS STAFF

Dispenses investigational product (IP)

Manages inventory

Monitors storage conditions (temperature)

Maintains accountability/data/records (Vestigo web-based IDS system)

Receives monitor visits (and audits)

Responds to questions from study teams/sponsors

WHAT DOES IDS DO? LEAD PHARMACISTS

Each protocol is assigned a lead pharmacist to be the primary driver of the protocol in IDS

Work up new protocols to distill pharmacy process

Create information sheet for every protocol

Train IDS staff (and ancillary pharmacy staff as needed) on new protocols

Revise protocols as required by amendments or study updates

Communicate with study teams regarding their protocols

AFTER HOUR EXPECTATIONS

ON – CALL AFTER HOURS

In an **emergency**, an IDS clinical pharmacist can be paged by:

- 919-216-9727or through WebExchange

They will provide assistance with:

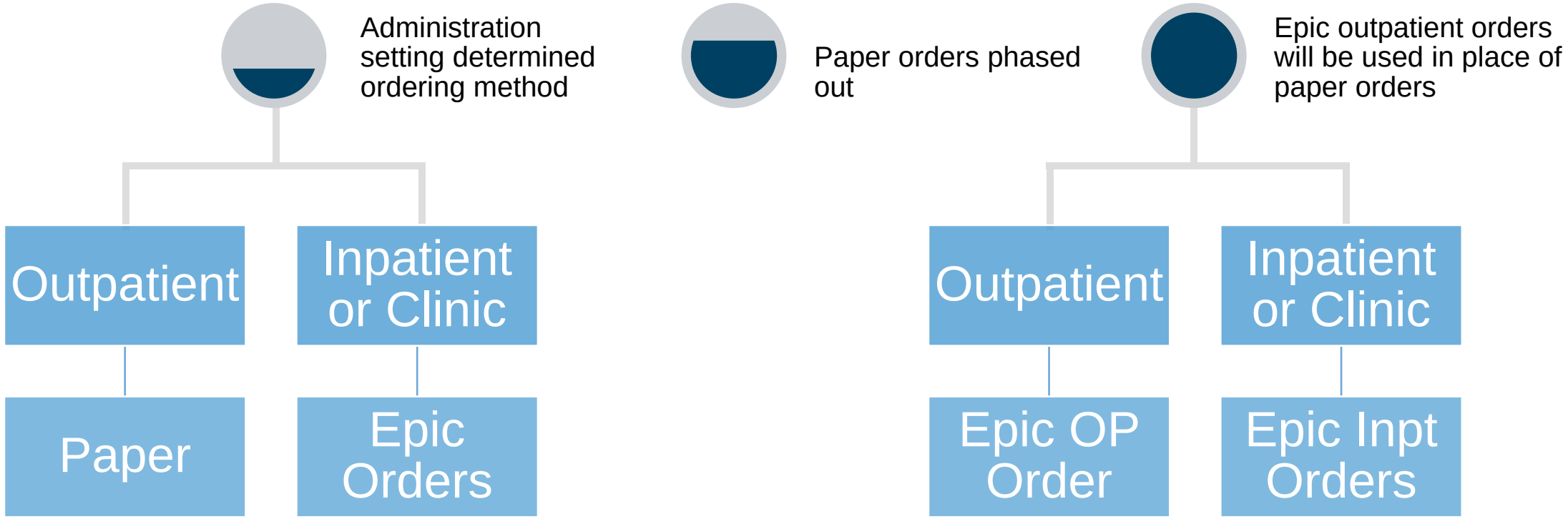
- Individual drug or research questions
- The breaking of a treatment blind
- Provide support for inpatient or IV room pharmacy staff who may be unfamiliar with a particular research protocol

AFTER HOUR DISPENSING

If a research protocol will require after hour dispensing, this must be arranged well in advance

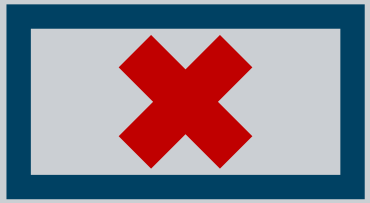
After hours dispensing or 24 hour dispensing increases the complexity score and can lead to higher fees

IDS MOVING AWAY FROM PAPER ORDERS



CAN NON-STERILE PRODUCTS BE COMPOUNDED BY IDS?

- Blinding for solid oral dosage forms
- If pharmacy special formulations already makes it, we can purchase from them

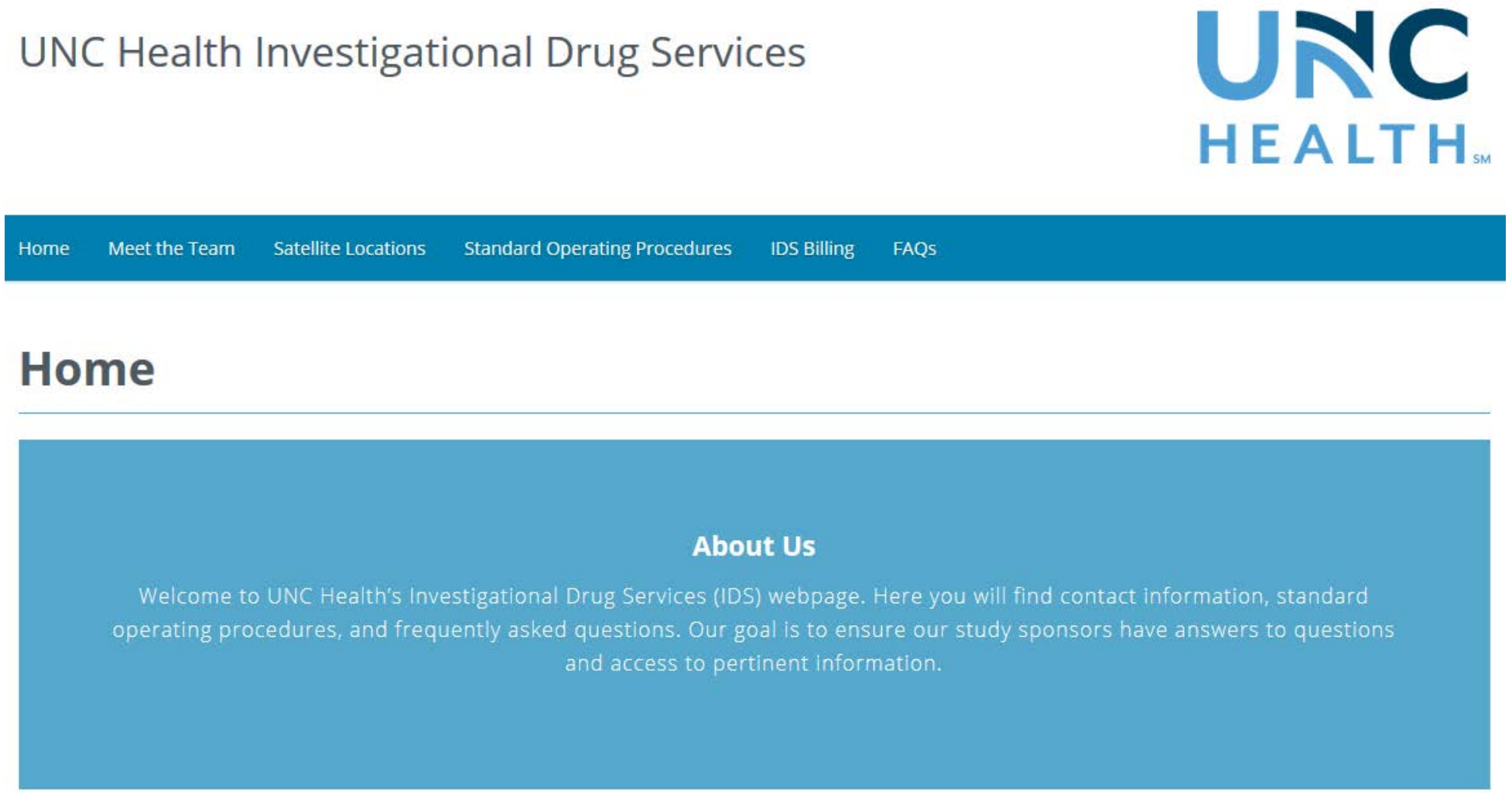


- Mixing powders
- Filling capsules with powders
- Suspensions
- Creams

COMMUNICATION WITH IDS

Quick Answer	• Call us at 984-974-3777
Send Documents	• Email Lead Pharmacist • Email shared inbox uncids@unchealth.unc.edu
Monitor Visit Schedule	• Call 984-974-3777 to schedule a monitoring visit • We can accommodate 2 monitors per day per location • 1 month in advance for scheduling
Remote Monitor Visits	• For newer studies, IDS documentation is stored electronically → prefer that monitors review documents remotely • Vestigo access can be extended at any time, just call IDS

IDS WEBSITE


UNC Health Investigational Drug Services
UNC HEALTH SM
Home
Meet the Team
Satellite Locations
Standard Operating Procedures
IDS Billing
FAQs
Home
About Us
Welcome to UNC Health's Investigational Drug Services (IDS) webpage. Here you will find contact information, standard operating procedures, and frequently asked questions. Our goal is to ensure our study sponsors have answers to questions and access to pertinent information.

DO I NEED TO USE IDS FOR MY MED-RELATED PROTOCOL?

At UNC Medical Center, the clinical and distributional services of IDS are required	*Joint Commission requirements*
Any agent/drug (potentially including supplements) could be considered investigational	*If IND required → investigational* *If IND not required → could still be considered investigational*
Sometimes decided on a case by case basis	*If you're unsure, just ask!*

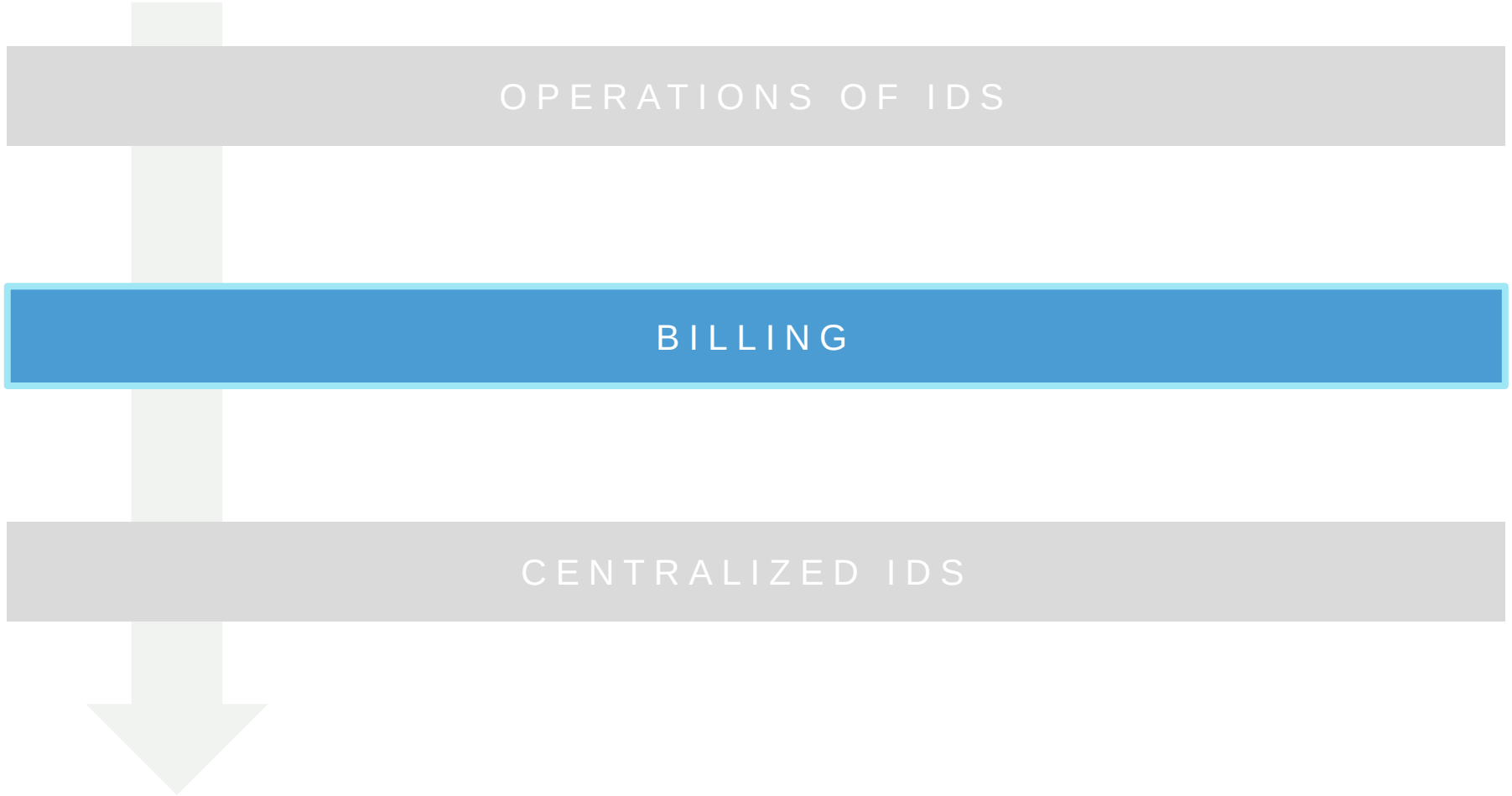
HOW AND WHEN DO I INITIATE A REQUEST FOR IDS SERVICES

Use Clinical Research Management System (CRMS)

- Submit protocol materials to IDS
- Embedded worksheet will estimate complexity score and estimate billing
- IDS will review and send confirmation memo
- Coordinator requests a pharmacist assignment through CRMS
- Lead pharmacist assigned by IDS manager
- Study ready for dispensing 6 weeks after lead pharmacist assigned

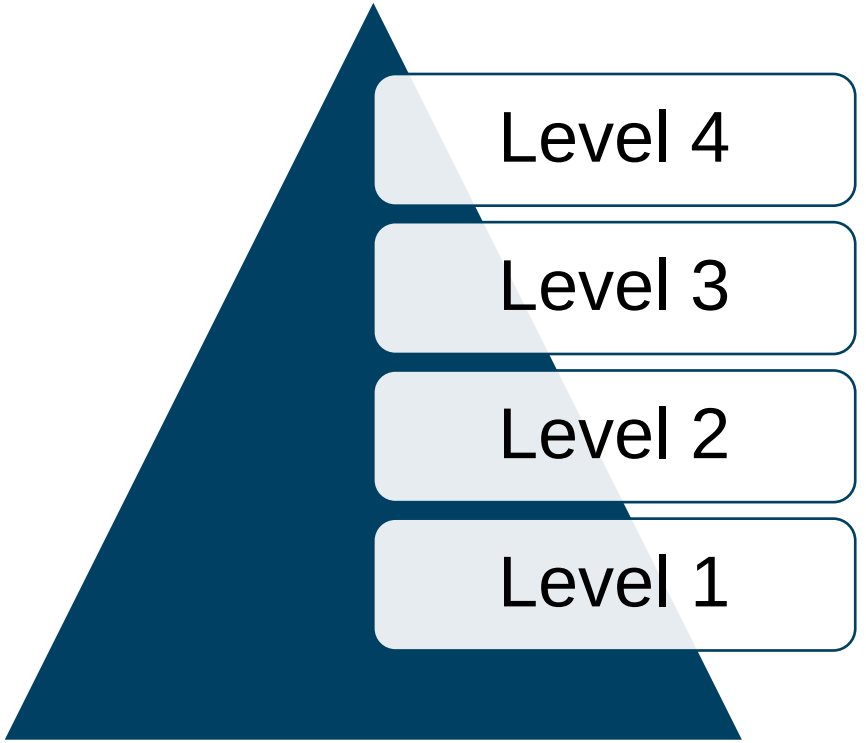
Request for IDS services in CRMS should be submitted simultaneously with contract negotiation (OCT) and request for IRB approval

AGENDA



IDS BILLING

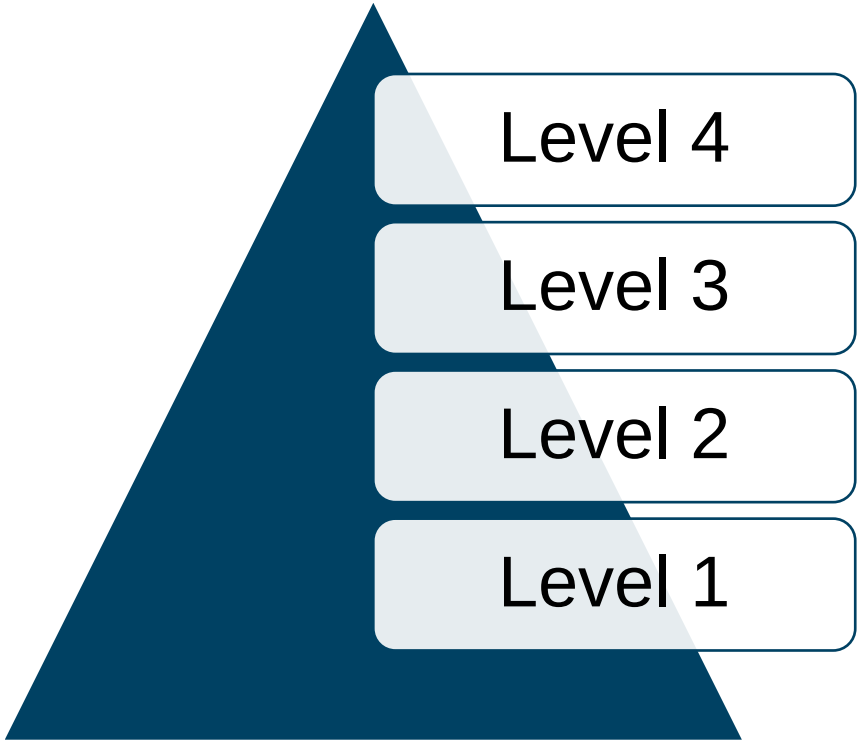
- **Billing processed through Vestigo**
- **Bills will come from Support@McCreadiegroup.com**
  - Please whitelist this email domain
  - If you aren't getting bills, please contact IDS
- **Bills will be sent via email to whomever is designated as the billing contact in CRMS**
- **If your study is open any portion of the month you will be billed for that month.**
  - Notify IDS of study closings ASAP to avoid further billing
- **Complex protocol**
  - More pharmacy labor → Higher IDS fees
- **CRMS submission estimates protocol complexity**
  - Point-based system
  - Must be completed before IDS will process a confirmation memo for IRB
  - Score may be modified by IDS once lead pharmacist prepares study for dispensing



4 levels of complexity - the level determines fees

IDS BILLING UPDATED

- **Go-live date: October 1, 2020**
- **New model will only be applied to new studies with pharmacist assignment after October 1, 2020**
- **Two tiers for billing**
  - One for industry studies / One for IITs and network trials
  - Each still has 4 levels (as before), but dollar amounts vary by tier
  - Level determined by points assigned to items that make a study more complex for IDS
  - Calculation of billing level has also been updated
- **Introduction of ad hoc fees**
  - Charged for individual activities (see fee schedule)
- **Individual items defined and explained in definitions document**



4 levels of complexity - the level determines fees

IDS BILLING

START UP FEE

Only charged once

Non-refundable

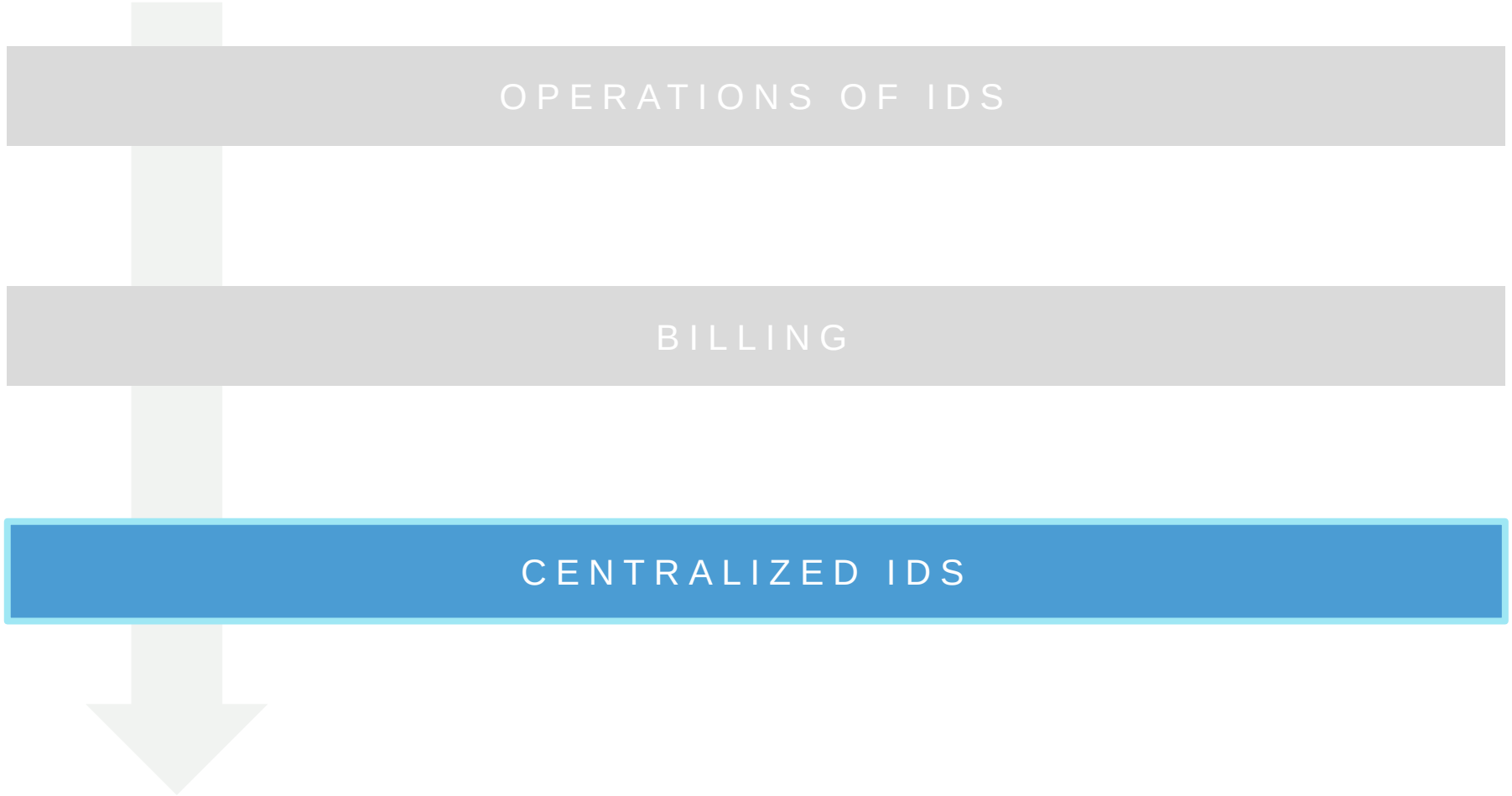
Charged at pharmacist assignment

MONTHLY FEE

Begins when IP is delivered to IDS

Ends when IP is removed from pharmacy and any close-out visit has been conducted

AGENDA

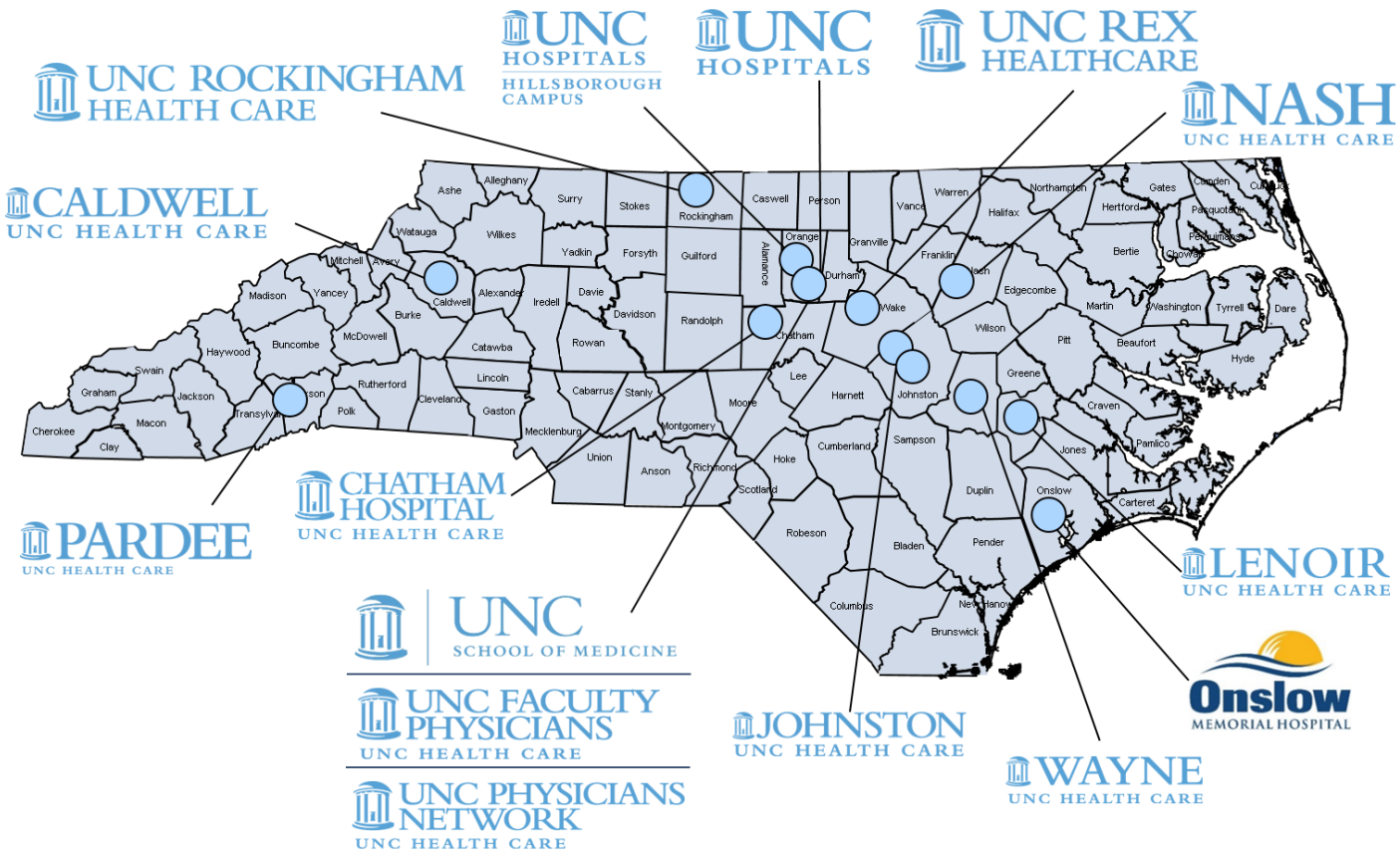


GROWTH OF HEALTHCARE SYSTEM CREATES NEW OPPORTUNITIES

15% growth in open studies from FY19 (500 studies) to FY20 (580 studies)

10,033 total dispenses in CY20

FY21 projections of more than 600 active studies with expansions to Eastowne and Children's Raleigh



ONGOING INITIATIVES TO CONTINUE FURTHER EXPANSION

Billing Restructure

Electronic Pharmacy IDS Notebooks

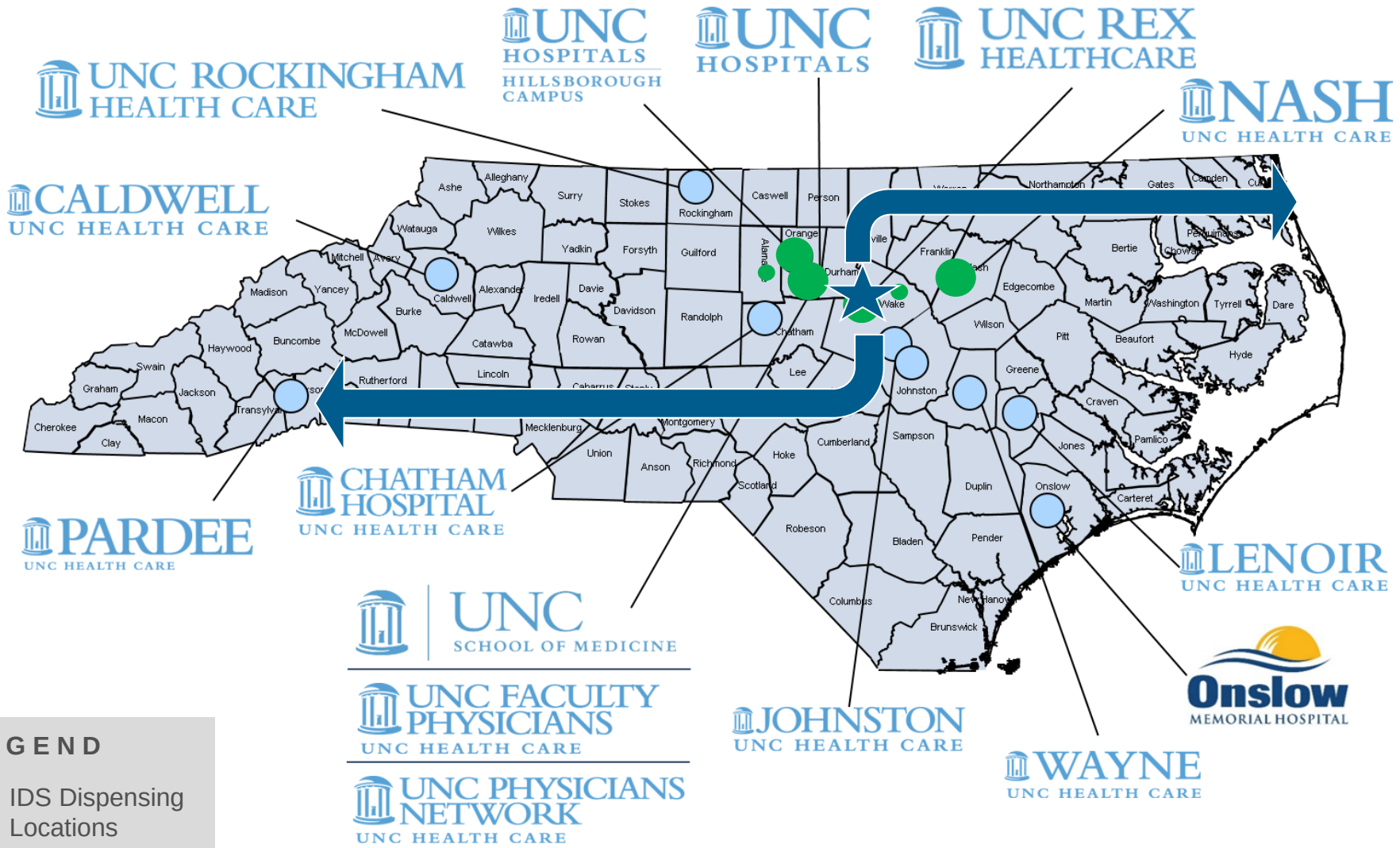
Contract Requirements for Pharmacy

Centralized Space

Eastowne, UNC Children's, and HMOB

FTE Hiring

VISION TO CENTRALIZE IDS TO SERVE HEALTH CARE SYSTEM



LEGEND

IDS Dispensing Locations

INVESTIGATIONAL DRUG SERVICES (IDS): WHAT & WHY

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System Clinical Manager, Investigational Drug Services
UNC Health
Phone (984) 974-0040
Andrew.Thorne@unchealth.unc.edu

UNC HEALTH℠

UNC INVESTIGATIONAL DEVICE POLICY

Marie Rape, RN, BSN

TraCS Regulatory Service

marie_rape@med.unc.edu

919-966-6844

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

What Is A Medical Device?

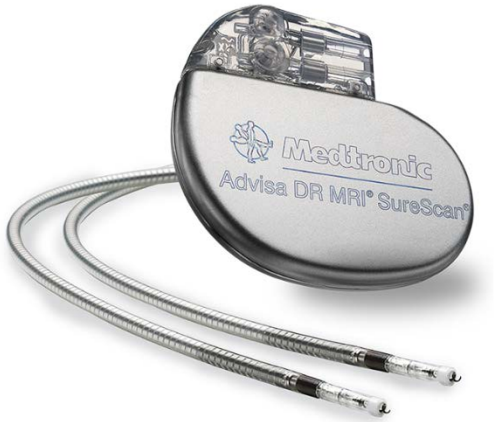
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which:

- Is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or
- Intended to affect the structure or any function of the body, and
- Does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Section 201(h) of the FD&C Act

A device achieves its primary intended purposes through physical action

What Is A Medical Device?



What else can be classified as a Device?

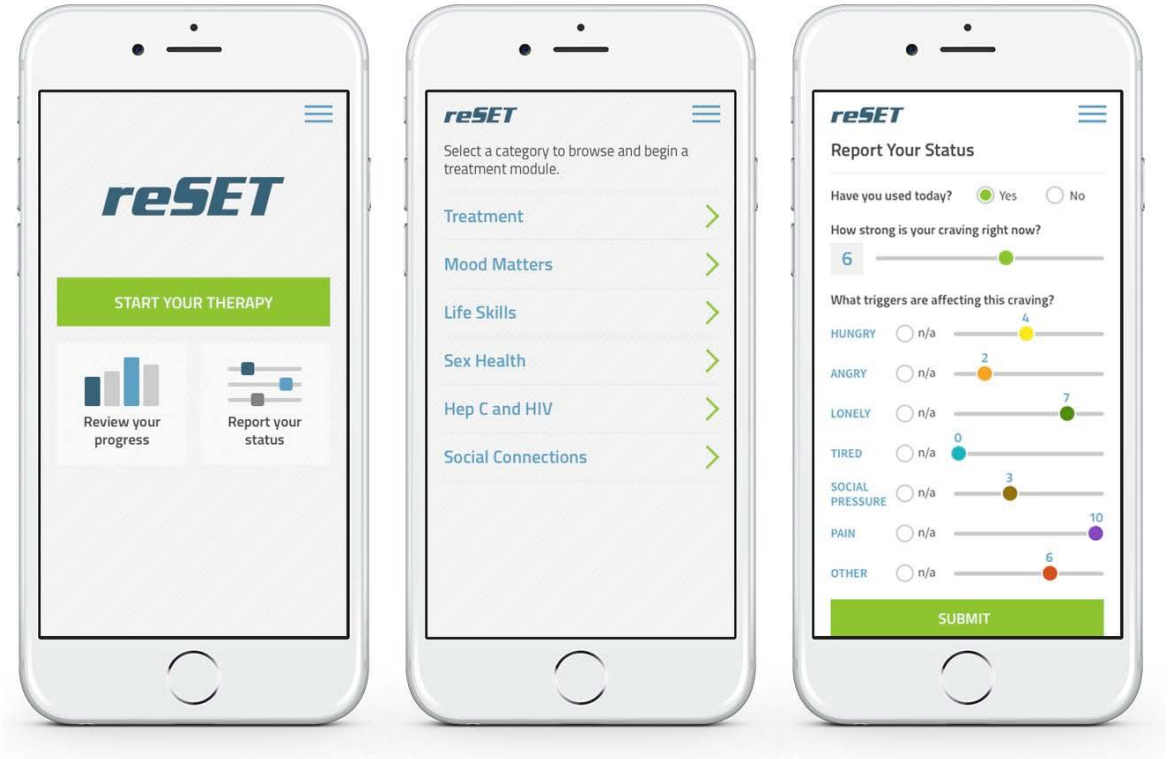
Devices don’t need to be applied to or implanted in someone to be considered a device.

Novel blood tests, diagnostic algorithms, and software can all be classified as a device if they meet the federal definition: “**Is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease**”

Section 201(h) of the FD&C Act

FDA's new focus on APPS

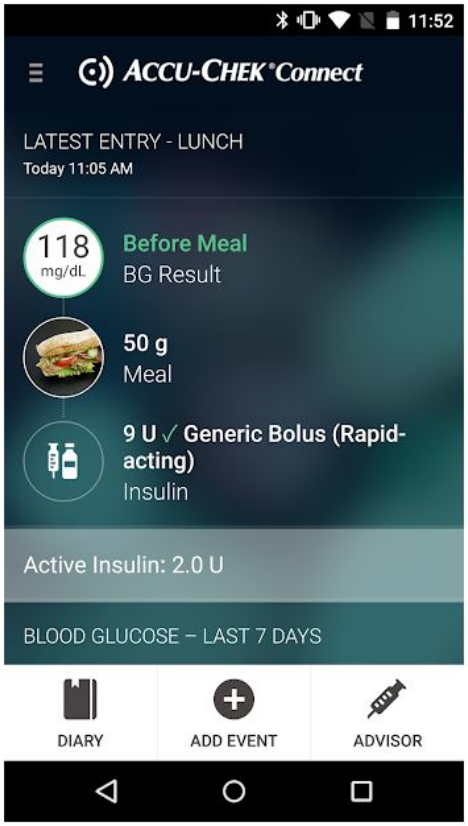
"Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease"

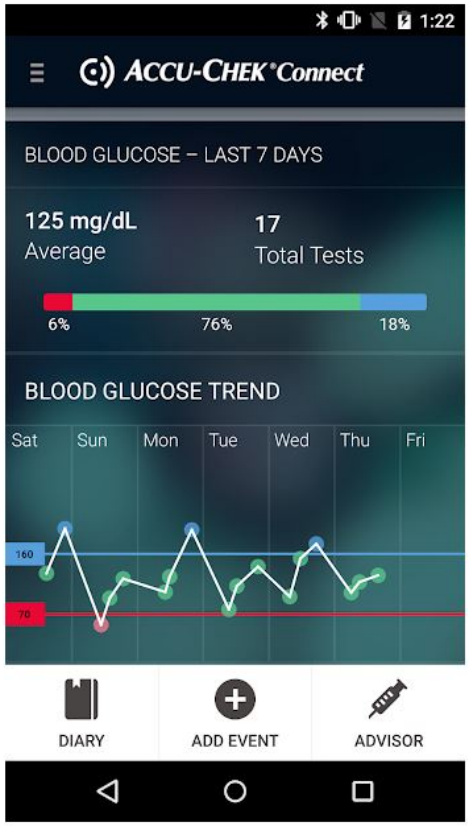


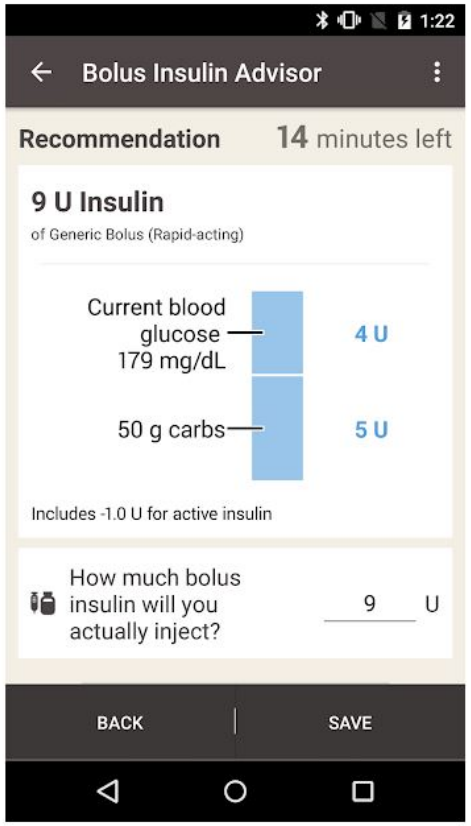
reSET® : a prescription digital therapeutic to be used in conjunction with standard outpatient treatment for substance use disorder (SUD)

FDA's new focus on APPS

"Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease"







UNC Device Policy 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 investigational devices:
https://research.unc.edu/human-research-ethics/resources/ccm3_034228/

- 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.
- If the study is Investigator-Initiated, additional steps must be taken. (Federal submission and approval, PI oversight, etc.)

Receipt, Storage, and Use

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

- Device Storage-
  - Secure and segregated.
  - Clearly identified as investigational

- Device Use-
  - Each device number documented and associated with specific subject

Receipt, Storage, and Use

DEVICE RECEIPT					DEVICE USE				DEVICE RETURN/REPAIR/DESTRUCTION						
Date Rec'd	Initials of Receiver	Lot #/ Serial or Model #	Device Type / Batch #	Comments	Date Used	Initials of Device Dispenser	Participant ID	Comments	RET= Returned DES= Destroyed REP=Repaired	Date	Initials	Auth #	# of Units	Reason	Comments

NC TraCS IDE and IND Assistance

It is crucial if your PI is running an Investigator-Initiated Device Study (or drug study!) that they understand the federal requirements involved with holding an IND/IDE. This includes annual reporting, amendment and new protocol submissions, and SAE reporting.

NC Tracs can assist with:

- Determining if an IND or IDE is necessary, or if exemption is possible.
- Preparing IND & IDE submissions to the FDA
- Communicating with the FDA to ensure a smoothly executed clinical investigation
- Contact amandawood@RTI.org

- ReGARDD.org : A shared CTSA website that is comprised of helpful tools, templates, decision trees, and educational resources to support academic investigators' regulatory needs. Hosted and maintained by UNC, Duke, Wake Forest, and RTI.

ReGARDD
Regulatory Guidance for Academic Research of Drugs and Devices