

# PEARLS Overview and Research Team Management

PEARLS

April 12, 2019



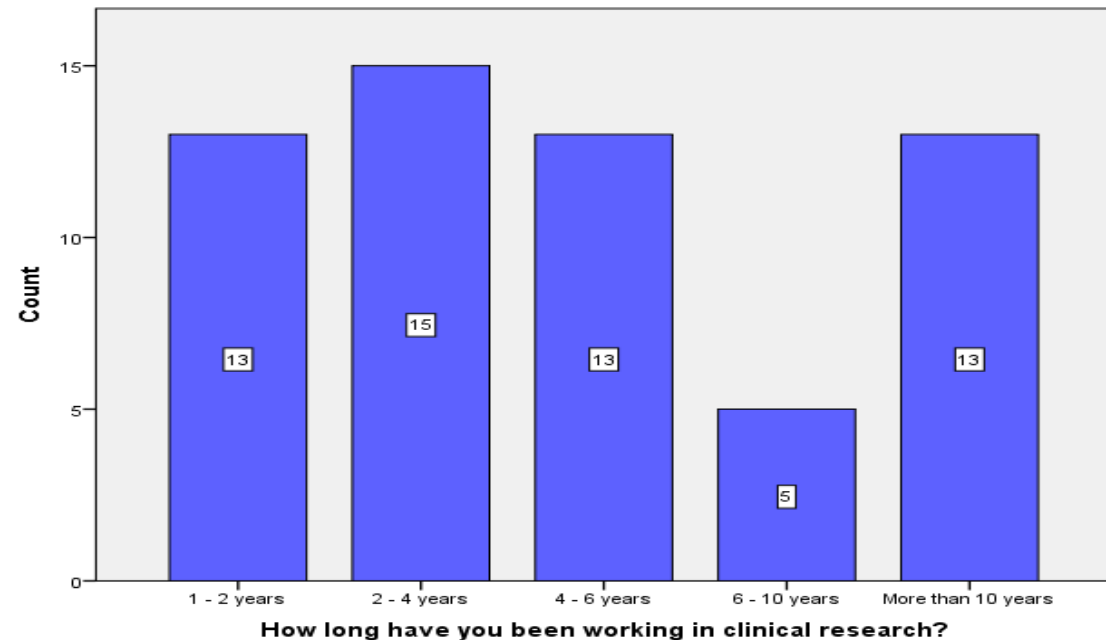
# Today's Speakers

- **Nadine Spring, MPH, MS, CCRC**, Director, Clinical Research Services, Emory Department of Pediatrics
  
- **Kathy Stephens, RN, MSN**, Clinical Research Manager, Infectious Diseases

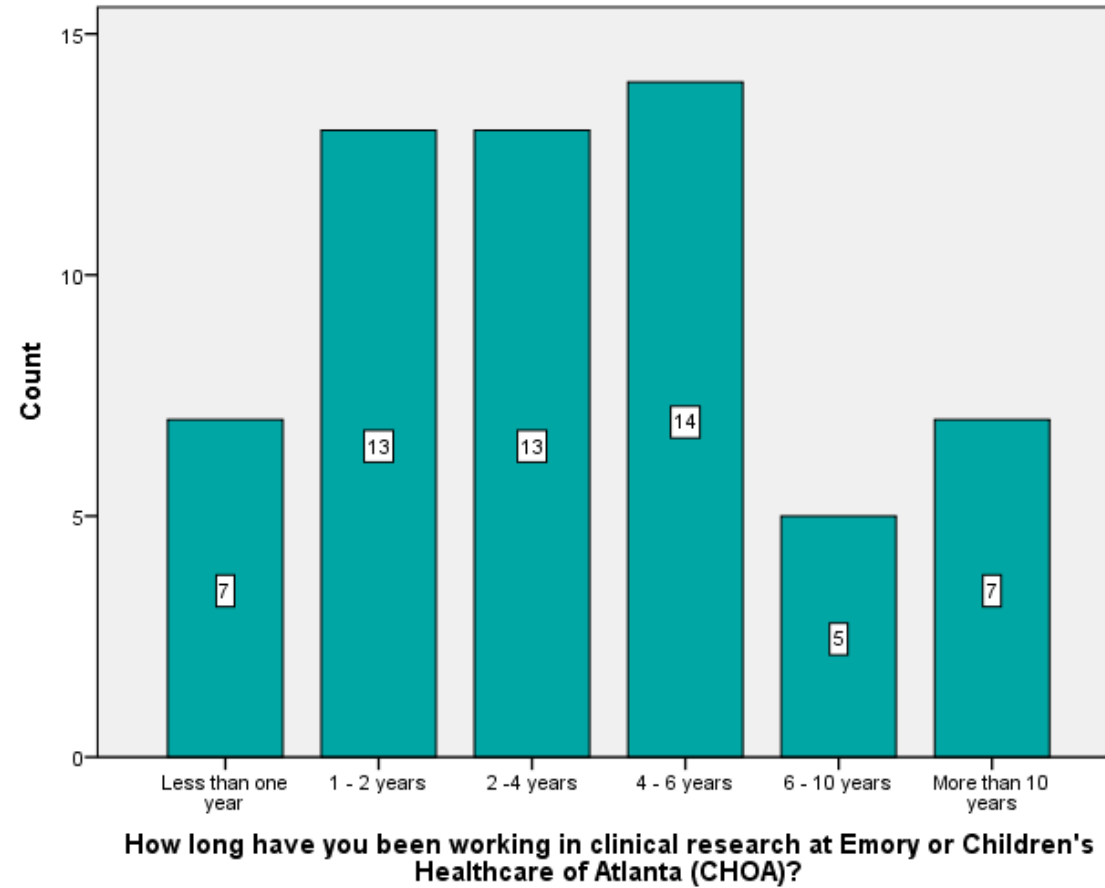


# Pediatric EducAtion Research Lunch Series (PEARLS)

- Needs assessment in early 2019
- 59 responses
  - 25% in clinical research for 2 – 4 years
  - 22% in clinical research for 1 – 2 years, 4 -6 years, and more than 10 years

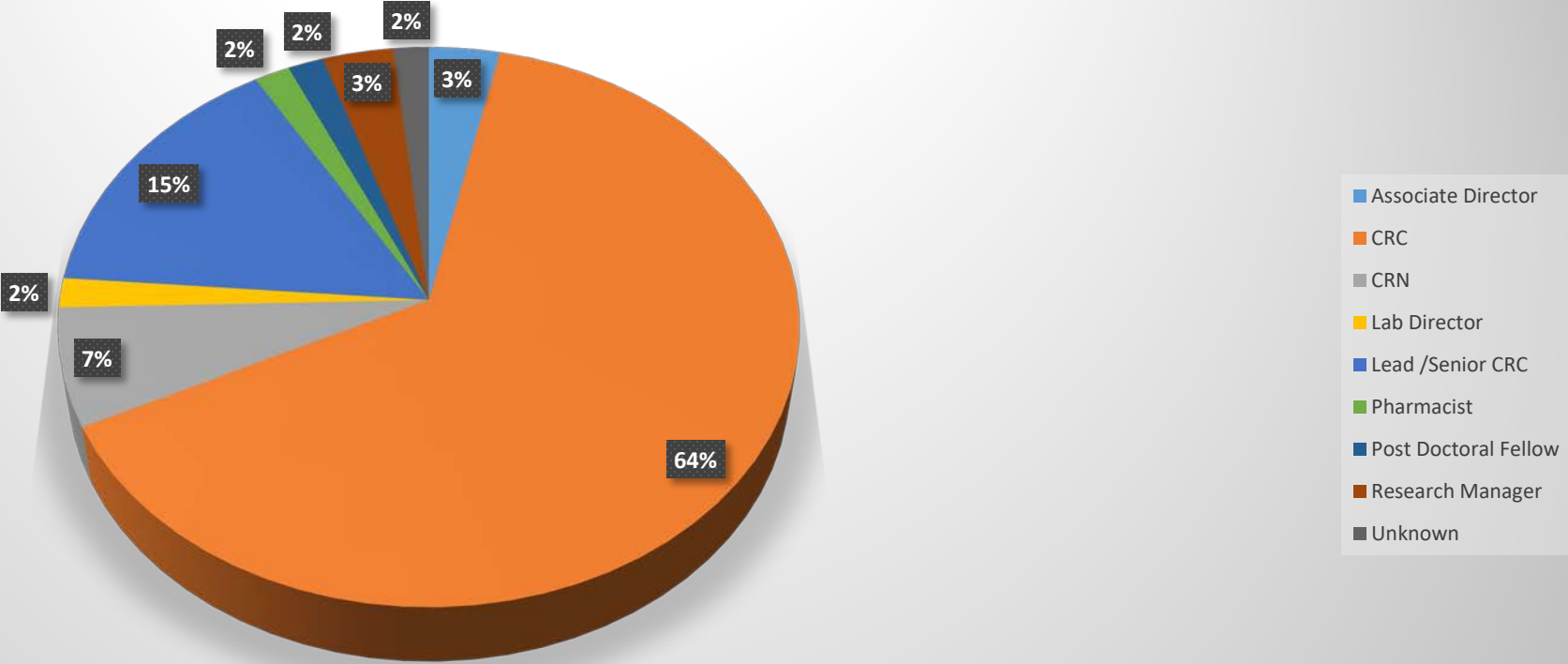


# Employment at Emory or CHOA

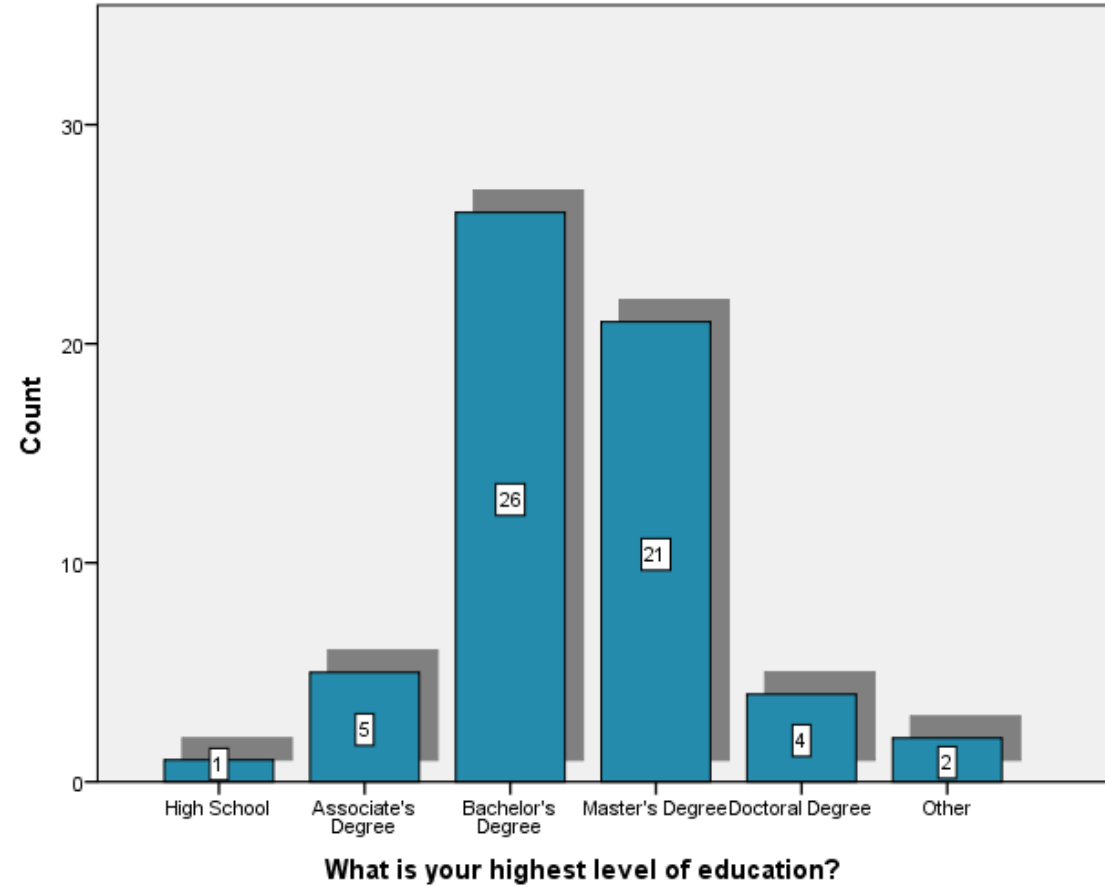


# Job Titles of Respondents

Job Titles for Clinical Research Personnel Completing the 2019 PEARLS Assessment

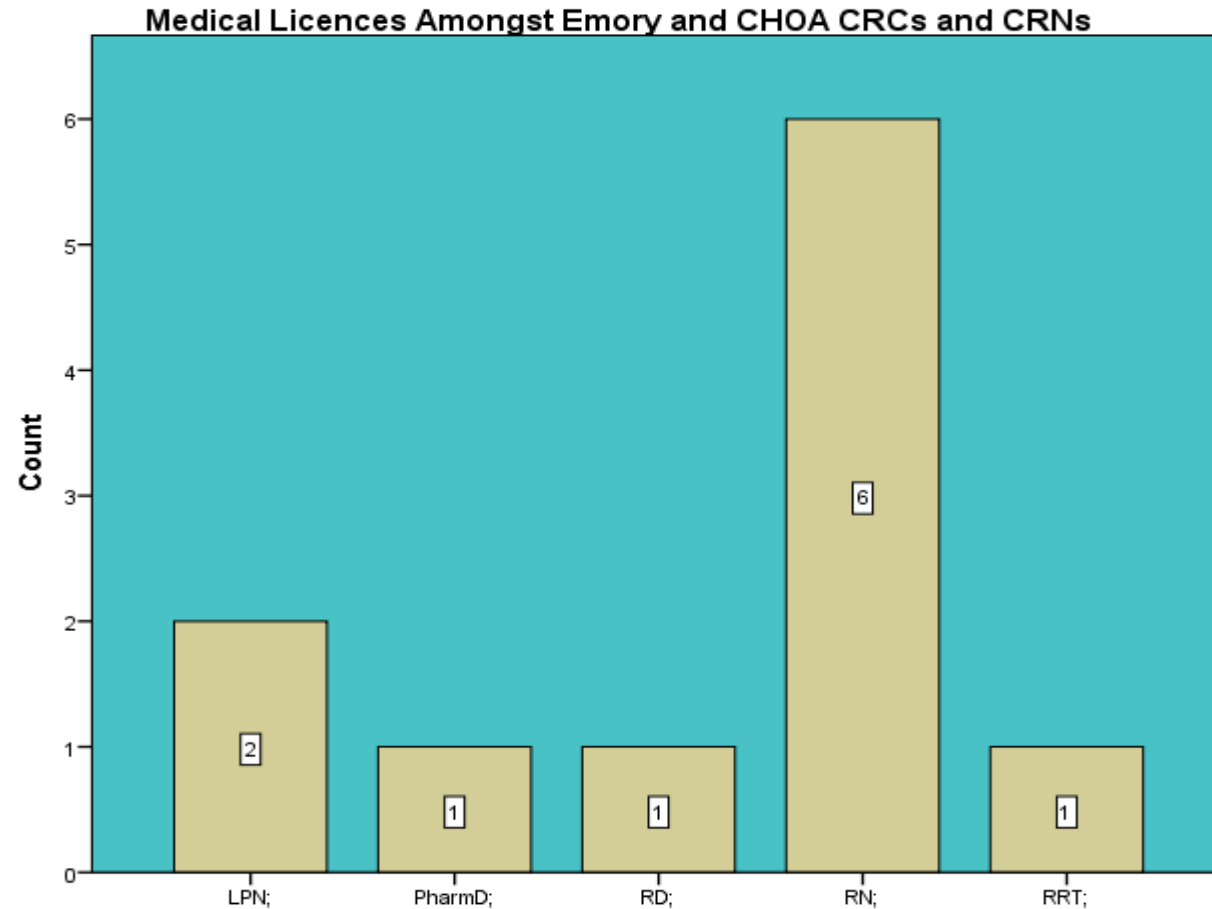


# Educational Level



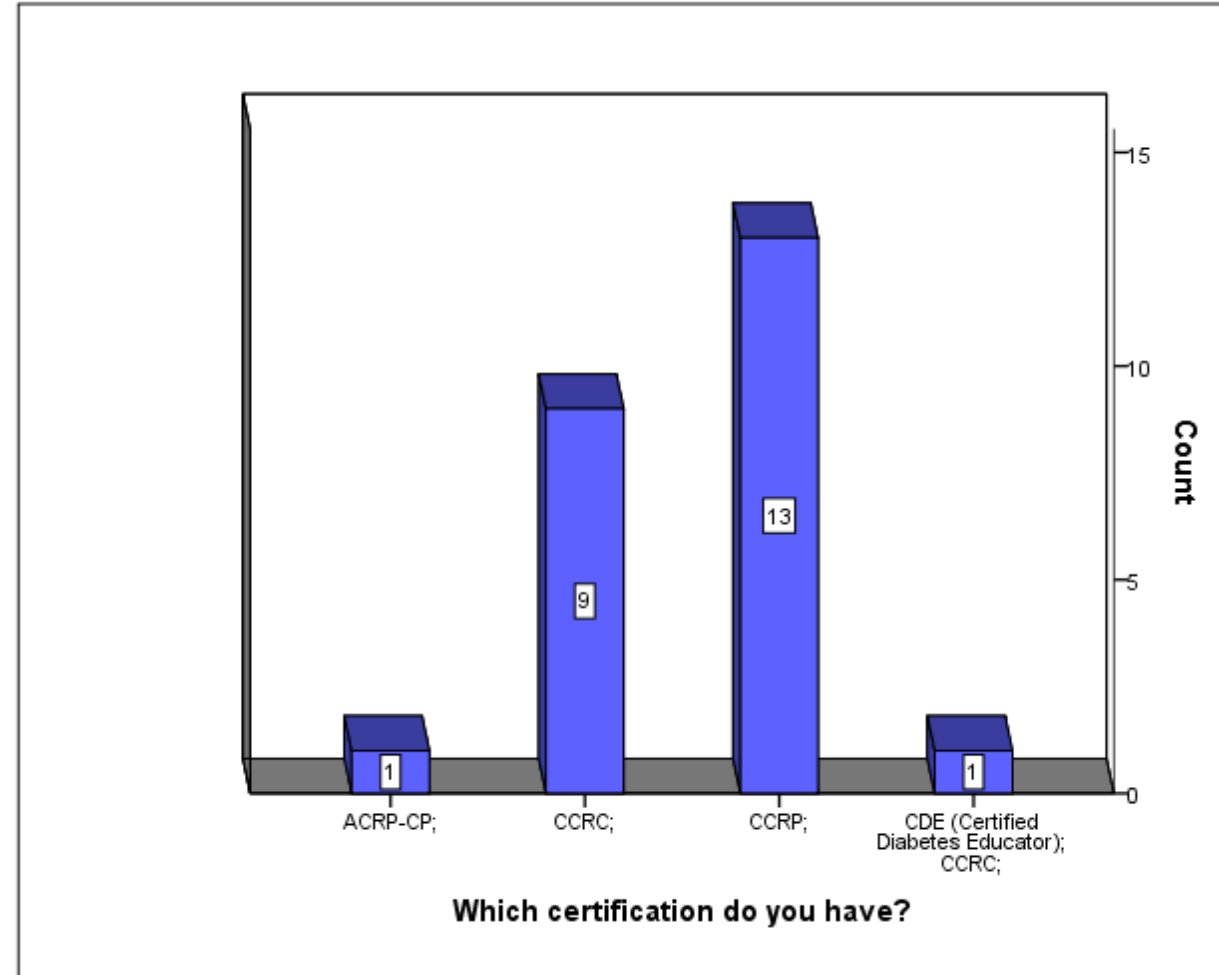
# Licensed Providers

- 11 are licensed healthcare providers



# Clinical Research Certification

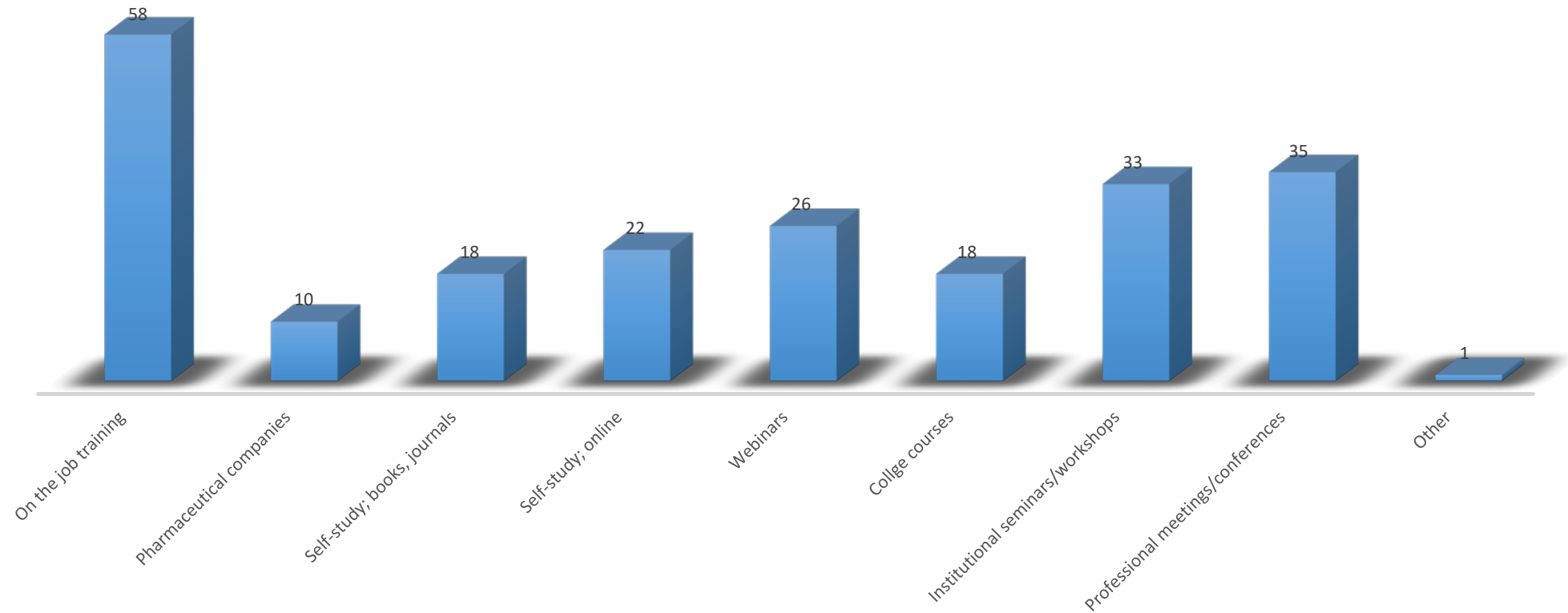
- 41 % Certified



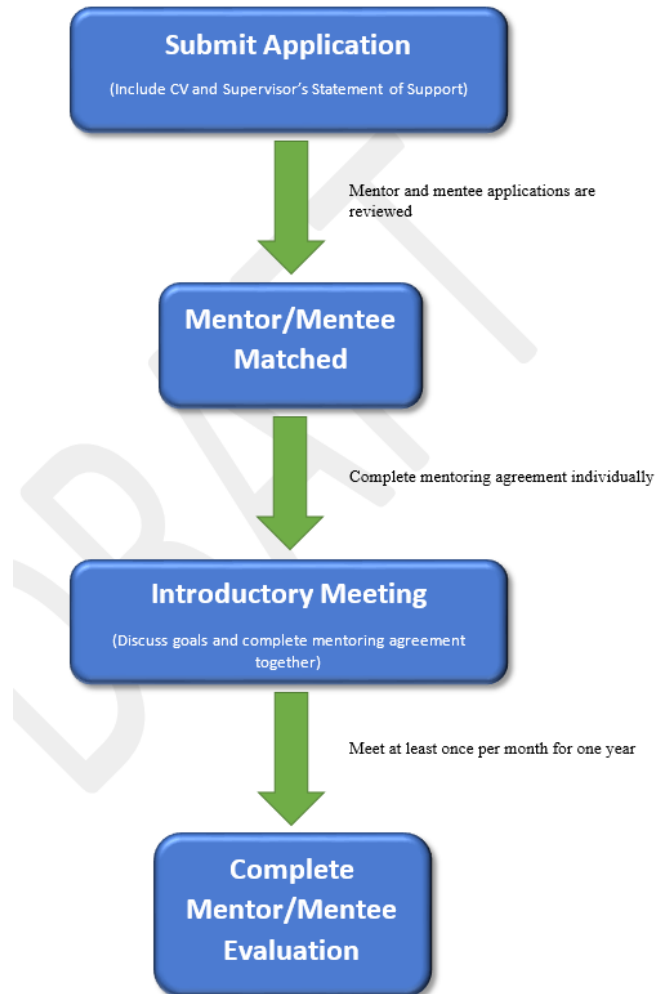


# Clinical Research Training

How were you trained for your job in clinical research?

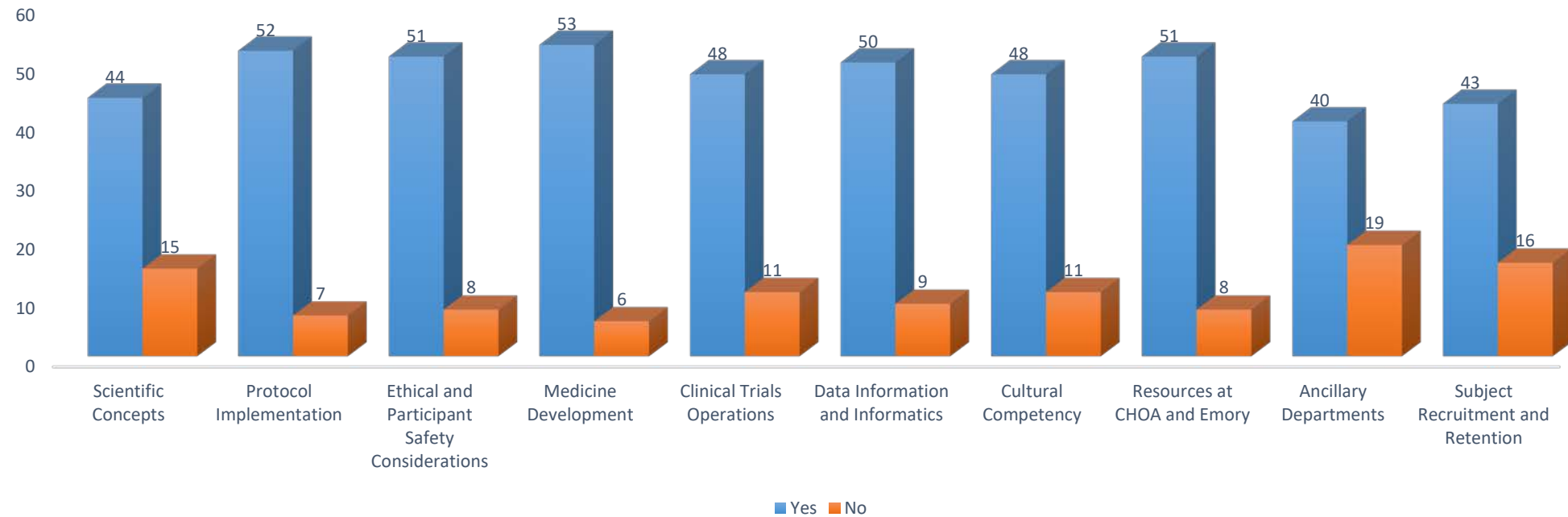


# Schematic of the Mentoring Program

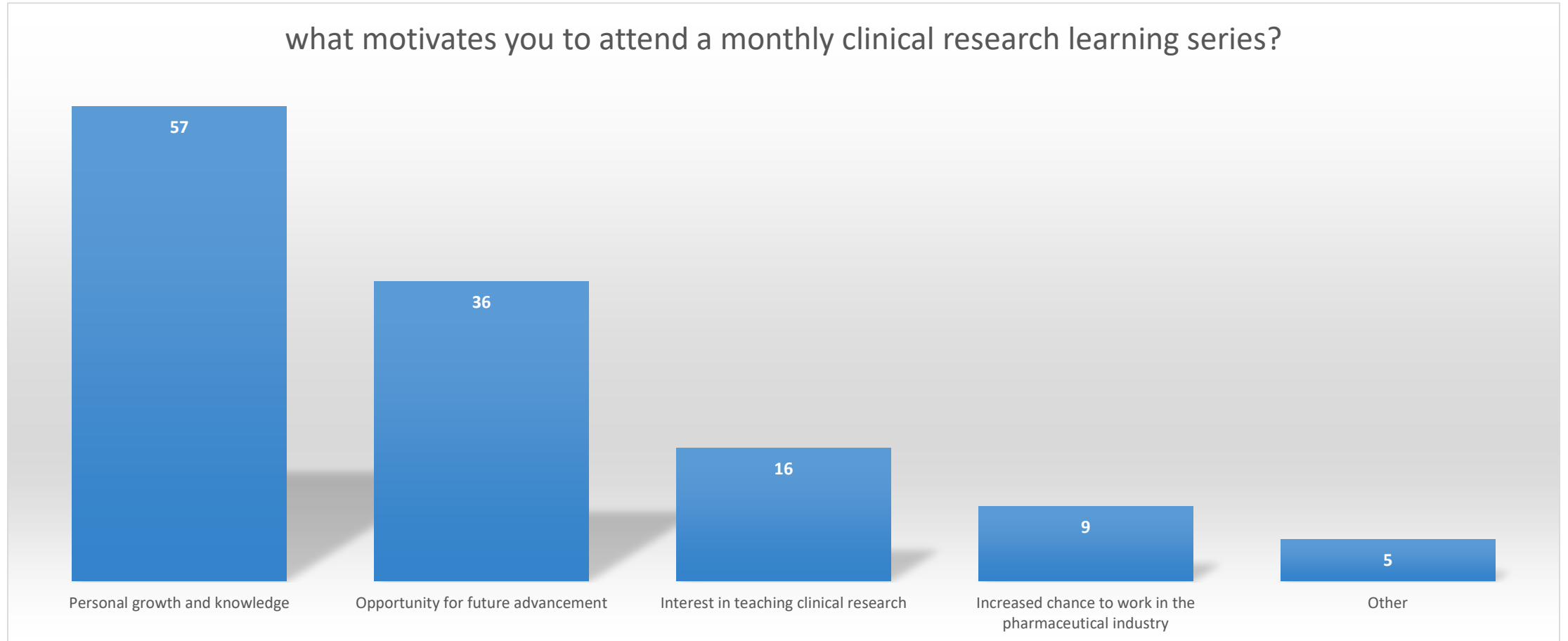


# Lunch Series Topics

Would you be willing to attend a lunch session on each of these areas?

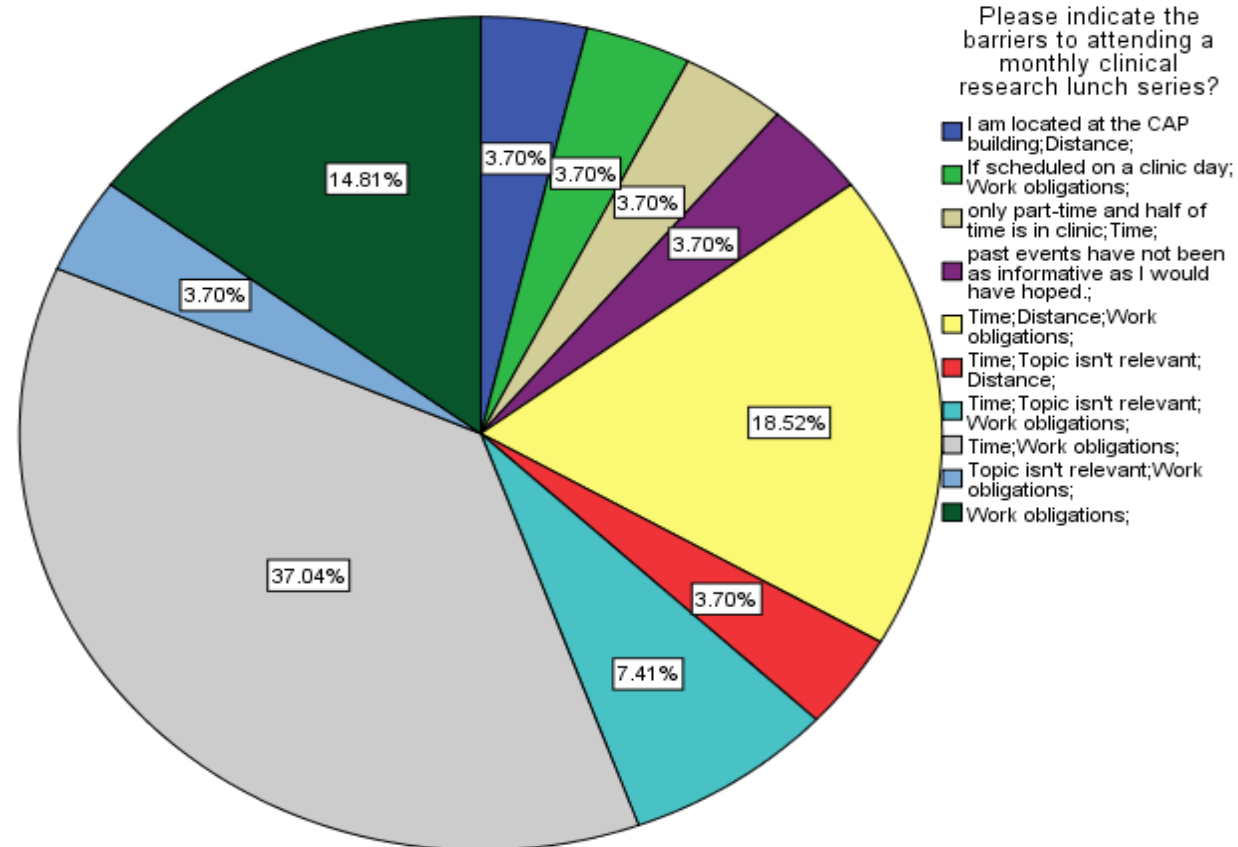


# Reasons for Attending a Monthly Research Series



# Barriers to Attending

- 46% indicated there are barriers to attending a monthly lunch series



# PEARLS Planning

- Volunteers from Emory and CHOA
- Continue to be driven by CRCs
- Reviewed survey responses and started the planning process
- Combination of panels, single speakers, multiple speakers, followed by discussion or question and answer
- Ability to submit pre-survey questions prior to the session

# 2019 Topics

- PEARLS Overview
- Research Team Management
- Audit, Monitoring, and Compliance
- Cultural Competency
- External IRBs
- Pre-Award Process
- Post-Award Process
- Pediatric Institute
- Career Development in Clinical Research
- Ancillary Departments



# 2020 Topics

- Consenting Do's and Don'ts
- Source Documents and Good Document Practice
- SAE/AE Reporting, Identifying, When to Report
- Patient Interaction and Advocacy
- Coordinating Multi-site Studies
- Subject Recruitment and Retention
- Device and Drug Studies
- Preparing for a Monitoring Visit
- Cultural Awareness in Research





# PEARLS Planning Committee

- Margo Kamel, Maria Cordero, Nadine Spring, Nia Moyer, Nikita Rao, Rebecca Cleeton



# Questions

Nadine Spring

[Nadine.spring@emory.edu](mailto:Nadine.spring@emory.edu)

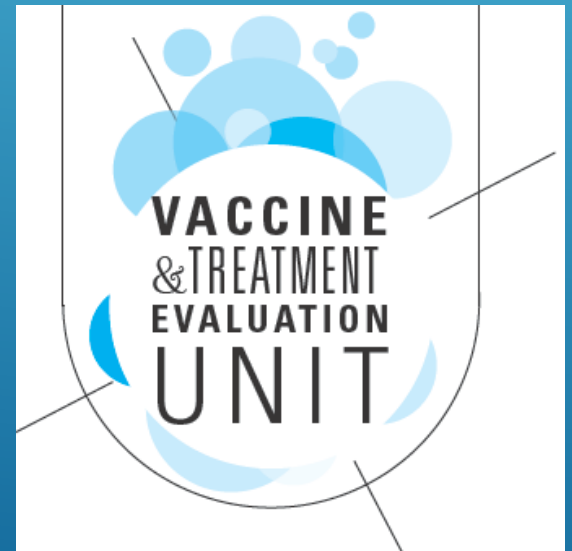
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# RESEARCH TEAM MANAGEMENT

ESTABLISHING A COMMON RESEARCH GOAL

Kathy Stephens, RN, MSN  
Clinical Research Manager  
Pediatric Infectious Diseases



# RESEARCH TEAMS

❖ SIZE: 2 → 30

❖ **ESSENTIAL** Team members:

- Principal Investigator
- Coordinator(s)
  - Nurses
  - CRCs
  - Research Assistants

❖ **SUPPORT:**

- Lab
- Recruiting
- Administrative
- Regulatory
- Quality Management

❖ **CLINICAL TRIALS:**

- Industry Sponsored
- Investigator Initiated
- Federal: NIH/CDC sponsored
- Multi vs. Single Site

❖ **TEAM COMMUNICATION TOOLS**

- Shared Box for Current Protocol Documents
- Online and current scheduling system
  - CR assist
- Study Visit Tracker
- Monitor reports and QM
- Group Me ©

# GETTING STARTED

## ❖ Concept/Sponsor

- Evaluate logistics for “team”
- Budget to support
- Create a realistic plan
- Set up Team Communication Tools

# IDENTIFY TEAM ROLES

- ❖ Overall Team Coordinator
  - ❖ Specific Protocol Coordinator(s)
  - ❖ Support team members needed
- 
- ❖ Is the protocol ready?
  - ❖ Communicate with PI and team !
  - ❖ Establish a Study Team Secure Box

# PROTOCOL TEAM PREPARATION

- ❖ “MAIN” study coordinator determines how to prepare and implement
- ❖ Identify team members
- ❖ Meet with team and PI. **Review protocol together.**
- ❖ Establish Training Plan for team (protocol, data collection, certifications)
- ❖ Assign team members to address specific tasks
  - Recruitment
  - Study visit schedule – staffing needs, room scheduling, PI calendar
  - Pre-study checklists
  - Lab supplies
  - Additional study materials – expiration dates
- ❖ Set up Visit Tracker
  - Share with team on Secure Box
- ❖ Weekly team meetings

# IMPLEMENTATION PLANNING:

- ❖ ICF
- ❖ IRB
- ❖ Stipends
- ❖ CRFs
- ❖ Training
- ❖ OCR
- ❖ Lab
- ❖ Pharmacy
- ❖ Study visit site

## Main Coordinator

- Budgeting
- Staffing
- Communication Tools
- Recruitment/success



# IMPLEMENTATION - RECRUITING

## ❖ Identify participant population:

- Hospitalized patients
  - Attending / Healthcare team (other services needed)
- Out-patient clinics
  - Clinic manager / Work flow
- Volunteers
- Multi- Site: Egleston, Scottish Rite, Hughes Spaulding, EUH, EUHM, Grady

## ❖ FIND THEM:

- Screening plan
- Contact plan
- Selection plan

# IMPLEMENT A TRAINING PLAN FOR THE TEAM:

- ❖ Regulatory
  - ❖ ERMS
  - ❖ GTMS/EPIC
  - ❖ Monitor visits
- 
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# STUDY VISITS: BE CONSISTENT – EVERYONE DOES THE SAME THING

## Pre Study Visit:

- Assemble supplies
- Consent & paperwork
- Review subject chart
- Reimbursement


## During Study Visit:

- Use computer/tablet
- Document & Review
- Schedule next visit
- Progress Note

## Post Study Visit:

- QM (by someone else)
- Reporting
- Update Box
- Review errors with team

# TIPS FOR SUCCESS

- ❖ Arrive & set up early (15 min before)
  - ❖ Send Daily schedule to ALL team members
  - ❖ Use Team Communication Tools
  - ❖ Check supplies weekly (expiration dates)
  - ❖ Weekly team meetings
  - ❖ Progress Notes facilitate communication
- 

QUESTIONS?

