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 EducA tion Rese arch Lun ch 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

How long have you been working in clinical research at Emory or Children’s Healthcare of Atlanta (CHOA)?
Job Titles of Respondents

Job Titles for Clinical Research Personnel Completing the 2019 PEARLS Assessment

- 64% Associate Director
- 2% CRC
- 7% CRN
- 2% Lab Director
- 15% Lead /Senior CRC
- 3% Pharmacist
- 2% Post Doctoral Fellow
- 2% Research Manager
- 2% Unknown
Educational Level

What is your highest level of education?

- High School: 1
- Associate's Degree: 5
- Bachelor's Degree: 24
- Master's Degree: 21
- Doctoral Degree: 4
- Other: 2

Count
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

1. Submit Application
   (Include CV and Supervisor's Statement of Support)

2. Mentor/Mentee Matched
   Mentor and mentee applications are reviewed

3. Introductory Meeting
   (Discuss goals and complete mentoring agreement together)
   Complete mentoring agreement individually

4. Meet at least once per month for one year

5. Complete Mentor/Mentee Evaluation
Lunch Series Topics

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

![Bar chart showing willingness to attend lunch sessions on various topics.](image-url)

**Topics:**
- Scientific Concepts
- Protocol Implementation
- Ethical and Participant Safety Considerations
- Medicine Development
- Clinical Trials Operations
- Data Information and Informatics
- Cultural Competency
- Resources at CHOA and Emory
- Ancillary Departments
- Subject Recruitment and Retention

<table>
<thead>
<tr>
<th>Topic</th>
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<th>No</th>
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<tr>
<td>Scientific Concepts</td>
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<td>Protocol Implementation</td>
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<td>Ethical and Participant Safety</td>
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<td>Safety Considerations</td>
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<td>Medicine Development</td>
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<tr>
<td>Clinical Trials Operations</td>
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<td>Cultural Competency</td>
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<td>Resources at CHOA and Emory</td>
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<td>19</td>
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<tr>
<td>Ancillary Departments</td>
<td>43</td>
<td>16</td>
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Reasons for Attending a Monthly Research Series

- Personal growth and knowledge: 57
- Opportunity for future advancement: 36
- Interest in teaching clinical research: 16
- Increased chance to work in the pharmaceutical industry: 9
- Other: 5

What motivates you to attend a monthly clinical research learning 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

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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
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