LUGPA 2024 ANNUAL MEETING Research Directors and Coordinators Working Group Thursday November 14, 2024 Chicago Downtown Marriott Magnificent Mile Hotel Northwestern/Ohio State/Purdue (6th Floor)

 Moderator: Joshua Ortiz-Guzman, Ph.D, Director of Research Rio Grande Urology
Presenters: Cheryl Zinar RN, BSN, Clinical Research Director, MidLantic Urology and National Director, Clinical Research Operations, Solaris Health Amy Nelson, BS, MA, CCRC, Director of Research Adult Pediatric Urology and Urogynecology

1:00 p.m. – 2:45 p.m. Session 1 Introduction and Panel Presentations

A. "Mission Research Possible"- Building the Ultimate Research team

- a. Site support staff- data entry, regulatory, billing who are you hiring?
- b. Where do you find employees?
- c. CCRPS- about \$300.00 p/person
- d. Fast Track pricey, ability to hire students, certificate

https://clinicalresearchfastrack.com/ (602-883-7944)

e. What do you look for in a CV when hiring?

B. "From Lab to Ledger": Mastering Research Billing for Financial Success

a. Poll question:

1.what are some issues you face in your practice regarding billing2. Who handles your research finances at your practice?3.What do you hope to take home from this discussion?

C. Budget Building

a. Polling question:

1. Who negotiates your budgets

2. Do you accept SOC in your budgets?

- b. Standard of Care vs. Sponsor Paid costs- do you partake
 - a. How do you negotiate this?
 - b. Do you have an SOP or budget policies?
 - c. Do you use an integrated model?
 - d. Device vs. IMP- Does it matter?
 - e. Do you complete a cost analysis- if so, how?

D. Common Challenges in Research Billing and Receiving

- a. CFO understanding research accrual and payment structures
- b. Receiving payments in timely manner
- c. Risk of billing research services as SOC
- d. How are you keeping track of AP and AR?
- e. Quick books, spreadsheets, CTMS, Verification?
- f. Communication with Shareholders?
- g. Late payments from Sponsors?
- h. Remittance Notifications?

E. Strategies for improvement

a. Poll question: Do you use a CTMS system, if so which one?

- a. Pros and Cons
- b. What system helps most with your site needs?
- c. Are you building this cost into your budget?
- d. Compliance audits of on your billing practices for studies

2:45 p.m. - 3:30 p.m Break

3:30 p.m. – 5:00 p.m. Session 2: Advancing Personalized Medicine with AI and Biorepositories in Healthcare

A. Introduction

- a. Welcome and session overview
- b. Brief introduction of speakers and topics

B. Keynote Presentation

"Integrating AI, Personalized Medicine, and Biorepositories in Clinical Research: Current Landscape and Future Directions"

- a. Overview of recent advancements
- b. Role of biorepositories in advancing personalized medicine
- c. Case studies of successful implementations
- d. Challenges and opportunities

C. Panel Discussion and interactive Q&A

"Balancing Innovation, Ethics, and Sustainability in AI-Driven Clinical Research and Biobanking"

Discussing key issues in:

- a. Data privacy and security in biobanking and AI applications
- b. Algorithmic bias in healthcare AI and its impact on biospecimen analysis
- c. Ensuring equitable access to AI-driven personalized medicine and biorepository resources
- d. Regulatory considerations for AI in clinical trials and biobanking
- e. Discovery and innovation opportunities for individual practices using biorepositories
- f. Review potential for expanded service offerings enabled by AI and biorepository collaborations

D. Closing Remarks and Next Steps

- a. Summary of key takeaways
- b. Information on how to stay connected and continue the discussion