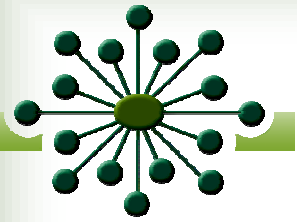


2009 Web Seminar Series

# **Fundamentals of Clinical Research in the CTN**

Instructors: Ron Jackson, M.S.W.  
Christie Thomas, M.P.H.



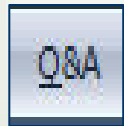
# Questions or Comments

- Enabled through several options



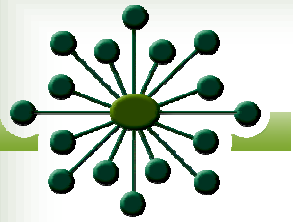
- Press\*1 on your telephone

- The operator will un-mute your line



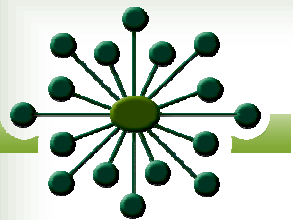
- Q/A feature will capture your question or comment

- Presenter will view question as soon as possible



# Introduction

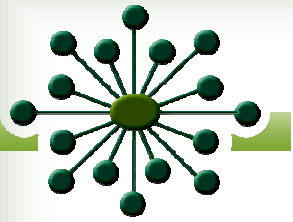
- This is a two-hour seminar orienting novice research staff to the CTN and the clinical research environment within the CTN.
- Participants will receive explanation of the essential principles critical to facilitating CTN research in a clinical treatment program.



# Introduction

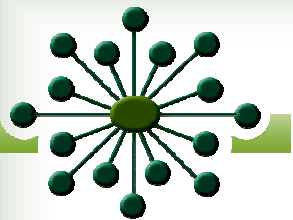
## Polling Questions





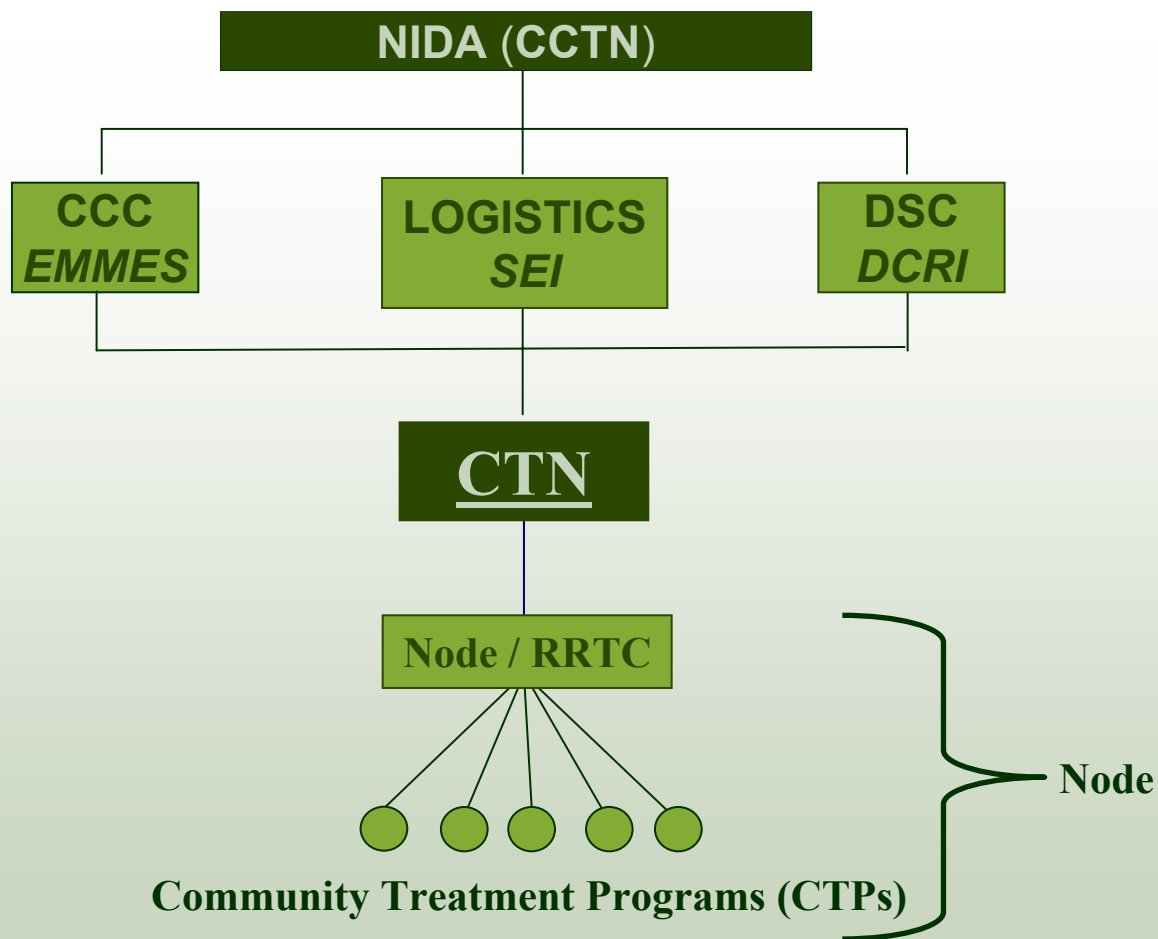
# Training Outline

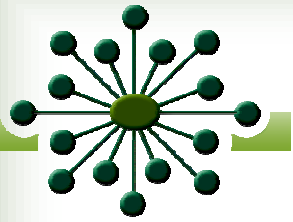
- Topic 1: CTN overview
- Topic 2: Research team
- Topic 3: Research protocol
- Topic 4: Navigating the Network to ensure success



# Topic 1

## CTN Overview



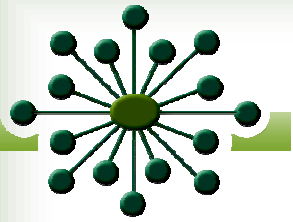


# Topic 2

## Research Team

1 of 2

- Sponsor (NIDA)
- Executive Committee
- Lead Node
- Node Principal Investigator (PI) and Team
- CTP PI and Team

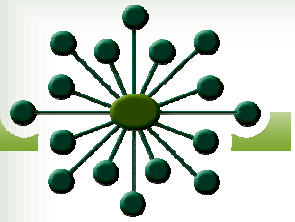


# Topic 2

## Research Team

2 of 2

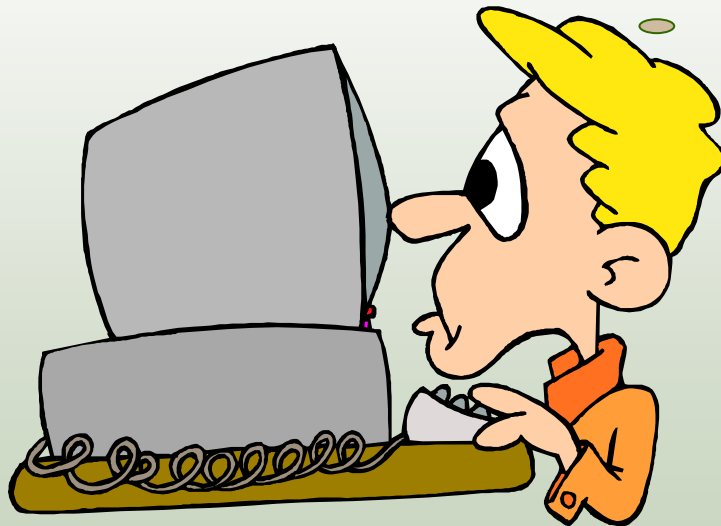
- CTP PI
- CTP Co-PIs
- CTP Study Coordinator/Research Assistant
- CTP Study Research Assistant
- Therapists/Counselors
- Technicians
- Pharmacist
- Clinician
- Other Staff

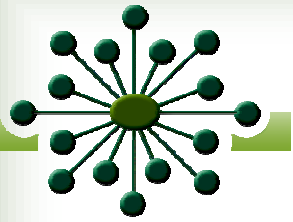


# Topic 2

## Polling Questions

*"Hmm....A...no C,  
errr...B, yeah B."*



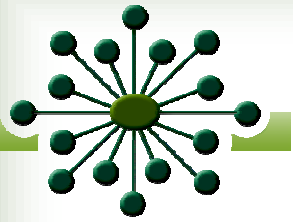


# Topic 3

## Research Protocol

1 of 5

- Research Protocol
  - Provides a plan for the essential aspects of the proposed research
  - Key to standardized study conduct
  - Clearly and succinctly describe (the 5 W's)
    - Why the study is being done
    - What will be done in the study
    - Where the study will be done
    - Who is involved in the research study
    - When study interventions will take place
  - Requires initial and continuing IRB approval

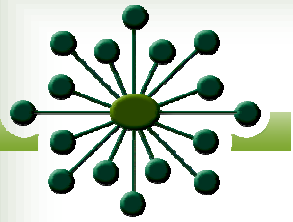


# Topic 3

## Research Protocol

2 of 5

- Research Question
  - Primary and secondary
  - Question influences proper Study Design
  
- Background and Significance
  - Provides rationale for current study
  - Relevance in obtaining informed consent

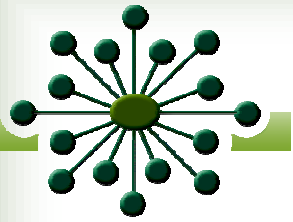


# Topic 3

## Research Protocol

3 of 5

- Study Design and Procedures
  - Study Population
    - Inclusion / Exclusion Criteria
      - Their significance
      - Reason for strict adherence
      - Impact on recruitment strategy
  - Randomization
    - Produces comparable study groups
    - Removes potential allocation bias
    - Statistical significance
  - Recruitment, Retention and Follow-up

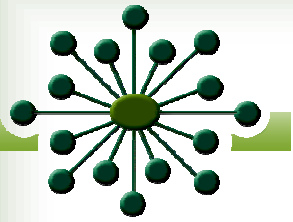


# Topic 3

## Research Protocol

4 of 5

- Data Collection and Management
  - Maximizing Quality Data
    - Protocol design & Operations Manual
    - Forms
    - Training
    - Pretesting
  - Electronic Data Capture (EDC)
    - Timeliness
    - Queries
    - Source

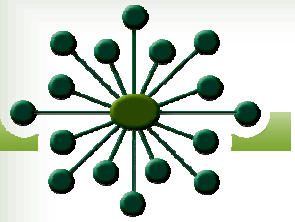


# Topic 3

## Research Protocol

4 of 5

- Reporting and Monitoring
  - Safety
    - Minimize participant risk
    - Monitor & report adverse events
  - Quality Assurance
    - Protocol Adherence
    - Monitoring and Audits
  - Regulatory Oversight
    - DSMB, IRB, Sponsor, Executive Committee

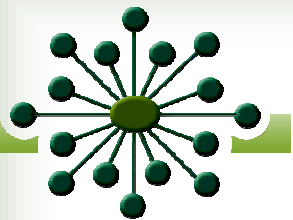


# Topic 3

## Research Protocol

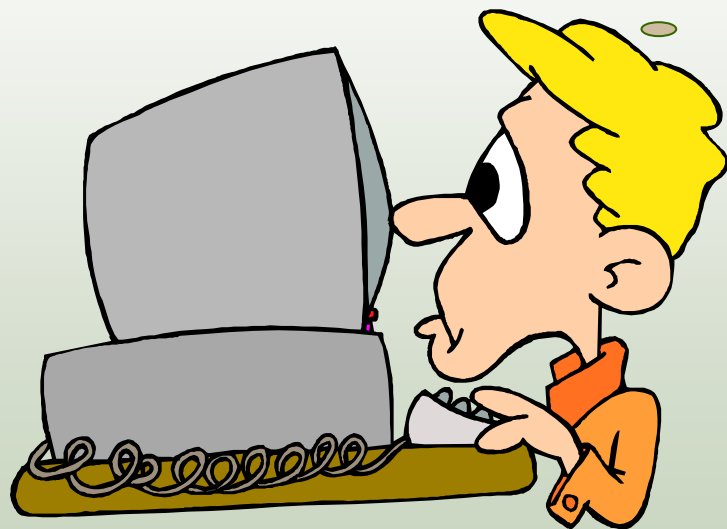
5 of 5

- Close-out
- Data Analysis
- Reporting Results
  - Publications committee
  - Blending Products

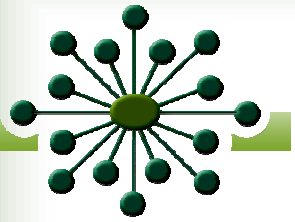


# Topic 3

## Polling Questions



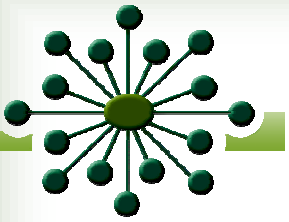
*"Hmm....A...no C,  
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## Topic 4

# Navigating the network to ensure success

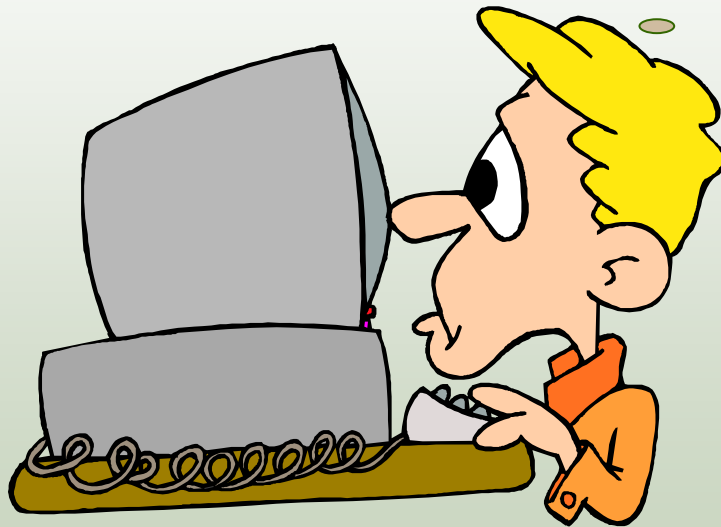
- It's all about relationships
  - CTP
    - Research vs. non-research staff
  - Node
  - Protocol Team
- Communication
  - Importance of being on call
  - Role of e-mail as documentation
  - Feedback to the system

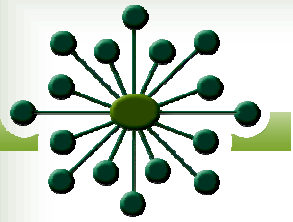


# Topic 4

## Polling Questions

*"Hmm....A...no C,  
errr...B, yeah B."*

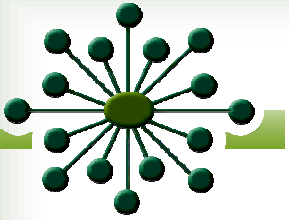




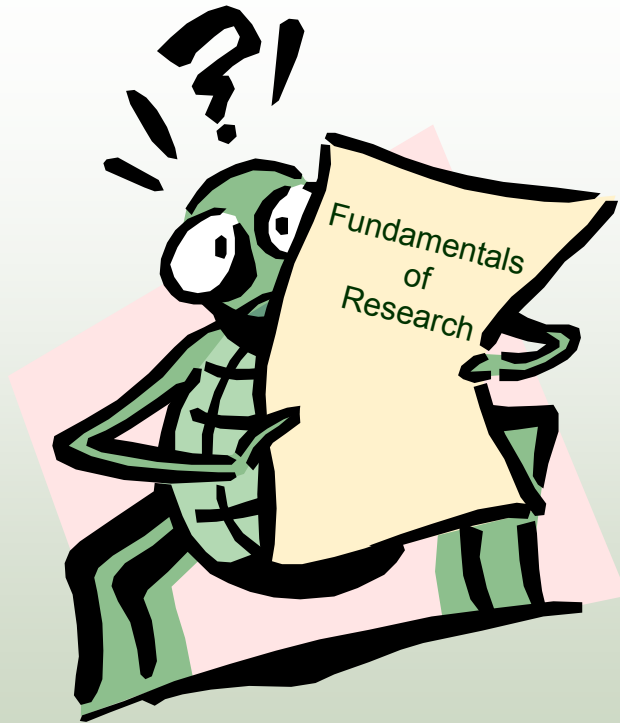
# Summary of Training

- Well-designed clinical trials adhering to these fundamental principles...
  - Protect human research participants
  - Protect research staff
  - Protect the public interest
  - Ensure the continued support for clinical trials by maintaining high standards

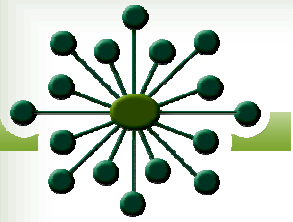




# Questions



Questions? Press \*1 on your telephone or use the Q/A feature!



# Conclusion

**This concludes our presentation today. Thank you for joining.**

- Upcoming Webinars
  - Site Management Tools and Practice Workshop Series
    - 4/2/09, 4/23/09, and 5/7/09
  - Resolutions for Unexpected Site Challenges
    - 6/11/09
  - Quality Assurance and Site Monitoring Visits
    - 7/14/09
  - Recruitment and Retention Gray Zone
    - 8/11/09
  - Writing Site Specific SOPs
    - 9/15/09
  - Ethical Principles in Clinical Research
    - 11/19/09



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