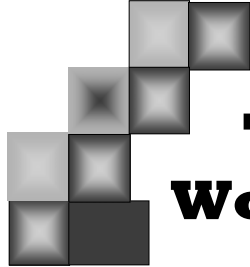




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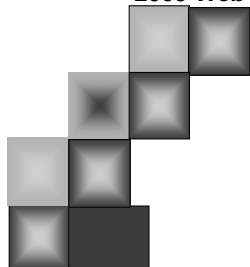


# **Site Management Tools and Practice Workshop: Session 1**

Instructors: Frankie Kropp, M.S.  
Gloria Miele, Ph.D.



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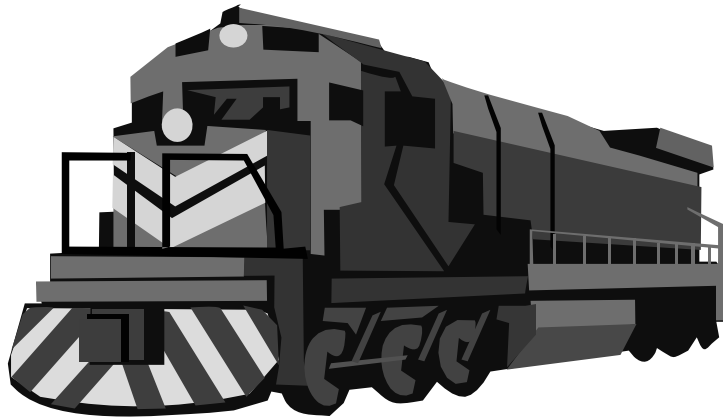
# **Part One: WHY PROJECT MANAGEMENT?**

Roles and Responsibilities

# **So, why have a Project Manager anyway?**



## **A Metaphor**





## The Engineer

- The engineer is the person in charge of and responsible for the locomotive(s). He or she is also in charge of the mechanical operation of the train, the speed of the train and all train handling.



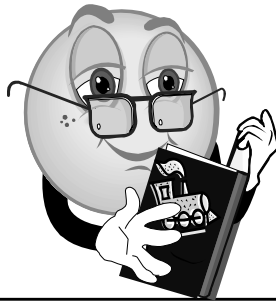
## The Conductor

- The **Conductor** is the railway employee charged with the management of a freight, passenger, or various other types of train, and is also the direct supervisor of the train's "Train Crew". All train crew members on board the train work under his or her direction. The Conductor and Engineer, who is in charge of the locomotive(s) and any additional members of the "Engine Crew" share responsibility for the safe and efficient operation of the train and for the proper application of the railways' rules and procedures.



## A RAILROAD STORY

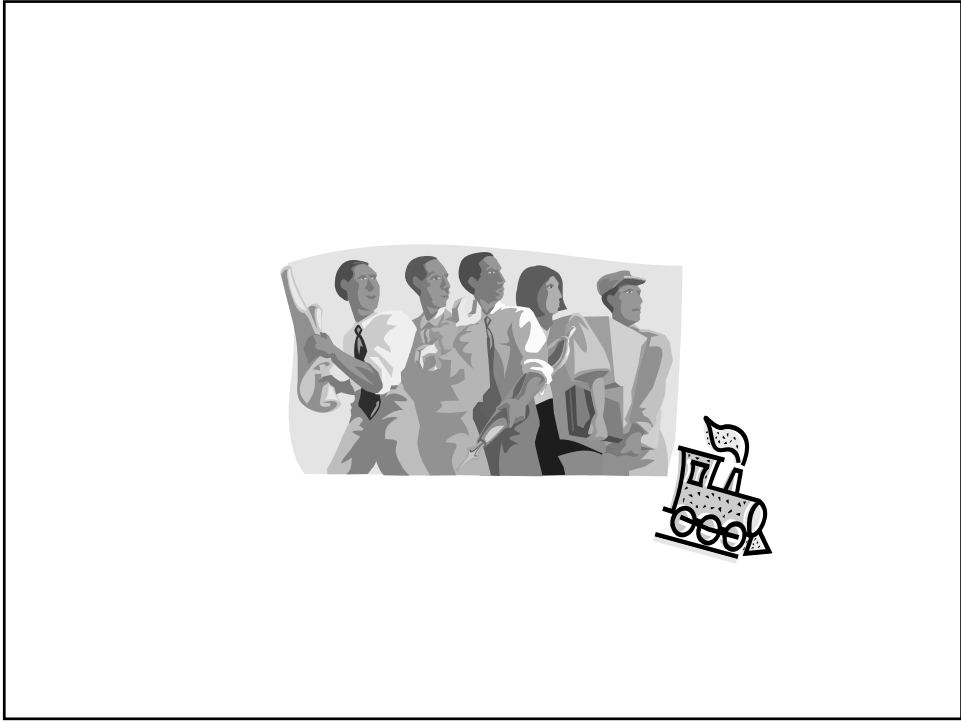
- Once upon a time, there was a railroad called NIDA Rail Lines...

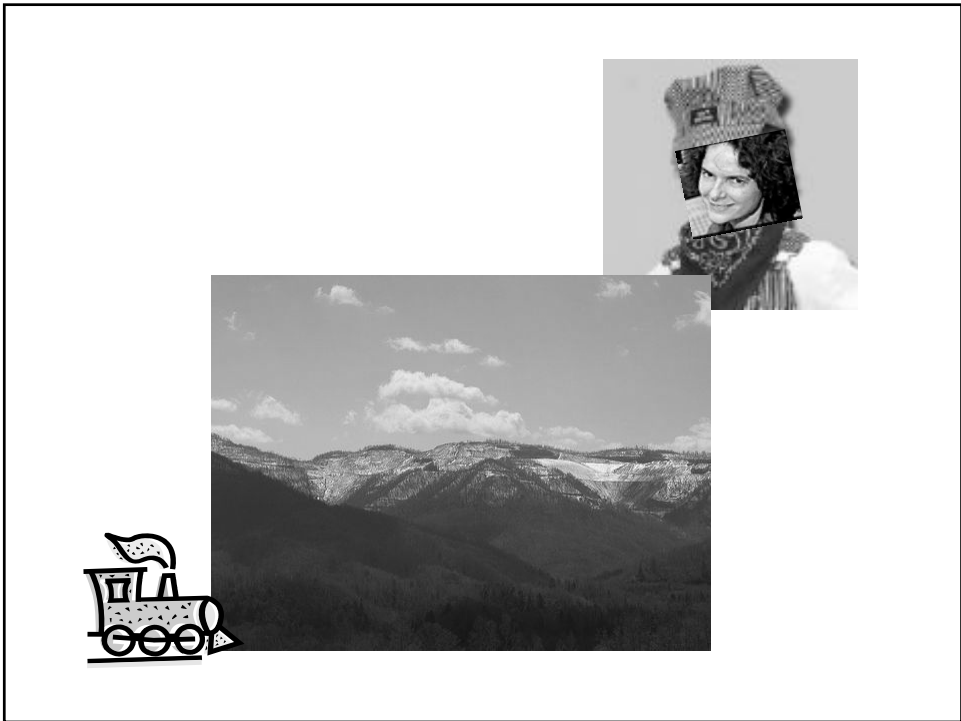
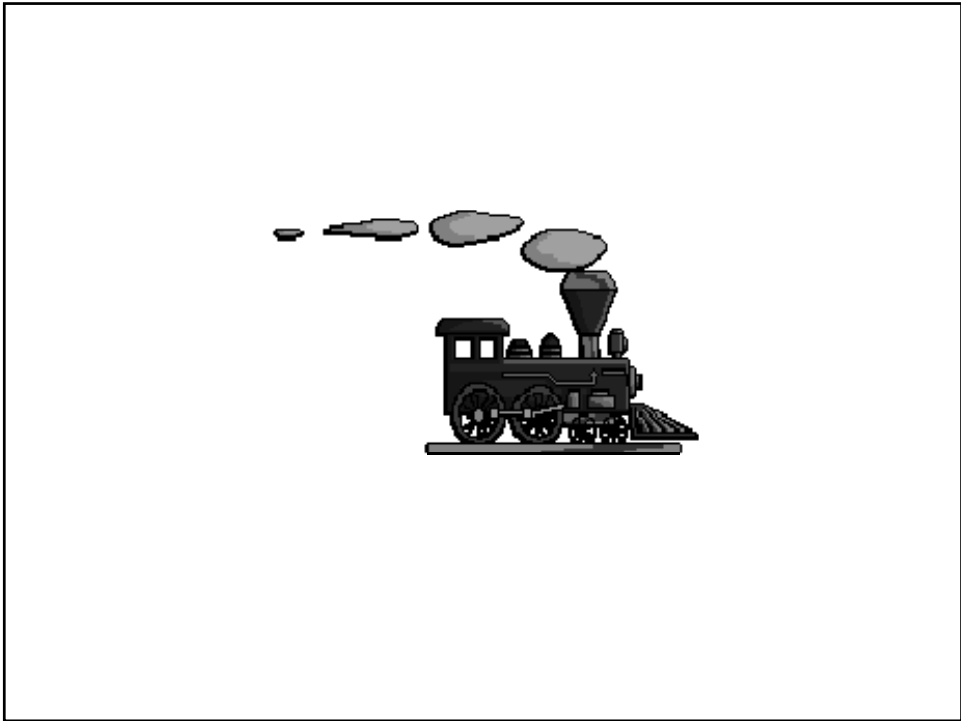


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## So, why Project Management?

- Although each railroad position is different and comes with varying levels of responsibility, each crew member has a unique role to play.
- The Conductor is there to make sure that each role and its procedures integrate smoothly with the others.

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When there is a lack of coordination...





## Three Levels of Project Management

- Participating Single Site
  - Conductor for just one train
- Participating Multiple Sites
  - Conductor for several trains, but within one region
- Lead for Multiple Sites
  - Lead Conductor for all the trains going to that destination



## UPFRONT

- Determine your level of responsibility and limits of authority
  - Guidance and direction from Node PI
  - Guidance from Lead Investigator/Lead Team
  - Clarification with Site PI/study supervisory staff



## Ready to look at Responsibilities?

# All Aboard!!!

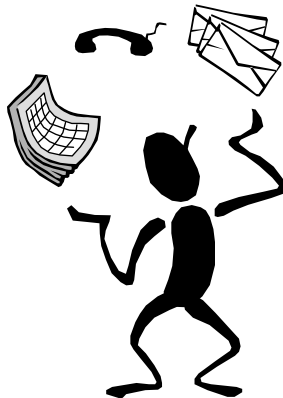


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## Project Management Responsibilities



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## **Liaison**

- Node to Site
- Site to Lead Node
- Site to Site
- Site/Node to CCC/DSC



## **Communication**

- Study Team
- Local Node Team
- Outside Entities (contract vendors, etc)



## **Staff**

### **Supervision/Mentoring**

- Depends on where you are serving as the Project Manager
- At minimum, your role is to guide and mentor



### **Logistics Management**

- Direct vs. Indirect Management
- Problem-Solving
- Coordination
- Documentation



## Monitoring Progress

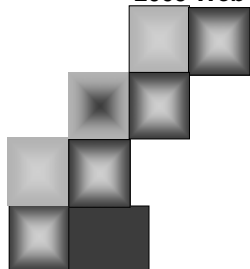
- Not the same as being a study  
"Monitor"
- Study-wide Reports
- Internal Reports
- Ongoing project management meetings

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## Part Two: Developing a Project Plan



## DEVELOPING A PROJECT PLAN

# Protocol Review



## Review and Provide Feedback

- Participate during development if possible
- Provide feedback on:
  - Inclusion/Exclusion
  - Potential PVs
  - Contradictions
  - Time Schedules
  - Potential Staffing Issues



## Review and Summarize Logistics

- Check in with Lead Team



## Sample Contact

Dear Lead Team,

I will be serving as the project manager for the implementation of your trial, “(name of study)” at (name of site). From our past experiences, we have learned that study implementation progresses more smoothly if the study site is provided with the following materials prior to study implementation:

- Detailed operations manual
- Study handouts and advertising materials
- Checklists for the Research Assistant (RA) for each study visit and, if appropriate, for the RA and the clinician(s) for each treatment session
- Sample progress notes for the RA
- Study Binders containing the appropriate dividers and paperwork. This includes copies of logs to be used for the study, CRFs, etc.
- Drug accountability forms, when appropriate.

I realize that lead sites differ in the degree to which they provide these materials, and so I wanted to check with you on whether you plan to provide these materials to the sites. If not, we will provide them for our site. In terms of the study binders (e.g., source, CRF, Essential Documents, etc.), you may not plan to provide the binders themselves but are you planning on providing guidelines for how they should be set up (i.e., what materials belong in which sections etc.) or is this set up at the discretion of the site?

We look forward to working with you on this study.



## Review and Summarize Logistics

- Check in with Lead Team
- Summarize for Local Team



## Review and Summarize Logistics

- Check in with Lead Team
- Summarize for Local Team
- Consult with PI



# DEVELOPING A PROJECT PLAN

## Timeline Development



## Timeline Development

### CCTN Recommended Timeframes for Protocol Development

CTN Protocol Milestone		Expected Date Completed	Actual Date Completed
Protocol Development	Concept approved for protocol development		X
	"Short" protocol version reviewed by IRB/Protocol Review Board (IRB) (1 month after concept approval)	X + 1 mo.	
	Full protocol reviewed by Data and Safety Monitoring Board (DSMB) (6 months after concept approval)	X + 6 mo.	
	Final protocol submitted to NIDA (1 month after DSMB review)	X + 9 mo.	
	Final protocol finalized (10 months after concept approval)	X + 10 mo.	



# Timeline Development

## CCTN Recommended Timeframes for Trial Preparation

CTN Protocol Milestone		Expected Date Completed	Actual Date Completed
Trial Preparation	Protocol approved for implementation		Y
	Site selection completed (4 months after protocol approved for implementation)	Y + 4 mo.	
	All data systems and databases in production (6 months after protocol approved for implementation)	Y + 6 mo.	
	Investigators' meeting (7 months after protocol approved for implementation)	Y + 7 mo.	
	First site endorsed (8 months after protocol approved for implementation)	Y + 8 mo.	



# Timeline Development

## CCTN Recommended Timeframes for Trial Conduct

CTN Protocol Milestone		Expected Date Completed	Actual Date Completed
Trial Conduct	First participant randomized (8 months after protocol approved for implementation)	Y + 8 mo.	
	Last participant randomized (based on sample size and randomization rate)	\$	
	Trial completed (last participant completes last follow-up) (based on sample size and randomization rate)	\$	
	Database locked (2 months after last follow-up)	\$	Z

Once the first participant is randomized, dates in cells with "\$" ("Last participant randomized", "Trial completed" and "Database locked") are calculated based on the actual date the first participant was randomized, the sample size, the number of participating sites and the expected randomization rate.



## Timeline Development

### CCTN Recommended Timeframes for Publication

CTN Protocol Milestone		Expected Date Completed	Actual Date Completed
Publication	Final Study Report submitted to NIDA (4 months after database lock)	Z + 4 mo.	
	Primary outcome paper submitted to journal (6 months after database lock)	Z + 6 mo.	
	Primary outcome paper accepted		
	Data posted on CTN's Public Data Share (18 months after database lock)	Z + 18 mo.	



## Timeline Development

- Implementation
  - Recruitment
  - Intervention Phase
  - Follow-up
- Post-Implementation
  - Study close-out



# DEVELOPING A PROJECT PLAN

## HR Plan



# Identifying Staff Requirements

- Begin with the basic information obtained from the protocol during the review

Example 1

1@ 1.0 FTE  
1@ 0.5 FTE  
2@ 0.25 FTE

Study  
Start up

Data  
Lock

2.0 FTE

Example 2

1@ 0.5FTE 2@ 0.75FTE 1@ 1.0FTE 2@ 1.0FTE 2@ 1.0FTE 1@ 0.5FTE 2@ 0.5FTE  
2@ 0.5FTE 1@ 0.5FTE 2@ 0.5FTE 1@ 0.5FTE 2@ 0.5FTE

Study  
Start up

Data  
Lock

2.0 FTE



## Identifying Staff Requirements

- Begin with the basic information obtained from the protocol during the review
- Next, consider the time and personnel required for each procedure

### RA PROCEDURES

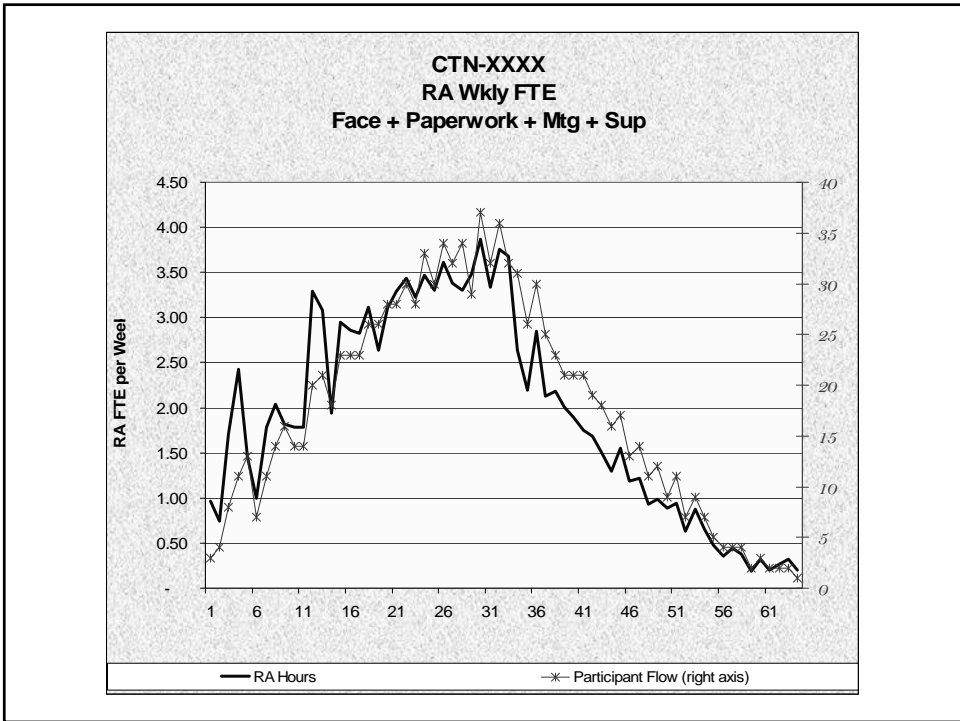
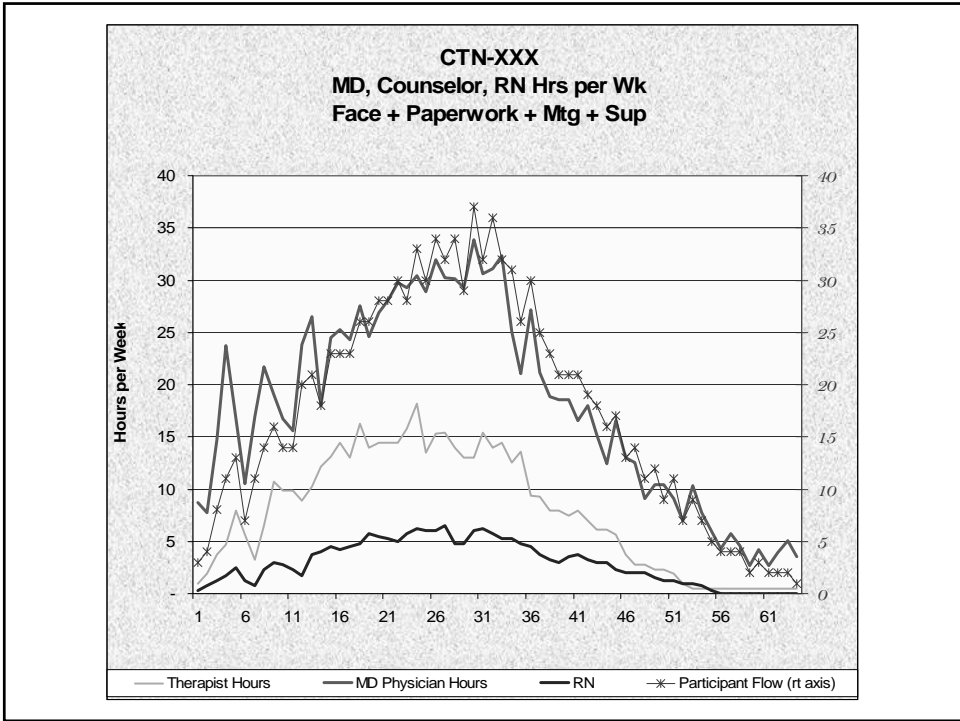
#### Screening Visit 1

Consent	45 min
ASI	45 min
RBS	30 min
UDS	5 min
TLFB	15 min

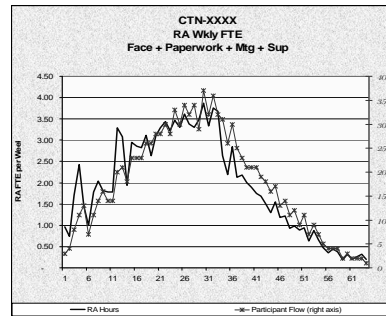


## Identifying Staff Requirements

- Begin with the basic information obtained from the protocol during the review
- Next, consider the time and personnel required for each procedure
- Consider the study's timeline



- Begin with the basic information obtained from the protocol during the review
- Next, consider the time and personnel required for each procedure
- Consider the study's timeline
- Finally, consider the existing staff and determine whether additional staff/expertise will be needed for the study



## Staffing Plan

Once decisions are made:

- Indicate number of each staff type needed
- Separate pre-implementation hours from recruitment/treatment phase hours
- Identify staff for each position
- Indicate which positions will require new hires



# DEVELOPING A PROJECT PLAN

## Budgeting



## Budget

Prepared by Lead Node



## Budget

- Personnel
- Supplies
- Equipment
- Travel
- Participant reimbursement
- Advertising



## DEVELOPING A PROJECT PLAN

### Site Selection



## Site Selection

Process that may entail a number of steps,  
including:

- Questionnaire
- Interviews
- Site visit



## Site Selection

Criteria that may be considered:

- Program characteristics
- Client characteristics
- Staff characteristics



## Site Selection

### Program Characteristics

- Number of new admissions, patient flow, patient retention
- Services provided – outpatient, IOP, residential, methadone
- Rural/urban
- Space for research offices



## Site Selection

### Client Characteristics

- Inclusion/exclusion criteria
- Demographics, such as gender, age, race, etc.
- Substances of abuse

### Staff Characteristics

- Research experience, willingness to participate, attitudes/experience with empirically-based treatments, time availability



## Session One Summary

- Today we have discussed:
  - Roles and Responsibilities
  - Developing a Project Plan
    - Protocol Review
    - Timeline Development
    - HR Plan
    - Budgeting
    - Site Selection
  
- *Resources for you:*
  - Protocol Issues Collection Sheet
  - Staffing Plan
  - Sample Budget



## NEXT TIME

- Building the Study Team
- PreImplementation
  - Development and use of Site Plans and Tools

“See” you then!!!