

## D. Research Design and Methods

The guts of the thing

### Don't Invite Angela



- Aims, Background, Prelim studies, should all lead here.
- No new concepts
- No disappearing concepts
- No mystery
- No suspense, except for that pesky research question

## Start with an overall plan.

- Make the reviewer feel smart... Create a road map, then follow it.
- Overall strategy, linked to aims
- Parts of design
- How presented in the proposal, part by part

## Sampling

- OVERALL Sampling strategy, plan
- Rationale for how it fits aims
- Define population, and if random, sampling frame, justify sample size
- POWER both here and in analysis
- If convenience or clinical, describe pipeline, quantify flow
- If qualitative, provide plan for how sampling will be theoretically driven

## Criteria

- Inclusion and Exclusion Criteria
- HOW criteria operationalized (by whom?)
- Feasibility or preliminary data on how many will fit criteria in setting
- Fit of criteria with AIMS, Setting
- Any populations excluded? Justify
- Is there a screening stage? Criteria for that.

## Recruitment

- OVERALL plan for recruitment
- Sites, how individuals are approached
- Stages of data collection
- Interaction with community based sites for recruitment
- Points of recruitment and how they interact with study, consistency with aims

# GROUPS

- Groups create comparison, needs to be consistent with aims, question
- Randomization: random procedure used, how performed, how and when informed
- Pre-existing groups—need to be justified by aims, and feasibility

# Interventions

Characteristic	<u>Experimental Condition</u> CTI	<u>Control Condition</u> ERP
<b>Staffing Pattern</b>	Team of clinicians & case workers	Individual support service (SS) & mental health (MH) workers
<b>Reentry Planning</b>	Community and Prison based	Prison based
<b>Location of Staff</b>	Community-based, connecting with parole for those under parole	Prison-based, connecting with parole for those under parole
<b>Clinical Supervision</b>	Regular supervision	No regular supervision
<b>Staffing</b>	Masters level experienced clinician with 2 BS+ level case managers	Existing Prison SS and MH staff with .5FTE MH caseworker as ERP planner.
<b>Integrated Treatment MH and SA</b>	Outside the prison	None inside or outside the prison
<b>Objective</b>	To build connections to community-based resources, facilitate access to resources, and encourage treatment engagement and reduce recidivism	To establish immediate connection to housing & treatment providers
<b>Community Contact</b>	Regular contact for nine months	No contact
<b>Service Coordination Between Settings</b>	Coordination provided by team with clinical supervision	Coordination enhanced by ERP Planner

## Fidelity and Assurance

- Operationalizes the IV in trials
- Use accepted measures if available, describe how implemented, timetable
- If not—then operationalize adequate implementation, and develop fidelity standards or assurance standards
- Multiple sources of information
- Implementation problems are sources of data for new knowledge

## Training

- Need to describe both educational background and training needs for research staff—clinical staff, consistent with aims.
- Include plan for training in specialized intervention--consultants
- Supervision of staff, specifically clinical supervision in some cases

## Roles of Staff

- Clearly operationalize staff roles, accountability patterns
- What are distinct roles of research, providers, partners in process
- Medical/Legal Accountability
- Relationship is related to Retention

## Quantitative Data

- OVERALL Data collection strategy, including datapoints, justified by aims, background expectations.
- Measurement details, each measure with metrics, details on how used, source.
- Secondary, Administrative, or Record Data—how collected? Are arrangements made with data providers?
- Data management, cleaning, security

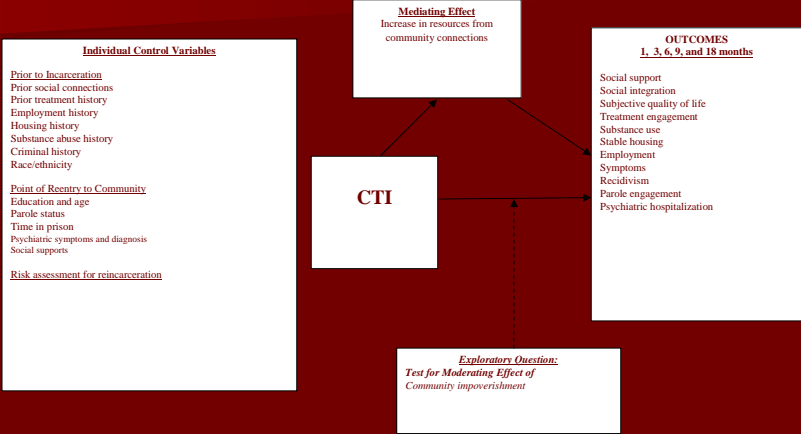
## Qualitative Material

- OVERALL Strategy
- Method or theoretical approach, specific details on interviewing, observation, memos, note taking etc.
- Concrete details that support the overall approach
- Comparison to level of detail in quantitative methods...
- Congruence of “mixed” methods

## Analysis

- OVERALL Description of analysis strategy
- Test the hypotheses
- Test the theory or model
- Exploratory questions
- Statistical power
- Power as it relates to pilot studies—more important to have effect size estimates?

# Analysis needs to match figure...



# Final Details

- Limitations, framed to sell the proposal
- Time line
- Human subjects

## Particular Mechanisms

- R34, for NIMH
- R03
- R21
- METHODS include process of moving research to next project—perhaps an R01



"Joyce, how do you spell 'juggling'?"