



# Developing Your Design and Research Plan



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# Continuity

- Everything else leads up to and anticipates your Research Plan
- There should be a smooth, continuous flow across sections:
  - Abstract: Engage the reviewer
  - Specific Aims: What will be accomplished?
  - Background: What has been done so far?  
Significance: Why is this research important?
  - Preliminary Studies: What have *you* done so far?
  - **Research Plan**: What will you do and why?



Total narrative pages: 25

Normally sections A-C occupy about 6 pages



leaving about 19 pages for your Research Plan

# Writing the Research Plan

- **STRUCTURE:** A clear, logical flow of information that explains how the study will be done
- **SEQUENCE:** Present procedures in the order that they will occur
- **SPECIFY:** Detailed description of exactly how key procedures will be done
- **EDIT:** No typos, inconsistencies, grammatical gaffs, or vagueness

# Structure: Give the Reviewer an Organized, Numbered Outline

Centered headers for major sections:

- A. Specific Aims
- B. Background and Significance
- C. Preliminary Studies
- D. Research Design and Methods
- E. Human Subjects

# Logically Sequenced Side Headers Within Each Section

Example:

- D. Research Design and Methods
  - D.1. Overview of Research Design
  - D.2. Participants and Screening
  - D.3. Inclusion/Exclusion Criteria
  - D.4. Assessment Procedures
  - D.5. Treatment/Experimental Groups
  - D.6. . . . .



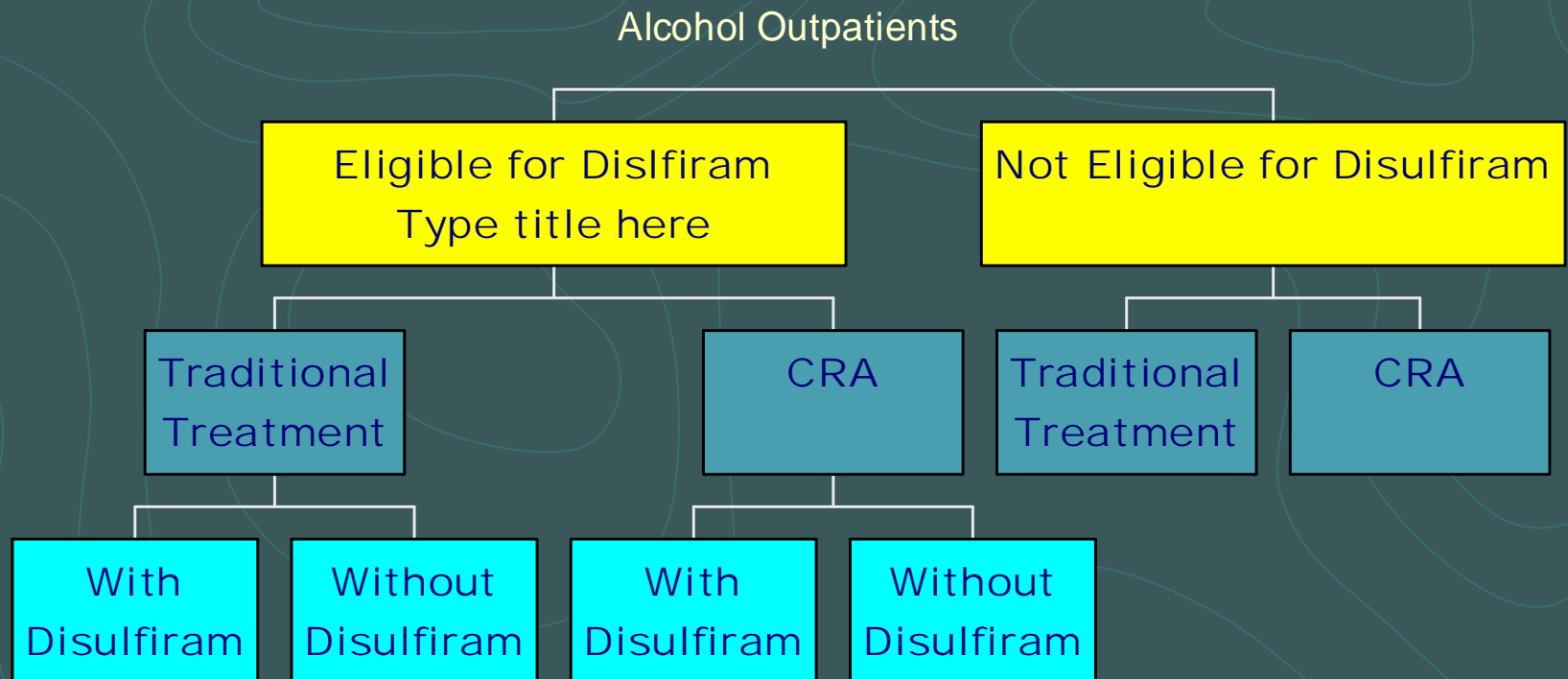
# Major Components of the Research Plan



# 1. Design Overview

- At the very beginning, give the reviewer a clear description of the study design
- Consider a diagram of the design
- Establish major terms/names, and stick with them throughout

# Design Diagram Example





# General Tip

- For significant decision points, where reviewers might wonder why you didn't do X instead of Y
- Explain the alternatives that you considered, and why you went with the option that you chose

# Example Design Decision Points

- How many groups?
- How do groups differ?
- Randomization? How you will do it
- Sample size – Why?
- Stratification?
- Group or individual?
- Number/length of assessment points?

## 2. Participants

- Source population – size, attributes
- Recruitment procedures
- Screening procedures
- Inclusion/exclusion criteria
- Point of consent & procedures
- *Document over-ample ability to enroll the needed sample within time and budget*

# Specify Assessment Timetable

	Enrolled	2 Month	4 Month
1/07	4	0	0
2/07	4	0	0
3/07	4	4	0
4/07	4	4	0
5/07	4	4	4
6/07	4	4	4
.....			
1/08	0	4	4
2/08	0	0	4

# Specify Milestone Timetable

7/06	Staff hired; training begins
1/07	Recruitment begins
3/07	2-month follow-ups begin
5/07	4-month follow-ups begin
12/07	Recruitment completed
5/07	Follow-ups completed
7/07	Data analyses begin
10/07	First report submitted for publication

# Timetables

- If space is a problem, performance timetables can legitimately be placed within the budget justification section (no page limit) because they directly affect the effort and budget needed in each project year

# Inclusion/Exclusion Criteria

- Who is eligible to be in the study, and why? (inclusion criteria)
- Who must be excluded from the study and why?
- How will criteria be ascertained?
- Specific inclusion of:
  - Women
  - Minorities
  - Children

# 3. Assessment Procedures

## ● Data collection

- How will data be collected?
- Who will collect them?
- Training/supervision of staff
- Quality assurance for data fidelity
- Confirmation of self-report?

## ● Assessment points

- How many?
- Spacing / duration
- Tracking ability and procedures

### 3. Assessment Procedures

- Selection of measures (Next time)
- Specification of key variables
- Procedures for missed data
- Assess reliability of measurement?
  - Inter-rater reliability
  - Test-retest stability
- Federal certificate of confidentiality

# 4. Interventions / Experimental Conditions

- What is done in each condition?
- Manual / specification of procedures
- Who delivers the intervention?
- Training / monitoring / supervision
- Fidelity assurance
- Certification and decertification (red-lining)
- Do interventionists need to consent?
- Adverse event reporting
- Data and safety monitoring board

# 5. Data Management

- Data entry procedures (future session)
- When are data entered?
- Who has access?
- Confidentiality protections
- Data and file management

## 6. Analysis Plan

- Statistical Power Analysis (mandatory)
- Preliminary analyses
- Organize primary analyses by specific aim
- Get solid statistical consultation on design of analysis plan, and justify the approach that is proposed
- Secondary/ancillary analyses