

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:
25 pages (for now)

Normally sections A-C occupy
about 10 pages

leaving about 15 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.
- **Revise, revise, revise.**
- **EDIT:** No typos, inconsistencies, grammatical gaffes, 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:

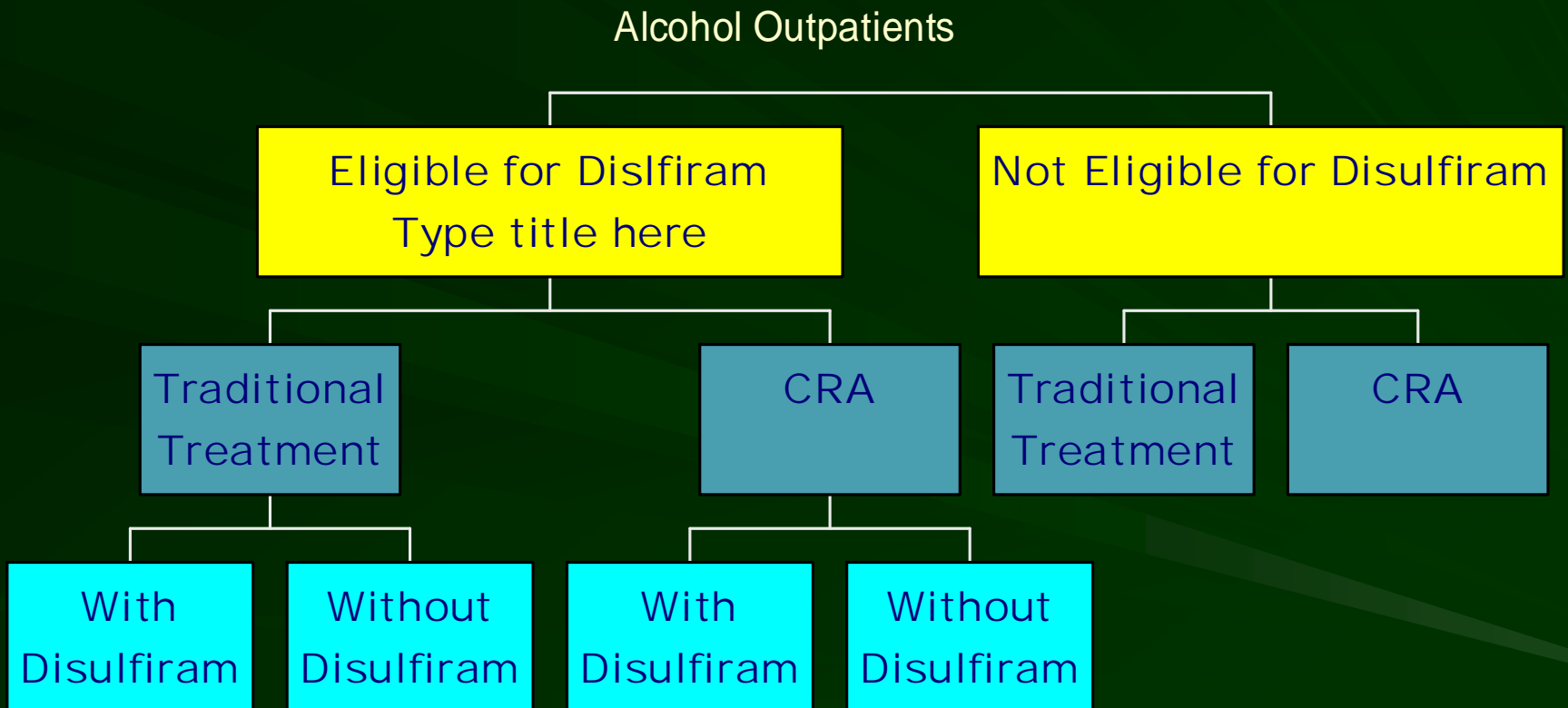
- D. Research Design and Methods
 - D.1. Overview of Research Design
 - D.2. Participants and Screening
 - D.3. Inclusion/Exclusion Criteria
 - D.4. Consent Procedure
 - D.5. Assessment Procedures
 - D.6. Treatment/Experimental Groups
 - D.7.

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

- Loose or stringent inclusion criteria?
- How many groups?
- How do groups differ?
- Control group treatment?
- Randomization? How will you do it?
- Blinding?
- Sample size – Why?
- Stratification?
- Number/length of assessment points?
- Choice of assessment instruments?
- Primary outcome variables?

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
etc.			

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
5/08	Follow-ups completed
7/08	Data analyses begin
10/08	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 inform 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 (contd.)

- Selection of measures (Future session)
- Specification of key variables
- Procedures for missing 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 (Section E)
- Data and safety monitoring plan (Section E)

5. Data Management

- Data entry procedures (future session)
- When are data entered?
- Who has access?
- Confidentiality protections
- Data and file management
- Again, much of the detail can go in Section E.

6. Analysis Plan

- 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
- Statistical Power Analysis (mandatory)

Power Analysis

Do I have the sample size I need in order to detect the expected effects?

What Is an Effect Size?

- Cohen's d
 - Numerator: Mean X - Mean Y
 - Denominator: Pooled standard deviation
- An effect size of 1.0 indicates that the two means are separated by one standard deviation
 - Small effect < .40
 - Medium effect .40 to .79
 - Large effect > .80

There are other bases for judging effect size

- For example, relative risk ratio
 - Ratio relative to a comparison group (e.g., placebo)
 - 1.0 indicates no difference in risk
 - 2.0 indicates twice the risk
 - 0.5 indicated half the risk
- Confidence intervals around the risk ratio
 - A risk level is significantly different if its confidence intervals do not include 1.0

Bases for Estimating Your Effect Size

- Pilot data
- Prior reports from other investigators
- Clinical significance: How large an effect would matter?

Sample Size Sufficiency

- In essence, you want enough participants to have an 80% or better chance of detecting as “significant” ($p < .05$) the expected effect size
- This is the principal justification for the sample size proposed.

You Need a Statistician

- Unless you have this expertise yourself, you need a statistician to help you compute and properly describe your power analyses in relation to your analytic plan
- The IRG for your application will include a highly competent and critical statistician