

Putting Together Your Application

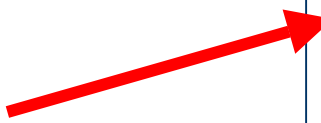
Thomas F. Hilton, Ph.D.

*Program Official for Organization &
Mgt. Science*

Nat'l. Inst. on Drug Abuse/NIDA

Page 1 of the 398

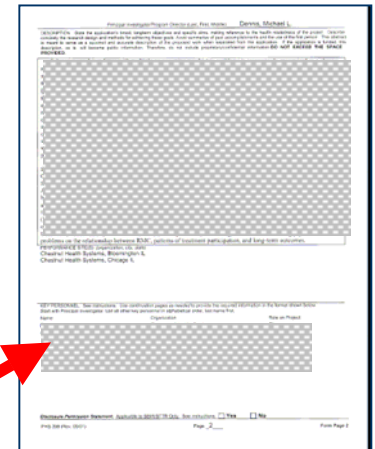
- What is in a title – a lot, so describe the project.
- Triple-check the accuracy of the information.
 - Imagine if we have the wrong phone number when we try to make an award.
 - What you put in there stays for years.
- Check “New Investigator” if appropriate
 - Human subjects? (probably)
 - HS Exempt? (depends)
 - Clinical trial? (unlikely)



Form Approved Through 05/2004		* PI DENNIS MICHAEL L		DUPLICATE 10/2000	
Department of Health and Human Services		2 Ref 0481323-05		PW 3206801	
8 5 3 0 2 3		Date: (MO, DAY) (OR) (YR)		Received 03/01/2003	
1. TITLE OF PROJECT Early Re-intervention Experiment 2 (ER2)		2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (If "Yes," also include FHSR#) Number: PA 01-097		3. FUNDING SOURCE Federal <input checked="" type="checkbox"/> Non-Federal <input type="checkbox"/>	
4. PRINCIPAL INVESTIGATOR (Last, first, middle initial) Name: MICHAEL L DENNIS		5. NEW INVESTIGATOR <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		6. PI'S TITLE ER Ph.D.	
7. HOME CARE FOR ANIMALS (If "Yes," also include FHSR#) Name: [REDACTED]		8. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT (If "Other," also include FHSR#) Name: [REDACTED]		9. ADDRESS (Street, city, state, zip code) [REDACTED]	
10. TELEPHONE AND FAX (Area code, number and extension) Tel: 301-827-3443 X25400 Fax: 301-827-4061		11. VERIFIABLE ANIMALS <input type="checkbox"/> No <input type="checkbox"/> Yes		12. HUMAN SUBJECTS <input type="checkbox"/> No <input type="checkbox"/> Yes	
13. HUMAN SUBJECTS (If "Yes," also include FHSR#) Name: [REDACTED]		14. COSTS REQUESTED FOR PROPOSED RESEARCH (Budget period) Total: \$91,452		15. COSTS REQUESTED FOR PROPOSED RESEARCH (Budget period) Total: \$845,185	
16. APPLICANT ORGANIZATION Name: [REDACTED] Address: [REDACTED]		17. TYPE OF ORGANIZATION Public <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private <input type="checkbox"/> For-profit <input type="checkbox"/> Not-for-profit Non-profit <input type="checkbox"/> General <input type="checkbox"/> Special Purpose <input type="checkbox"/> Non-charitable <input type="checkbox"/> Social and Economically Disadvantaged		18. AUTHORITY IDENTIFICATION NUMBER 37-0964629 ORAN No. (if available): 12-506-6173 Congressional District: 15	
19. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED BY AWARD (Name, title, address) Name: [REDACTED] Title: [REDACTED] Address: [REDACTED]		20. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name: [REDACTED] Title: [REDACTED] Address: [REDACTED]		21. SIGNATURE OF APPROVED PI (Date of signature) Date: 3-26-03	
22. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE (Signs that the information here is true, complete and accurate to the best of its knowledge, and that the organization agrees to accept responsibility for the scientific conduct of the award and to comply with applicable Federal and State laws and regulations.) Name: [REDACTED] Title: [REDACTED] Address: [REDACTED]		23. OFFICIAL SIGNING FOR OFFICIAL NAMED IN 13 (Date of signature) Date: 3-28-03		24. SIGNATURE OF APPROVED PI (Date of signature) Date: 3-28-03	

Page 2 of the 398

- Your abstract is the public face of your project.
- Many people in the process use it to decide about your application.
 - Few people will read the whole application.
 - Publicly available, Congress reads it when auditing NIH grants.
- List key players – not everyone in the project.



Budget & Bios

- Helps reviewers determine if requested support is adequate to succeed.
 - Overview expertise of key players.
 - Introduce each team member & their role (1 para ea.)
 - Summarize the role of each consultant (1-2 sentences ea.)
 - Describe significant supplies and travel (1 para ea.)
 - Biosketches
 - Include only relevant achievements and publications.
 - Summarize research support for each
 - Ensures people are not over extended or
 - Avoids paying twice for the same work.

Resources & Environment

- Helps reviewers learn about the setting and capabilities to carry out the study.
 - Research Computers
 - Research Office space
 - Clinic size, types of services, etc.
 - Linkages necessary to succeed
 - Access to information systems, etc.

Grant Purpose

- You want a grant to study what?
- Your key aims for the project are?
- What is the payoff to you & PH?



Probe – before you plunge.

Test the waters before you invest time and resources, or you risk getting soaked.

- Is NIH the right place to seek support?
- Does my project align with the institute's mission?
- Is my study idea responsive to the RFA?
- Does my planned level of effort exceed the value of the problem I want to address?
- Do we have the talent and resources to succeed?

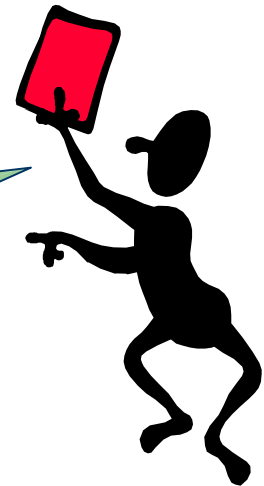


Problem / Background

Explain why the literature or your research leads you to think this topic needs study.

Any pilot info?

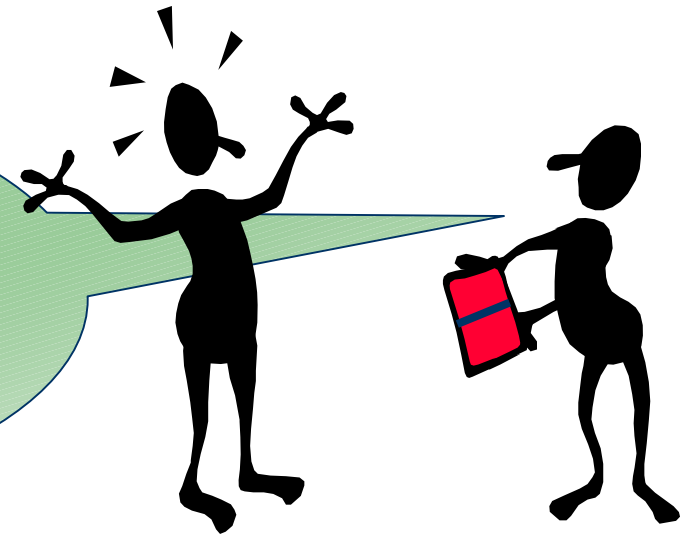
There are at least a dozen studies showing that drop-in clinic patients who drop out of treatment mention lack of staff concern as a contributing factor....



Significance

What is the payoff to science AND to public health?

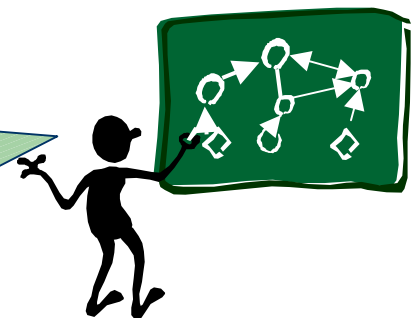
Jones & Smith showed in their 2003 study that retaining drop-in clinic patients in treatment could save \$1,100 per incident in reduced need for re-treatment and lowered contagion.



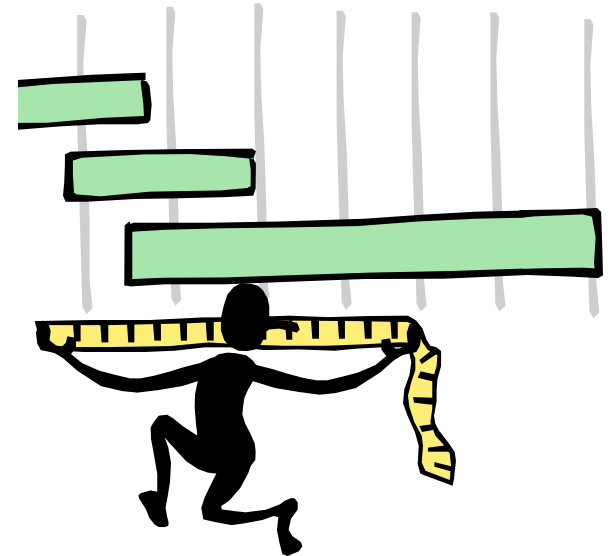
Question

Derived from the background literature, what model will guide your hypotheses and what hypotheses will you test?

I think that ASA theory will explain why patients will stay when service orientation is high, and what will re-engage patients who have left.



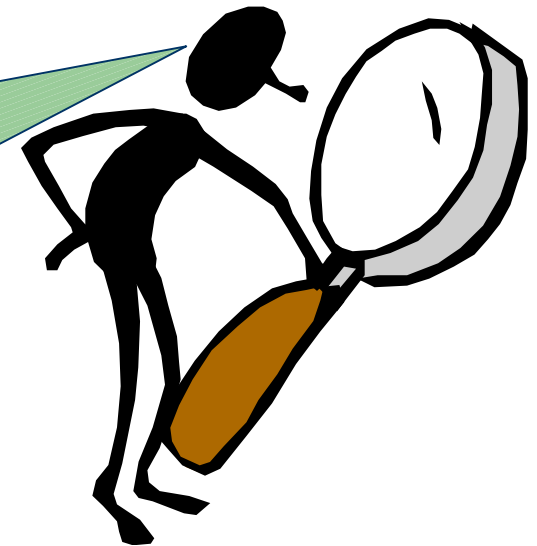
Moderators Eat Up Power!



Analyses

What statistical approach will ensure a fair test based on your data?

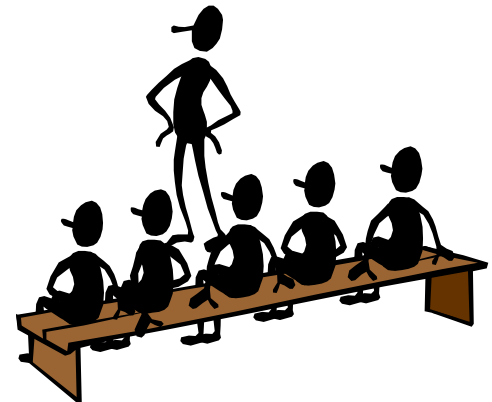
I want to run a lagged panel correlation and SEMs comparing dropouts, re-engagers, and stayers within and between clinics with SO training and without it.



Team

Who do you envision as helping on the project?

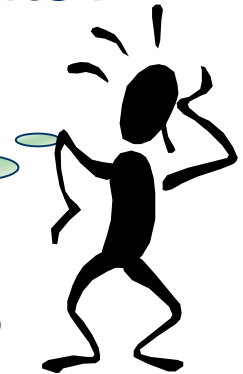
- Disease experts
- MIS experts
- Statisticians
- Economists
- Field colleagues
- Theory consultants



Human Subjects Protection

- Remember that staff can be human subjects.
- Adequately describe the subject pool, selection criteria, consenting.
- What are the risks, and how will you protect against them? respond to adverse events?
- Convince that it is worth the risks.
- Describe data safeguards.

Don't forget a data & safety monitoring plan.



Inclusion

To minimize health disparities:

- You must include:
 - Males & Females
 - Children (people 18-21 are also children)
 - Minorities
- If you cannot include all, explain why for each characteristic.
- Don't forget to include a targeted enrollment table.

Principal Investigator/Program Director (Last, First, Middle): McCarty, Frank

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: A Case Study of NY's Infrastructure to Improve Practice

Total Planned Enrollment: 90

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		Total
	Females	Males	
Hispanic or Latino	10	31	41
Not Hispanic or Latino	17	32	49
Ethnic Category: Total of All Subjects *	27	63	90
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	25	38
White	14	38	52
Racial Categories: Total of All Subjects *	27	63	90

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects"

PHS 398 (2000) (Rev. 05/07) Page 56 Targeted/Planned Enrollment Form/ Page

TIPS

- Have as many people review the final as time permits.
- Pick naïve reviewers – they ask the hardest questions.
- Run spell & grammar check.
- Remember:
 - Reviewers are smart, educated, sophisticated – BUT --
 - Reviewers not as familiar with your world as you are, so be sure to clearly describe your project and plans.

GOOD LUCK!

