NIH Proposal Writing Workshop

DAY 2 | 5.11.2024 | AFTERNOON SESSION

FACENTE CONSULTING
UNDERSTAND • IMPLEMENT • TELL YOUR STORY

Plan for the Afternoon

1. **Writing the Approach Section**

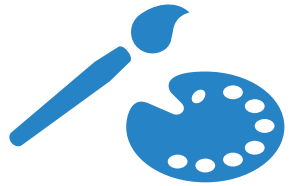
Overview of the Approach

What is your action plan?

Detailed research design and methods

- Level of detail and focus depends on funding type
  - E.g., need more for R01 (12 pages) than R21 (6 pages)
  - E.g., K/F grants focus more on developing research capacity whereas R grants show your existing capacity to carry out the aims

Paint a clear picture for the reviewer to show them you know what you are talking about!



Approach: A general outline (R01)

Overview of project and theoretical framework, if a behavioral intervention	1/2 page to 1 page *(if including framework)*
Overview of study setting (institutions, locations, sites)	1/2 page to 1 page
Overview of research team and their expertise specific to this project	1/2 page to 1 page
Your preliminary studies relevant to this project	1-1.5 pages
Methodology and Study Aims *(described more in a moment)*	**6-8 pages**

Approach: A general outline (R21)

Overview of project and theoretical framework, if a behavioral intervention	1/4 page to 3/4 page *(if including framework)*
Overview of study setting (institutions, locations, sites)	1/4 page to 1/2 page
Overview of research team and their expertise specific to this project	1/4 page to 1/2 page
Your preliminary studies relevant to this project	1/4 page
Methodology and Study Aims *(described more in a moment)*	**3.5 - 4 pages**

General Format of the Approach

C. APPROACH

C.1. Overview and Timeline. This study encompasses [#] phases, as detailed in Table 1 below:
•Phase I involves [something re planning, prep]
•Phase II involves [whatever comes next – usually development of something or pilot implementation] Phase III involves [typically something like evaluation of the intervention, data analysis, and/or dissemination of findings].

Table 1: Study Timeline *sample info below, change to what's appropriate*

Component and Task Name	Start	Finish	Duration	Year 1				Year 2			
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
I. *prep*	7/1/14	12/31/14	6 mo.								
II. *implementation*	1/1/15	6/30/15	6 mo.								
III. *analysis and dissemination*	7/1/15	7/31/16	12 mo.								

General Format of the Approach

C.2. The Study Setting. This study will take place in XXX. Include a sentence or two that describes the setting – epidemiology, history as a study site for you, capacity, etc. Why are you picking this site?

C.3. The Research Team. **Dr. Andrew Medina-Marino** (Co-PI) is wonderful for all these reasons. He has all this great expertise and history with the South African site. Dr. Medina-Marino has worked extensively with **Dr. Shelley Facente** (Co-PI), who has all this great expertise and history, especially connected with SA and you're your research topic. They are such a great team for this and that reason, you're lucky you have the opportunity to fund them to do this work (convey this more subtly of course).

Other Key Personnel (role) has this history and expertise. For this project, s/he will do XYZ.

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General Format of the Approach

C.4. Preliminary Studies.

Study 1. At X timeframe we did Y, and found Z. This has laid the foundation for our work in this proposed study because A,B,C.

Study 2. At X timeframe we did Y, and found Z. This has laid the foundation for our work in this proposed study because A,B,C.

Study 3. At X timeframe we did Y, and found Z. This has laid the foundation for our work in this proposed study because A,B,C.

General Format of the Approach

C.5. Methodology and Study Aims.

SPECIFIC AIM 1: Retype Aim 1 here.

Rationale. Text.
Methods and Procedures. Text.
Data Collection. Text.
Information management (if applicable). Text.
Quality Assurance (if applicable). Text.
Data Analysis. Text.
Potential Challenges. Text.

General Format of the Approach

C.5. Methodology and Study Aims.

SPECIFIC AIM 1: Retype Aim 1 here.

Rationale. One paragraph here about the rationale for doing Aim 1. This is where you should specific a quick overview of what you will do to achieve the aim. You can use the following segway sentence:

To Achieve Aim 1, we will:

Leverage our existing sored specimens….

Use our well established mobile clinics…..

Conduct a 3-arm RCT…

General Format of the Approach

Methods and Procedures.
Talk here about the very specific methods and procedures you will be using to achieve Aim 1. You may also want to have subsections about key points, such as:
(a) Laboratory testing: Where you then talk about exactly how you will test the specimens in the laboratory.
Other important things to cover here would be recruitment/enrollment, education/training of staff, counseling of patients, delivery of results, whatever else you might do like that.

Data Collection. Describe here how you will collect data, what data points you will collect (broad brush strokes are OK), how identifiable the data points will be, and whether data will be maintained in aggregate or not. You don't have to go TOO much into detail here about confidentiality because you have a separate human subjects section, but you want to give reviewers confidence that will be appropriate and judicious with your data collection.

General Format of the Approach

Information management (if applicable). If you are going to be gathering information from anywhere (i.e. national surveillance data, clinical data collected via the health center separate from this study, etc) you may want to describe that process here. If you are providing any information back to providers for clinical use, etc. that should also be described here.

Quality Assurance (if applicable). Describe here how you will be keeping track of whether the methods/procedures/data collectoin are being conducted as planned, and what you will do to correct if not.

General Format of the Approach

Data Analysis. Here's where you describe how you will be analyzing the data you collect for this aim. You don't need too much detail here about statistical analyses because there is a separate section for that, but you may want to explain in basic terms what you will be expecting to understand at the close of this aim, and why that is important. You may also want to say, if relevant, how previous studies have given you the impression that you will be successful at gathering the proposed data and getting a useful outcome from it.

Potential Challenges. Briefly explain here what challenges you anticipate in completing this aim, and what plans you have to overcome/mitigate those potential challenges should they arise.

General Format of the Approach

SPECIFIC AIM 3: Retype Aim 2 here.

Rationale. Text.
Methods and Procedures. Text.
Data Collection. Text.
Information management (if applicable). Text.
Quality Assurance (if applicable). Text.
Data Analysis. Text.
Potential Challenges. Text.

SPECIFIC AIM 3: Retype Aim 2 here.

Rationale. Text.
Etc.

General Format of the Approach

C.6. Sample Size Estimations and Statistical Analyses

Sample Size. Talk here about what your sample size is, why you chose that size, how long you think it will take to achieve that size, and how you came up with that sample size.

Primary analysis. The primary analysis is to compare/explore/whatever X,Y,Z. Based on A, we hypothesize B. Our sample size of C achieves D power to detect this, at a E significance level.

Secondary analyses. In addition to the primary analysis, we will conduct analyses to do X. Here's the statistical tests, etc. we will use to determine this, and what we expect to learn.

Feasibility and acceptability. Describe in a few sentences how you will determine feasibility and acceptability of your proposed intervention, if applicable.

Statistical considerations and data management. Sample text for what you might want to include here:
Descriptive statistics including mean, standard deviation, median, inter-quartile range and frequency distribution will be generated for outcome variables as well as provider and case-patient characteristics. Graphics such as bar charts, box-plots, and histograms will be used to present the data and check for skewness and normality. Transformations of the outcome variables will be explored and performed if needed. For all statistical investigations, tests for significance are two-tailed. All analyses will be conducted with Stata 9.0 (Stata Corporation, TX, 2006).

Approach: Methods and Procedures

Overview of methods (high-level), followed by subsections of detailed methods:

- Inclusion/exclusion criteria (if human subjects involved)
- Recruitment/screening/enrollment/consent processes (if human subjects involved)
- Research procedures (both with human subjects and any laboratory protocols, etc.)
- Data collection and management plans

Activity

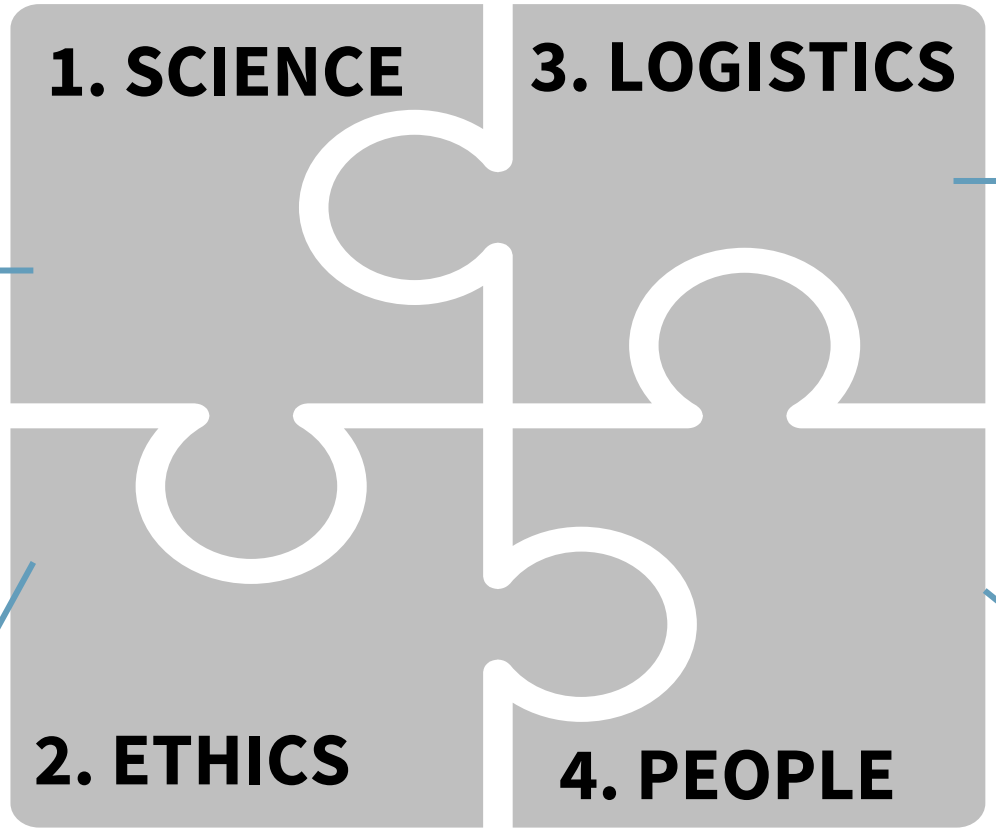
Think about Aim 1 of the STI grant:

Aim 1: Evaluate three different screening strategies to decrease the burden of CT/NG/TV among pregnant women, and reduce adverse birth outcomes. Hypothesis 1 (H1): Compared to a one-time diagnostic test for STIs at a woman's first ANC visit, repeat testing algorithms will significantly reduce adverse birth outcomes. H2: Compared to diagnostic screening with follow-up test-of-cure (ToC), repeat screening and treatment without any ToC will significantly decrease STIs at delivery. Approach: A three-arm randomized controlled hybrid-effectiveness trial will be conducted; **Arm 1**) diagnostic screening and treatment at first ANC + ToC follow-up; **Arm 2**) repeat screening and treatment throughout ANC (no ToC); **Arm 3**) one-time diagnostic screening and treatment at first ANC, no ToC (control). Prevalence and incidence of CT, NG and TV at delivery and frequency of adverse birth outcomes by study arm will be assessed.

Note: In the past two days, we've covered the basics of most (but not all) parts of NIH grantwriting puzzle

- ✓ **Specific Aims**
- ✓ **Research Strategy** (significance, innovation, approach)
- ✓ **References**

- ✓ **Human Subjects Package**
- Clinical Trials



- Cover letter
- Project Abstract
- Statement of Public Health Relevance
- Budgets
- Budget justifications
- Facilities and Resources
- Equipment
- Resource sharing plan
- Foreign justification
- Multi-PI plan

- ✓ **Biosketches**
- Letters of Support
- Consortium agreements