Approach Section, Part 2

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Adapted from Brad Gaynes' UNC project overview (and others)

Approach

- The “how” of what you’re going to do

- After the aims, the most likely section to “ding” your proposal (assuming the reviewer gets past the Aims).

Approach Sections

- Overview (may come after next two sections)
- Rationale (Justification & Feasibility)
- Preliminary Studies
- Study Design
- Study Setting or Site
- Study Population (Selection Criteria, Sampling, Recruitment)
- Data Collection (Questionnaire, Exam, Lab data, Quality Control, etc.)
- Measurements (Outcome, Factor of Interest, Confounders)
- Data Management and Data Analysis (Frequencies, Bivariable, Multivariable, Approach to Missing Data)
- Sample Size and Power
- Limitations/Alternative Strategies
- Future Directions & Impact Statement

Approach

- Map your approach section to your aims

- Condense text to reduce unnecessary redundancy
  - e.g. if study population does not vary, you only need to describe once
  - often need separate analysis sections for each aim

Rationale

- Consider having a rationale section early to address those issues that reviewers may be “worried” about.

- Answer the questions you *know* they will have.

Preliminary Studies

- Your chance to show that you CAN do the work
- Try to tell a story here, too
- Can also show that you have a great TEAM
- Should be related to the grant proposal, Not all work you've ever done

Outcomes

- Be sure that your aims map to your outcomes
  - it should be clear from your aims/hypotheses what your *specific* outcomes will be
  - Outcome measures should be obvious to reviewers
    - Table
    - Bullets per outcome

Sample Size and Power

- Biostatisticians do more than sample size calculations
- This section is critical for feasibility
- Justify your assumptions in the calculations
  - reviewer will not check calculations, but will wonder about what went into them
  - A table with different assumptions is sometimes helpful

Sample Size

- Be sure to demonstrate that you can recruit the expected sample size

- Work through how many persons are seen, what proportion will be approached, how many will consent, how many will remain in study, etc.

Examples

Table 8: Detectable differences; α=0.05, ICC = 0.03					
		10% increase		15% increase	
Primary Outcome	SOC Est.	PPP Est.	Power	PPP Est.	Power
PrEP persistence (12 months)	10%	20%	79%	25%	98%
PrEP persistence (6 months)	20%	30%	65%	35%	92%
Abbreviations: Est = estimate; diff=difference; ICC = intraclass correlation coefficient; PPP = postpartum prevention package					

effect size SOC	effect size intervention	students per school	ICC	Min Clusters	n per group	Total N
0.15	0.25	200	0.04	25	2420	4840
0.15	0.30	200	0.04	13	1201	2402
0.15	0.25	200	0.05	30	2957	5914
0.15	0.30	200	0.05	15	1468	2936
0.15	0.25	200	0.06	35	3494	6988
0.15	0.30	200	0.06	18	1734	3468

Limitations & Potential Problems

- Be forthright in admitting limitations
- Discuss alternatives
  - justify why you made the choice you did
  - why was your design the strongest?
- Identify potential problems – and solutions
- Just key points- Not a huge litany and if covered in other sections, don't mention again
- (Not more than ½ page)

Examples

- Missing Data approaches/strategies to minimize
- Evolution of Guidelines and how research might accommodate the changes
- Choice of Design (Step Wedge vs Clinic Randomization vs Pre-Post Quasi experimental)
- Contamination of Standard of Care Sites

Future Directions & Impact Statement

- Often helpful to include a statement of where the research will lead

- Include “Impact Statement” to leave the reviewer with a positive note of what your study will contribute

About 1 brief paragraph- 2-4 sentences.

Integrating Grant

- Refer to Tables/Figures
- Refer to Biosketches rather than repeating in “Team Description”
- Refer to “Letter of support” where applicable