Preparing an NIH Grant

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Overview

- Read instructions carefully in form PHS 398.
- Grant limited to 25 pages.
- Appendix used for publication reprints, questionnaires, and occasionally for detailed information related to methods.
- Appendix should not include fundamental study issues.
- Important that grant is well written and attractive.
Specific Aims

- Describe hypotheses of study.
- Be very specific.
- Generally brief, limited to 1 page.
Background and Significance

- Describe why the study is important.
- Review medical problem, burden of disease, importance from public health perspective, and possible confounders.
- Summarize other relevant studies emphasizing limitations and weaknesses.
- Emphasize why your study is important.
Background and Significance

- If possible bring in costs.
- Complete section with a summary paragraph that reinforces most important points.
Progress Report / Preliminary Studies

- Investigators
  - Establish experience and competence of investigators
  - Emphasize special qualifications
  - Citations for papers submitted or accepted for publication can be listed
Progress Report / Preliminary Studies

- Pilot data
  - VERY IMPORTANT SECTION.
  - When ever possible (Always!) include small pilot study that demonstrates feasibility of study, validity of important variables, and/or information necessary for sample size.

- Continuation and Supplemental
  - Describe progress made, publications, and study personnel.
Methods
Study Population

- Entry criteria
  - Justify
  - Alternatives
- Exclusion criteria
  - Justify
  - How many subjects expect to loose
- Source of subjects
- Document that you have a representative population composed of adequate women and minorities
Study Design

- Describe and justify study design
- Explain why did not use alternative designs
  - Prospective vs retrospective
  - Cohort vs case-control
  - Randomized clinical trial vs observational study
Data Collection

- Study outcomes
  - Define specifically
  - Justify choice and explain why did not use other options

- Study variables
  - Focus on primary variables
Analysis

- Seek assistance from statistician.
- Carefully link with specific aims.
- Describe in detail exactly what test and statistical program (SAS) will be used.
- Descriptive, univariate, stratification, and multivariate analysis.
- Describe regression models with exact variables to be controlled for.
Sample Size

- Describe factors that determine sample size (i.e., alpha, beta, number of controls, and difference want to detect).
- Document your sample size assumptions.
- Document that you can comfortably recruit an adequate number of subjects.
- Use tables such as detectable relative risk or power and number of patients required.
- Carefully justify your choice of sample size.
Study Procedures

- Who and how will the project be performed.
- Time it will take to carry out data collection (documented with pilot data).
- Quality control measures.
- Detailed time table for each phase of the study.
Limitations

- Potential confounding variables
  - List or make a table with confounders
  - Define and describe the important variables
  - Explain how they will be controlled for

- Potential biases
  - Describe potential biases and how they will be overcome
Limitations -2

- Other Problems
  - Comprehensively describe problems and how they will be overcome.
  - REMEMBER...You get credit for recognizing problems, and...
  - PENALIZED for ignoring important potential limitations.
Summary

- Reinforce the significance of study and why the project is worth funding.
- Don’t hesitate to repeat and emphasize strengths of the study.
Other Sections

- Introduction
  - Used for revised grants
  - Describe how the grant was changed by listing revision for each comment included in the critique
  - Be courteous
  - Limited to 3 pages
Other Sections-2

- Human subjects
- Include letters from collaborators and study sites indicating there willingness to participate
- Consortium/contractual arrangements
Overall Summary

- Carefully follow directions.
- Leave plenty of time (3-6 months) to complete an application.
- Seek assistance from someone with experience and success with grants.
- Describe specifically each part of the study and JUSTIFY, JUSTIFY AND JUSTIFY.
Overall Summary - 2

- Plan to resubmit 2-3 times. Persistence pays!
- Carefully respond to reviews. If reasonable, try to do what the reviewer requests.