Successful Grant Writing: Outline and Objectives

Presentation Outline:
- Overview
- Grant sections descriptions
- Tips for successful grant writing

Advocate Health Care
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How is grant writing the same / different? ... as other medical writing

<table>
<thead>
<tr>
<th>Same</th>
<th>Different</th>
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<td>Scientific, technical writing</td>
<td>Persuasive versus technical reporting</td>
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<td>Hypothesis testing</td>
<td>Application versus Proposal</td>
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<tr>
<td>Clear and specific communication about design, methods, sample</td>
<td>Inclusion of resources and budgeting with justification</td>
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<tr>
<td>Literature and evidence based</td>
<td>Project timeline and implementation plan</td>
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TEN Reasons Grant Applications Get Rejected

1) Program activities are not based on best practices
2) Proposals are unclear or missing required information
3) Program need has not been adequately identified in the proposal
4) Programs are not well thought out (portions are inconsistent with one another)
5) Proposals are too ambitious for the amount of time and/or money requested or proposals are not ambitious enough for the amount of time and/or money requested
6) Budget is vague, inconsistent, or unrealistic
7) Staff expertise is not conducive to program activities
8) Program has a bad track record for completing activities
9) Proposals are submitted after the due date (a deadline is a deadline)
10) Proposal submitter has good ideas but the proposal is written poorly
Tips for Grant Titles

- Proposal titles should be
  - Concise, easy to understand, easy to remember
  - Focused on a clearly identifiable programmatic area
    - (e.g., Devices for MR-Guided Therapy vs. MR-Guided Therapy of Brain Cancer)

- Proposal titles should not be
  - Lengthy (longer than about 60 characters)
  - A statement, a result, or a conclusion
Tips for Titles: Consider using the PICO format...

- Patient/Population – Who or What?
- Intervention – How?
- Control – What is the main alternative? (If Appropriate)
- Outcome – What are you trying to accomplish, measure, improve, effect?
- Avoid using generic words, such as project or proposal
- Do not include names of foundations or companies
- Get rid of unneeded words
Tips for Titles: Examples

-The title is the total summary of the proposal and should open a drawer in the reader’s mind… into which you drop your hypotheses and ideas.

-Consider words like: Examine(ing).. Evaluate(ing).. Assess(ing)..

-Strong Title choice:
  - Assessing the effect of E2F1 on p53 in the ischemic myocardium
  - Evaluating the Efficacy of an Adjunctive Yoga Based Therapy in the Treatment and Management of Irritable Bowel Syndrome

-Poor Title choice:
  - Adjunctive Yoga Based Therapy Can Manage Irritable Bowel Syndrome
Research Question & Hypothesis and Specific Aims

- Write your study purpose, rationale, or hypotheses.
- What do you believe to be the answer to the complication?
- Strategies that work
- Important and reasonable overall goals
- Clear deliverables (the short-term goals)
- Indication that methodological approach is feasible
- Strategies that don't work
- Overly ambitious goals
- Aims that cannot be achieved given the timeline, budget, experimental design
- Lack of evidence of need
Objective & Hypothesis: Example

- Our long-term goal is to elucidate the molecular basis for suppression of innate immunity by type III effectors. The objective of this application is to identify targets of the *P. syringae* type III effector HopU1, a mono-ADP ribosyltransferases (ADP-RTs), and to determine its roles in bacterial pathogenesis. The central hypothesis of the proposed experiments is that the targets of the HopU1 ADP-RT type III effector will be components of innate immunity.

  - ... then List Specific Aim(s)
Specific Aims: Example

The Specific Aims of this application are as follows:

1. Determine the molecular consequence of ADP-ribosylation on the function of AtGRP7 and elucidate the role this protein plays in innate immunity.

2. Identify additional substrates of HopU1 and verify their involvement in innate immunity.

3. Analyze the affect that HopU1 has on host-microbe interactions.

- Outcomes will ideally be:
  - Determining process with just ONE protein
  - Finding OTHER proteins that are similar
  - Finding the extent of the effect
Background & Significance

- Use the literature to establish any previous work related to your research question.
- Describe the gaping hole in the literature and how your specific aims will attempt to address it.
- Remember to cite your references throughout your protocol!
  - Pick a style from your favorite journal.
  - Most people use numbered superscripts.
  - The main thing is to be consistent.
Background and Significance cont’d.

- Main objective
- Define and distinguish the need (background) vs. impact (significance) of the proposed work
- Structure by paragraph
- Explain the need
- Present related work (of others)
- Define the significance (impact of the proposed work)
Methods

- **DESIGN:** used to address specific aims (i.e., retrospective cohort, cross-sectional, prospective cohort, randomized controlled trial)
  - Example: This will be a prospective observational study, with the treatment group consisting of patients with a malignant diagnosis, and the control group consisting of women undergoing a biopsy with a completely benign diagnosis using a 1:2 randomization ratio.

- **SUBJECTS:** where will obtain, time period, specific inclusion and exclusion criteria
  - Example: The study population will consist of women age 40 and above, undergoing either an excisional breast biopsy, or a needle core biopsy of the breast for abnormal mammogram or ultrasound, or for a palpable mass in the Caldwell Breast Center, Park Ridge, Illinois between 2012-2013. Women under age forty will be excluded because of the lower risk of being diagnosed with breast cancer. Other exclusion criteria include pregnancy at the time of biopsy, and previous treatment for breast cancer. Also, males will be not considered in the current study. No exclusions will be made based on participant’s race and ethnicity.
Methods cont’d.

- **PROCEDURES**: experimental treatments/interventions (if any), methods of obtaining data, description of variables. Information about chart review as well as primary outcome variable and all secondary outcome variables
  - Information about how randomization will happen (If Appropriate)
  - Include a Data Form and Timeline
  - Surveys or Questionnaires taken from previously published literature with validation methods cited
SAMPLE SIZE CALCULATION/POWER ANALYSIS: write up of how many subjects you will need in your study group(s) to achieve an 80% power of detecting a difference based on the magnitude of the difference given from published literature, pilot data or expert clinical opinion.

- **Example:** Sample size estimates call for a minimum of 160 participants in the experimental and control arms and were based on a standardized effect size of 0.33 (expected effect size of interest being an absolute difference of 0.5 mg/dl in serum creatinine at 48 h by an expected SD of 1.5 based on previous literature), B = .20, power = 80%, and alpha = 0.05 (Tepel et al. NEJM 2000;343:180-4).

DATA ANALYSES: provide a thorough description of the statistical tests planned, and your criterion for significance (e.g., p < 0.05)

- **Example:** Descriptive statistics (means, SDs) will be reported for all continuous variables and frequencies (%) for all categorical variables. HLM and LLM will be compared between groups using Independent T-test; dichotomous variables will be analyzed by Fishers Exact Test. A P value of .05 will be considered statistically significant in all analyses. All analyses will be performed with SPSS software (v.10.0, SPSS, Chicago).
Budget

- Make your budget is realistic
- Include only those items that are allowed
- Make your budget specific and appropriate
- Include enough information so the reviewer knows who is being budgeted, for how much, and the % of FTE of each person budgeted.
- Include all required costs, i.e., mandated meetings, etc.
- Don’t make assumptions - always include a justification for every line in the budget
Data Safety Monitoring Board (DSMB)

- An independent group of experts that provide expertise and recommendations to the study investigators.

- Primary responsibilities of DSMB:
  - periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy
  - make recommendations regarding the continuation, modification, or termination of the trial. The DSMB considers study-specific data as well as relevant background knowledge about the disease, test agent, or patient population under study.
Data Safety Monitoring Board (DSMB) cont’d.

- Particularly necessary for studies involving interventions that entail potential risk to the participants (e.g., treating patients with breast cancer with a drug indicated for diabetes)
- Level of monitoring should be commensurate with the risks and the size and complexity of the study.
- If applicable, provide action plan for the DSMB
Site Data Monitoring Plan (SDMP)

- In-person evaluation carried out by an independent representative(s) at the site(s) at which the clinical investigation is being conducted.

- SDMP can:
  - identify data entry errors (e.g., discrepancies between source records and Data Forms/Case Report Forms (CRFs) and missing data in source records or CRFs)
  - provide assurance that study documentation exists
  - assess the familiarity of the site’s study staff with the protocol and required procedures and compliance with the protocol
  - provide a sense of the quality of the overall conduct of the study (e.g., attention to detail, thoroughness of study documentation, appropriate delegation of study tasks, and appropriate investigator supervision of site staff performing critical study functions)
  - include information about how regular monitoring and reporting of Adverse Events and Annual Renewals will take place
Site Data Monitoring Plan (SDMP) cont’d.

- SDMPs are necessary for all studies involving interventions that entail potential risk (physical, financial to the participants).
- SDMP can be devoted to assessing the critical study data and processes and evaluating significant risks and potential site non-compliance.
- Particularly critical early in a study, especially if the protocol is complex, and includes novel procedures with which investigators may be unfamiliar.
- If applicable, provide action plan for the site monitoring plan.
Formulas for Success

- Strive for perfection, linearity, and clarity
- Read and edit your proposal in its entirety
- Garner support from peers; incorporate their feedback
- Have someone not familiar with your topic/program to read the proposal for clarity
- Ensure that administrative information is accurate and up to date
- Add up and justify budgets meticulously
- Use diagrams, tables, figures to make things more understandable
For the Reviewers

- Organize to make them “happy”
- Make it easy for them to understand
- Make it easy for them to find things
- Make it easy for them to be your advocate
- Don’t make them “work hard”

Also, keep the following in mind:

- Readers are “raiders” for information; want only “need to know” information; prefer concise texts; prefer well-designed documents with graphics.
How can you make reviewers happy?

- Follow the instructions carefully
- Use buzzwords, headings and transitions, explain jargon
- Make your proposals upbeat, positive, and interesting
- Use bullet points
- Include white space; be concise in your writing
- Complete and include all forms
- Read and edit your proposal in its entirety
Always....

- Read the proposal instructions first
- Include everything you are asked to include
- Say it succinctly but don’t make assumptions
- Commit only to activities you can fulfill
- Build evaluation criteria into your proposal (process measures and outcome measures)
- Write as if you have already been funded for the grant and are explaining what you will be doing (We will implement...)
- Outline your proposal before you begin writing it, use key headings and subheadings from the guidance
- Write clearly, concisely, and professionally (don’t use acronyms or other jargon without first providing an explanation of its meaning)
References

- Purdue University Online Writing Lab
  - https://owl.english.purdue.edu/owl/resource/981/1/

- University of North Carolina Writing Center
  - https://writingcenter.unc.edu/handouts/grant-proposals-or-give-me-the-money/

- GuideStar

- Center for Injury Prevention Policy and Practice

- Previous internal Advocate research department presentations
Presentation Feedback

Thank you for your review.

If you would like to provide feedback on the content of the presentation, please complete the short survey which can be found at this link: Presentation Evaluation Survey

- Please note the survey should not take more than 5 minutes to complete.

Thank you in advance for completing the survey!
Thank You!