Foundations of Scholarly Writing
Session 5

Best Practices For Writing the Main Sections of a Grant Proposal

Anne Marie Weber-Main, PhD
Office of Faculty Affairs and Diversity
Department of Medicine
Every Proposal: *What, Why, How, Who, Where, When*

1. **What** do you intend to do?
2. **Why** (and to whom, including the funder) is the work important?
3. **How** are you going to do the work?
4. **Who** is on the team?
5. **Where** is the work being conducted?
6. **When** will the project (and specific deliverables) be completed?
<table>
<thead>
<tr>
<th>Core Information Delivered</th>
<th>Proposal Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What</strong> do you intend to do?</td>
<td>Specific Aims, Objectives, Research Questions</td>
</tr>
<tr>
<td><strong>How</strong> are you going to do the work?</td>
<td>Design and Methods, Approach, Preliminary Work, Implementation Plan</td>
</tr>
<tr>
<td><strong>Why</strong> is the work important?</td>
<td>Significance, Need/Problem Statement, Anticipated Results and Impact</td>
</tr>
<tr>
<td><strong>What</strong> is the <strong>payoff</strong> of the work?</td>
<td>Impact, Dissemination, Sustainability, Future Work, Specific Deliverables, Trainee Success</td>
</tr>
<tr>
<td><strong>Who</strong> is doing the work?</td>
<td>Team, Biosketches, Preliminary Work, Letters of Support</td>
</tr>
<tr>
<td><strong>Where</strong> is the work being done?</td>
<td>Environment, Resources, Collaborating Sites</td>
</tr>
<tr>
<td><strong>When</strong> will the work be completed?</td>
<td>Months/years of funding requested, Project Timeline</td>
</tr>
<tr>
<td>Is the project cost-effective?</td>
<td>Budget, Budget Justification + Impact</td>
</tr>
<tr>
<td>Are regulatory and administrative criteria met?</td>
<td>Human subjects, “face page,” etc.</td>
</tr>
</tbody>
</table>
Non-starter

A person, plan, or idea that has no chance of succeeding or being effective.
Stand out in the crowd
WHY - Significance, Impact: The project itself (your idea)

Missteps to avoid:

• **Who cares?** Proposing work that is too derivative or incremental (small advancement)

• **What does it mean?** Generating lots of data, but interpretation may be difficult or impossible (limited impact)

• **Is this feasible?** – Approach includes a fatal flaw, a few moderate flaws, or numerous minor concerns (“methods for doing XX are not adequately described”)

• **For CDAs, questionable impact on the PI’s career development:**
  - More mentoring not needed (PI is ready now for independence)
  - PI needs to branch out beyond primary mentor’s work (too dependent)
  - Inadequate training plan, mentoring team
WHY - Significance, Impact: How you write about it

Missteps to avoid:

• Relying exclusively on LIKA (*little is known about*) argument
• Not clearly distinguishing what’s new about your project (compared to literature, your own preliminary work)
• Writing only (or mostly) about significance of the *overall field* vs. *your project’s specific aims*
• Composing impact statements that are “empty generalities”
• Overstating the impact
WHY - Significance, Impact

**Tips for success:**

- Build a clear, concise argument for project overall and each specific aim (filling a knowledge gap, overcoming a barrier, capitalizing on an opportunity)

- Directly answer the question: If my project is successful, what will be possible that wasn’t possible before?

- Offer multiple “points of impact”
  - Short, medium, longer term
  - Your specific research area, plus extension to related areas
  - Different stakeholders: researchers, patients, providers, policy makers
There is a national need to train providers to be good stewards of health care resources.

- Rising healthcare costs, lots of waste in healthcare delivery
- ACGME may add “cost-conscious care” as a competency in residency training

Here at U of MN, great start on training residents in high value care.

- Existing 18-month longitudinal Value-Based Care (VBC) curriculum for IM residents and medical students rotating through IM services; evidence of increasing trainees’ knowledge and positive attitudes about VBC
- Next step: Expand curriculum to include practice-based audits to improve trainees’ skills (practice patterns) in providing features of value-based care.
- Positive side effect (and something we will measure): changes in physician faculty’s behaviors
High throughput methods to measure cotinine in dried blood spots will provide opportunities to:

- Accurately measure secondhand smoke exposure (SHS)
- Increase identification of childhood SHS exposure
- Move biomarker measurement of SHS exposure into clinical arena
- Inform changes in health care policy
Example: Short, Medium, Longer Term Impact

This research will...

a) Determine whether obesity bias influences important aspects of provider behavior,

and

b) Inform the development of interventions to improve patient-centered quality of care for obese and overweight patients.

c) Project is an important step toward achieving the long-term goal of improving health care quality and disease outcomes for obese individuals by identifying and eliminating barriers to high-quality health care.

**Short-term impact:**
New knowledge, direct output of the proposed project

**Medium-term impact:**
How this new knowledge might be applied

**Longer-term impact:**
Translation of TBD intervention into practice, resulting in better quality health care for obese patients
“...write bullets that tell your reviewers what they can expect from your research as outcomes.... Accompany each...with a precise, substantive statement of why that expected outcome is important.”

Aim 1:

• Expected results:

• Importance of this outcome:
Our **objective** in this R01 application is to characterize the disposition (absorption, distribution, metabolism, and elimination) of compound X in children with hematological malignancies and determine the effects of obesity on the toxicity and efficacy of this agent.

**Aim 1: XXX**  From this aim we will learn the magnitude of X exposure variability that is attributed to being obese.

**Aim 2: XXX**  From this aim we will learn which drug metabolizing enzymes are altered in the state of obesity.

**Aim 3: XXX**  From this aim we will determine the therapeutic threshold for compound X’s effectiveness.

**Collectively**, such knowledge concerning disposition in obese children will have a significant **positive impact** on the development of optimal drug dosing regimens in pediatric patients to maximize efficacy, while minimizing potential adverse drug effects, in the treatment of serious diseases with therapeutic agents.
WHAT - Specific Aims (Objectives)

NIH requires specific aims page:
Highly condensed, self-contained synthesis of your project that emphasizes the following:

- Brief background information (knowns, unknowns, barriers)
- Long-term research goal
- Overall study objective/hypothesis
- Specific aims (outline of 2-4 aims)
- Novelty, implications, and importance of the work

IMPORTANT: The Specific Aims page sets the tone for the rest of the research plan.
Specific Aims (Objectives)

Missteps to avoid:

• Too ambitious/too limited in their scope
• Describe only “what” the project proposes (a list of experiments or analyses), with little to no emphasis on the “why” (knowledge to be gained)
• Too general, lack specificity
  • Offer inadequate info on methods
  • Expected outcomes not defined
• Domino aims

Tips for success:

• Of the right scope for the specific funding mechanism
• Clearly express the “why” of the research; they focus on the core knowledge to be gained
• Include succinct, informative summary of core methods for achieving each aim
• Accompanied by specific hypotheses
• Aims are related to, but typically not dependent on, one another
Example: *What vs. Why Aims*

**Needs improvement:**

**Aim 1.** Perform proteomics analysis of an ABC strain that hyper-secretes known XYZ substrates.

**Better:**

**Aim 1.** Identify XYZ-dependent effector proteins that promote *ABC* replication and/or persistence.

- We hypothesize that XYZ secretes many effector proteins and that certain XYZ substrates are required to establish persistent infection.
- We will perform proteomics analysis of an ABC strain that hyper-secretes known XYZ substrates to identify new effectors, and use genetics to define those required for virulence.
HOW - Approach (Design, Methods)

Missteps to avoid:

• Neglecting to justify design and methods choices

• Failing to balance two reviewer needs:
  - Enough detail to evaluate study quality, feasibility
  - Brevity

• Making it difficult for reviewers to find key information
Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

Explain your rationale!

• Why this design?
• Why these measures?
• Why these analyses?
• Will it work?

Convince me!
For all major choices (e.g., hypotheses, design, approach):

• Briefly describe (and cite) the theory, other literature that undergirds your choice

• Acknowledge weaknesses in your approach, then convincingly justify your choices

• Consider what might go wrong and present viable alternatives
The study will be presented as an investigation of two highly effective and safe methods of pain relief, with the aim of determining whether one has advantages over the other for laboring women and their babies.

We will recruit patients by offering information about the study in two settings: (1) during prenatal courses and (2) upon admission to the Birthplace at Fairview University Medical Center. By educating women first during the prenatal course and again early in labor, we are avoiding ethical concerns about obtaining informed consent from women in pain and under the stress of active labor.
The conceptual framework for our project is the *Strategic Framework for Improving Racial and Ethnic Minority Health and Eliminating Racial and Ethnic Disparities*.... Figure 1 depicts the general structure of the framework (five components) and how our proposed project aligns with each component.

Unequal distribution of obesity related poor health outcomes by income, race and location

School nutrition practices that encourage unhealthy eating

Lack of policies that promote healthy eating at school

School policies that encourage healthy eating

School policies that prohibit marketing

School policies that prohibit sales of junk foods

Improve school food environment

Improve eating behaviors at school

Eliminate nutrition related disparities in school settings

Reduce health disparities gap in school settings
<table>
<thead>
<tr>
<th>Area of Focus</th>
<th>Course or Meeting</th>
<th>Goal of Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proteomics and Metabolomics Techniques</td>
<td>PUBH 6160 – Metabolomics&lt;br&gt;UM Mass Spectrometry and Proteomics Workshop (3 days)</td>
<td>To obtain formal knowledge and hands-on training regarding metabolomics and proteomics techniques</td>
</tr>
<tr>
<td>Data Processing and Handling</td>
<td>PUBH 6420 – Introduction to SAS Programming&lt;br&gt;PUBH 6325 – Data Processing with PC-SAS&lt;br&gt;CSci 5707 – Principles of Database Systems Basics of Database Development, Microsoft Access I and II</td>
<td>To become familiar with SAS programming and database creation, manipulation, and management</td>
</tr>
<tr>
<td>Biostatistical Analysis</td>
<td>STAT 3022 – Data Analysis&lt;br&gt;PUBH 7470 – Statistical Analysis for Translational and Clinical Research</td>
<td>To improve my knowledge of statistical methods commonly used in patient-oriented research</td>
</tr>
</tbody>
</table>
HOW - Approach
Balance Detail and Brevity

**Completeness**
Enables reviewers to evaluate your proposed approach to answering the question (feasibility, generalizability)

**Brevity, simplicity**
Reviewers want a sophisticated overview (vs. cookbook) of design and methods, with only the “right” details

Detail is a powerful weapon. Learn when and how to use it!
**HOW - Approach**

**Missteps to avoid:**

**Details Often Missing or Inadequately Described in Research Proposals:**

- Info about control groups or experiment
- Preliminary data/prior experience/team expertise to support *each aim*
- Potential pitfalls to proposed approach
- Plans for troubleshooting
- Future directions
Library for health research reporting

The EQUATOR Network library currently contains:

- An introduction to reporting guidelines
- Comprehensive lists of the available reporting guidelines, listed by study type:
  - Experimental studies
  - Observational studies
  - Diagnostic accuracy studies
  - Biospecimen reporting
  - Reliability and agreement studies
  - Systematic reviews
  - Qualitative research
  - Mixed methods studies
  - Economic evaluations
  - Quality improvement studies
  - Other reporting guidelines
  - Reporting data
  - Statistical methods and analyses

Quick links to reporting guidelines:

- CONSORT checklist and flow diagram
- CONSORT extensions
- TREND checklist
- STARD checklist & flow diagram
- STROBE checklists
- PRISMA checklist and flow diagram
Study sample:

- Are inclusion/exclusion criteria fully described, well-justified?
- Are reasons for selecting this sample clear (not merely convenience)?
- Are there important potential biases in sample selection?
- Are there too many exclusions that are not well justified, or are important exclusions overlooked?
- Is availability of adequate numbers of participants from the sampling frame assured?
- Are there enough participants in the setting to do this study as described?
Intervention

• Is the intervention well-described—can you understand what will be done, or is it a “black box”?

• Is the protocol standardized so that it is likely to be reproducible in other settings?

• Is there blinded administration of the intervention protocol?

• Is there randomization to study groups?

• Will adherence to the intervention be monitored? Will the effects of nonadherence be considered?

• Are safety issues regarding the intervention addressed?

• Is an appropriate control group selected?

• Are issues of contamination or co-interventions in the control group addressed?
For CDA, reviewers need enough detail to judge the following:

1. **Candidate**
   - Does the candidate have potential to be an independent and productive investigator?
   - Is the candidate’s research record of high quality? Papers?
   - Is there evidence of a commitment to the program objectives?
   - Do the 3 letters of reference strongly support all aspects of the grant?
For CDA, reviewers need enough detail to judge the following:

2. Career Development Plan/Career Goals and Objectives/Mentoring Plan

• Is mentor(s) an expert in the topic of the research plan?
• Are candidate’s prior training and experience appropriate to the proposed training plan?
• Are didactic research training plans explicitly stated?
• Will the plan contribute to the development of scientific independence?
• How will mentors interact and support candidate (letters must be consistent)?
• How will progress be evaluated? (Include a timeline with milestones)
For CDA, reviewers need enough detail to judge the following:

3. Research Plan

- Is question of scientific merit?
- Are the design and methods robust?
- Does the research plan fit with the other (training) sections?
- Will successful completion of the research help meet the candidate’s career development objectives?

This section needs to be of high scientific quality but must also integrate with career development.
## Review criteria for K applications

<table>
<thead>
<tr>
<th>Criterion</th>
<th>What is assessed</th>
</tr>
</thead>
</table>
| **Candidate**                                 | • Your potential  
• Your record  
• Your commitment                                                                                                                                  |
| **Career Development Plan**                   | • Likelihood of contributing to PI’s development, independence  
• Content, scope, phasing, and duration of the plan  
• Alignment with stated objectives  
• Plans for monitoring, evaluating progress                                                                                                       |
| **Research Plan**                             | The usual *(scientific and technical merit)*, plus:  
• Relevance to research career objectives  
• Potential to develop/enhance research skills  
*If flawed, involvement of mentors in project dev. is questioned!                                                                                   |
| **Mentor(s), Consultant(s), Collaborator(s)**  | • Qualifications match project, training needs  
• Superb statements (details of training plan, benchmarks, extent of mentoring and supervision, resources)  
• Mentoring track record  
• Research productivity and funding                                                                                                                    |
| **Environment and Institutional Commitment to Candidate** | • Assurance of > 75% time for research and training  
• Existing commitments to candidate (start up funds, etc)  
• Facilities, resources (including people), training opportunities  
• Assurance that the institution intends the candidate to be an integral part of its research program                                                 |
Approach

Aim 1
- Hypothesis
- Prelim Data relevant to aim 1
- Proposed Experiments
- Anticipated results, etc.

Aim 2
- Hypothesis
- Prelim Data relevant to aim 2
- Proposed Experiments
- Anticipated results, etc.

**Tips for success:**

**HOW - Approach**

Organize your content
HOW - Approach
Organize your content

- Approach
  - Design overview, Subjects
  - Outcome Measures, Core methods
  - Analysis plan, Power calculations
  - Expected Results, Alternative approaches
  - Future work, Timeline

Analyses for aim 1
Analyses for aim 2

Tips for success:
Example: Procedures

Consultation Meeting: for expert review of measures

Translation of Questionnaires: from English to Spanish

Pre-testing and Pilot Development Phase: test-retest reliability, etc.
Example: Protocol by Treatment Group

Safety Counseling (Control) Group. The control group will be offered 6 counseling calls over 12 weeks focused on home safety... (Appendix C. Safety Counseling Protocol). Each call will last 10-15 minutes. After 12-month data collection, we will send parents in the control group their child’s XX test results.

Biomarker+Counseling (Intervention) Group. The intervention group will receive the results of their child’s XX measurement via letter, followed by an outreach call and a telephone counseling intervention.
**Goal:** Brief text that sets up the main point of the experiment(s) and the overall approach.

**Results:** Brief text describing major findings. Refer to Tables/Figures if included.

**Relevance:** Explicit statement of how these findings support or inform the proposed work.
### How - Approach

**Visualize your content (tables, figures)**

#### Table 1. Study Measures

<table>
<thead>
<tr>
<th>Variables</th>
<th>Measure</th>
<th>Data Collection Time Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[variable 1]</td>
<td>Survey</td>
<td>X</td>
</tr>
<tr>
<td>[variable 2]</td>
<td>Score</td>
<td>X X X</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[outcome 1]</td>
<td>Blood test</td>
<td>X X X X</td>
</tr>
<tr>
<td>[outcome 2]</td>
<td>Questionnaire</td>
<td>X X X</td>
</tr>
</tbody>
</table>

#### Table 2. SNPs in Donor Genes Associated with Recipient Outcomes

<table>
<thead>
<tr>
<th>Kidney Allograft Outcomes</th>
<th>Liver Allograft Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>eNOS (G894T) and graft lossref</td>
<td>TLR4 rs4986790 &amp; rs4986791 and graft lossref</td>
</tr>
<tr>
<td>TNF (-308G/A) and CANref</td>
<td>H0-1 (-413A/T) and graft lossref</td>
</tr>
<tr>
<td>IL-6 (-174 G/C) and CANref</td>
<td>CYP3A5*3 [6986A&gt;G] and Tacrolimus levelsref</td>
</tr>
<tr>
<td>TNF-α rs309362 (G/A) and delayed graft functionref</td>
<td></td>
</tr>
<tr>
<td>TLR4 rs4986790 &amp; rs4986791 and ischemia reperfusion injuryref</td>
<td></td>
</tr>
<tr>
<td>PAI-1 gene (4G/5G) and graft lossref</td>
<td></td>
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</tbody>
</table>

Table used with permission of Ajay K. Israni, MD

#### Table 3. Benchmarks of Achievement

<table>
<thead>
<tr>
<th>Activity</th>
<th>Assessment Measure</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coursework</td>
<td>Progress towards master's degree, GPA</td>
<td>Every semester</td>
</tr>
<tr>
<td>Publications</td>
<td>At least 1 first-authored and 1 co-authored paper per year</td>
<td>Semi-annually</td>
</tr>
<tr>
<td>Grant writing</td>
<td>Pre-review of proposal drafts</td>
<td>Years 3, 4, and 5</td>
</tr>
</tbody>
</table>

**Tips for success:**
HIV-infected, ART-naive persons with Cryptococcal Meningitis
Study Entry at 7-10 days of anti-fungal therapy

Early ART Group
Start ART at <72 hours after study entry
n=210

Standard ART Group
Start ART at ≥4 weeks after study entry
n=210

Figure 4. Preconditioning on healthy controls. The HAAF treatment involves the HG clamps, while the euglycemic clamps are used for control.

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>6</td>
<td>9</td>
<td>12</td>
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<tr>
<td>Staffing</td>
<td></td>
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<tr>
<td>Staff training: Phase I (pilot study)</td>
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<tr>
<td>Prepare study material/database</td>
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<tr>
<td>Screening and Recruitment</td>
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<tr>
<td>Follow Up Assessments</td>
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<tr>
<td>Data Entry and Cleaning</td>
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<tr>
<td>Initial Analyses for Preliminary papers</td>
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<tr>
<td>Analyses for Final Papers</td>
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<tr>
<td>Presentations, Manuscripts</td>
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</tbody>
</table>
Bad advice about figures

Missteps to avoid:

Impress reviewers by using complex illustrations with many panels, arrows, boxes, drawings, and photos. The more stuff you can squeeze in, the smarter you'll look. Condense labels into tiny boxes, so that key parts are unreadable. Also assume that the illustrations are self-explanatory—no need for a pesky extended caption.

Source: http://chronicle.com/article/How-to-Fail-in-Grant-Writing/125620/
Before the statistical section can be developed, what information does the statistician need? (e.g., hypothesis, study design, most important outcome, clinically meaningful difference, total # of evaluations and measurements)

What information is needed to calculate power and sample size?

What design/statistical aspects of a study are often overlooked or inadequately described (e.g., case-control matching, data quality)?
Overall
Devote the most effort to the most-read proposal sections

- Specific Aims (1 page for NIH proposals)
- Abstract (often targeted to lay readers)
Overall

Write “reviewer-friendly” prose

<table>
<thead>
<tr>
<th>DON’T</th>
<th>DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Make the reader backtrack.</td>
<td>Compel the reader forward.</td>
</tr>
<tr>
<td>Use lots of jargon or tortuous syntax</td>
<td>Use simple, declarative sentences, limited specialized terms and abbreviations.</td>
</tr>
<tr>
<td>Tell readers everything there is to know about the field.</td>
<td>Write succinctly, logically, telling a (short) story.</td>
</tr>
<tr>
<td>Make the reader work hard to find information.</td>
<td>Use strong outlining, signal important information</td>
</tr>
</tbody>
</table>
## Overall

Use “reviewer-friendly” formatting

<table>
<thead>
<tr>
<th>DON’T</th>
<th>DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have large chunks of uninterrupted text.</td>
<td>Use short paragraphs, subheadings, graphic elements.</td>
</tr>
<tr>
<td>Use a font type and size that is hard to read.</td>
<td>Use a legible font and point size.</td>
</tr>
<tr>
<td>Cram text from margin to margin.</td>
<td>Incorporate white space, graphics.</td>
</tr>
<tr>
<td>Riddle your grant with misspellings and grammatical errors.</td>
<td>Spellcheck and vigorously proofread before you submit the final proposal.</td>
</tr>
</tbody>
</table>
Always build in time for internal peer review by friendly (but honest) colleagues – and rewriting in response to these critiques!

Perhaps most important:

- EXCELLENT
- GOOD
- AVERAGE
The Proposal

An exercise in persuasion: Sell your idea! The goal is to persuade reviewers that your proposed project deserves funding and that you/your team are extremely well suited to conduct the work.

The Idea

The Grant

The Project

• Research
• Training
• Equipment
• Program

The Impact
Your questions?