GRANT WRITING AND THE GRANT REVIEW PROCESS: What You Need To Know

Marie Davidian
Department of Statistics
North Carolina State University

http://www.stat.ncsu.edu/~davidian
Two broad topics in 20 minutes

1. Writing a high-quality grant application
2. The evaluation process

Note: Because of my experience, this will be NIH-centric
Writing a high-quality grant application

- Why write an NIH research grant?
- What to write?
- How to write?
Why write an NIH research grant (R01, R03)?

- The *National Institutes of Health* is the largest supporter of statistical research relevant to and motivated by applications in the health sciences
- *Funding* and *time* for methodological research (be your “own boss”)
- Form of *peer review*
- Contribute to the *research enterprise* and *support* of *your institution*
- Contribute to the *advance* of statistical and subject-matter science
What to write?

- Focus on research whose *relevance to real problems* arising in one or more health areas is *clear*
- Focus on research related to *priorities* identified by the Institutes of NIH (general areas, specific Requests For Applications, Program Announcements)
- *No* “theory for theory’s sake”
- Stay within your *methodological expertise* (and include *collaborators* to assist with material on which you lack expertise)
- Have a *genuine connection to* and *knowledge of* the health area issues
- Most importantly, tackle problems you are *interested in solving*!
What to write?

Inspiration:

- Realization that models and methods in your research area are *applicable* to specific health problems
- Realization that there are issues in your *collaborative work* that need new solutions
- Discussions with a (often senior) biostatistical colleague reveal a *potential synergistic partnership*
How to write?

- Follow the instructions *exactly*! Find out the procedures for *internal processing* at your institution.
- Obey all *page limits, margins, spacing*, etc.
- Allow yourself 3–6 months of *focused effort*
- Talk to *successful recipients*
- Examine *successful applications*
How to write?

The Research Plan:

- Specific Aims
- Background and Significance
- Preliminary Studies (or Progress Report)
- Research Design and Methods

Guiding principles:

- Relevance to health sciences research
- Clarity
- Detail and specificity regarding what you plan to do
How to write?

Specific Aims: *What will be accomplished?*

- Introductory blurb – *attention grabbing*!
- *Concrete*, enumerated outline of specific problems to be tackled. . .
- . . . and brief discussion of why they are *important* and need study
- ∼ 1 page
How to write?

Specific Aims: 3–5 aims for statistical methods grants

- *May or may not be related* to a common theme (but *beware* of “lack of focus”)
- Each aim may have interrelated *sub-aims*
- Development of a *new estimation technique* for a particular problem (motivation, derivation, properties)
- *Extension* of that estimation technique to a more complicated but related setting
- *Application* of the methods developed to specific data sets
How to write?

Background and Significance: Why is it important?

- “Importance” – in terms of advancing health sciences research and improving biostatistical practice, not just statistical theory

- Why what is available is inadequate, needs improvement

- Exhibit your command of relevant literature – cite recent and important papers, but no need to do an exhaustive literature review

- Exhibit your knowledge of the health sciences applications to which the work is relevant

- Not very technical – a high-level “sales pitch”

- ~ 5–6 pages
How to write?

**Preliminary Studies:** *What have you already done?*

- Describe your *previous work* and its importance and relevance to the proposed research
- Demonstrate that you are *well-qualified* and *know* and *have worked* in the relevant area(s)
- Describe your *collaborations* with health scientists in the areas motivating the research
- Provide relevant *published or accepted papers*
- ~ 3–4 pages
How to write?

Research Design and Methods: Exactly what will you do?

• DETAIL !! Detail should be in what you intend to do, NOT in what has already been done!

• Don’t be vague or generic – specificity!

• Describe a well-planned, concrete, systematic strategy for how to proceed for each aim

• Preliminary results to demonstrate potential for success, e.g., a small simulation in a simple case, sketch of likely analytical arguments

• Level of detail may differ across aims

• At least half of the 25 pages
The evaluation process

- Submitting your grant application
- The review process
- Tips for success
Submitting your grant application

- NIH research grants *must* be submitted *electronically* through Grants.gov using the *SF424 (R&R) application*

- Learn about this *well in advance* – a good website is http://www.grants.nih.gov/grants/grants_process.htm

- Also learn the *internal procedures* for submission at your institution

- You also must register with the *eRA Commons* (your institution must do this for you) – more in a moment
Submitting your grant application

Cover letter:

- Particular *Institutes* that might be interested

- Note if you are responding to a particular *Program Announcement* (PA) or *Request for Applications* (RFA)

- People who *should not* review your application due to professional conflicts (*rare*)

- *Under no circumstances* name people who you think *should* review your application (*NIH* will determine who does . . .)

- *Request of assignment to a particular* “study section”
Submitting your grant application

**eRA Commons:** NIH’s Electronic Research Administration website

- A *central portal* for interchange of information regarding NIH grants
- *Current status* of pending grant applications and funded grants
- *Score* and *Summary Statement* for your grant application

https://commons.era.nih.gov/commons/
The review process

Where does my grant go? The Center for Scientific Review (CSR)

- Receives most NIH grant applications and coordinates their review
- Assigns your application to a specific NIH Institute or Center
- Assigns your application to a peer review group known as a “study section”

http://cms.csr.nih.gov/
The review process

**Study section:**

- Members with expertise in a particular *scientific area*
- Meet face-to-face *three times a year*
- Coordinated by a *Scientific Review Officer (SRO)*, an NIH official with expertise in the scientific area
- The SRO assigns members as *reviewers* for each application
  
- The study section evaluates *scientific merit* of grant applications
- The study section *DOES NOT* decide which applications are *funded*
The review process

Some study sections of interest to statisticians:

- **Biostatistical Methods and Research Design** (*BMRD*)
- **AIDS Clinical Studies and Epidemiology** (*ACE*; statistical methods relevant to HIV research)
- **Biomedical Computing and Health Informatics** (*BCHI*; large clinical database development/data mining)
- **Biodata Management and Analysis** (*BDMA*; computational biology, bioinformatics)
- **Genomics, Computational Biology and Technology** (*GCAT*; microarray, population genetics, gene mapping)
- **Modeling and Analysis of Biological Systems** (*MABS*; modeling complex biological systems)
- **Social Sciences and Population Studies** (*SPSS*; econometrics, survey methods)
The review process

BMRD study section: Dr. Ann Hardy, SRO

- ~ 21 regular members from biostatistical and sociology methods professions + ad hoc members as needed
- Typically reviews ~ 30–50 grant applications per meeting

Logistics:

- Dr. Hardy receives applications for review by BMRD, notes conflicts
- Dr. Hardy assigns each application a primary reviewer, a secondary reviewer, and a discussant based on expertise
- Each assigned reviewer will read it in detail and prepare a written critique
- All applications are distributed to all members about 1.5 months in advance of the study section meeting
The review process

Before the meeting:

• All study section members \textit{must} have eRA Commons logins

• Dr. Hardy activates the \textit{Internet Assisted Review (IAR)} feature

• Reviewers submit \textit{critiques} and \textit{preliminary scores} in IAR

• \textit{Electronic versions} of all applications are available in IAR

• Reviewers can only view \textit{their own critiques} until...

Three days before the meeting:

• Dr. Hardy \textit{closes} IAR to critique/score submission/editing

• \textit{All reviewers} can now view critiques/scores for \textit{all applications} (except those with which they are \textit{in conflict})

• Reviewers of each application can \textit{read the critiques of the other reviewers} for the application and think about them...
The review process

Scores: Each reviewer gives a priority score in the range 1.0–5.0 reflecting his/her assessment of scientific merit (low is good)

1.0–1.5 Virtually flawless
1.5–2.0 Significant, few weaknesses, easy fix
2.0–2.5 Very promising, need to consider critiques seriously
2.5–3.0 Very good, some areas of notable weakness
3.0–5.0 Serious weaknesses in conceptual underpinnings and/or methods and design

• Different reviewers interpret this scale differently
The review process

Critiques:

- **Significance** – Is the research *important*? Will it have *impact*?
- **Approach** – Is the strategy sound and *likely to be successful*?
- **Investigator** – Is(are) the investigator(s) qualified? Do they have appropriate backgrounds/records?
- **Innovation** – Is the work *novel and creative*? Or just standard (e.g. routine extensions)?
- **Environment** – Are appropriate *resources* available?
- **Overall evaluation** – What are the *strengths and weaknesses*? Is the work likely to *advance* science? Biostatistical practice? Do the strengths *outweigh* the weaknesses? Can the weaknesses be “*fixed*?”
The review process

The meeting: One day, all day

• The Chair and Dr. Hardy run the meeting

• Each application is discussed for approximately 15–20 minutes; members in conflict leave the room

• The three reviewers give their preliminary scores

• The primary reviewer summarizes his/her critique

• The secondary reviewer adds additional comments, followed by the discussant

• All members then discuss the application, ask questions of reviewers

• Following discussion, reviewers and all members give final scores

• Reviewers may modify critiques based on the discussion
The review process

The discussion:

- Covers the *issues in the critiques* in detail
- Chair tries to keep focus on the *big picture* rather than *minutiae*
- Reviewers/members *may or may not* reach consensus
- Chair tries to *summarize*, make sure scores *reflect accurately* the level of enthusiasm
- Also discussed: *human subjects research issues*
- *Budget* – discussed *AFTER* scoring!
- Is the requested total effort, number of investigators, number of years *reasonable* for the work proposed?
The review process

**Streamlining:** Although read and critiqued by 3 reviewers, some applications are *not discussed* to save time

- *Prior to the meeting*, Dr. Hardy identifies applications whose average score in IAR across the three reviewers is *above the median* score (the “*lower half*”)
- These are nominated for *streamlining* – they will *not* be discussed
- *Almost always*, all reviewers are in good agreement
- Any member not in conflict *can object*, and the application *will be discussed* and is *unscored*
- The applicant receives the critiques but *no score*
- If your application is streamlined, it *does not mean* it is “*bad!*”
The review process

Score: Should appear within a few days in Commons

- Averaged across members $\times 100$
- Assigned a percentile rank based on the average score (low is good)
- Generally, score of 100–150 (average across study section members $\times 100$) is “good” $\Rightarrow$ “good” percentile

Summary statement: Should appear within a month

- The summary statement includes the reviewer’s critiques and a summary of the discussion written by Dr. Hardy
The review process

**Funding:** Determined by the *percentile* and “*payline*” for the *Institute*

- Your *Program Officer* may be able to help with “*borderline*” cases

**Bad news:** If not funded, you may submit an *amended application* (2 tries after original)

- Are the issues raised “*fixable*’?

- *Respond* to issues raised in critiques

- Demonstrate that you have taken the critiques seriously – don’t *whine* or *criticize* the reviewers

- *Three-page Introduction Section* summarizing how you have addressed the issues

**Good news:** If funded, your institution is notified, account set up!
Tips for success

Some personal observations: What makes a successful application?

- **Importance and relevance** – Does the research address important health area problems? Will it move the substantive science and biostatistical methodological development forward in a significant way? Will it advance biostatistical practice?

- **Originality** – Does the proposed research involve innovative and clever ideas (as opposed to straightforward extensions)?

- **Involvement** – Is the PI involved in collaboration with scientists in the health area? Does s/he demonstrate a good knowledge of the health area and of the need for the methods?

- **Applications and dissemination** – Will the PI demonstrate the methods on interesting data? Develop/disseminate software?

- **Clarity** – Nothing annoys a reviewer more than not being able to figure out straightforwardly what you are planning to do!
Tips for success

Top three things that lead to a good score:

• Strong case for *relevance* to biomedical science

• *Innovation* \(\neq\) fancy theory!

• *Detail* and *clarity* about what will be done

Top three things to avoid:

• Giving more detail on what *has been done* than what *will be done*

• Presenting a simple case of what you propose and then saying “we will extend this” to a more complicated situation but providing *no detail* on the approach you will use

• Failing to make a *convincing case* for the need for the research, either on health-related or biostatistical methodology grounds
Tips for success

The NIH review process:

- Reviewers have been through the grant application *themselves*, so they *know* how much work it is to prepare a grant application
- Reviewers are looking for *good science*
- Reviewers are *not* “out to get” applicants
- Understanding this and the process can help *you*

**Great website for junior investigators:** Check out the *Pathway to Independence* award especially

http://grants.nih.gov/grants/new_investigators/
Administrative issues

Some other parts of application: Besides the Research Plan

- Project Summary and Project Narrative
- Personnel
- Budget
- Biographical sketch
- Resources
Administrative issues

Project summary and narrative: Like an abstract

- Summarize the research and its relevance to public health
- Describe relevance in terms a layperson could understand

Personnel:

- Principal Investigator (PI) is responsible for overseeing the project
- Key personnel – PI, Co-investigators, postdocs, computer programmers, technicians, consultants
- Other significant contributors
- Research assistants (aka graduate students)

NIH biographical sketch: Needed for all key personnel, other significant contributors
Administrative issues

Budget: Direct costs

- Salary ("person-months;" usually $\leq 6$ months for PI), fringe benefits
- Travel, supplies (e.g., a PC), tuition
- Typically $100,000$–$250,000$ per year

Modular grant application: If direct costs $\leq 250,000$ per year

- Simplified system – request funding in $25K$ increments
  (1 “module” $= 25K$)
- Specify only percent effort, any special purchase – no detailed budget required
Administrative issues

**Budget:** Facilities and Administration (aka F&A, indirect costs, overhead)

- Support for institutional *infrastructure* – buildings, phones, copying, libraries, postage, computer network, . . .

- Calculated as a *percentage* of direct costs at your institution’s *negotiated rate*

**Total budget:** *Direct costs* + *F&A*

- Additional considerations if the project involves personnel at *other institutions* ("*subcontracts*")

- Typical *project period* 3–4 years
Administrative issues

Internal processing: The grant is made to your institution, *not* to you!

- Application must be approved by your institution – *approval of authorized university official*
- Learn what is involved at your institution *well in advance*!
- *Must budget time for this*!

Submission: *MUST be submitted by the deadline!* *No exceptions!*
Administrative issues

**Human subjects research:** Typically, BMRD research *does not* involve *human subjects*, but you *must* address this!

- Your research *does not* involve human subjects if subjects are not living or you do not have individual-subject data
- Your research *does not* involve human subjects if you and *all personnel* have no access to identifying information
- Your research *does not* involve human subjects if you have a *documented agreement* with the provider of the data that you will not have access to identifying information (unless that provider is one of the personnel on your grant!)
- *Read the instructions regarding human subjects research carefully!*
Administrative issues

Progress report: Funds are allocated on yearly basis

- To receive next year’s funds, must document progress

Competing continuation: “Renew” the project

- Not guaranteed!

- Add Progress Report documenting results of previous project period to the Preliminary Studies section of Research Plan

- New research ideas and continuation of previous ones