

## STATISTICAL GRANTS FROM NIH

### *Writing a Successful Grant Application: What You Need To Know*

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## 1. Why write an NIH grant?

- NIH is the *largest supporter* of statistical research relevant to and motivated by applications in medicine and public health
- *Funding* and *time* for methodological research
- A form of *peer review* and indication of *academic success*
- Contribute to the research enterprise and support of *your institution*
- Contribute to the *advance* of statistical and subject-matter science

**Here:** Focus on *research grants*

- R01, R03 mechanisms

## Outline

1. Why write an NIH grant?
2. What to write????
3. How to write???
4. Submitting your grant
5. The review process: Biostatistical Methods and Research Design (BMRD) Study Section
6. Strategies for success!
7. Administrative issues

## 2. What to write???

### Why does NIH support biostatistical methods research?

- *Recognition* that new biostatistical methods are required to address long-standing and new challenges in health sciences research
- *Expectation* that biostatistical methods research will be *directly relevant* to such challenges

### How does NIH support biostatistical methods research?

- Mainly through individual *institutes* (e.g. NCI, NIAID, NIEHS, etc)
- . . . so that biostatistical methods research should be seen as targeting problems in *specific disease/health areas*

## 2. What to write???

**Result:** Your best chance for *success*

- Focus on research whose relevance to *real problems* arising in one or more health areas is *clear* and can be *convincingly demonstrated*
- Focus on research related to *priorities* identified by the institutes (general areas, specific Requests For Applications, Program Announcements)
- No "theory for theory's sake"

**Additionally:** Focus on research you are clearly *qualified* to conduct

- *Methodological expertise*
- *Connection to* and *knowledge of* the health area issues

## 2. What to write???

**Typical inspirations:**

- Realization that models and methods in your research area are *applicable* to specific health problems
- Problems arise in your *collaborative work* that need new solutions
- Discussions with a (often senior) biostatistical colleague reveal a *potential synergistic partnership*
- Visit to <http://www.nih.gov> and <http://grants.nih.gov>

**More specifics momentarily...**

## 3. How to write???

**To begin:**

- Forms and instructions (follow *exactly*: *PHS 398* at <http://grants.nih.gov/grants/forms.htm>)
- Receipt dates (*cast in stone*) <http://grants.nih.gov/grants/dates.htm>
- Allow yourself *six months* of focused effort
- Talk to *successful recipients*
- Examine *successful applications*

## 3. How to write???

**THE RESEARCH PLAN:** 25 page limit, margins, spacing, type-size (*strictly enforced!*)

- *Specific Aims*
- *Background and Significance*
- *Preliminary Studies*
- *Research Design and Methods*

**Guiding principles:**

- *Relevance* to health sciences research
- *Clarity*
- *Detail and specificity* regarding what you plan to do

### 3. 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
- ~ One page

**Biostatistical methods grants:** 3–5 aims, *may or may not be related* to a common theme

- 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
- Development of a *new estimation technique* for another problem and extension thereof
- *Application* of methods developed to specific data sets for *demonstration* and drawing *subject-matter inferences*

### 3. 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 knowledge of existing relevant biostatistical research – *references!* But *no need* to do a comprehensive 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

### 3. 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)
- Provide relevant *published or accepted papers* in Appendix
- ~ 3–4 pages

### 3. 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!
- Level of detail may *differ* across aims
- Show that you have a *well-planned*, *concrete*, *systematic strategy* for how to proceed for each aim
- So if you propose a new estimator, give a *detailed rationale* and *derivation* and describe *implementation*
- *Preliminary results* to demonstrate potential for success, e.g., a small simulation in a simple case, sketch of likely analytical arguments you'll use to derive properties
- At least *half* of the 25 pages!

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### 4. Submitting your grant

**Cover letter:** Be sure to mention

- That your application proposed new biostatistical methods and would be best reviewed by the *BMRD study section* (or other relevant study section, e.g., AARR6)
- That your application is focused on problems in a certain *disease/health area* and would be most interesting to certain institutes (e.g., problems in cancer ⇒ NCI)

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### 5. The review process: BMRD study section

**Biostatistical Methods and Research Design (BMRD) study section:** Reviews most biostatistical methods grants (formerly SNEM-5)

- Ann Hardy, *Scientific Review Administrator* (SRA)
- ~ 20–25 members from biostatistical profession
- Applications distributed in advance to all members
- *Primary*, *secondary* reviewers and a *discussant* read in detail, write a *critique*, present to the full panel for discussion
- Score in range 1.0–5.0
- *Streamlining* – some applications “*unscored*” (3.0–5.0)
- Roster [http://www.csr.nih.gov/Roster\\_proto/sectionI.asp](http://www.csr.nih.gov/Roster_proto/sectionI.asp)

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### 5. The review process: BMRD study section

**Usual NIH scoring:**

- 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

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## 5. The review process: BMRD study section

### 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, mainly data analysis with mildly modified techniques)?
- *Environment* – Are appropriate resources and personnel available?
- *Overall evaluation* – What are the strengths and weaknesses? Is the work likely to advance science? biostatistical practice?

## 6. Strategies for success!

### Some personal observations: What makes a successful application?

- *Importance and reach* – Does the proposed research address important and timely health area problems? Will it move *biostatistical methodological development* forward in a significant way? Will it advance *biostatistical practice* in a significant way?
- *Originality* – Does the proposed research involve innovative and clever ideas (as opposed to straightforward extensions)?
- *Currency* – Is the research in an area of biostatistical methodology that is undergoing development (as opposed to one that has already seen much work)?
- *Clarity* – Nothing annoys a reviewer more than not being able to deduce straightforwardly what you are planning to do!

## 6. Strategies for success!

### Some personal observations: What makes a successful application?

- *Relevance to subject-matter science* – Does the research have the potential to uncover new insights that could advance a particular health science area?
- *Involvement and familiarity* – Is the PI involved in collaboration with scientist in the health area? Does s/he demonstrate a good knowledge of the health area and the need for the methods? Will subject-matter specialists be involved in the project?
- *Applications and dissemination* – Will the PI apply the new methods to existing and evolving data to demonstrate advantages? Does s/he plan to develop and disseminate software and accounts of use of the methods?

## 6. Strategies for success!

### Top three things that lead to a good score:

- Strong case for *relevance*
- *Innovation*
- *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 how
- Failing to make a *convincing case* for the need for the research, either on health-related or biostatistical methodology grounds

## 6. Strategies for success!

### Some tips:

- Writing a grant is *hard work!*
- But it can be a wonderful way to *force* you to organize your thoughts and ideas, leading to be better research!
- Best way to learn – from investigators who have been successful
- For your first attempt – consider working with a senior colleague who “*knows the ropes*”

## 7. Administrative issues

**Structure of application:** Besides the *Research Plan*

- *Project Description*
- *Personnel*
- *Budget*
- *Resources and Environment*

## 7. Administrative issues

**Project Description:** Like an *abstract*

- Summarize the research and its significance for *non-specialists*
- Will be made *public* if grant is funded

### Personnel:

- *Principal Investigator* (PI) is responsible for overseeing the project (*key personnel*)
- *Other key personnel* – Co-investigators, postdocs, computer programmers, technicians, consultants
- *Research Assistants* (aka graduate students)
- *NIH Biographical Sketch* for all *key personnel*

## 7. Administrative issues

**Budget:** *Direct costs*

- Salary (“*percent effort*”), fringe benefits (usually  $\leq 40\%$  for PI)
- Travel, supplies (e.g., a PC  $< \$5K$ ), 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

## 7. 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* + *em F&A*

- Typical *project period* 3–4 years

## 7. Administrative issues

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

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

**Submission:** *MUST be received by the deadline!*

- Sent by overnight courier (e.g., FedEx) – get the *tracking number* so you can monitor progress
- Original + 5 copies + 5 copies of Appendix
- *Cover letter!*

## 7. Administrative issues

**Human subjects research:** If you will be doing anything with *data* collected on humans, your research *involves human subjects*

- Even if the data are already collected or published!
- Even if the data were or are currently being generated from an NIH-supported study!
- You must check “*yes*” on the Item 4 of the Face Page of PHS 398!
- If you will be working with data where you have *no identifying information* on the subjects, the research may be *exempt* from human subjects regulations under *exemption No. 4*
- *Read the instructions regarding human subjects research carefully!* Failure to provide accurate information may *compromise* your application!

## 7. Administrative issues

**Funding decisions:** Awards made to *best-scoring* applications

- Assigned a *percentile* rank based on raw score
- For BMRD, percentiles are determined by scores in *current* and *previous two rounds*
- *Low is good* – usually < 20th percentile
- Generally, score of 100-150 (average across study section  $\times 100$ ) is “*fundable*”
- PI receives *Summary Statement* in  $\sim 6-8$  weeks after study section meets with critiques and score – final decision on funding made *later*

## 7. Administrative issues

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

- Are the issues raised “*fixable?*”
- Respond to issue 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!

## 7. Administrative issues

**Progress report:** Funds are allocated on *yearly basis*

- To receive next year’s funds, must document progress
- PHS form 2590

**Competing continuation:** “*Renew*” the project

- *Not guaranteed!*
- Replace *Preliminary Studies* section of Research Plan with *Progress Report* documenting results of previous project period
- New research ideas and continuation of previous ones