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## Developing Scientific Research Proposals (Grant Writing)

2003 Epidemiology and Biostatistics Summer Session



Michael Gaziano, MD, MPH

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### Course Instructors

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### Course Overview

1. Specific aims
  2. Overview
  3. Background, Significance and Preliminary studies
  4. Methods: overall design, recruitment
  5. Methods: measures, data management
  6. Statistical Analysis
  7. Power
  8. Abstract, Budget and Peer review
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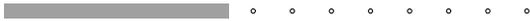
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## Session 1

# Overview of Grant Writing



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## Overview of Grant Writing

- Before getting started
- A successful grant
- Funding opportunities and mechanisms
- Determine funding agency interest
- Structure of research proposals
- Characteristics of a good application
- The peer review process



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## Before Getting Started

- Why write a grant?
- Do you have the time?
- Do you understand the commitment?
- Are you familiar with the process?



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## The Process

1. Idea
2. Literature Search
3. Explore funding options
4. Learn the rules
5. Consider pilot projects
6. Write the grant/budget
7. Submit
8. Grant Review
9. Score
  - Funded
  - Not funded



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## A Successful Grant (Adapted from AHRQ)

- Good Idea
- Good Science
- Good Application



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## Good Idea (Clever idea even better)

Ideas come form many sources:

- Federal Register or through
- An RFA or RFP
- Your own clinical work
- A published report
- A mentor or colleague



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### Good Idea

- Testable hypothesis with a well defined rationale
- Achievable scope
- Hypothesis and research aims related to longer-term scientific objectives
- Demonstrates awareness of relevant published literature
- Critique of current literature
- Pilot data

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### Good Science

- Rationale for methods selected; consideration of alternative methods
- Includes details to assure the reviewers that new methods have a reasonable chance of working
- Spells out assumptions and limitations of the research
- Identifies possible problems, pitfalls and planned solutions

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### Good Science

- If later phases are contingent on results of initial stages, offers alternatives to fit outcomes
- States criteria for evaluating success or failures
- Presents power analysis in detail
- Involves statistician in proposal development and in research

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## Good Application

- Read and follow instructions
- Note page limitations, especially for the research plan
- Discuss protection of human subjects
- Never assume the reviewers will "know what you mean"
- Use appendices judiciously
- Consult with colleagues, agency program staff, and the Executive Secretary of the review Group

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## Funding

Find the best potential sources of funding

- VA
- NIH
- Specialty Societies (AHA, ACS, etc)
- Foundations
- University organizations/departments
- Industry
- Others

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## Funding

Know the cold, hard funding realities – for example

- VA pay lines range from 20-50% depending on the service
- In 1999, NIH funded 31.6% R01's (many were continuation grants).
- In 1999, AHRQ only funded ~ 8% of R01's! .

The message: Strategize your research portfolio if you plan an academic career.

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## Research Funding Opportunities

### Department of Veterans Affairs (VA)

VA Research has 4 services:

- Medical Research
- Health Services Research and Development (HSR&D)
- Rehabilitation Research and Development (RR&D)
- Cooperative Studies Program (CSP).

Requests for funding can be made to any of the services.

Funding for epidemiology merit reviews and career development is under Medical Research.

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## Research Funding Opportunities

### National Institutes for Health (NIH)

The mission of the NIH is to acquire new knowledge to help prevent, detect, diagnose and treat disease and disability that will lead to better health for the population. NIH consists of a confederation of 25 different Institutes with different policies, priorities and types of awards available in these Institutes.

Institutes/centers can make extramural awards.

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## Research Funding Opportunities

### The Agency for Healthcare Research and Quality (AHRQ)

The AHRQ mission is to conduct and support research that develops and presents scientific evidence on all aspects of health care and to synthesize and disseminate available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers and educators.

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### VA Career Development and Transition Awards

Types of awards	Career Development, Career Scientists
Who is eligible?	5/8 time or applying for eligibility, Health Professionals, PhD's
Require LOI?	Yes
Time & Award Amount	3 years
Application process	HSR&D, Med Res, EPI, and RR&D – 1313 Series; 2 times per year
Turnaround time	4-6 months
Review process	Local review for HSR&D; National Peer Review
Percent Funded	HSR&D ~30%; Med Res ~30%
Other	3 year MD awards; 5 yr PhD awards

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### NIH Career Development and Transition Awards

Types of awards	12K Series Awards
Who is eligible?	Health Professionals, PhD's, US Citizen, Not prior PI
Require LOI?	No
Time & Award Amount	3-5 years; renewable for more senior awards
Application process	398; Regular submission dates 3 times per year
Turnaround time	5-6 months
Review process	Regular Peer Review
Percent Funded	~35%
Other	Generally 75% effort

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### NIH Career Development and Transition Awards

- The NIH K Kiosk for career development training is an incredible resource!
  - Visit it at: <http://grants.nih.gov/training/careerdevelopmentawards.htm>
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### Dissertation Awards

Awards based on

- 1) merit
  - 2) relevance to agency mission
  - 3) availability of funds
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### VA Small Grant Awards

Types of awards	Seattle ERIC Pilots and RR&D HSR&D and Med Res – not available
Who is eligible?	5/8 time or applying for eligibility
Require LOI?	Both = Yes
Time & Award Amount	Both = 1 year max; EPI ≤ 25,000; RR&D ≤ 50K
Application process	ERIC/Seattle – 6 pages RR&D – 1313 Series
Turnaround time	3-4 months
Review process	National
Percent Funded	ERIC – 20-30% RR&D – 30-40%

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### NIH Small Grant Awards

Types of awards	R03; R21 Only available in 50% of NIH Institute & Centers
Who is eligible?	Health Professionals, PhDs, US Citizen
Require LOI?	No
Time & Award Amount	Usually 1 year; 50-150K
Application process	398; Regular NIH review cycle
Turnaround time	4-6 months
Review process	Study Section Review
Percent Funded	~ 30%

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### AHRQ Small Grant Awards

Types of awards	R03
Who is eligible?	Health Professionals, PhDs, US Citizen; Usually a beginner award
Require LOI?	No
Time & Award Amount	Up to 1 year; 100K; no travel or payment to a federal employee
Application process	398; Accepted ongoing basis
Turnaround time	3 months
Review process	Study Section – a little "softer" review; riskier ideas OK
Percent Funded	10%; about 30 awards/year

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### Advantages and Disadvantages of Research Funding Types

#### Federal Agencies

Advantages – Established mechanisms; peer review system best available

Disadvantages – Lots of bureaucracy, requires certification in research office

Considerations – Time, patience and coordination needed

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### Advantages and Disadvantages of Research Funding Types

#### Private Industry / Pharmaceutical

Advantages – Short application and time to funding

Disadvantages – ? Credibility of research investigator role in pharmacy designed research

Considerations – Strings, who owns data, control of publications, potential conflict of interest

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### Advantages and Disadvantages of Research Funding Types

#### Private Foundations / Professional Societies

Advantages – Usually shorter application and time to funding, but not always.

Disadvantages – ? Credibility of research rigor, usually grants are for lesser amounts compared

Considerations – ? Strings, potential conflict of interest!

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### VA Epidemiology Research

- Office of R&D initiative; applies to biomedical, health services and rehab epidemiology research. Reviewed as part of Merit Review Cycle.
- Web site: [www.va.gov/resdev/ps/psmr/msr\\_programs.cfm#16](http://www.va.gov/resdev/ps/psmr/msr_programs.cfm#16)

Program Component	Submission Deadline	Reference Document
LOI to request budget in excess of \$150K	Oct 21 (for spring cycle) April 21 (for fall cycle)	Teletype 03/25/98; R&D website
Notice of intent to submit proposal	Nov 21 (for spring cycle) May 21 (for fall cycle)	Information available on R&D website
Initial data transmitted via PROMISE	Dec 07 (for spring cycle) June 07 (for fall cycle)	Memo: Reminders and Guidelines
Research proposals	Dec 21 (for spring cycle) June 21 (for fall cycle)	M-3, Part II, Chapter 4; Memo

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### VA Trials Research

- The CSP accepts LOIs for large-scale multi-center trials as well as observational studies year round. LOI are sent out for peer review. Decisions for a planning meeting are made year round.
  - Accepted LOIs are assigned to one of the CSP coordinating centers for planning and grant preparation.
  - Proposals are reviewed at CSEC, the CSP study section, in May and October
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## Research Funding Mechanisms at NIH

### Types of Awards and the Key to Crack the Code

Examples:

R01 = Investigator Initiated

R21 = Exploratory/Developmental Grant

R03 = Small Project

P01 = Research Program Project,

U01 = Research Project Cooperative Agreement

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## Research Funding Mechanisms at NIH

### Information for Management, Planning, Analysis and Coordination (IMPAC) Used by NIH and DHHS for Extramural Programs

A (Training Programs)

E (Health Professions)

F (Fellowship)

K (Research Career)

R (Research Projects)

U (Cooperative Agreements)

Y (Inter-/Intra-Agency Agreements)

For a complete listing – go to the NIH web site and search on IMPAC.

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## Definitions

**Program Announcement (PA)** – formal expression of an institute's ongoing interest in funding a particular area of science. Applications go through the regular R01 mechanisms, may be submitted for any review cycle and may cite the PA.

**Request for Application (RFA)** – solicits grants or cooperative agreements on a specific topic with a specified receipt data and set-aside funds. The RFA number needs to be cited on the application for appropriate consideration. These applications are usually reviewed by a special peer review group organized by the Center for Scientific Review and the sponsoring Institute(s).

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## Definitions

**Request for Proposal (RFP)** – solicits contract offers for bids and proposals on a designated scope of work to be conducted providing deliverables in a specified time frame.

**Cooperative Agreement** – a support mechanism with substantial Federal scientific and/or program involvement. It is anticipated there will be extensive inter-agency interaction after the granting the award in the conduct of the research.

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## Determine Agency Interests

- Know your audience (funding agency).
- Visit VA research web sites.
- Visit the NIH CRISP website to see abstracts for funded NIH research projects.
- Determine whether there is a good fit between your research interests and their agency mission and funding priorities!
- Agency personnel are available to speak with investigators.

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## Determine Agency Interests

- Contacts are encouraged before and during the preparation of an application.
- Program staff provide feedback on the "fit" of the research with the agency's interests.
- For RFA's program staff provide needed additional information for inclusion in your proposal beyond the PHS 398.
- Determine which study section you want. If you don't specify, the Center for Scientific Review will decide for you.

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## VA Applications

**Tell them what you are going to tell them, tell them and then tell them what you told them!**

- I. Research objectives and specific aims
- II. Background / Work Accomplished
- III. Significance
- IV. Methods
- V. Protection of human subjects
- VI. Project management plan

(1313 Series Forms)

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## NIH Applications

**Tell them what you are going to tell them, tell them and then tell them what you told them!**

- |                                 |                   |
|---------------------------------|-------------------|
| I. Specific aims                | VI. Sample size   |
| II. Background and significance | VII. Logistics    |
| III. Preliminary studies        | VIII. Limitations |
| IV. Research design             | IX. Summary       |
| V. Analysis by aim              |                   |

(PHS 398 application; 25 pages excluding human subjects and references)

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## Applications

### Who uses the 1313 Series?

Investigators for all VA submissions.

### Who uses the PHS 398?

NIH and AHRQ use this format for investigator initiated research. Not all the agencies within in the Department of Health and Human Services (DHHS) use the PHS 398, so if you are submitting an research grant application to agencies other than NIH or AHRQ contact the program officer for instructions. The NIH Center for Scientific Review (CSR) receives 45,000 grants per year to distribute to Agencies and Institutes.

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### Characteristics of a Good Application

- Organization – present information logically and clearly
- Keep related ideas and information together
- Be creative in use of headings, figures, bullets
- Visual clarity – some items don't xerox (photographs, colors)
- Don't make the reviewer work any harder than necessary!  
(example interchangeable technical words, abbreviations, going back and forth to the appendices)
- Use active voice, topic sentences and good transitions

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### Characteristics of a Good Application

- Coordinate sections and make sure they relate to specific aims
- Include well designed tables and figures with accurate and informative titles
- Identify the problem areas and address them before reviewers have a chance – have alternate approaches for potential pitfalls
- Provide a project time frame that accurately summarizes project activities
- Proof read (multiple times) – get colleagues to do also

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### The Peer Review Process

- Relax; Take a short break
- Respond to all agency queries promptly
- Consider submitting supplemental information if there are new developments
- Consider using your hard work for other purposes: background for a manuscript or review article, other grants, etc.
- The review process is out of your control and can be variable
- Don't ever be discouraged by the review process

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