Conceptual and Practical Issues in Funding through the National Institutes of Health: The Example of Cancer Control

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April 19, 2012
Outline

• Orientation
  – To NIH and a key contact
  – The Program Director
  – University of Montana research

• The application and the application process

• The review

• Discussion
Funding is partly a process of learning the system and the resources.

**Learn where your ideas fit**

- Which Institute?

- It isn’t necessarily obvious
  - The National Cancer Institute has the largest set of behavioral scientists in NIH
    - A social psychologist leads my program

- Harold Varmus, a noble prize winning physician & molecular biologist now leads NCI
27 NIH institutes and centers fund grants

http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription/
http://cms.csrweb.nih.gov/PeerReviewResourcesNew/
Gateways to NIH information

www.cancer.gov/aboutnci/budget_planning_leg/plan-2012

www.grants.nih.gov/grants/oer.htm
Funding is partly a process of being reviewed by the right group

Learn where your ideas fit

- Which Institute is important

But also think about

- Which Division?
  - Go to the Institute’s sites and look at their divisions

- Which Study Section?
  - Center for scientific review describes the study sections
Current NIH Funding at the University of Montana

- 59 active grants administered by 13 NIH institutes & Centers
- National Center for Research Resources and National Institute of Environmental Health Sciences administer 50% of UMT’s grants (n=29)

<table>
<thead>
<tr>
<th>UMT grants by Institute &amp; Center*</th>
<th>#</th>
<th>%</th>
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<tbody>
<tr>
<td>NIH Institute</td>
<td></td>
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<tr>
<td>N. Center for Research Resources</td>
<td>17</td>
<td>28.8</td>
</tr>
<tr>
<td>(▲ to Center for Advancing Translational Sciences)</td>
<td></td>
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</tr>
<tr>
<td>N. Institute of Environmental Health Sciences</td>
<td>12</td>
<td>20.3</td>
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<tr>
<td>N. Institute of Neurological Disorders and Stroke</td>
<td>9</td>
<td>15.3</td>
</tr>
<tr>
<td>N. Institute of General Medical Sciences</td>
<td>6</td>
<td>10.2</td>
</tr>
<tr>
<td>N. Institute of Allergy and Infectious Diseases</td>
<td>5</td>
<td>8.5</td>
</tr>
<tr>
<td>N. Institute on Drug Abuse</td>
<td>2</td>
<td>3.4</td>
</tr>
<tr>
<td>N. Cancer Institute</td>
<td>2</td>
<td>3.4</td>
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</tbody>
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*Plus 1 grant each: N. Center for Complementary and Alternative Medicine; N. Human Genome Research Institute; N. Heart, Lung, and Blood Institute; N. Institute on Aging; N. Institute of Child Health and Human Development; N. Institute of Mental Health
2 National Cancer Institute grants

- *Signal transduction enzyme inhibitors from extremophilic microbes as anticancer...* (5R01CA139159-03); PI: Andrea Anne Stierle

- *Crystallographic analysis of CDC42 regulated interaction of PAR6C with RIT...* (1R15CA137609-01A1); PI: Celestine J Thomas
NCI is the biggest player in NIH

- NCI is one Institute ...
  - With nearly half the budget of NIH
    - FY2011 - approximately $3 billion for research

- NCI has 6 Divisions that fund research
  - Division of Cancer Biology,
  - Division of Cancer Epidemiology & Genetics
  - Division of Cancer Prevention,
  - Division of Cancer Treatment
  - Division of Extramural Activities
  - Division of Cancer Control and Population Sciences
    - FY2011 - $454 million total research project grants & center grant dollars awarded
    - Represented 83% of total division budget

http://fundedresearch.cancer.gov
Reduce risk, incidence, and deaths from cancer as well as enhance the quality of life for cancer survivors.

Conduct and support an integrated program of high-quality genetic, epidemiological, behavioral, social, applied, and surveillance cancer research.
DCCPS research portfolio FY2011
Total grants: 837  Total dollars: $454 million

FY11 Grants Mechanisms as a % of Total Dollars

- R01: 62%
- R03: 22%
- R21: 9%
- Ps: 4%
- Us: 1%
- Other: 2%
DCCPS Trends – Number of Research Grant Awards FY1998-FY2011
Within NIH and NCI there are some major independent groups:

- Center for Scientific Review
- NCI Review
- Grants Administration
- Program
Find some help within the institute or center – the PD

Program Director (PD)
- Oversees the technical, scientific, or programmatic components of grants in an NIH portfolio
- Some are masters level trained
- Most are PhDs or MDs

Program Directors will help
- Understand Institute/Center priorities
- Guide you to the right funding announcement or study section
- Advise about resources, general concepts
- Encourage networking and connections
- Explain emphasis and tenor of the review
Program Directors are your “friends”

Use the website & meetings to match your ideas to a Program Director

- Program/Branch/Staff with proposed research—
  NCI’s DCCPS Web site: 
  http://cancercontrol.cancer.gov/od/meet_staff.html

E-mail brief query

- About research interest and funding to Program Director
- Include: “If this area of research is not suitable for the [Program/Branch/Office], please direct me to appropriate Program Director”

Ask Program Director if you may...

- E-mail abstract or specific aims
- E-mail or telephone to discuss grant mechanism and objectives
Before contacting NCI program staff…suggested background reading

NIH Guide for Grants and Contracts

http://grants.nih.gov/grants/guide/

DCCPS Web site: www.cancercontrol.cancer.gov

Priorities

- Current funding announcements
- Abstracts of active grants
- Publicly available data sets, other research resources
- Theoretical frameworks for cancer control, if applicable
Before You Apply

Do your homework, develop your ideas, have your grant reviewed …
Typical timeline for a new individual research project grant application (R01)

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Submission</td>
<td>February</td>
<td>June</td>
<td>October</td>
</tr>
<tr>
<td>Review</td>
<td>June</td>
<td>October</td>
<td>February</td>
</tr>
<tr>
<td>Council</td>
<td>September</td>
<td>January</td>
<td>May</td>
</tr>
<tr>
<td>Earliest Award</td>
<td>December</td>
<td>April</td>
<td>July</td>
</tr>
</tbody>
</table>

You need to be starting a year or 2 before submission
Types of research funding opportunities
Types of funding opportunity announcements (FOAs)

Program Announcement (PA):
- Statement of ongoing research interest by Institute or Center
  - No set-aside monies (usually)
  - Investigator-initiated awards are now in response to a parent PA


Request for Applications (RFA):
- Special research initiative
  - Set-aside monies and specially assembled review group
  - If not funded, consider submitting as NEW grant
Finding grant opportunities

Parent Announcements

• “Parent” FOAs are your ticket to applying for investigator-initiated research

• Use the Parent electronic application package for your chosen grant program (i.e. R01, R03, R21 etc.)

Parent announcements listed at—
Grant submission: eligibility requirements

• Read the FOA
• Check eligibility requirements in FOA carefully
  - RFA, PA, PAR, PAS, etc..
• General
  - Related to the FOA (i.e. submission deadline)
  - Human subject requirements
    • Know them and address them well
  - Institute requirements regarding submission
    • Budget approval, letters of intent, etc....
Types of grant mechanisms

- **R03**: Small Research Grant
- **R21**: Exploratory/Developmental Grant
- **R01**: Large Research Grant
R03: small research grants

Provides

- Short-term awards for testing new techniques
- Secondary analyses of existing data
- Development of innovative projects that could provide a basis for more extended research

Characteristics

- < $50K per year, 2-year maximum (nonrenewable)
- 2 submissions—initial and 1 amended
- Special NCI review committee
R21: exploratory/developmental grants

Supports
- Development of pilot projects
- Feasibility studies
- Intervention studies that are creative, novel, high-risk/high-payoff, and produce innovative advances

Characteristics
- Up to $275K/year for 2 years (nonrenewable)
- 2 submissions—initial and 1 amended
R01: research project grants

Traditional

- Investigator-initiated grant providing support for discrete, specified research
  - If > $500K/year, need to request NIH Center for Scientific Review (CSR)/Institute Program Director approval to submit—at least 6 to 8 weeks before submission deadline for NCI DCCPS
  - Up to 5 years (usually 3–5 years)
  - 2 submissions—initial and 1 amended
Writing a Grant Application
Develop your idea - early

Is it
- Original?
- Innovative?
- Significant to Public Health?

Enlist
- Collaborators

Review
- Successful NIH grant applications
What are reviewers looking for?

Rationale
Coherence
Specificity
Consistency
Clarity

Say it again and say it again

Say it clearly
Theory can help
But the theory needs to...

**Be consistent**
- Do not name a theory in one place and never mention it again

**Be integrated**

Demonstrate the theoretical influence in specific terms in all application sections
- Abstract
- Background
- Research strategy

If design calls for a survey show how it is based on your chosen theory
‘Big 4’ in proposal writing

1. Abstract
2. Specific Aims
3. Research Strategy
4. Biographical Sketch
5. Resources & Facilities

Fundable NCI Grant Application
Introduction

Aims
- 2-3 aims with narrative for:
  An overall Goal
  Specific Aims that lead to the goal
  AIMs that are Linked to hypotheses & analyses

Hypotheses
  State null and alternative hypotheses and their direction
  Implications if hypotheses are / are not supported

Operationalize definitions

Public Health Relevance
Fundable
NCI Grant Application
Background to problem and literature search
- Current articles that directly support study aims
- Publications of potential reviewers

Significance and rationale
- Does the study address an important public health problem?
- How will your study fill a gap in the research?

Preliminary studies or progress report

Theoretical model
Research Strategy

Research design and approach

Replicate Colorectal Cancer Screening in Chinese Americans Intervention based on Diffusion of Innovation Theory

Dissemination Study with Vietnamese American Patients at

Evaluate Dissemination Study based on RE-AIM Framework

Quantitative Evaluation (Individual Patient Level)
- Reach
- Effectiveness

Quasi-Experimental Study
Section D.6 (Figure 3) and Section D.7

Process Evaluation (Clinic Setting Level)
- Adoption
- Implementation
- Maintenance

Qualitative Study
Section D.8 (Table 6 and Table 7)

Use graphs & figures
Quantitative designs

- Consistent analytic plan and approach for each aim (basic to complicated)
- Use highest order analysis (descriptive to multivariate)
- Link analyses to Aims, Hypotheses
- Include biostatistician from beginning

Qualitative designs

- Detailed analysis and specifics, software,

TIP: NIH Qualitative Methods in Health Research Opportunities and Considerations in Applications and Review: http://www.obssr.od.nih.gov
### Research Strategy Timeline

<table>
<thead>
<tr>
<th>Dissemination Study Procedures</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
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</thead>
<tbody>
<tr>
<td>Material Development</td>
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<td>Focus Groups</td>
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<tr>
<td>Pre-Implementation chart audit</td>
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<tr>
<td>Implementation</td>
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<tr>
<td>Post-intervention chart audit</td>
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<tr>
<td>Evaluation</td>
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<tr>
<td>Data analysis</td>
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</table>

### Process Data Procedures

<table>
<thead>
<tr>
<th>Key informant interviews &amp; focus groups</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
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</thead>
<tbody>
<tr>
<td>Data analysis</td>
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### Report Writing

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
</tr>
</thead>
</table>

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Dissemination Study Procedures:
- Material Development
- Focus Groups
- Pre-Implementation chart audit
- Implementation
- Post-intervention chart audit
- Evaluation
- Data analysis

Process Data Procedures:
- Key informant interviews & focus groups
- Data analysis

Report Writing
Personal statement
Briefly describe why your experience and qualifications make you particularly well suited for your role in the project.

Publications
Limit the list of publications or manuscripts to no more than 15.
Make selections based on recency, importance to the field, and/or relevance to the application.
Resources

- Provide a description of how the scientific environment will contribute to the probability of success of the project

- Describe the institutional investment in the success of the investigator
Budget

Justify effort & expertise for all personnel
- New PI should be > 20% effort
- Consultants from other institutions are less expensive than “co-investigators”
- NIH Policy on Multiple Principle Investigators
  Tip: http://grants.nih.gov/grants/multi_pi/

Budget
- Anticipate future salary / operating increases
- Include 1-2 trips for conference presentations
- Equipment and supplies
- NCI often cuts budgets
  Tip: Use of existing and shared resources is valued
Human subjects

- Inclusion of minorities, women, children, genders
- Protection
- Exemptions, if applicable
- Potential benefits / risks

Recruitment and informed consent

- Vulnerable populations
- Incentives
- Informed consent
  - Participation
  - Use of information
Data Safety and Monitoring Plan

Policy on Data Sharing
http://grants.nih.gov/grants/policy/data_sharing/
Obvious and not so obvious

Organized, lucid write-up
– Crisp, clear story of your project

Link aims, hypotheses, measures, analyses
– Don’t assume reviewers “will know what you mean”

Include well-designed tables and figures
– Link measures to theory and literature

Hook-up
With successful NIH mentor with funding
With skeptics and peers to review before submission
Enhancing Peer Review at NIH
http://enhancing-peer-review.nih.gov
Do your homework before write and before you submit

Everything You Wanted to Know About the NCI Grants Process

Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

Electronic Submission of Grant Applications and FAQs

Funding Opportunities and Notices
  - http://grants.nih.gov/grants
Understanding the Review
First Level of Review: Scientific Review Group
- Evaluates scientific merit
- Scores applications
- Recommends level and duration of support

Second Level of Review: Advisory Council
- Assesses quality of scientific review
- Recommends funding to Institute Director
- Evaluates program priorities and relevance
- Advises Institute policy and strategy
Peer review – process from submission through summary

Application Receipt and Assignment of Study Section

Study Section Meeting
  – Final approval

Summary Statements
Application: submission, receipt, assignment

Submission
- About 80,000 grant applications are submitted to NIH each year, of which less than 25% are funded
- Competing grant applications are received for three review cycles per year

Receipt
- Applications go through a triage:
  - Referring officer
    • Study section
  - Program Director

Assignment
- Based on a match between the research proposed and the overall mission of the Institute or Center
- Multiple assignments are made for applications that are appropriate for more than one Institute or Center
  • You will also get a Program Director in that Institute
  • That would be us….we can help

Your title, abstract and cover letter can influence assignment

Applications are referred to an Institute or Center as the potential funding component
Study section: key distinction

Standing study section
   - Review Investigator initiated grants

Special emphasis panel
   - For Program Announcements with Review (PAR) and Research Funding Announcements (RFAs)
Review participants

Scientific Review Officer
- Designated federal official
- Recruits and selects reviewers
- Ensures proper review criteria used to evaluate applications

Reviewers
- 5-50 reviewers on each panel
- Associate Professor or higher with scientific expertise (1 renewed or 2 R01 grants)
- Representation: Gender, minority, geography, institution

Institute Program Staff
- As observers
- Advise panel on program priorities and goals
Fact
As many as 60-100 applications are reviewed by each study section
Peer review meeting

Prior to Study Section Meeting
- Each application assigned three or more reviewers
- Reviewers read applications and write critiques
- Most reviewers assigned 3- applications
- Post preliminary scores are reviews on the Internet Assisted Website

At Study Section Meeting
- All assigned reviewers offer initial score (1-9)
- Primary reviewers presents application and offers comments/critiques
- Other assigned reviewers offer additional comments/critiques
- Discussion among entire group
- All assigned reviewers provide final score (1-9)
- Each reviewer on the panel scores the application
Review criteria

Significance
Innovation
Approach
Investigator(s)
Environment

Scoring 1-9: whole numbers

Overall Evaluation & Impact/Priority Score
Intended to Reflect Impact on Field
# Scoring criteria

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
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</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Very strong with only numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>A few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact  
**Moderate Weakness:** A weakness that lessens impact  
**Major Weakness:** A weakness that severely limits impact
Post scientific review actions

Calculations
- Of priority scores and percentile rankings

Preparation
- Of summary statements

Removal
- Of applications from National Advisory Council / Board consideration
Meeting results are documented by SRO in a summary statement and forwarded to the PI and the assigned NIH Institute or Center, where a funding decision is made.

Summary Statement Contains

- Priority score and percentile ranking
- Overall resume and summary of review discussion
- Essentially unedited critiques
- Human subject concerns – Inclusion of women, minorities, children
- Budget recommendations
- Administrative notes

FACT: A fundable score does not mean you will be funded
National Advisory Council or Board Review
How are awards are made?

Scientific merit
(Review Committee)

Program or public health priorities
(Senior Leadership)

Availability of funds
Where to go for help-1

Electronic Submission and the SF424 (R&R)

Grants.gov registration, submission
- [http://www.grants.gov/contactus/contactus.jsp](http://www.grants.gov/contactus/contactus.jsp)
- Grants.gov Customer Service
  - E-mail: support@grants.gov
  - Phone: 1-800-518-4726

eRA Commons support, post submission questions
- [http://era.nih.gov/commons/index.cfm](http://era.nih.gov/commons/index.cfm)
- eRA Commons Help Desk
  - E-mail: commons@od.nih.gov
  - Phone: 1-866-504-9552 or 301-402-7469

Forms transition and grant questions
- E-mail: grantsinfo@nih.gov
- Phone: 301-435-0714
Where to go for help

Overview of Electronic Submission
http://era.nih.gov/ElectronicReceipt/

Frequently Asked Questions
http://era.nih.gov/ElectronicReceipt/faq.htm

Avoiding Common Errors
http://era.nih.gov/ElectronicReceipt/avoiding_errors.htm

Training Resources, Videos, Quick Reference Materials
http://era.nih.gov/ElectronicReceipt/training.htm
Inside the NIH grant review process video

Fact
Center for Scientific Review developed a video of a “mock” study section meeting to show how NIH grant applications are reviewed.

Acknowledgements

Erica S. Breslau, Ph.D., M.P.H.
Veronica Y. Chollette, R.N., M.S.
Sarah Kobrin, Ph.D., M.P.H.
Heather Edwards, Ph.D.
Electronic Submission www.grants.gov
Grant Registration

Can take up to 8 weeks!

http://www.grants.gov/applicants/get_registered.jsp
Grant submission: guide your application

Applications assignment to NIH Institutes are based on

- Overall mission and interests of the Institute/Center
- Funding Opportunity Announcements (FOA)s

Write a cover letter

- Request an institute assignment
  • Consider requesting a dual assignment
- Request the right study section
  • Review the sections’ missions and rosters