Grants 101

July 25, 2016

I. Training & Career Development Awards
   Sheila Lukehart

II. Introduction to Research Administration at the UW
    Monica Fawthrop

III. NIH Structure & Behind the Scenes at Study Section
     Tom Hawn
Grants: A View From the Other Side

Outline

1. NIH Structure & Facts

2. Behind the Scenes at a Study Section
NIH Structure & Funding

Getting the Facts
1879

- Yellow fever destroyed the Mississippi Valley
- A $30,000 bid (RFA) from the US Army for Universities
- 1st peer-reviewed applications for research.

1887

- Marine Hospital Service established, NIH roots started
- Director Joseph Kinyoun

1930

- NIH officially named

Adapted from slide From Toni Scarpa, head NIH CSR
Department of Health and Human Services

Total Budget = $1092 Billion in 2016
FY 2016 NIH Budget -- $32.3 Billion

2003: $27.1 billion
2004: $28.0 (+3.1%)
2005: $28.6 (+2.2%)
2006: $28.6 (-0.2%)
2007: $29.2 (+2.1%)
2008: $29.2 (0%)
2009: $30.4 (+4.1%)
2010: $30.8 (+1.4%)
2011: $30.7 (-0.3%)
2012: $30.6 (-0.3%)
2013: $29.2 (-4.5%, sequestration)
2014: $30.1 (+3.0%)
2015: $30.3 (+0.01%)
2016: $32.3 (+6.2%)
2017: $33.1 requested
## Top NIH Funded Institutions 2013

The Good News: UW Has Flourished

<table>
<thead>
<tr>
<th>ORGANIZATION</th>
<th>CITY</th>
<th>STATE</th>
<th>AWARDS</th>
<th>FUNDING</th>
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<tbody>
<tr>
<td>JOHNS HOPKINS UNIVERSITY</td>
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<td>MD</td>
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Good News: High Success Rates for Career Awards

<table>
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<th>Success Rate (%)</th>
<th>2004</th>
<th>05</th>
<th>06</th>
<th>07</th>
<th>08</th>
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<tr>
<td>K02</td>
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<td>38</td>
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<td>42</td>
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<td>K08</td>
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<td>K22</td>
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<td>29</td>
<td>29</td>
<td>27</td>
<td>23</td>
<td>26</td>
<td>25</td>
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<td>K23</td>
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<td>22</td>
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</table>
Funding Rate: applicants, any award in the year
Success Rate: A0+A1 applications combined
Award Rates: A0+A1 applications separated

*Excludes awards made with American Recovery and Reinvestment Act (ARRA) funds, and ARRA-solicited applications.
“...runs in our family. My father and grandfather are also working as postdocs.”

Reasons for Optimism
Science is satisfying
Science is important
UW does better than average
Career awards higher success
The Fundamental Tenets for NIH (1946)

1. The only possible source for adequate support of our medical research is the taxing power of the federal government.

2. The federal government and politicians must assure complete freedom for individual scientists in developing and conducting their research work.

3. Reviews should be conducted by outside experts essentially without compensation.

4. Program management and review functions should be separated.

Surgeon General Thomas Parran, Jr.
NIH Structure

Office of the Director

National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Cancer Institute
National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders
National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Drug Abuse
National Institute of Environmental Health Sciences
National Eye Institute
National Institute of General Medical Sciences
National Heart, Lung, and Blood Institute
National Human Genome Research Institute
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Center for Complementary and Alternative Medicine
Fogarty International Center
National Center for Research Resources
National Library of Medicine
National Institute of Biomedical Imaging and Bioengineering
National Center on Minority Health and Health Disparities

NIH Institutes
http://www.nih.gov/icd/

Center for Information Technology
Clinical Center
Center for Scientific Review
No funding authority
Scenario—Who to Ask at NIH

You are ready to apply for a grant and have many questions. Where do you get information? What do you apply for?

1. Study Section Chairperson
2. Grants Management Specialist
3. NIH Scientific Review Officer (SRO)
4. NIH Program Officer (PO)
Dual Review System for Grant Applications

**First Level of Review = CSR Scientific Review Group (SRG)**

**NIH owns review process**
- The Scientific Review Officer, a federal employee, nominates the review panel, assigns applications and is responsible for the meeting

**Study section owns the science review**

**Ownership of application:**
- CSR from receipt to posting of Critiques
- Institute/Center after Critique posting
The SRO and the Program Officer

- **Scientific Review Officer (SRO)**
  - 240 SROs in CSR
  - Legal Responsibility for Study Section Mtg
  - Selection of Study Section Members
  - Assignment of Applications
  - Follow the law, the rules and the regulations
  - Assisted by Grants Management Specialist

- **Program Officer**
  - Role before and after review
  - Key “translator” of summary statements for investigator
  - Responsible for programmatic, scientific, and/or technical aspects of a grant.
Solicit Advice Broadly …

Mentor
Fellows
Post-docs
Colleagues
NIH

“Perhaps I’ll enjoy sharing what’s on your iPod, honey, when Hell freezes over.”
Part II:
Behind the Scenes at an NIH Study Section
Evolution of Study Sections

1946
The First NIH Study Section

An NIH Study Section Today
Study Sections

- Organized into IRGs (Integrative Review Groups)

- Headed by an SRO (Scientific Review Officer)

- 12-25 members, essentially all from academia
  - About ½ are ad hoc reviewers

- 60-100+ applications per meeting
  - ~10 per member
  - 3 reviewers per applications

- Information from CSR web site:
  http://cms.csr.nih.gov/
  - Study section scope
  - Roster of reviewers
  - Policies
  - Schedules

- Study sections are advisory - they do not fund applications.
Review Process - Before the Meeting

- 4 months prior: Applications submitted
- 2 months prior: Applications assigned for review (~10 per person)
- 1 month prior: 3 reviewers for each application (R1, R2, R3)
- 1 week prior: Scores and critiques are uploaded
- Each criterion is given a score: 1, 2, 3…9 (best to really bad)
  - Not discussed at the Study Section
  - included in the Summary Statement
- Each reviewer gives an overall Impact Score
  - Impact Score is not the mean of the criteria scores
  - Impact score is key and the only score discussed
- Initial scores and critiques become available to all committee members
- Applications are ranked in order of initial mean Impact Scores
- Lower 40-60% are not discussed (Impact Score of 4.5 – 5.0 and above)
  - Any “triaged” application can be resurrected at the meeting for discussion for any reason
  - Applicants receive the critiques and individual criteria scores
  - Impact Score is not given
Overall Impact: Provide an overall impact score to reflect your assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable).

Scored Review Criteria: Determination of scientific merit: Impact scores
1. Significance
2. Investigator(s)
3. Innovation
4. Approach
5. Environment

Additional Review Criteria: can impact scores
1. Protection for human subjects (and inclusions)
2. Vertebrate animals
3. Biohazards
4. Resubmission, Renewal, Revision

Additional Review Considerations: do not impact scores
- Select Agents
- Resource sharing plan: Data sharing, model organisms, & GWAS
- Budget
- Authentication of Key Resources

Scoring scale of 1 – 9 (Best to worst)

Budget: does not impact scores. Discussed after the final vote.
<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td><strong>Review Criteria</strong></td>
<td><strong>Review Criteria</strong></td>
<td><strong>Review Criteria</strong></td>
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<tr>
<td></td>
<td>• Overall Impact</td>
<td>• Overall Impact</td>
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<td></td>
<td>• Candidate</td>
<td>• Candidate</td>
<td>• Significance</td>
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<tr>
<td></td>
<td>• Sponsor, Collaborators, Consultants</td>
<td>• Career development plan</td>
<td>• Approach</td>
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<tr>
<td></td>
<td>• Research Training Plan</td>
<td>• Career goals and objectives Plan to provide mentoring</td>
<td>• Innovation</td>
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<tr>
<td></td>
<td>• Training Potential</td>
<td>• Research Plan</td>
<td>• Investigator</td>
</tr>
<tr>
<td></td>
<td>• Institutional Environment &amp; Commitment to Training</td>
<td>• Mentor(s), consultants, collaborators</td>
<td>• Environment</td>
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<tr>
<td></td>
<td></td>
<td>• Environment &amp; Institutional commitment</td>
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## Pre-Meeting Rank Order

### ~1 Week Prior

<table>
<thead>
<tr>
<th>App</th>
<th>R1</th>
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<th>R3</th>
<th>Ave</th>
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### ~3 days prior

<table>
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<th>Read Other Reviews &amp; Adjust Score</th>
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</table>

<table>
<thead>
<tr>
<th>App</th>
<th>R1</th>
<th>R2</th>
<th>R3</th>
<th>Ave</th>
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<tr>
<td>A</td>
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<td>1</td>
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<td>1.67</td>
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<tr>
<td>B</td>
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<tr>
<td>C</td>
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<td>2</td>
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<td>2.67</td>
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<td>D</td>
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<tr>
<td>E</td>
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<tr>
<td>F</td>
<td>2</td>
<td>2</td>
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<td>2.67</td>
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<td>7</td>
<td>7</td>
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</tbody>
</table>

### Badness #1

D

### Badness #2

F
Scoring System

• Criterion Score
  • Whole numbers: 1-9
  • 1 (exceptional); 9 (um, well let’s just hope you never get a 9)
  • Given by reviewers but not discussed at study section
  • Provided in Summary Statement of all applications (discussed and not discussed)

• Overall Impact Score
  • Whole numbers (at first): 1-9
  • Not the mean of the criteria scores
  • Different criteria are weighted by each reviewer
  • Each review recommends a score
  • All committee members score within the range
  • Can vote outside the range, but must state that you are doing so

• Final Impact Score
  • Mean of all scores x 10
  • 10 – 90
  • Percentiled against similar applications across 3 meetings (not so for F’s and K’s)
  • Unknown to the committee (except the chair)

• Payline
  • Varies among institutes
  • http://www.aecom.yu.edu/ogs/NIHInfo/pavlines.htm

Adjectives Used
1 Exceptional
2 Outstanding
3 Excellent
4 Very Good
5 Good
6 Satisfactory
7 Fair
8 Marginal
9 Poor
## Impact Score

<table>
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<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
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<td>Exceptional</td>
<td>Strengths</td>
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<td>2</td>
<td>Outstanding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td></td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td></td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
<td>Weaknesses</td>
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<td>9</td>
<td>Poor</td>
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## Criteria Scores

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<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
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</thead>
<tbody>
<tr>
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<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
<td>Very 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
1. Shows recent scoring pattern of ~15,000 applications
2. Score is well spread over a range of ~10 - 69
3. In a regular study section panel, ~5% of applications get a score of 10-20 and about 2% perform poorly.
Where and When Do Reviewers Review Grant Applications?

- At home
- On a plane (likely no internet)
- At the last minute - and thus a bunch in one sitting
- Hence, reviewers can be stressed, anxious, & not terribly sympathetic
- They may lose interest

- *Do not make the reviewer think!*
- *Do not make the reviewer read papers or go to the internet*
- *Do not tick off the reviewers!*

Don’t let the reviewer become…

- Baffled,
- Bitter,
- or Bored

Slide from Bill Parks
The Review Process - at the Meeting

- Begin at 8 am EST (i.e., 5 am PST)
- Cramped room full of lap tops and several jet-lagged reviewers
- Review Grants in order - best to less best
- 15-20 min per application (shorter is best)
- Go to 6-7 pm
- Eat, sleep
- Repeat next day
The Review Process - at the Meeting

What happens?

• Application is announced and conflicts identified
• Chair asks the 3 reviewers to state their scores
• Primary reviewer discusses strengths and weaknesses using the scored criteria as a guide (but without stating criterion scores)
• Other reviewers concur or discuss differences
• Additional Review Criteria: Animals, Human Subjects, Resubmission
• Discussion opens to the committee
• Reviewers restate their scores (e.g., 2-4-5, 3-3-3)
• A range is established (e.g., 2-5, 3-3)
• Chair asks if anyone plans to vote outside of the range
• Committee posts scores online
• Additional Review Considerations: Budget, Resource Sharing, Bioethics training
• Repeat with the next application in order
Summary Statement

- Face Page
- Summary of Discussion
- Description (abstract you wrote)
- Overall Impact and Scored Criteria
- Addition Review Criteria
  - Protection of Human Subjects
  - Inclusion of Women, Minorities, and Children
  - Vertebrate Animals
  - Biohazards
  - Resubmission
- Additional Review Considerations
  - Responsible Conduct of Research
  - Budget
  - Foreign Training
  - Resource Sharing Plan
- Additional Comments to the Applicant
  - Excess text in the wrong place
  - Advice for resubmission
Vagaries of Peer Review

• Reviewers are humans; humans err
• Assigned reviewers have the most influence on scoring
• A passionate reviewer (pro or con) can influence the group
• Any committee member can vote outside of the “range”
• Final Impact Score is usually (~85% of the time) close to the initial impact score
  • Scores change >1 point on only 15% of grants
  • Rarely for ESI applications (less than 1%)

Good video of a mock Study Section
http://www.youtube.com/watch?v=fBDxI6l4dOA
Some Top Reasons Why Grants Don’t Get Funded

**IMPACT PROBLEM**
- Lack of new or original ideas.
- Uncertainty concerning future directions (where will it lead?).
- Lack of knowledge of published, relevant work.
- Absence of a sound hypothesis and clear scientific rationale.

**STRATEGY or FORMAT PROBLEM**
- Diffuse, superficial, or unfocused research plan.
- Unrealistically large amount of work.
- Lack of *preliminary data* and/or experience with essential methodologies.
- Questionable reasoning in experimental approach.

**INVESTIGATOR PROBLEM**
- Poor training potential.
- Poor productivity.
- Mentor is not qualified, poorly funded, and/or not productive.
If All Else Fails ....

[Image: Cartoon of man holding sign saying "WILL CURL LIP FOR FOOD."]
Additional Information

The NIH has put together a series of podcasts in their “All About Grants” webpage (see link below). It looks like a fantastic resource, especially for early stage investigators.

General topics include:
Getting to know NIH and the Grants Process
Preparing a Successful Grant Application
Advice for New and Early Career Scientists
Submitting your Application
How NIH Grants are Reviewed
Life as an NIH Grantee (Post-Award Activities and Requirements)

http://grants.nih.gov/podcasts/All_About_Grants/index.htm
Website References

NIH

NRSA (T+F Grants):  http://grants.nih.gov/training/nrsa.htm

K Career Development Awards:
http://grants.nih.gov/training/careerdevelopmentawards.htm
NIH Award Mechanisms
Training and Career Timetable

Stage of Research Training / Career

Pre-Bac
GRADUATE/ MEDICAL STUDENT
POST DOCTORAL
EARLY
MIDDLE
SENIOR

Awards
- Pre-Bac Institutional Training Grant (T34)
- Predoctoral Institutional Training Grant (T32)
- Predoctoral Individual NRSA (F31)
- Predoctoral Individual MD/PhD NRSA (F30)
- Postdoctoral Institutional Training Grant (T32)
- Postdoctoral Individual NRSA (F32)
- NIH Pathway to Independence (PI) Award (K99/R00)
- Mentored Research Scientist Development Award (K01)
- Mentored Clinical Scientist Development Award (K08)
- Mentored Patient-Oriented RCDA (K23)
- Mentored Quantitative RCDA (K25)
- Independent Scientist Award (K02)
- Midcareer Investigator Award in Patient-Oriented Research (K24)
- Senior Scientist Award (K05)

Small Grant (R03)
Research Project Grant (R01)
Exploratory/Development Grant (R21)
T & F Grants

• Institutional Awards: T32
  – Institution, not the individual, applies for the award
  – Not available at all schools, departments, divisions

• Individual Awards: F32
  – Mentored
  – Independent—can interact with other NIH Awards
  – Depending on the award, all doctorates or restricted to clinical doctorates
  – NIH support varies by Institute

TOTAL YEARS of F and T NIH Grant Support=3 YEARS
NRSA Fellowships and Training Grants (F & T Awards) for Individuals With or Earning a Health-Professional Doctorate

- Short-Term Training Grant (T35)
- Institutional Training Grants (T32)
- Postdoctoral Fellowships (F32)
- Senior Fellowships (F33)

Medical School  Residency  Specialty/Sub-Specialty  Independent Investigator
NRSA Fellowships and Training Grants (F & T Awards) for Individuals With or Earning a Research Doctorate

- Predoctoral Fellowships (F31)
- Institutional Training Grants (T32)
- Postdoctoral Fellowships (F32)
- Senior Fellowships (F33)

- MARC COR (T34)
- College
- Graduate School
- Postdoctoral
- Independent Investigator
F32 NRSA Success Rates

Kirschstein-NRSA post-doctoral fellowships (F32s)
Competing applications, awards, and success rates
NRSA Support Varies by Institute

NRSAs by Institutes - 2007
• A Principal Investigator (PI) who has not yet competed successfully for a substantial, competing NIH research grant (R01 or ‘higher’) is considered a New Investigator

• [http://grants1.nih.gov/grants/new_investigators/resources.htm](http://grants1.nih.gov/grants/new_investigators/resources.htm)
Early Stage Investigator (ESI)

- An individual who is classified as a New Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent)

Extension of ESI Eligibility

- The 10-year period may be extended to accommodate special circumstances (e.g. medical concerns, disability, pressing family care responsibilities, or active military duty service)
What Affects New Investigator Status?

• PI of an R03 or R21? No
• PI of an NIH contract? No
• PI of a grant with another Federal agency? No
• PI of an SBIR/STTR? No
• PI of a U01, specifically for a foreign investigator? Receipt of U01 removes NI status.
• Inheriting an R01 from a PI who moved away or died? No
Other Grant Sources To Consider

NIH Loan Repayment Program

For individuals with clinical doctorate degrees working in specified areas of biomedical science, predominantly patient-oriented research

Examples of Sources of Non-Federal Grants

American Heart Association
Infectious Diseases Society of America
Cystic Fibrosis Foundation
Parker B Francis Foundation