Grants 101
July 28, 2017

I. NIH Structure & Behind the Scenes at Study Section
   Tom Hawn

II. Introduction to Research Administration at the UW
    Monica Fawthrop

III. Training & Career Development Awards
     Sheila Lukehart
Outline

1. NIH Structure & Facts

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

Getting the Facts
Responses to Yellow Fever

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
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.
Department of Health and Human Services

Total Budget = $1092 Billion in 2016

- NIH 54%
- Other 24%
- CDC 8%
- FDA 3%
- HRSA 11%
FY 2017 NIH Budget -- $34.1 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
2015: $30.3
2016: $32.3
2017: $34.1
2018: $35.2 billion requested
Funding Rate: applicants, any award in the year
Success Rate: A0+A1 applications combined
Award Rates: A0+A1 applications separated
## 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>
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<td>JOHNS HOPKINS UNIVERSITY</td>
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<td>MD</td>
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<td>STANFORD UNIVERSITY</td>
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Training and Career Timetable

Stage of Research Training / Career

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)
- Mentored Research Scientist Development Award (K01)
- Mentored Clinical Scientist Development Award (K08)
- Mentored Patient-Oriented RCDA (K23)
- Mentored Quantitative RCDA (K25)
- Mentored Career Transition (K22, PhD Eligible)
- NIH Pathway to Independence (PI) Award (K99/R00)
- Midcareer Investigator Award in Patient-Oriented Research (K24)

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
F32 NRSA Success Rates

UW Experience:
Division of Pulm Crit Care
2006-16
21/38 funded (55%)

Kirschstein-NRSA post-doctoral fellowships (F32s)
Competing applications, awards, and success rates
# Good News: High Success Rates for Career Awards

<table>
<thead>
<tr>
<th>Success Rates</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
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<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2014</th>
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<tr>
<td><strong>K08</strong></td>
<td>36%</td>
<td>35%</td>
<td>31%</td>
<td>31%</td>
<td>35%</td>
<td>38%</td>
<td>36%</td>
<td>30%</td>
</tr>
<tr>
<td><strong>K23</strong></td>
<td>40%</td>
<td>39%</td>
<td>34%</td>
<td>36%</td>
<td>44%</td>
<td>47%</td>
<td>44%</td>
<td>40%</td>
</tr>
<tr>
<td><strong>K99</strong></td>
<td>36%</td>
<td>34%</td>
<td>27%</td>
<td>33%</td>
<td>38%</td>
<td>44%</td>
<td>38%</td>
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<table>
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<th>2016</th>
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<td><strong>K08</strong></td>
<td>46</td>
<td>50.6</td>
<td>44.3%</td>
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<tr>
<td><strong>K23</strong></td>
<td>42.0</td>
<td>38.3</td>
<td>44.6%</td>
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<table>
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<tr>
<th>NIAID</th>
<th>2010</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>K08</strong></td>
<td>38</td>
<td>44.9</td>
<td>29.1%</td>
</tr>
<tr>
<td><strong>K23</strong></td>
<td>56.0</td>
<td>34.4</td>
<td>40.5%</td>
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</table>
Part II: NIH Study Sections

Outline

1. Pre
2. During
3. Post

1946
The First NIH Study Section

An NIH Study Section Today
1. Study Section Characteristics: NIH Structure

Office of the Director

- National Institute on Aging
- National Institute of 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/

No funding authority
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
  - Study section scope
  - Roster of reviewers
  - Policies
  - Schedules
- Study sections are advisory - they do not fund applications.
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)

Except Ks Reviewed within Institute rather than CSR

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

Second Level of Review
NIH Institute/Center Council
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.”
Review Process - Before the Meeting

- 4 months prior: Applications submitted
- 2 months prior: Applications assigned for review (~10 per person)
  - 3 reviewers for each application (R1, R2, R3)
- 1 week prior: Scores and critiques are uploaded
  - Initial scores and critiques become available to all committee members
- Score revision phase
- 2-3 days prior: 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

90% of Grant Fates are Sealed Before the Meeting Begins
R Level Review Criteria

- Overall Impact: likelihood for the project to exert a sustained, powerful influence on the research field(s)

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

- Premise—Use this Word in Grant!

- **Rigor & Transparency**

- **Additional Review Criteria:** can impact scores
  1. Protection for human subjects (and inclusions)
  2. Sex as a Biological Variable
  3. Vertebrate animals
  4. Biohazards
  5. 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>
<th>Scored Review Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individual Training</strong></td>
</tr>
<tr>
<td><strong>F-series Grants</strong></td>
</tr>
<tr>
<td>- Overall Impact</td>
</tr>
<tr>
<td><strong>Review Criteria</strong></td>
</tr>
<tr>
<td>- Candidate</td>
</tr>
<tr>
<td>- Sponsor, Collaborators, Consultants</td>
</tr>
<tr>
<td>- Research Training Plan</td>
</tr>
<tr>
<td>- Training Potential</td>
</tr>
<tr>
<td>- Institutional Environment &amp; Commitment to Training</td>
</tr>
<tr>
<td><strong>Career Development</strong></td>
</tr>
<tr>
<td><strong>K-series Grants</strong></td>
</tr>
<tr>
<td>- Overall Impact</td>
</tr>
<tr>
<td><strong>Review Criteria</strong></td>
</tr>
<tr>
<td>- Candidate</td>
</tr>
<tr>
<td>- Career development plan</td>
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<tr>
<td>- Career goals and objectives</td>
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<tr>
<td>- Plan to provide mentoring</td>
</tr>
<tr>
<td>- Research Plan</td>
</tr>
<tr>
<td>- Mentor(s), consultants, collaborators</td>
</tr>
<tr>
<td>- Environment &amp; Institutional commitment</td>
</tr>
<tr>
<td><strong>Investigator Initiated</strong></td>
</tr>
<tr>
<td><strong>R-series Grants</strong></td>
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<tr>
<td>- Overall Impact</td>
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<tr>
<td><strong>Review Criteria</strong></td>
</tr>
<tr>
<td>- Significance</td>
</tr>
<tr>
<td>- Approach</td>
</tr>
<tr>
<td>- Innovation</td>
</tr>
<tr>
<td>- Investigator</td>
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<tr>
<td>- Environment</td>
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</table>
## Pre-Meeting Rank Order

### ~1 Week Prior

<table>
<thead>
<tr>
<th>App</th>
<th>R1</th>
<th>R2</th>
<th>R3</th>
<th>Ave</th>
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<td>1</td>
<td>2</td>
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<tr>
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<td>E</td>
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<td>F</td>
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<td>4</td>
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<td>7</td>
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</table>

### ~3 days prior

Read Other Reviews & Adjust Score

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<tr>
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<th>R2</th>
<th>R3</th>
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<tbody>
<tr>
<td>A</td>
<td>2</td>
<td>1</td>
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<tr>
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</table>
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](http://www.aecom.yu.edu/ogs/NIHInfo/pavlines.htm)

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**Adjectives Used**

1. Exceptional
2. Outstanding
3. Excellent
4. Very Good
5. Good
6. Satisfactory
7. Fair
8. Marginal
9. Poor
## Criteria Scores

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<tr>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<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

**Don’t let the reviewer become…**

- Baffled,
- Bitter,
- or Bored

- *Do not make the reviewer think!*
- *Do not make the reviewer read papers or go to the internet*
- *Do not tick off the reviewers!*
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:
  
  Short description of proposal
  
  Discuss Overall Impact
  
  Discusses strengths and weaknesses using the scored criteria as a guide (but without stating criterion scores)
- Reviewers 2 & 3: concur or discuss differences
- Discussion opens to the committee
- Additional Review Criteria: Animals, Human Subjects, Resubmission, Authentication of Resources
  - 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=fBDxl6l4dOA
Some Top Reasons Why Grants Don’t Get Funded

The Candidate
Poor training potential.
Poor productivity
Uncertainty concerning future directions (where will it lead?).

The Mentor
not qualified, poorly funded, and/or not productive

The Science
Lack of new or original ideas.
Diffuse, superficial, or unfocused research plan.
Lack of knowledge of published, relevant work.
Lack of preliminary data and/or experience with essential methodologies.
Questionable reasoning in experimental approach.
Absence of a sound hypothesis and clear scientific rationale.
Unrealistically large amount of work.
“...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 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
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
NIH Award Mechanisms