Grants 101

August 30, 2021

I. Introduction to Research Administration at the UW Monica Fawthrop

II. Training & Career Development Awards Ellen Schur

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

Outline

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

1. NIH Structure & Funding



Getting the Facts

National Institutes of Health

US Department of Health and Human Services









Director of NIH Francis Collins, MD PhD

NIH History



Responses to Yellow Fever

- Yellow fever destroyed the Mississippi Valley
 - A \$30,000 bid (RFA) from the US Army for Universities
 - 1st peer-reviewed applications for research.
- Marine Hospital Service established, NIH roots started
 - Director Joseph Kinyoun
- 1930 NIH officially named

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**
- 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.

Slide From Toni Scarpa, head NIH CSR

Study Section Characteristics: NIH Structure



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 X
- 2. Grants Management Specialist
- 3. NIH Scientific Review Officer (SRO)
- 4. NIH Program Officer (PO)

Solicit Advice Broadly ...



Mentor Fellows Post-docs Colleagues NIH

"Perhaps I'll enjoy sharing what's on your iPod, honey, when Hell freezes over."

The SRO and the Program Officer

Scientific Review Officer (SRO)

240 SROs in CSR Legal Responsibility for Study Section Mtg Select Study Section Members Assign Applications Assisted by Grants Management Specialist

Program Officer (PO)

Role before and after review

Key "translator" of summary statements for investigator

Responsible for programmatic, scientific, and/or technical aspects of a grant.

Dual Review System for Grant Applications

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

> Except Ks Reviewed within Institute rather than CSR

Second Level of Review NIH Institute/Center Council

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

How do you perceive the world?



Department of Health and Human Services

Total Budget = \$1300 Billion in 2021



FY 2021 NIH Budget -- \$42.9 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: \$37.0 2019: \$39.1 2020: \$41.7 (↑6.6%) (President proposed $34.4 (\downarrow 12\%)$) 2021: \$42.9 (↑3%) 2022 proposed: \$52.0 (†17.5%)

Not as Rosy with Inflation Adjustment



Award Rates are low ... (NIAID example 2021)

Grant Type	Payline	Status	Description
R01 (non-new Pls)	14 percentile	Fiscal Year	Research Projects for established investigators
R01 (new PIs)	18 percentile	Fiscal Year	Research Projects for new and early- stage investigators

Funding, Award and Success Rates* for Research Project Grants Fiscal Years 1990-2013



Success, Funding, & Investigator Success Rate Graph



Success Rate: A0+A1 applications combined **Funding Rate:** applicants, any award in the year

Cumulative Investigator Rate: the number of Funded Investigators in a single fiscal year divided by the Cumulative Applicant Investigators for a five fiscal year range.

R01-Equivalent Investigators: Number of Competing Investigators and Funding Rates





Top NIH Funded Institutions 2019

The Good News: UW Has Flourished

ORGANIZATION	CITY	STATE	AWARDS	FUNDING
JOHNS HOPKINS UNIVERSITY	BALTIMORE	MD	1401	\$763,565,791
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	SAN FRANCISCO	СА	1295	\$684,912,356
UNIVERSITY OF MICHIGAN AT ANN ARBOR	ANN ARBOR	мі	1282	\$591,487,816
UNIVERSITY OF PENNSYLVANIA	PHILADELPHIA	РА	1200	\$582,337,151
DUKE UNIVERSITY	DURHAM	NC	905	\$571,409,121
UNIVERSITY OF PITTSBURGH AT PITTSBURGH	PITTSBURGH	PA	1116	\$546,388,511
UNIVERSITY OF WASHINGTON	SEATTLE	WA	1017	\$526,962,825
STANFORD UNIVERSITY	STANFORD	СА	1073	\$526,216,444
WASHINGTON UNIVERSITY	SAINT LOUIS	мо	996	\$523,835,750
UNIV OF NORTH CAROLINA CHAPEL HILL	CHAPEL HILL	NC	939	\$509,869,004
MASSACHUSETTS GENERAL HOSPITAL	BOSTON	МА	959	\$499,645,254
YALE UNIVERSITY	NEW HAVEN	СТ	1003	\$489,089,050
UNIVERSITY OF CALIFORNIA, SAN DIEGO	LA JOLLA	СА	990	\$488,194,359
COLUMBIA UNIVERSITY HEALTH SCIENCES	NEW YORK	NY	929	\$478,662,311
UNIVERSITY OF CALIFORNIA LOS ANGELES	LOS ANGELES	СА	882	\$451,516,818
LEIDOS BIOMEDICAL RESEARCH, INC.	FREDERICK	MD	61	\$419,208,017
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI	NEW YORK	NY	640	\$393,791,422
EMORY UNIVERSITY	ATLANTA	GA	749	\$382,045,521
BRIGHAM AND WOMEN'S HOSPITAL	BOSTON	МА	567	\$338,400,990
NORTHWESTERN UNIVERSITY AT CHICAGO	CHICAGO	IL	633	\$333,396,842
UNIVERSITY OF ALABAMA AT BIRMINGHAM	BIRMINGHAM	AL	622	\$328,106,722
NEW YORK UNIVERSITY SCHOOL OF MEDICINE	NEW YORK	NY	523	\$314,302,627
UNIVERSITY OF WISCONSIN-MADISON	MADISON	wi	624	\$314,183,951
FRED HUTCHINSON CANCER RESEARCH CENTER	SEATTLE	WA	270	\$305,091,811
UNIVERSITY OF MINNESOTA	MINNEAPOLIS	MN	701	\$303,239,238

Good news: F32 NRSA Success Rates Higher than R01



2017 28.0% 2018 27.4% 2019 28.8% 2020 29.4%

UW Experience: Division of Pulm Crit Care 2006-19 24/46 funded (52%)

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

Good News: High Success Rates for K Career Awards

	2004	2005	2006	2007	2008	2009	2010	2014	2017	2018	2019	2020
Success Rates	36%	35%	31%	31%	35%	38%	36%	30%	31	32.5	31.9	33.1
K08	40%	39%	34%	36%	44%	47%	44%	40%	43.6	39.7	44.2	41.2
K23	36%	34%	27%	33%	38%	44%	38%	38%	34.0	37.7	37.1	37.7
К99			100%	20%	23%	29%	25%	22%	23.4	26.2	24.0	25.1



UW Experience: Division of Pulm Crit Care

2006-19

K awards (individual & institutional) **30/34 funded (88%)** Other fellowship awards (e.g. VA CDA, Foundations) **30/36 funded (83%)**

Scenario—Does it matter where I get reviewed?

You worked on viruses that cause lung cancer are ready to apply for a K08 or K23 grant. Which K grant and institute do you apply to?

 NCI
 NIAID
 NHLBI
 NIDA
 Depends on their priorities, funding rates, & where your mentor is known
 Depends on their priorities, funding rates, & where your mentor is known

Be Careful News: Heterogeneity in Success Rates



<u>Remember:</u>

K grants: Choose your institute (reviewed within Institute)

R grants: Choose Study Section (reviewed at CSR)

https://report.nih.gov/success_rates/

How do you perceive the world?



Funding is difficult, but ..

Success rates are higher than individual application rates Cumulatgive investigator rates are even higher F/T awards have higher success rates than Rs K awards have higher success rates than Rs UW does much better than average

Part II: NIH Study Sections

Outline

- 1. Pre
- 2. During
- 3. Post

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
- 60-100+ applications per meeting
- Information from CSR web site: <u>http://cms.csr.nih.gov/</u>
 - Study section scope
 - Roster of reviewers
- Study sections are advisory they do not fund applications.



Academic Rank of All CSR Reviewers

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

Sex as a Biological Variable

- 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

 Premise
 - 2. Investigator(s)
 - 3. Innovation
 - 4. Approach A Rigor & Transparency
 - 5. Environment
- 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

Use these Words in Grant!

> Don't be Sloppy

Scored Review Criteria: F vs K vs R

Individual Training F-series Grants

Overall Impact

Review Criteria

- Candidate
- Sponsor, Collaborators, Consultants
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment to Training

Career Development K-series Grants

Overall Impact

Review Criteria

Candidate

- Career development plan
 Career goals and objectives
 Plan to provide mentoring
- Research Plan

 Mentor(s), consultants, collaborators

 Environment & Institutional commitment

Investigator Initiated R-series Grants

Overall Impact

Review Criteria

- Significance
- Approach
- Innovation
- Investigator
- Environment

Scoring System

- Criterion Score
 - Whole numbers: 1-9
 - 1 (exceptional);
 - 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
 - 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/paylines.htm

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

Study Section Scoring Range

CSR All 2014-01 Histogram



- 1. Shows recent scoring pattern of ~15,000 applications
- 2. Score is well spread over a range of ~10 69

Triaged or Not Discussed

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
- <u>Do not tick off the reviewers!</u>

Don't let the reviewer become...



Pre-Meeting Rank Order

	~1 W	/eek P	rior				~3 c	lays pr	ior	
Арр	R1	R2	R3	Ave	Read	Арр	R1	R2	R3	Ave
А	2	1	2	1.67	Reviews	А	2	1	2	1.67
В	2	2	2	2	Score	В	2	2	2	2
С	3	2	3	2.67		С	3	2	3	2.67
D	4	2	3	3	☐ R1 Badness ➡	D	2	2	3	2.33
Е	3	3	3	3	- ///	E	3	3	3	3
F	2	2	8	4	Badness	F	2	2	4	2.67
G	6	6	6	6		G	6	6	6	6
Н	7	7	7	7		Н	7	7	7	7

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 random order (this is a change—used to be- 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



At the Meeting: Scoring



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

Solution

Poor training potential Poor productivity or applying too early Jncertainty concerning future directions (where will it lead?).	More preliminary data & papers Define Niche
The Mentor Not qualified, poorly funded, and/or not productive	Co-Mentor
The Science Bad fit with primary institute	Strategic Planning
_ack of new or original ideas. _ack of experience with essential methodologies.	Data & Papers
Diffuse, superficial, or unfocused research plan. _ack of knowledge of published, relevant work. Questionable reasoning in experimental approach.	Grantsmanship & Scientific Development

Questionable reasoning in experimental approach. Absence of a sound hypothesis and clear scientific rationale. Unrealistically large amount of work.

The Candidate

Start early: Aims page <u>very</u> early. Also, tend to the "small stuff" early.

Provide mentoring committee & didactic plan

Communicate clearly—summary figures, models, polished text

Provide compelling science (this is what reviewers enjoy!)

Start early: Make time for colleagues to review. Polished draft 1 month before deadline.

Ponder how you perceive



<u>Reasons for Optimism</u> Science is satisfying Science is important UW does better than average Career awards higher success



By Bohsky

Additional Information

NIH General Grant 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

Grants Page: <u>http://grants.nih.gov/grants/oer.htm</u>

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

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 **patientoriented 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



T & F Grants

Institutional Awards: T32

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Awards

Pre-Bac	Pre-Bac Institutional Training Grant (T34)	_	Institution, not the individual, applies for the award Not available at all schools.
GRADUATE/ MEDICAL STUDENT	 Predoctoral Institutional Training Grant (T32) Predoctoral Individual NRSA (F31) Predoctoral Individual MD/PhD NRSA (F30) 		departments, divisions
POST DOCTORAL	 Postdoctoral Institutional Training Grant (T32) Postdoctoral Individual NRSA (F32) 		
EARLY	Mentored Research Scientist Development Award (K01) • Mentored Clinical Scientist Development Award (K08) Mentored Patient-Oriented RCDA (K23) Mentored Quantitative RCDA (K25)		
<u>ک</u>	 Mentored Career Transition (K22, PhD Eligible) NIH Pathway to Independence (PI) Award (K99/R00) 		
AIDDIE CARE	 Midcareer Investigator Award in Patient-Oriented Research (K24) 		
SENIOR			

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

Individual Critiques

Criteria Scores

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

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