

# NIH Scientific Review

Inside the black box of study section

*My perspective*

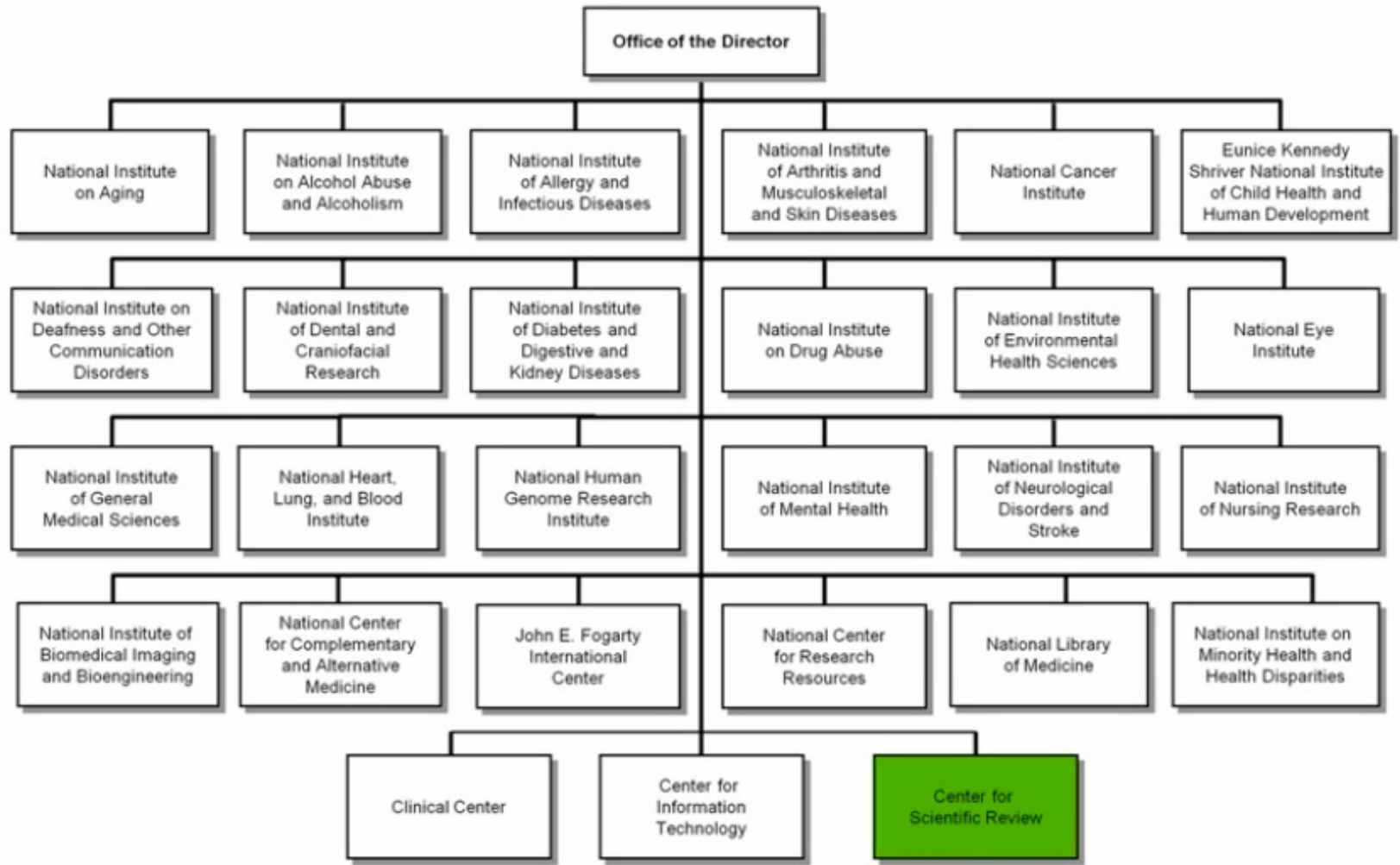
# Disclosures

- The contents of this talk are based on my personal experiences with grant applications and review. Please rely on NIH documentation for precise rules, not this presentation.

# Key NIH Players

- Center for Scientific Review
- Institute Program Officer
- Institute Grants Management staff

# National Institutes of Health



# Center for Scientific Review (CSR)

- Point of intake for all new applications
  - Your primary contact is the Scientific Review Officer (SRO)
- Responsible for reviewing the vast majority of grants = **First Level Review**
  - **Review completed in study section**
- Works independently of Program staff
  - important for independent peer-review

# Institute Program Staff and Advisory Council

- Your primary contact = Program Officer
  - Useful in discussing potential projects, institute priorities
  - Not useful for discussing First Level Review
- Receives summary statement from the Center for Scientific Review
- Grants Management staff
  - No direct role for you until decision to fund
  - Typically will work with UCSF fiscal staff

# NIH Cycles of review

- Three times annually (usually 9-12 months for each cycle, overlapping)
  1. Submission
  2. Assignment for review
  3. Scientific review (First Level Review)
  4. Summary of review and forwarding to program
  5. Program review (Second Level Review)
  6. Recommendations to Council and Council review
  7. Funding

**A closer look at integrated review  
groups  
*"Study Section"***



# Integrated Review Groups (IRG)

- Groups of peers/experts in the field of research aligned by scientific topic
- Under the direction of CSR not Program staff or NIH institutes
  - Allows for independent review
- Nearly 250 such groups, not including Special Emphasis Groups assembled for specific calls for applications (special RFAs)

# The first stop for your application

- Division of Receipt and Referral at CSR
  - Initially reviews the grant to ensure you have been adequately adherent to application rules
  - Assigns your study section
  - Assigns the institute(s) thought to be most interested in your application for sponsorship

**HOW CAN YOU HELP?**

**YOUR COVER LETTER**



# Cover Letter

- Recommend a study section appropriate for your work
  - Review available study sections online to find those that best fit
  - Recommend the section you would like to target
- Suggest institutes or centers who you would like to consider for sponsorship
  - If you have talked to program staff, indicate this

# Cover Letter

- Identify special circumstances for the review
  - AIDS grants: “This should be coded as an AIDS grant”
  - Continuing review for study section members
- Identify expertise needed for review, particularly if absent in existing IRG
- Identify potential conflicts of interest
- DO NOT suggest reviewers

# IRG assignment

- Occurs shortly after grant is received and reviewed by the Division of Receipt and Referral
- Posted on eCommons, and you are sent an email that your application has changed
- Review assignment to ensure there are no gaps in expertise
  - If so, correspond with your SRO

# **STUDY SECTION**

# Members of the Study Section

- 15-30 peers at the doctoral level who have expertise in the broad area of science pertinent to your field
- There may be no-one who understands the details of your work and there are likely to be many members who don't have working knowledge of specifics related to your research focus



# Members of the Study Section

- Many are very busy scientists
- Each will be assigned 7-9 grants to read in detail and critique
- All are expected to read or at least be familiar with the 40-50 grants submitted to the study section

# Members of the Study Section

- Most will be tired from long flights the day before
- Study section members are paid about \$200 for a study section and typically require 30-40 hours to prepare for each study section
- All are peers – study section participation is **service** – there are few benefits
- Extra reviewers may be recruited (ad hoc) to cover expertise for your grant or others

# Review of Your Grant

- Your grant will be assigned to 3-4 reviewers – primary, secondary, and other reviewers
- Reviewers will receive your grant about 6 weeks before study section
- Reviewers are required to submit scores and a preliminary critique 3-4 days before study section via eCommons
  - Reviewers are unable to see other reviewers' scores until they submit their own

# Review Criteria (R-series grants)

- Significance
- Innovation
- Approach
- Environment
- Institution

# Significance

- How will your proposed work advance the field
- What is the importance of your research question

# Innovation

- What are the cutting-edge techniques employed?
- What is particularly unique about your study?
  - Populations studied?
  - Approach?

# Approach

- Precisely how will you carry out the experiments?
- How will you analyze your work?
- What are potential limitations and pitfalls – how can they be mitigated?

# Investigator

- What expertise do you have to carry out the work?
- What is the strength of your research team?
- Do you have the depth within your team to address unexpected problems?



# Environment

- Do you have the setting, equipment, etc. to carry out the work?
  - Be careful with boiler plate resource pages – must address the details of your project (not someone else's, accidentally, and reviewers are not interested in reading the details of how your institution was founded!)

# Overall

- An overall score typically reflects the input from the 5 sub-scores
- However, one sub-score can have substantial impact on the overall score
  - E.g. well-written research with little to no potential impact on the field

# 9-Point Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

# Guidelines for Review

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weaknesses
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	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

# The Day Study Section Meets



# Setting

- Usually a hotel meeting room
  - Standard study sections now meet in different parts of the country to decrease the burden on those from the west coast
  - Some phone-in reviewers may be involved
  - NO food or drink provided
  - Usually from 8 AM until done, typically 8 – 10 hours (in my experience) with 1 hour for lunch

# Will My Grant be Discussed?

- New investigators are always discussed – first
- SRO will rank average overall scores and circulate a rank order of review before the meeting
- About the lower  $\frac{1}{2}$  will not be discussed at study section
  - Reviews from individual reviewers will be forwarded
  - A grant can be pulled up for discussion by any study section member with reason

# The Review

1. After those with conflict leave the room, the primary reviewer will concisely present the grant to the group, then inform the group of his/her critique – positive and negative
2. The secondary reviewer adds his/her comments
3. Other assigned reviewers provide additional comments, trying to limit them to those not already brought up



# The Review

4. The grant is open for discussion – all members of the study section discuss
5. The Study Section Chair summarizes the discussion
6. The assigned reviewers give their final overall scores – can be changed substantially from initial scores

# The Review

7. All study section members put their score into eCommons and simultaneously write them on a scoring sheet (back-up) in blinded fashion
  - Scores outside the range of that stated by primary reviewers are voiced with explanations

# The Review

8. Final comments are made on budget, human subjects, animal welfare, involvement of women/children/minorities, and biological risks (not part of the primary review)
9. After study section, assigned reviewers adjust their critique and submit this by eCommons

# Getting Your Score and Critique

- Final scores range from 10 to 90
- Scores are typically posted on eCommons within 3 business days
- Summary sheets are due within one month (1 week for new investigators)

General Grant Information		Online Released Documents	
Status:	Application awarded.	<a href="#">Summary Statement</a>	
Institution Name:	Application awarded.	<a href="#">Award FRR</a>	
School Name:	my institution	<a href="#">Abstract (Awarded Grant)</a>	
School Category:	School of Medicine	<a href="#">Additions for Review (0 documents)</a>	
Division Name:	OVERALL MEDICAL		
Department Name:	NONE		
PI Name:	Internal Medicine		
Application ID:	Sigmond Freud		
Proposal Title:	1R01HD000000-01		
Proposal Receipt Date:	Dream Therapy for Cardiac Patients		
Last Status Update Date:	07/17/2005		
Current Award Notice Date:	01/16/2006		
Application Source:	01/16/2006		
Project Period Begin Date:	Paper		
eApplication Status:	01/16/2006		
FOA:	01/16/2007		
NIH Appl. ID:			
Status History		Institute or Center Assignment	
Effective Date	Status Message	Institute or Center	Assignment Date
01/16/2006	Application awarded.	NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (Primary)	08/17/2005
01/16/2006	Application awarded.		
Application Information		Study Section	Advisory Council(AC) Information
Award Document Number:	R1MH	Scientific Review Group:	ZRG1 AAAA-
FSR Accepted Code:	Y		3
Snap Indicator Code:	Y	Council Meeting Date	2005/10
Priority Score:	19	(YYYYMM)	
Percentile:	0		

# Study Section – Important Points

- Only about 1/2 of grants undergo group discussion
- Your program officer has no role in review
  - He/she can attend, but must sit in a separate table away from the group and cannot talk
- All initial reviews are completed independently
- Easy to read grants are a plus

# Post-review

- Scoring does not mean funding
- You can discuss the summary statement with the program officer **AFTER** review. The SRO cannot discuss the review after.
- Getting a clear idea of funding after review is nearly impossible
  - “looks/does not look favorable”

# Practical Ideas

- Highly significant work
- Innovative ideas
- Clarity of writing
- Realistic aims and timelines
- Acknowledgment of limitations
- Proof read for grammatical errors – including research plan forms

**GOOD LUCK**

<http://public.csr.nih.gov/aboutcsr/contactcsr/pages/contactorvisitcsrpages/nih-grant-review-process-youtube-videos.aspx>