

# NIH Review Process

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CUIMC Office of Faculty Professional Development,  
Diversity, and Inclusion

**Talk will be recorded**

# NIH in Bethesda, MD



# NIH Structure and Resources

- Part of the US Department of Health and Human Services
- Comprised of 27 institutes and centers
- Close to 20,000 employees
- More than 80% of the budget goes to more than 300,000 research personnel at 2,500 universities and research institutions through more than 50,000 grants
- About 10% of its budget goes to 6,000 NIH scientists are conducting intramural research

# NIH Institutes (21)

1. National Cancer Institute (NCI)
2. National Eye Institute (NEI)
3. National Heart, Lung, and Blood Institute (NHLBI)
4. National Human Genome Research Institute (NHGRI)
5. National Institute on Aging (NIA)
6. National Institute on Alcohol Abuse and Alcoholism (NIAAA)
7. National Institute of Allergy and Infectious Diseases (NIAID)
8. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
9. National Institute of Biomedical Imaging and Bioengineering (NIBIB)
10. National Institute of Child Health and Human Development (NICHD)
11. National Institute on Deafness and Other Communication Disorders (NIDCD)
12. National Institute of Dental and Craniofacial Research (NIDCR)
13. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
14. National Institute on Drug Abuse (NIDA)
15. National Institute of Environmental Health Sciences (NIEHS)
16. National Institute of General Medical Sciences (NIGMS)
17. National Institute of Mental Health (NIMH)
18. National Institute of Neurological Disorders and Stroke (NINDS)
19. National Institute of Nursing Research (NINR)
20. National Library of Medicine (NLM)
21. National Institute on Minority Health and Health Disparities (NIMHD)



# NIH Centers (6)

- Center for Information Technology (CIT)
- John E. Fogarty International Center (FIC)
- National Center for Complementary and Alternative Medicine (NCCAM)
- NIH Clinical Center (CC)
- National Center for Advancing Translational Science (NCATS – used to be NCRR)
- **Center for Scientific Review (CSR)**

# Center for Scientific Review

- Center for Scientific (CSR) Review  
<http://public.csr.nih.gov/Pages/default.aspx>

**“Portal for NIH grant applications and their review for scientific merit”**

# NIH Peer Review System for Grant Applications



First Level of Review  
Scientific Review Group  
(Study Section)

Second Level of Review  
NIH Institute/Center Council



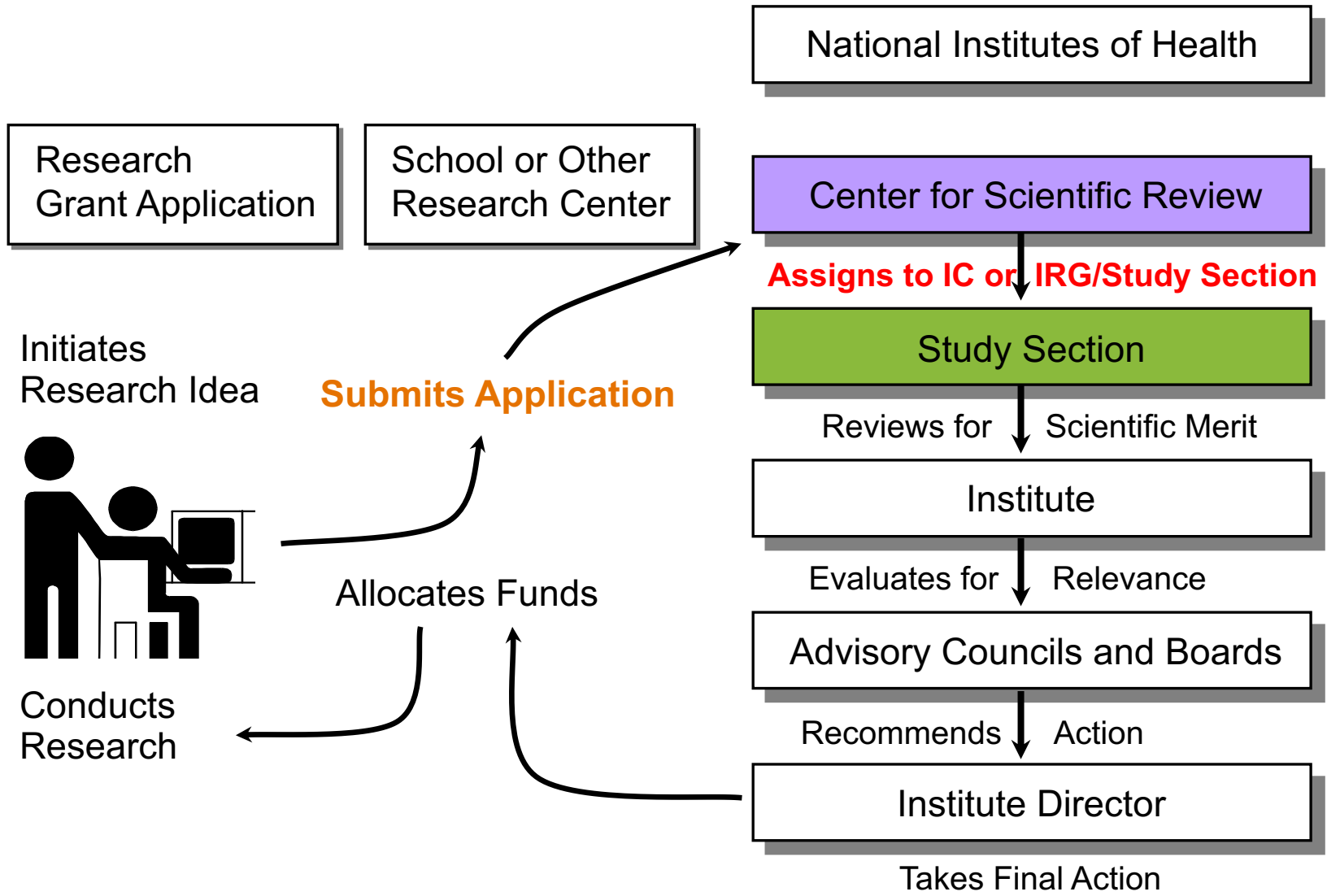
# The Gateway for NIH Grant Applications

## The Center for Scientific Review (CSR)



- Receives all NIH applications
- Refers them to NIH Institutes/Centers (IC) or to CSR Integrated Review Groups (a group of study sections)/Study sections

# Review Process for a Research Grant



# CSR Peer Review – Fiscal Year 2016

- 92,000 applications received
- 18,000 reviewers
- 247 Scientific Review Officers
- 1,600 review meetings



# STEP 1: Assignment

- Your proposal is submitted to the CSR.
- The CSR makes 2 assignments:
  - **Funding**: assigned to a **NIH IC (INSTITUTE or CENTER)**, for example, the NCI or NHLBI; they dole out the money
  - **Review**: assigned to the Integrated Review Group (group of study sections)/study sections in the CSR or an IC review group.
  - **CSR reviews includes most Ro1s, fellowships, and small business applications.**
  - **IC review groups handle applications that have institute-specific features (e.g., K-type career development awards).**

# IRG Assignment

- **Integrated Review Group (IRG)** = a cluster of “study sections” around a general scientific area (in CSR)
- **Study section** = a panel of 20 or more experts established according to scientific disciplines or current research areas for evaluating NIH proposals

*To see the full list of IRGs, study sections, and their membership, go to:*

<http://public.csr.nih.gov/StudySections/IntegratedReviewGroups/Pages/default.aspx>

<https://public.csr.nih.gov/RosterAndMeetings/Pages/default.aspx>

# Scientific Review Officer (SRO)

- **PhD or equivalent**
- Assigns applications to reviewers and organizes the conduct of the study section review.
- Invites standing vs. temporary reviewers
- **What is the role of the Chairperson?**

# What Your SRO Looks for When Recruiting Reviewers

- Demonstrated scientific expertise/research support
- Doctoral degree or equivalent
- Mature judgment
- Work effectively in a group context
- Breadth of perspective
- Impartiality
- Diversity
- Geographic distribution
- Have a broad range of scientific expertise and background
- **Likely experts in the field, but may not be in exact area of your application**

# Can I influence the choice of study section/institute? Yes, via the Assignment Sheet and Cover Letter

This may be used for a number of important purposes:

- **Suggest study section assignment**
- **Suggest awarding component  
(Institute/Center)**

# Demonstration

- <https://public.csr.nih.gov/studysections/pages/default.aspx>
  - Which Integrated Review Group (IRG) houses the study section on *Lung Injury, Repair, and Remodeling (LIRR)*?
  - What topics does this study section deal with?
  - When was their last meeting?
  - Who's the chairperson of this study section?
  - Who are the members of this study section?
  - Who is their SRO?



# STEP 2: The Review Process

- Several **months later**, your application is delivered to reviewers serving on your assigned IRG/study section.
- The study section convenes for a **2 day meeting** in DC/Bethesda area (sometimes on the west coast)
- Your application is reviewed by study section members (and NOT by NIH staff, although staff are present).
- Chairperson and SRO

# Study Section Procedures

## A few months before study section meeting

- Reviewers get mix of applications as R<sub>1</sub>, R<sub>2</sub>, and R<sub>3</sub> (sometimes there is a R<sub>4</sub>)
- Reviewers first identify those applications with a conflict of interest
- Reviewers do **not** typically read the applications that were not assigned

# Study Section Procedures

## A few days before study section meeting

- Reviewers submit written reviews and scores on-line prior to the meeting
  - Overall score
  - Each core review criteria (Significance, Innovation, etc)

# NIH Scoring System

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**

REVIEW CRITERIA AT A GLANCE – RESEARCH

	Research and Research Center (R, DP, RC, P, etc.)	Institutional R25	Conferences and Scientific Meetings R13/U13	SBIR/STTR (R41, R42, R43, R44)	Academic Research Enhancement Award (AREA) (R15)
<b>Overall Impact</b>	<i>Overall Impact</i>	<i>Overall Impact</i>	<i>Overall Impact</i>	<i>Overall Impact</i>	<i>Overall Impact</i>
<b>Red Review Criteria</b>  scored individually and considered in overall impact (R15)  & RFA: May add questions to scored criterion or additional criteria	<ul style="list-style-type: none"> <li>✓ <i>Significance</i></li> <li>✓ <i>Investigator(s)</i></li> <li>✓ <i>Innovation</i></li> <li>✓ <i>Approach</i></li> <li>✓ <i>Environment</i></li> </ul>	<ul style="list-style-type: none"> <li>✓ <i>Significance</i></li> <li>✓ <i>Investigator(s)</i></li> <li>✓ <i>Innovation</i></li> <li>✓ <i>Approach</i></li> <li>✓ <i>Environment</i></li> </ul>	<ul style="list-style-type: none"> <li>✓ <i>Significance</i></li> <li>✓ <i>Investigator(s)</i></li> <li>✓ <i>Innovation</i></li> <li>✓ <i>Approach</i></li> <li>✓ <i>Environment</i></li> </ul>	<ul style="list-style-type: none"> <li>✓ <i>Significance</i></li> <li>✓ <i>Investigator(s)</i></li> <li>✓ <i>Innovation</i></li> <li>✓ <i>Approach</i></li> <li>✓ <i>Environment</i></li> </ul>	<ul style="list-style-type: none"> <li>✓ <i>Significance</i></li> <li>✓ <i>Investigator(s)</i></li> <li>✓ <i>Innovation</i></li> <li>✓ <i>Approach</i></li> <li>✓ <i>Environment</i></li> </ul>
<b>Additional Review Criteria</b>  scored individually, but considered in overall impact score)  & RFA: May add new criteria or questions to each additional criterion	<p>R01-BRP only:</p> <ul style="list-style-type: none"> <li>• <i>Partnership and Leadership</i></li> </ul> <p>All:</p> <ul style="list-style-type: none"> <li>✓ <i>Protections for Human Subjects</i></li> <li>✓ <i>Inclusion of Women, Minorities, &amp; Children</i></li> <li>✓ <i>Vertebrate Animals</i></li> <li>✓ <i>Biohazards</i></li> <li>• <i>Resubmission</i></li> <li>• <i>Renewal</i></li> <li>• <i>Revision</i></li> </ul>	<ul style="list-style-type: none"> <li>✓ <i>Protections for Human Subjects</i></li> <li>✓ <i>Inclusion of Women, Minorities, &amp; Children</i></li> <li>✓ <i>Vertebrate Animals</i></li> <li>✓ <i>Biohazards</i></li> <li>• <i>Resubmission</i></li> <li>• <i>Renewal</i></li> <li>• <i>Revision</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Appropriate Representation</i></li> <li>✓ <i>Protections for Human Subjects</i></li> <li>✓ <i>Inclusion of Women, Minorities, &amp; Children</i></li> <li>✓ <i>Vertebrate Animals</i></li> <li>✓ <i>Biohazards</i></li> <li>• <i>Resubmission</i></li> <li>• <i>Renewal</i></li> <li>• <i>Revision</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Phase II</i></li> <li>• <i>Fast Track</i></li> <li>✓ <i>Protections for Human Subjects</i></li> <li>✓ <i>Inclusion of Women, Minorities, &amp; Children</i></li> <li>✓ <i>Vertebrate Animals</i></li> <li>✓ <i>Biohazards</i></li> <li>• <i>Resubmission</i></li> <li>• <i>Renewal</i></li> <li>• <i>Revision</i></li> </ul>	<ul style="list-style-type: none"> <li>✓ <i>Protections for Human Subjects</i></li> <li>✓ <i>Inclusion of Women, Minorities, &amp; Children</i></li> <li>✓ <i>Vertebrate Animals</i></li> <li>✓ <i>Biohazards</i></li> <li>• <i>Resubmission</i></li> <li>• <i>Renewal</i></li> <li>• <i>Revision</i></li> </ul>
<b>Additional Review Considerations</b>  scored individually and not considered in overall score)	<p>R01-BRP only:</p> <ul style="list-style-type: none"> <li>✓ <i>Technology Transfer</i></li> </ul> <p>All:</p> <ul style="list-style-type: none"> <li>• <i>Applications from Foreign Organizations</i></li> <li>• <i>Select Agents</i></li> <li>• <i>Resource Sharing Plans</i></li> <li>• <i>Authentication of Key Biological and/or Chemical Resources</i></li> <li>✓ <i>Budget &amp; Period of Support</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Recruitment &amp; Retention Plan to Enhance Diversity</i></li> <li>• <i>Training in the Responsible Conduct of Research</i></li> <li>• <i>Select Agents</i></li> <li>• <i>Resource Sharing Plans</i></li> <li>✓ <i>Budget and Period of Support</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Provision of Family Care Facilities</i></li> <li>• <i>Applications from Foreign Organizations</i></li> <li>• <i>Select Agents</i></li> <li>• <i>Resource Sharing Plans</i></li> <li>✓ <i>Budget and Period of Support</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Select Agents</i></li> <li>• <i>Resource Sharing Plans</i></li> <li>• <i>Authentication of Key Biological and/or Chemical Resources</i></li> <li>✓ <i>Budget &amp; Period of Support</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Select Agents</i></li> <li>• <i>Resource Sharing Plans</i></li> <li>• <i>Authentication of Key Biological and/or Chemical Resources</i></li> <li>✓ <i>Budget &amp; Period of Support</i></li> </ul>
<b>Additional Comments to Applicant</b>	<i>Additional Comments to Applicant</i>	<i>Additional Comments to Applicant</i>	<i>Additional Comments to Applicant</i>	<i>Additional Comments to Applicant</i>	<i>Additional Comments to Applicant</i>

# REVIEW CRITERIA AT A GLANCE – TRAINING

	Fellowship (F30, F31, F32, F33)	Career Development (K01, K02, K07, K08, K23, K24, K25, K99)	Institutional Training (T32, T35, K12)
<b>Overall Impact</b>	<u>Overall Impact/Merit</u>	<u>Overall Impact</u>	<u>Overall Impact</u>
<b>Primary Review Criteria</b> (scored individually and considered in overall impact score)	<ul style="list-style-type: none"> <li>✓ <u>Fellowship Applicant</u></li> <li>✓ <u>Sponsors, Collaborators, and Consultants</u></li> <li>✓ <u>Research Training Plan</u></li> <li>✓ <u>Training Potential</u></li> <li>✓ <u>Institutional Environment &amp; Commitment to Training</u></li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Candidate</u></li> <li>✓ <u>Career Development Plan/Career Goals &amp; Objectives/Plan to Provide Mentoring</u></li> <li>✓ <u>Research Plan</u></li> <li>✓ <u>Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)</u></li> <li>✓ <u>Environment &amp; Institutional Commitment to the Candidate</u></li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Training Program and Environment</u></li> <li>✓ <u>Training PD/PI</u></li> <li>✓ <u>Preceptors /Mentors</u></li> <li>✓ <u>Trainees</u></li> <li>✓ <u>Training Record</u></li> </ul> <p>Other T programs use other criteria</p>
<b>Additional Review Criteria</b> (scored individually, but considered in overall impact score)	<ul style="list-style-type: none"> <li>✓ <u>Protections for Human Subjects</u></li> <li>✓ <u>Inclusion of Women, Minorities, &amp; Children</u></li> <li>✓ <u>Vertebrate Animals</u></li> <li>✓ <u>Biohazards</u></li> <li>• <u>Resubmission</u></li> <li>• <u>Renewal</u></li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Protections for Human Subjects</u></li> <li>✓ <u>Inclusion of Women, Minorities, &amp; Children</u></li> <li>✓ <u>Vertebrate Animals</u></li> <li>✓ <u>Biohazards</u></li> <li>• <u>Resubmission</u></li> <li>• <u>Renewal</u></li> <li>• <u>Revision</u></li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Protections for Human Subjects</u></li> <li>✓ <u>Inclusion of Women, Minorities, &amp; Children</u></li> <li>✓ <u>Vertebrate Animals</u></li> <li>✓ <u>Biohazards</u></li> <li>• <u>Resubmission</u></li> <li>• <u>Renewal</u></li> <li>• <u>Revision</u></li> </ul>
<b>Additional Review Considerations</b> (scored individually and not considered in overall score)	<ul style="list-style-type: none"> <li>✓ <u>Training in the Responsible Conduct of Research</u></li> <li>• <u>Applications from Foreign Organizations</u></li> <li>• <u>Select Agents</u></li> <li>• <u>Resource Sharing Plans</u></li> <li>✓ <u>Budget &amp; Period of Support</u></li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Training in the Responsible Conduct of Research</u></li> <li>• <u>Select Agents</u></li> <li>• <u>Resource Sharing Plans</u></li> <li>• <u>Authentication of Key Biological and/or Chemical Resources</u></li> <li>✓ <u>Budget &amp; Period of Support</u></li> </ul>	<ul style="list-style-type: none"> <li>✓ <u>Recruitment &amp; Retention Plan to Enhance Diversity</u></li> <li>✓ <u>Training in the Responsible Conduct of Research</u></li> <li>• <u>Select Agents</u></li> <li>✓ <u>Budget &amp; Period of Support</u></li> </ul>
<b>Additional Comments to Applicant</b>	<u>Additional Comments to Applicant</u>	<u>Additional Comments to Applicant</u>	<u>Additional Comments to Applicant</u>



# Study Section Procedures

Is the overall score an average of the individual core review criteria?

- Overall = average of Significance, Investigators, Innovation, Approach, and Environment scores?
- Example:
  - Significance (4), Investigators (1), Innovation (2), Approach (5), Environment (1)
  - **What is the overall score???**

# Study Section Procedures

- For each application, the SRO averages the reviewer's overall scores.
  - $R_1 = 4$     $R_2 = 3$     $R_3 = 2$
  - **Average of overall scores = 3**
- Then, the applications are ranked by average overall score stratified by mechanism
  - R01 ranking
  - R03 ranking
  - R21 ranking
- Applications are then categorized by SRO into "discussed" and "not discussed" categories.
- **All of the reviews and scores of the assigned applications are posted online to reviewers as well as the list of discussed/not discussed applications.**

# Study Section Procedures

## At the study section meeting

- SRO, Chairperson, Other NIH staff, Reviewers
- SRO goes over list of discussed and not discussed applications, and asks if anyone wants to “rescue” an application
- **Not discussed applications:** only individual scores (not overall score) are given to applicants.
- Not all “not discussed” application are “bad”.

# Study Section Procedures

- Reviews start after deciding which applications will be discussed.
- When each grant is reviewed, anyone with a conflict is asked to leave the room. Then the assigned reviewers **declare their overall scores**.
- Then R<sub>1</sub> introduces the application and critique.
- R<sub>2</sub>-R<sub>4</sub> highlight new areas, areas of disagreement, reasons for their scores.
- Discussion ensues with **EVERYONE** in the room.
- Chairperson usually summarizes the reviewers' comments.

# Study Section Procedures

- At the end of all the discussion, your reviewers restate their scores.
- Then, all study section members score the application on the online score sheets, within the upper and lower limits set by the main reviewers (R1-R4).
- If outside the range, a study section member must include written summary why.
- **EVERYBODY** in the room votes – your final score is the average of all committee members' scores.
- Written reviews are supposed to be revised if the discussion changed the scores of the main reviewers (R1-R4).

# Study Section Procedures

- Gender/Children/Race-ethnicity
- Ethical issues
- Budget considerations



# Aftermath

- **1 WEEK AFTER THE MEETING:** You will receive your “score”.
- **R01, R21, R03** (as a percentile rank)
  - Mean overall score → multiply by 10 to get the priority score → percentile rank
  - The percentile rank is based on how the study section scored its last three meetings (includes non-discussed applications).
- **K awards** do not have a percentile (only use the priority score multiplied by 10)
- Payline determined by each institute and their budget; with consideration for ESIs

# Aftermath

- **6-8 WEEKS LATER:** You will receive a **SUMMARY STATEMENT**. This will include the reviewers' written critiques and summary of the group discussion.

# Your Summary Statement

**If an application is either discussed or not discussed:**

- Scores for each review criterion
- Critiques from assigned reviewers
- Administrative notes if any

**If your application is discussed, you also will receive:**

- An overall impact/priority score and percentile ranking
- A summary of review discussion (SRO)
- Budget recommendations

# Time from submission to funding



## Timeline: New Applications



**Receipt  
Date**



**Scientific  
Review**



**Council  
Review**



**Award  
Date**

**R01**

**February 5**

**July**

**October**

**December**

**June 5**

**October**

**January**

**April**

**October 5**

**March**

**May**

**July\_**

<http://grants.nih.gov/grants/funding/submissionschedule.htm>

# Questions?