NIH Research (R) Grants and the Peer Review Process

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Boyd Professor
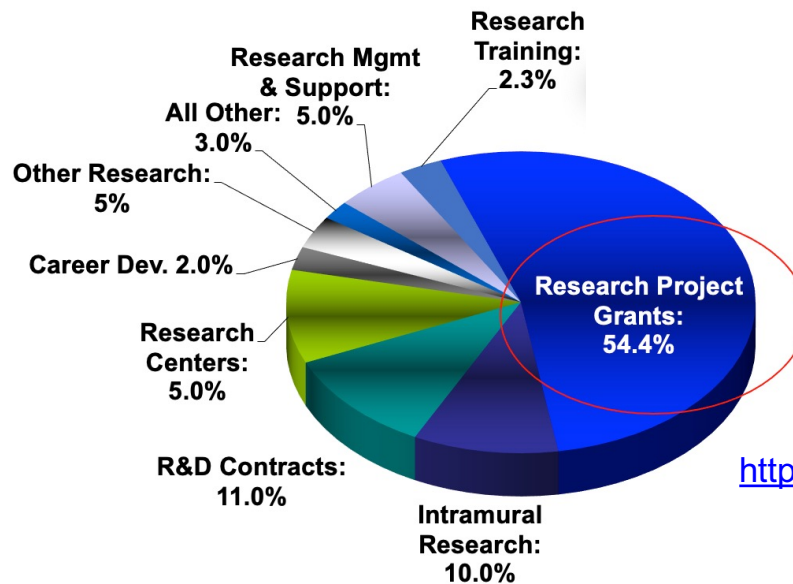Charles H. Barré Distinguished Professor of Chemistry
Louisiana State University
Baton Rouge, LA

3/30/2023

NIH operating budget (2022): ~45B

Research Training: 2.3%

Research Mgmt & Support: 5.0%

All Other: 3.0%

Other Research: 5%

Career Dev. 2.0%

Research Centers: 5.0%

R&D Contracts: 11.0%

Intramural Research: 10.0%

Research Project Grants: 54.4%

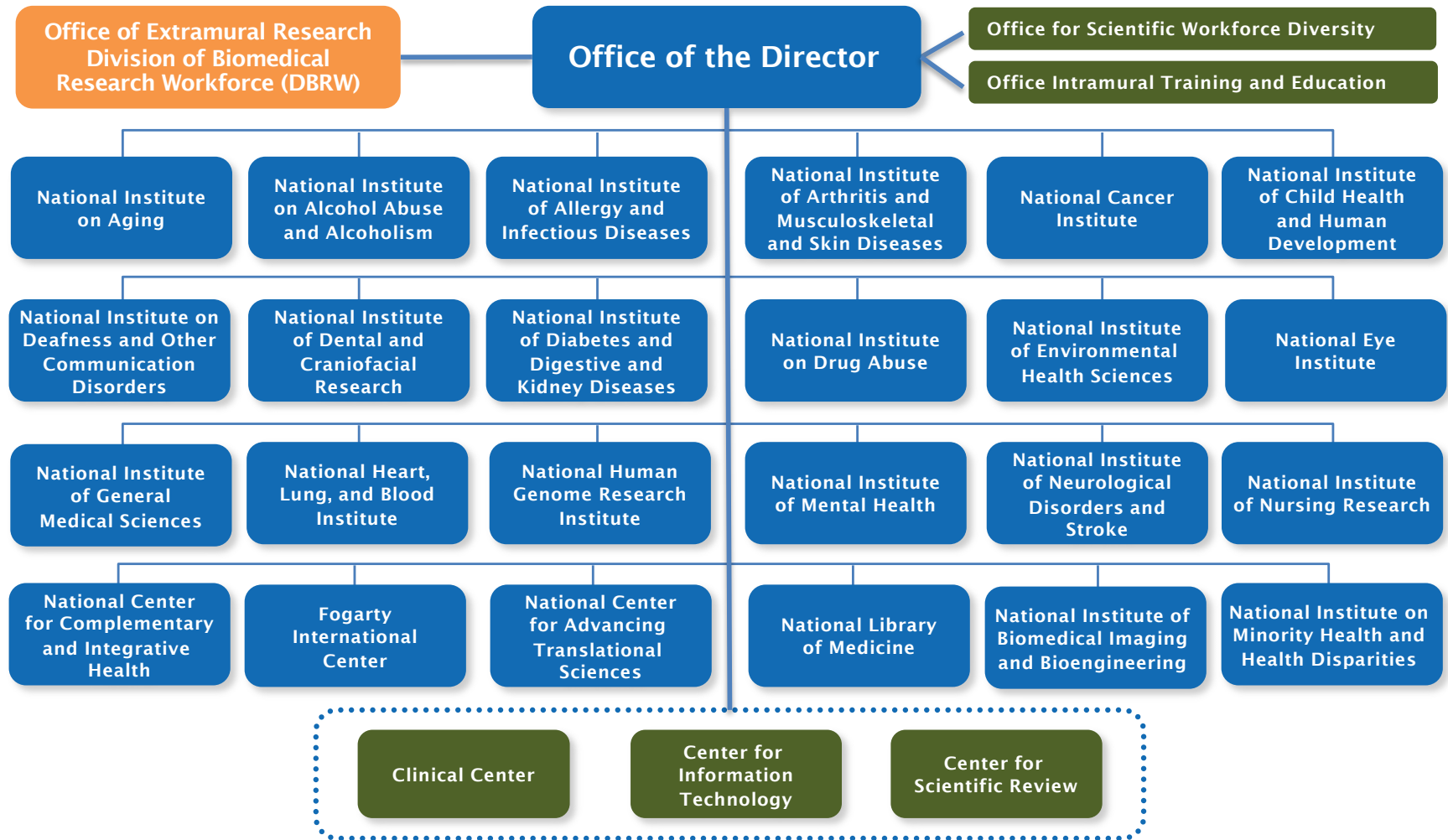http://officeofbudget.od.nih.gov/index.htm

NIH Mission:
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

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NIH includes 27 Institutes and Centers (IC)

Office of Extramural Research Division of Biomedical Research Workforce (DBRW)

Office of the Director

Office for Scientific Workforce Diversity

Office Intramural Training and Education

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 Integrative Health	Fogarty International Center	National Center for Advancing Translational Sciences	National Library of Medicine	National Institute of Biomedical Imaging and Bioengineering	National Institute on Minority Health and Health Disparities

Clinical Center	Center for Information Technology	Center for Scientific Review

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Where to Start?

NIH **GRANTS & FUNDING**
NIH Central Resource for Grants and Funding Information

https://grants.nih.gov

Search this Site

eRA | NIH Staff 🔒 | Glossary | FAQs | Help

| HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER |

2022-2023 NIH Grants Conference and PreCon Events

This conference season has concluded and resources are available.

Plans are underway for 2023-2024 virtual events - register today to stay informed:

- Webinars throughout the year
- Multi-day conference
- NIH and HHS expert guidance
- Institute, Center and Office contacts and resources

Learn More

How to Apply

Find Grant Funding

Funded Research (RePORT)

Open Mike Blog

News

ABOUT GRANTS

Navigate the NIH grants process.

- Grants Process Overview
- Get Started
- How to Apply

POLICY & COMPLIANCE

Learn about obligations of your grant award.

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance and Oversight

INFORMATION FOR...

Find key resources just for you.

- Researchers
- Research Administrators
- Reviewers

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Use RePORTER

https://reporter.nih.gov

Use Matchmaker

https://reporter.nih.gov/matchmaker

Search for FOA

➢ Review IC priorities and goals;

➢ Identify specific grant programs offered by each IC in NIH Guide for Grants & Contracts: https://grants.nih.gov/funding/searchguide/index.html#/

➢ Make early contact with program officers to ensure that their IC is the correct match;

➢ Find appropriate collaborators (complementary expertise).
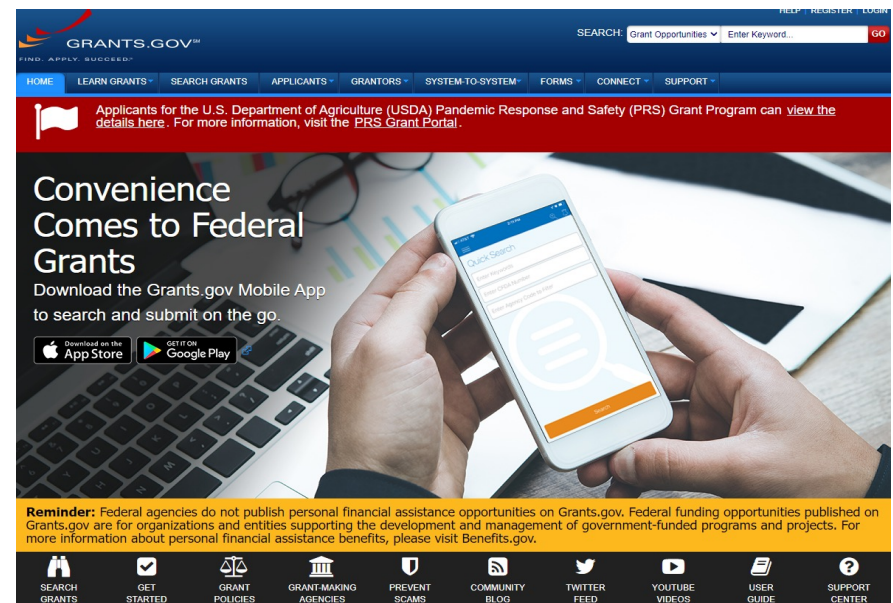
Timeline for NIH Applications

Submission*	Review	Council	Award
February	Jun/July	October	December
June	Oct/Nov	January	April
October	Feb/Mar	May	July

*Resubmissions usually one month later

Types of NIH Grants Programs

➢ **Research Grants (R series, e.g. R01, R03, R21, R15, R35)**

➢ Career Development Awards (K series, e.g. K01, K99)

➢ Institutional Research Training (T series, e.g. T32, T34)

➢ Individual Fellowships (F series, e.g. F30, F31, F32)

➢ Program Project/Center Grants (P series, e.g. P01)

➢ Resource Grants (various series)

R01 Research Grant

➢ Provides funding for 5 years ($500,000/year), renewable;

➢ **Requires preliminary data to support the proposed research;**

➢ Supports a variety of project types in areas representing the specific interests and competencies of the investigators;

➢ Proposed project must be related to the programmatic interests of one or more of the participating IC based on their scientific missions;

➢ **Includes 12 pages of Research Strategy.**

R01 Katz Award for ESI

➢ **First awards announced December 2021;**

➢ PD/PI must be designated as an ESI (within 10 yr of PhD; not a PI on an R award);

➢ Proposed research can rely on the prior work and expertise as foundation, but *must represent a different direction* (not just incremental expansion);

➢ Change in direction can involve a new approach, methodology, technique, discipline, therapeutic target, paradigm;

➢ **Should talk to your PO prior application;**

➢ Similar budget as regular R01: can request up to $500K/year in direct costs.

R35 Maximizing Investigators Research Award (MIRA)

➢ Provides up to $500,000/year, for up to 5 years, renewable;

➢ **Includes 6 pages of Research Strategy;**

➢ Enhances scientific breakthroughs but not all IC support this mechanism!

➢ Reduce time writing and reviewing grant applications and allow more time to conduct research, pursue new ideas;

➢ Enable investigators to develop new ideas in a stable research environment.

R35 MIRA Award for ESI

- Provides $250,000/year for 5 years, renewable;

- Enables ESI to:

  - apply early in their independent careers;

  - Secure funding to launch successful research careers;

  - Enhance ability to move to new research areas distinct from mentors;

  - Allow more time dedicated to research.

R03 Small Grant Program

➢ Provides funding for 2 years ($50,000/year), not renewable;

➢ **Includes 6 pages of Research Strategy**

➢ Supports a variety of project types, including:

    ➢ Pilot or feasibility studies;

    ➢ Development of new technology;

    ➢ Collection of preliminary data;

    ➢ Secondary analysis of existing data;

    ➢ Small, self-contained research projects.

R21 Exploratory/Developmental Research

➤ Provides funding for 2 years ($275,000 total), not renewable;

➤ Supports new, exploratory & developmental research projects;

➤ <u>Support for early stages of project development</u>;

➤ Preliminary data is not required, but may be included;

➤ **Only 6 pages Research Strategy!**

➤ Some R21 FOAs are issued by a IC for specific "exploratory" programs.

R15 Award

➤ Provides funding for 3 years ($300,000 total), renewable;

➤ **Eligible Institutions: < $6M/year, total NIH funding for 4 of the last 7 years**;

➤ PI cannot have another R grant at time of award!

➤ Preliminary data is not required, but may be included;

➤ Should strengthen the research environment of the institution;

➤ **Provides students with research training opportunities**;

➤ **Includes 12 pages Research Strategy!**

Two different R15 FOAs

- ➢ **AREA: Academic Research Enhancement Award**
  - ➢ Undergraduate-focused institutions (PAR-21-155)

- ➢ **REAP: Research Enhancement Award Program**
  - ➢ Health professional and Graduate Schools (PAR-19-135)

For AREA: Do the <u>non-health professional components</u> meet the funding requirement?
For REAP: Does the <u>Institution as a whole</u> meet the funding requirement?

https://grants.nih.gov/grants/funding/r15.htm
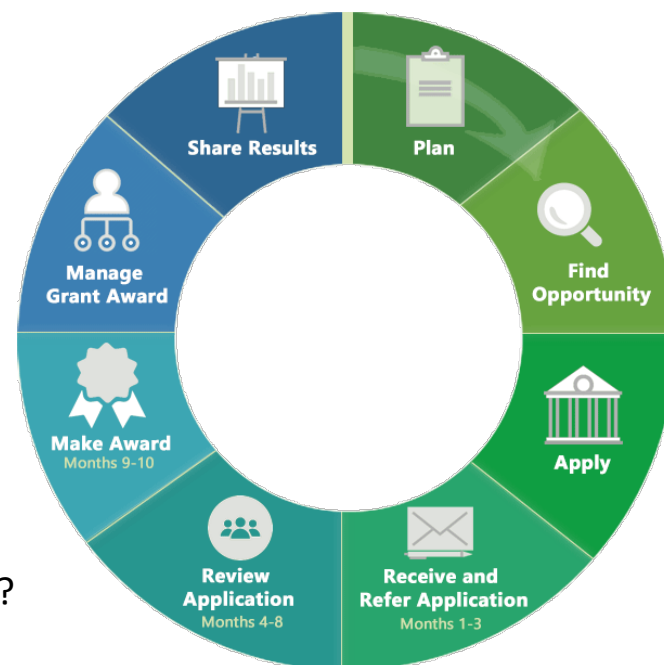
In R15 Student Training is Needed!

➢ Make sure students:

  ➢ Have help designing experiments, collect and analyze data;

  ➢ Co-author manuscripts;

  ➢ Present at meetings/conferences.

➢ PI should describe:

  ➢ History of mentoring students;

  ➢ History of co-author papers with students;

  ➢ How students will be recruited/retained.

Diversity Supplement to R Awards

➢ Administrative supplement to an existing, actively funded research grant designed to:

  ➢ Diversify the biomedical research workforce via support of investigators from diverse and underrepresented groups;

  ➢ Support many career stages from undergraduate to faculty;

  ➢ Could be a bridge to an F or K award;

  ➢ Expectation of a subsequent application for NIH support;

  ➢ Add to ongoing research and career development;

  ➢ Administratively reviewed by the Institute or Center (IC) funding the original grant.
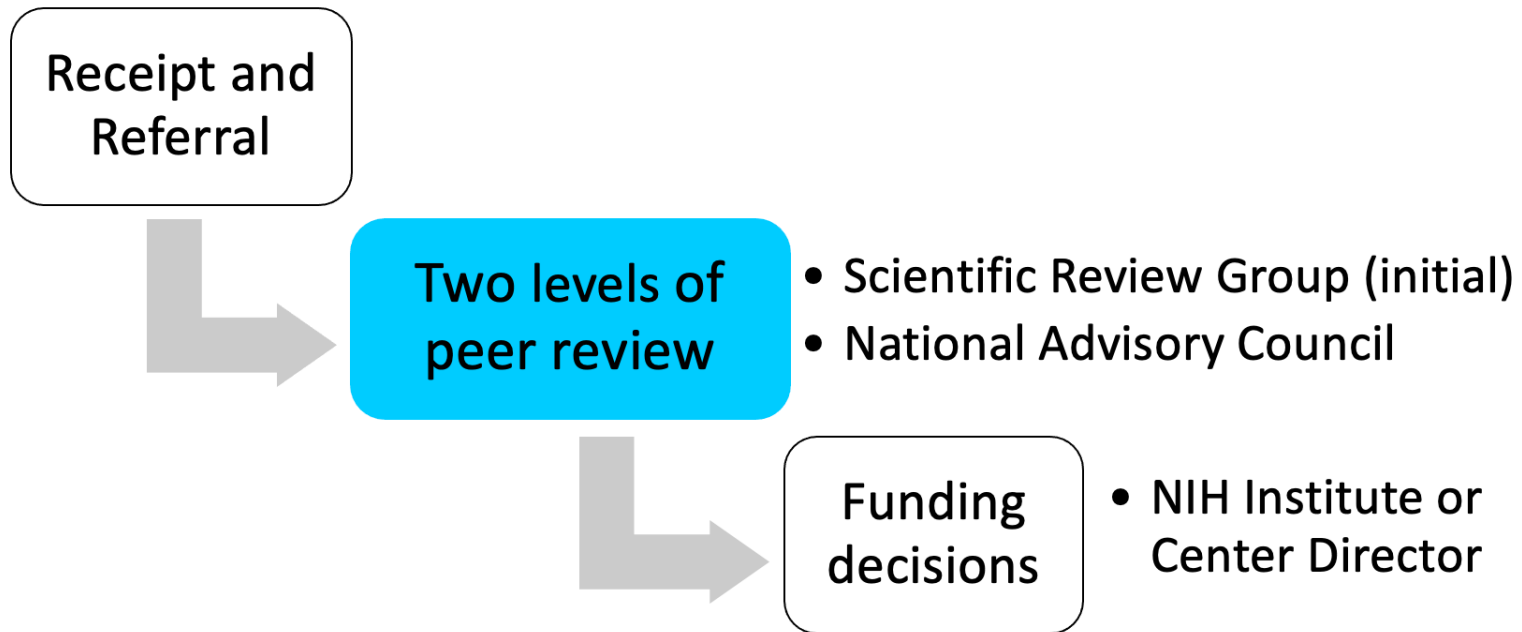
Working on a NIH Application

➢ Start planning early (6-8 months);

➢ Read the FOA carefully;

➢ Sketch out your Specific Aims;

➢ Check NIH RePORTER to identify IC, PO

➢ Reach out to a Program Officer to make sure:

  ➢ Is this area appropriate for the IC?

  ➢ Is the science a good fit for the funding announcement?

  ➢ Who is likely to review my application?

  ➢ Get feedback on your Specific Aims!

  ➢ Recommended: e-mail PO your aims and set up a phone call

➢ Align your application with the Review Criteria (Significance, Innovation Approach, Investigators, Environment)

The Grant Life Cycle

What happens to your NIH application?

Receipt and Referral

Two levels of peer review
- Scientific Review Group (initial)
- National Advisory Council

Funding decisions
- NIH Institute or Center Director

Peer Reviewers

- Mostly non-federal, extramural scientists;

- Recruited for expertise, managed conflicts of interest, balanced representation, stature in field, etc;

- For each application, ≥ three reviewers are "assigned" for **in-depth assessment**, written critiques, and criterion scores

- Assignments and conflicts of interest are confidential!

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Meeting Discussion Format

--------15 Minutes--------

|	
CHAIR	**Rule-out conflicts; Present an Application for review; Ask for Preliminary Impact Scores**
Reviewer 1	• Reviewer #1 - Introduce and provide a concise review (do not discuss in detail) • Describe the research program in terms of its likelihood to exert a sustained, powerful influence on the field • Focus on major score driving strengths & weaknesses. Provide reasons for the Overall Impact score. • Address additional review criteria such as Protections for Human Subjects, Gender/Minority/Children, Vertebrate Animals, Biohazards, Renewal
Reviewers 2 & 3	• Discuss areas of concurrence or disagreement with the previous reviewer's comments • Focus on additional comments or differences of opinion; Score driving strengths & weaknesses and reasons for your Overall Impact score
PANEL DISCUSSION	<u>Chair invites the panel members to discuss</u> • All members are asked to participate in the discussion - ask questions, provide additional comments • If anyone plans to vote outside the range, participate in the discussion now!
Summary	Chair summarizes the discussion, noting where consensus is apparent and where differences of opinion remain
Final Scoring	1. Final Overall Impact Score (Your initial/preliminary impact score is NOT binding) 2. Everyone in the room must vote online at IAR Site 3. Chair ask reviewers if anyone interested to vote outside the final Overall Impact Score range of the primary reviewers (must provide reasons for voting differently)
After Scoring, evaluate acceptability of:	• Resource Sharing Plans (Data Sharing Plan; Sharing Model Organisms; and GWAS) • Foreign Components • Authentication of Key Resources • Select Agent Research (hazardous biological agents and toxins) • Budget and Period of Support (justifications for period of support)

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Overall Impact or Criterion Strength	Score	Descriptor	Additional Guidance on Strengths and weaknesses
High	1	Exceptional	Applications with No weaknesses or Negligible weaknesses that do not affect the Impact
	2	Outstanding	
	3	Excellent	
Medium	4	Very Good	Strong but easily addressable minor weaknesses
	5	Good	**Strong with at least one minor weakness**
	6	Satisfactory	Some strengths with some moderate weaknesses
Low	7	Fair	Some strengths with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and many major weaknesses
Other Designations for Final Outcome			
AB	Abstention		**Minor Weakness:** Doesn't substantially lessen Impact
CF	Conflict of Interest		**Moderate Weakness:** Lessens Impact
DF	Deferred		**Major Weakness:** Severely limits Impact
ND	Not Discussed		
NP	Not Present		
NR	Not Recommended for Further Consideration		

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NIH scores are percentiled!

➢ In making funding decisions, NIH institutes consider *percentiles,* not overall impact scores;

➢ The scores helps to rank applications and percentiles are a function of rank;

➢ Calculation of percentiles uses the rank, not the score itself: *Percentile = 100 (Rank–0.5)/Total # of applications in 3 rounds*
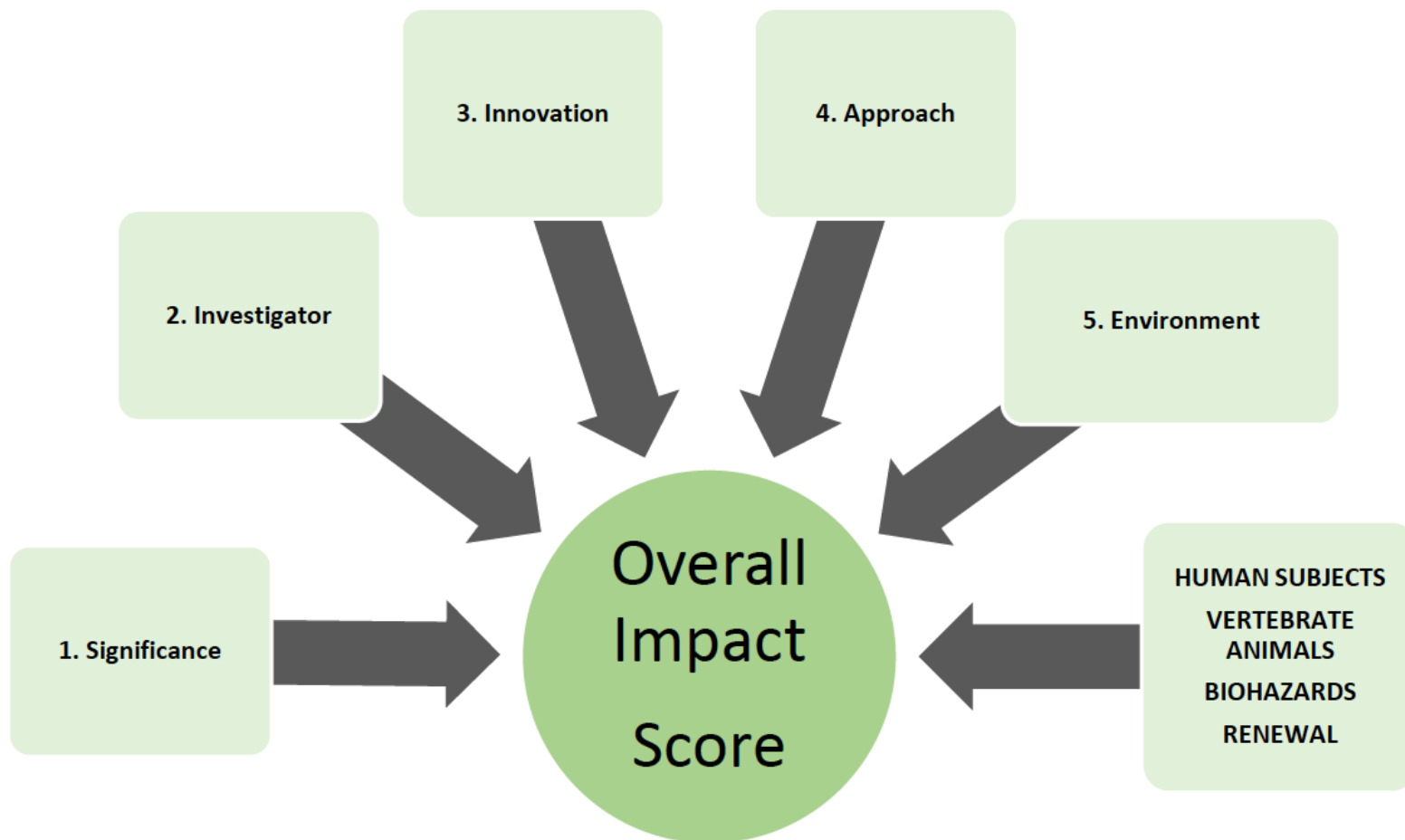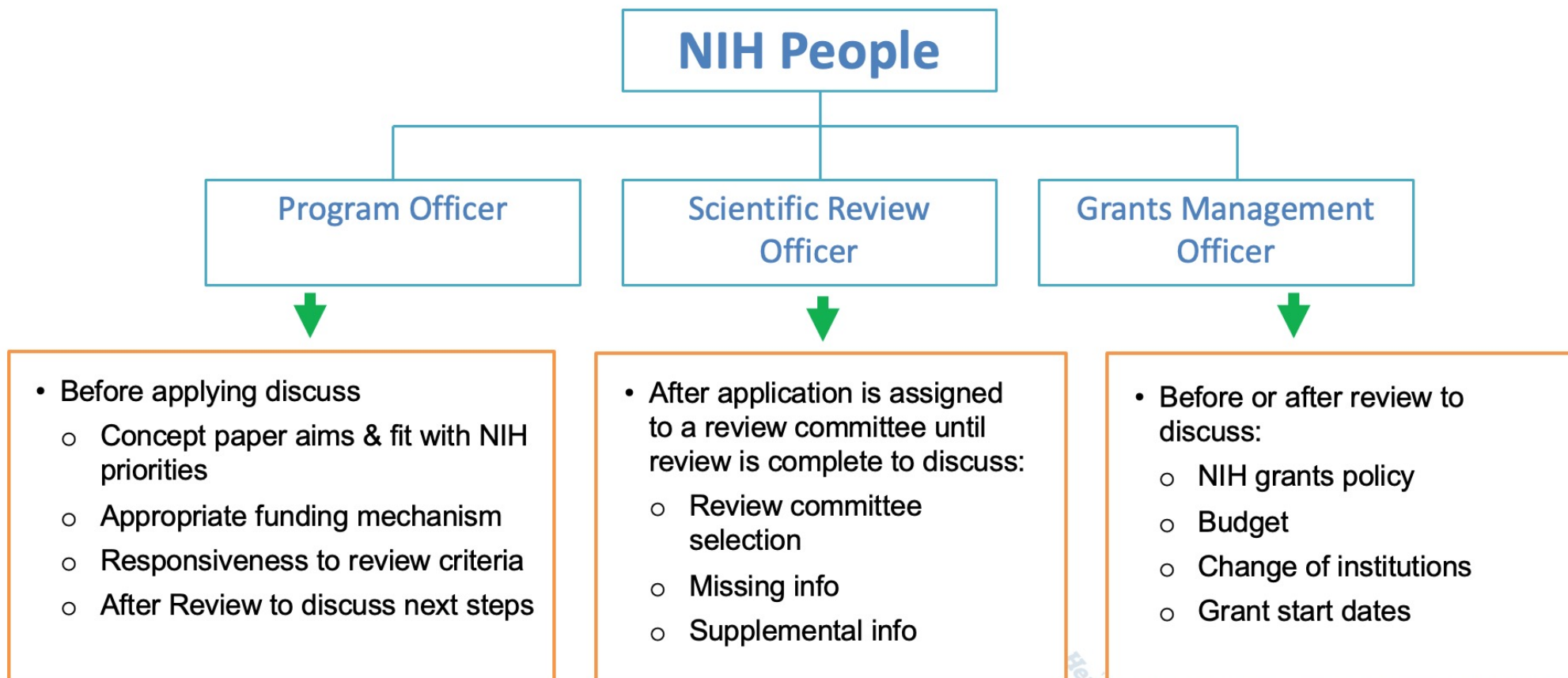
After the Application Review

- You may need to:
  - Submit Just-in-Time (JIT) information
  - Resolve human subject, vertebrate animal, inclusion codes
  - Consider your options:
  - — Submit a new application
  - — Revise and resubmit your application
  - — Appeal the review outcome ([NOT-OD-11-064](#))

Questions?

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