

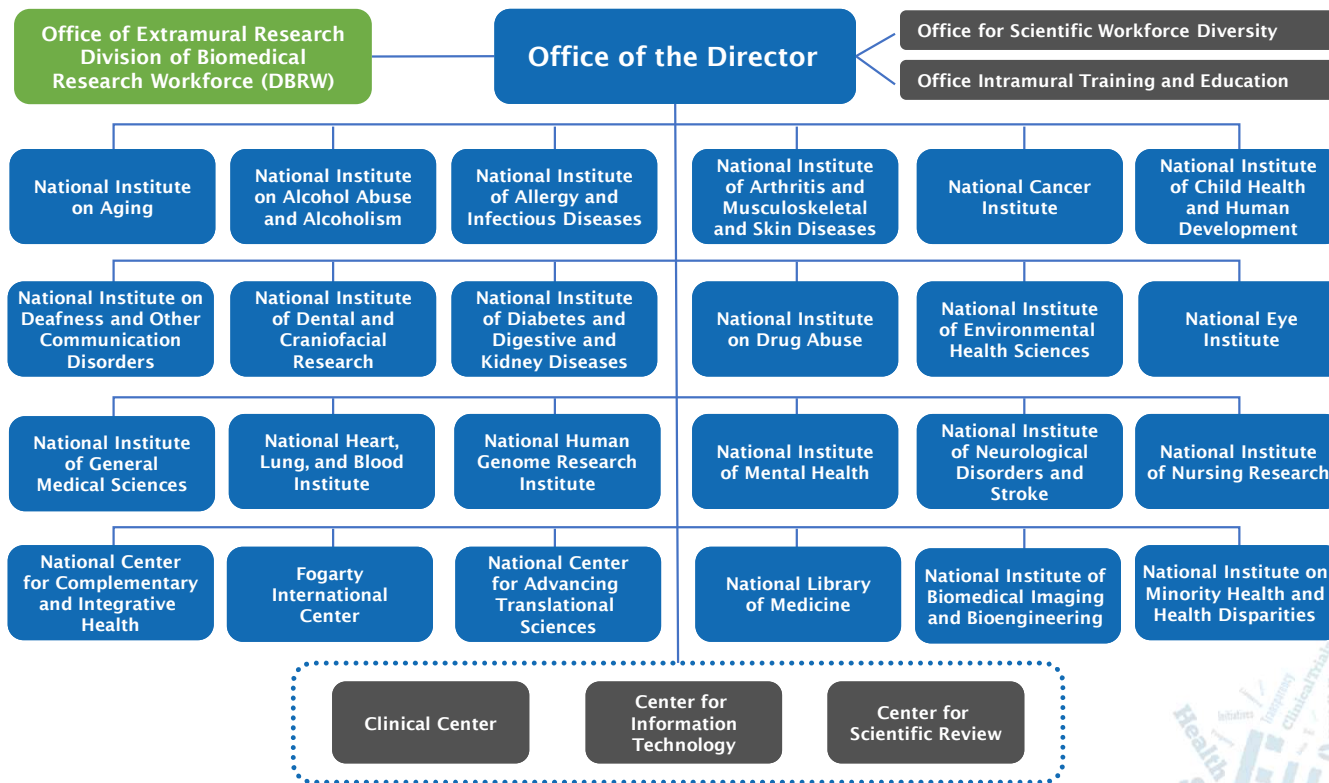
Writing an Effective K Application

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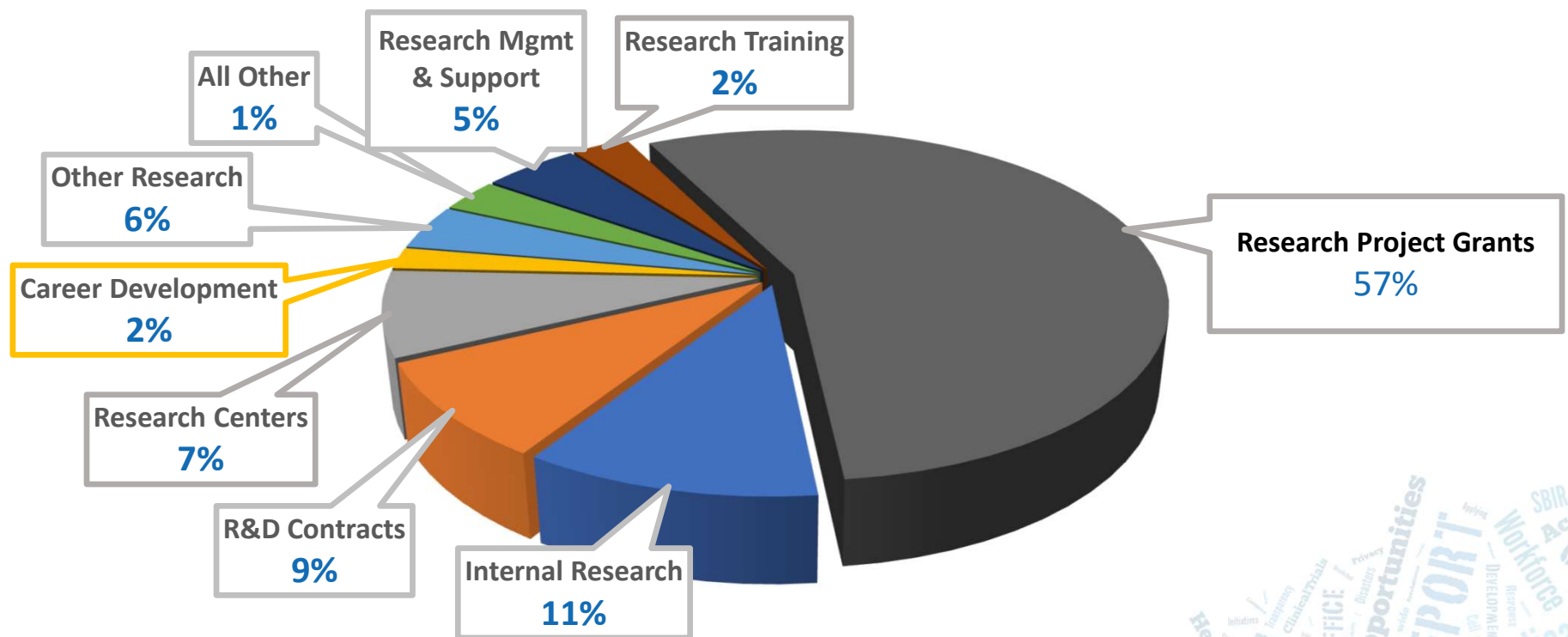


National Institutes of Health
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NIH includes 27 Institutes and Centers



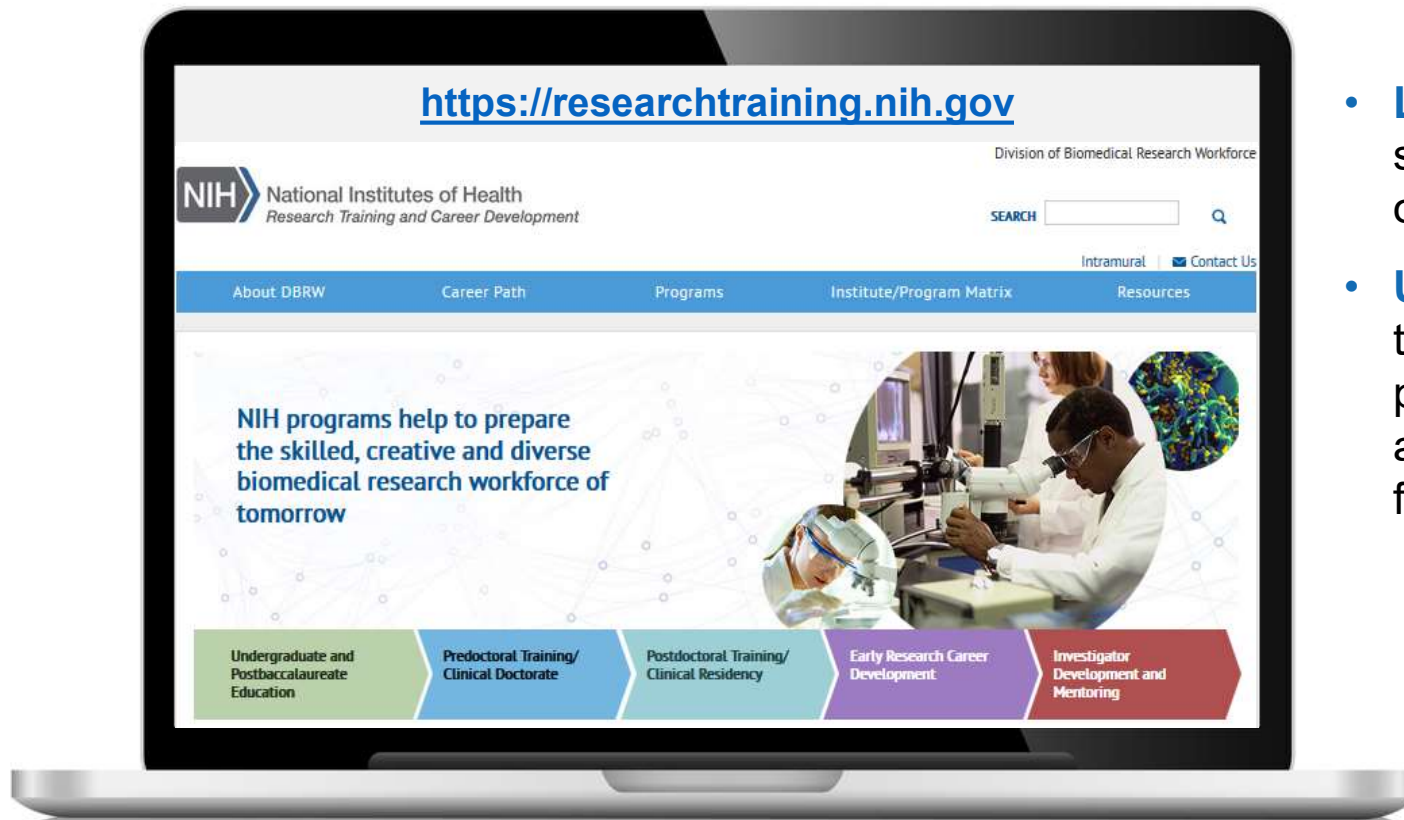
FY 2018 NIH Operating Budget: \$36,388,000



Postdoctoral and Early Research Career Training



NIH Research Training Website



- **Launched in 2015**, one stop for funding opportunities
- **Useful resource** for trainees, postdocs, potential K award applicants and early stage faculty



Career (K) Kiosk

K01

Mentored Research Scientist Career Development Award

For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.

K08

Mentored Clinical Scientist Research Career Development Award

To provide the opportunity for promising clinician scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research, and aid in filling the academic faculty gap in health profession's institutions.

K23

Mentored Patient-Oriented Research Career Development Award

To provide support for the career development of clinically trained professionals who have made a commitment to patient-oriented research, and who have the potential to develop into productive, clinical investigators.

K99/
R00

Pathway to Independence Award

To support both an initial mentored research experience (K99) followed by independent research (R00) for highly qualified, postdoctoral researchers, to secure an independent research position. Award recipients are expected to compete successfully for independent R01 support during the R00 phase.

Active FOAs (Parent & IC specific) can be found at:
<https://researchtraining.nih.gov/programs/career-development>

At that website click on each
K award type to view active FOAs



Pathway to Independence Award



K99/R00: Goal to facilitate *transition* from a mentored postdoctoral research position to an independent research position with *independent NIH research support* at an earlier stage than the current norm

Supports protected time (75%) in 2 distinct phases:

K99 – Phase 1- 2 years

- Mentored: must be affiliated with an institution
- Within 4 years of attaining PhD or completing clinical training
- 2007 awardees: 94.7% transition to R00; 2014 awardees 87.6% transition to R00.

R00 – Phase 2 (3 years)

- Independent (tenure-track or equivalent), own lab limited teaching and/or clinical responsibilities to assist pathway to next independent award.
- ‘Quality’ of tenure-track offer administratively reviewed by NIH staff before R00 awarded

No U.S. citizenship requirement for applicants to the **parent K99** ([PA-20-187](#); [PA-20-188](#); [PA-20-189](#))

NIAID Physician Scientist K99-R00: [PAR-20-209](#); [PAR-20-210](#); [NOT-AI-19-034](#); **Requires 50% effort; no U.S. citizenship requirement**

NIDCR Dual Degree Dentist Scientist K99-R00 ([PAR-18-432](#); [PAR-19-144](#); [PAR-19-141](#)) *no U.S. citizenship requirement.*

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative K99-R00 to promote diversity ([RFA-NS-19-043](#) [RFA-NS-19-044](#)) *requires citizenship/permanent resident status.*

Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity K99-R00 requires citizenship/permanent resident status; first due date February 12th 2020 ([PAR-19-343](#)); **Institutional UE5 Co-operative Agreement** due date November 15th 2019 ([PAR-19-342](#)) provides courses for skills development & mentoring.

Due to COVID two cycle extension of eligibility announced for Parent K99 [NOT-OD-20-158](#); NIDCR K99 [NOT-DE-20-031](#); Mosaic K99 [NOT-GM-20-051](#)



K01, K08 and K23 FOAs with different requirements

Funding Opportunity Announcements (FOAs) for K Awards will :

Require PD/PI to conduct an **independent clinical trial**

- [PA-20-176](#) (K01;14 IC)
- [PA-20-202](#) (K08;15 IC)
- [PA-20-206](#) (K23;17 IC)

K applicant/awardee has primary or lead responsibility for conducting & executing the trial (Funding is from the K award & may be an ancillary or feasibility study)

Permit **clinical trial research experience** but will NOT permit an independent clinical trial

- [PA-20-190](#) (K01;16 IC)
- [PA-20-203](#) (K08; 20 IC)
- [PA-20-205](#) (K23; 19 IC)

K applicant/awardee may propose research experience in a clinical trial led by the K award mentor or co-mentor.

Permit **Basic Experimental Studies with Humans (BESH)**

- [PA-20-191](#) (K01; 9 IC)
- [PA-20-201](#) (K08; 13 IC)
- [PA-20-204](#) (K23; 12 IC)

K applicant/awardee may propose basic science experimental studies involving humans which can be “prospective basic science studies involving human participants.”



Timeline for K Applications



RECEIPT DATE	REVIEW	COUNCIL	AWARD DATE
Feb 12 Resubmission Mar 12	Jun/July	October	December
Jun 12 Resubmission Jul 12	Oct/Nov	January	April
Oct 12 Resubmission Nov 12	Feb/Mar	May	July



Start Early

- Start at least **6 months prior** to the application due date (or begin planning even sooner)
- Get an **NIH Commons account** at least a month before the application deadline
- New Requirement for **ORCID ID** for K award applicants effective with receipt dates after January 25th 2020
- Know your organization's **Authorized Organizational Representative (AOR)** to assist with the application
- Notify your **referees early** and give them plenty of time to **submit letters of reference** (ensure they know you, have your current CV & if possible, aims of grant)



Plan Your Application

- Coordinate with your mentor(s) – **a K application is a collaboration between you & your mentor(s)**
- Put together a review committee to assist planning & provide critical feedback
 - Draft a short description of your specific aims & discuss these with the committee – chalk talk, diagrams, central hypotheses, scope
 - Do not write the entire grant before input received on aims
- Be sure the project is **distinct** from your mentor's research (although can be related) & that the mentor is supportive of future independence



Don't Propose Too Much

- Avoid an “over-ambitious” project – but it should be novel & significant!
- Your hypothesis should be testable & aims doable with the resources you are requesting (& mentor support)
- The scope of your hypothesis & aims should match available time and resources
- Your research & career development objectives should be related/matched



EXAMPLES

New Research Direction

- RNA Sequencing
- Novel imaging approaches
- Take advantage of core facilities

Career Development

- Bioinformatics workshop & courses
- Expert collaborator
- May be at other institution



Application Requirements

- Candidate Qualifications, Career Goals & Objectives
- Mentor(s), Collaborators & Consultants
- Institution's Environment & Commitment to the Candidate
- Specific Aims
- Research Strategy



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A Few Tips as You Write

Make Life Easy for Reviewers:

- Write clearly & concisely
- Label all components clearly
- Make sure figures & legends are readable
- Avoid TMI – a figure is worth a thousand words!
- Guide the reviewers with graphics as much as possible
- Edit & proofread

Know These Review Problems & Solutions:

- Write a compelling argument for why your career will be advanced to independence & enhanced by receiving a K award
- Write for both experts & non-experts in your field
- Cite the published work of experts with leading articles in the field



Candidate's Qualifications



Biographical Sketch:

- **Education/training**
- **Contributions to science:** background, findings, influence/impact, your specific role, cite publications or research products
- **Personal statement:** your research experience & other qualifications for this K award
- **Research support:** ongoing & completed research projects, accomplishments of you & your mentor(s)/colleague(s) attesting to qualifications of the research team

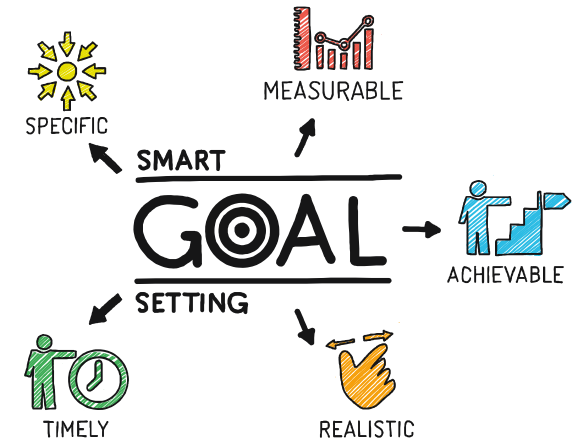
Candidates Background:

- Can coordinate with biosketch information
- Ensure **key information is provided**, even if it repeats the biosketch
- Commitment to academic research career
- Interactions, collaborations, Research achievements experience & potential
- Other relevant experience (leadership, teaching, mentoring)



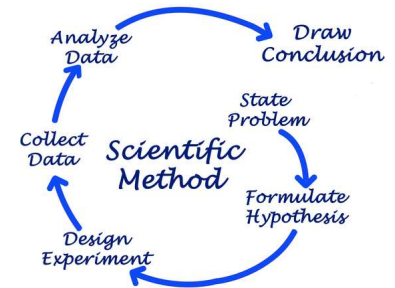
Specific Aims of the Project

- Test a central hypothesis & sub-hypotheses
- Solve a specific problem & address a critical barrier to progress in the field
- Challenge an existing paradigm or develop new technology
- All members of the review panel may read this page
- State the problem, why you can solve it, what's new & the hypothesis and sub-hypotheses related to each aim
- **End with why completing the aims will be a major contribution to the biomedical field or clinical practice and to your career development**
- A summary figure helps (now immediately after not in the specific aims)!



A Few Tips on the Hypothesis

- Strong, testable hypotheses rather than simple advance in technology or ‘collecting’ information
- Aim 2 should still be doable/meaningful if aim 1 does not pan out
- Ask questions that prove or disprove a hypothesis rather than use a method to search for a problem or simply collect information
- Methods are the means to perform your experiments. Your experimental results & appropriate statistical analyses will prove or disprove your hypothesis
- The hypothesis must be testable during the K award & with the level of available resources



Research Strategy

1. Significance:

- The importance of the problem you are trying to solve
- How your study & anticipated results will improve scientific knowledge, technical capability, or clinical practice in one or more fields
- How existing concepts, methods, technologies, treatments, or interventions may be impacted if the proposed aims are achieved

2. Innovation:

- How your proposed research will challenge or improve current research or clinical practice paradigms
- Novel theoretical concepts, approaches, methodologies, or interventions that may be developed or used
- Advantages over existing approaches, methodologies, instrumentation, or interventions



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Research Strategy

3. Approach:

- Methods & analyses to test the hypotheses and accomplish the specific aims (attention to positive & negative controls or randomization where appropriate).
- Benchmarks for success anticipated to achieve the aims.
- Potential problems & alternative strategies.
- For early stages of development, describe strategies to establish feasibility & manage high-risk aspects of the proposed work.
- Rigorous experimental design, power calculations, sufficient N, biological variables, appropriate statistical tests & authentication of reagents.



Additional Review Criteria & Review Considerations

Additional Review Criteria:

- Study Timeline for Clinical Trials
- Protection of Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards

Additional Review Considerations:

- Training in the Responsible Conduct of Research
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support



Rigor in K Award Application and Review

Element of Rigor	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact?
<i>Scientific Premise</i>	Research Strategy	Significance	N/A	Yes
<i>Scientific Rigor</i>		Approach	N/A	Yes
<i>Consideration of Relevant Biological Variables Such as Sex</i>		Approach	N/A	Yes
<i>Authentication of Key Biological and/or Chemical Resources</i>	New Attachment	N/A	Adequate or Inadequate	No



ORCID iD Requirement for Trainees, Fellows & Career Development (K) Appointees or Awardees: NOT-OD-19-109

- To enhance career tracking, NIH will require **O**pen **R**esearcher & **C**ontributor **I**dentifiers (ORCID iDs) for trainees, fellows & career development (K) appointees/awardees, beginning in FY 2020
- Required as part of the ***appointment*** process for trainees, scholars, and participants supported by the following activities, ***beginning in October 2019:***
 - T15, T32, T34, T35, T37, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, RL9
- Required at the time of ***application*** for fellowship and career development (K) awards, beginning with ***receipt dates after January 25, 2020:***
 - F05, F30, F31, F32, F33, F37, F38, F99/K00, FI2, K01, K02, K05, K07, K08, K18, K22, K23, K24, K25, K26, K38, K43, K76, K99/R00

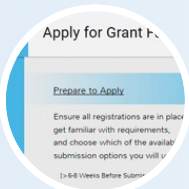
https://era.nih.gov/erahelp/commons/PPF_Help/8_2_orcid.htm



About Grants



Grants Basics



Grants Process Overview



Plan Your Application



How to Apply



Receipt & Referral



Peer Review



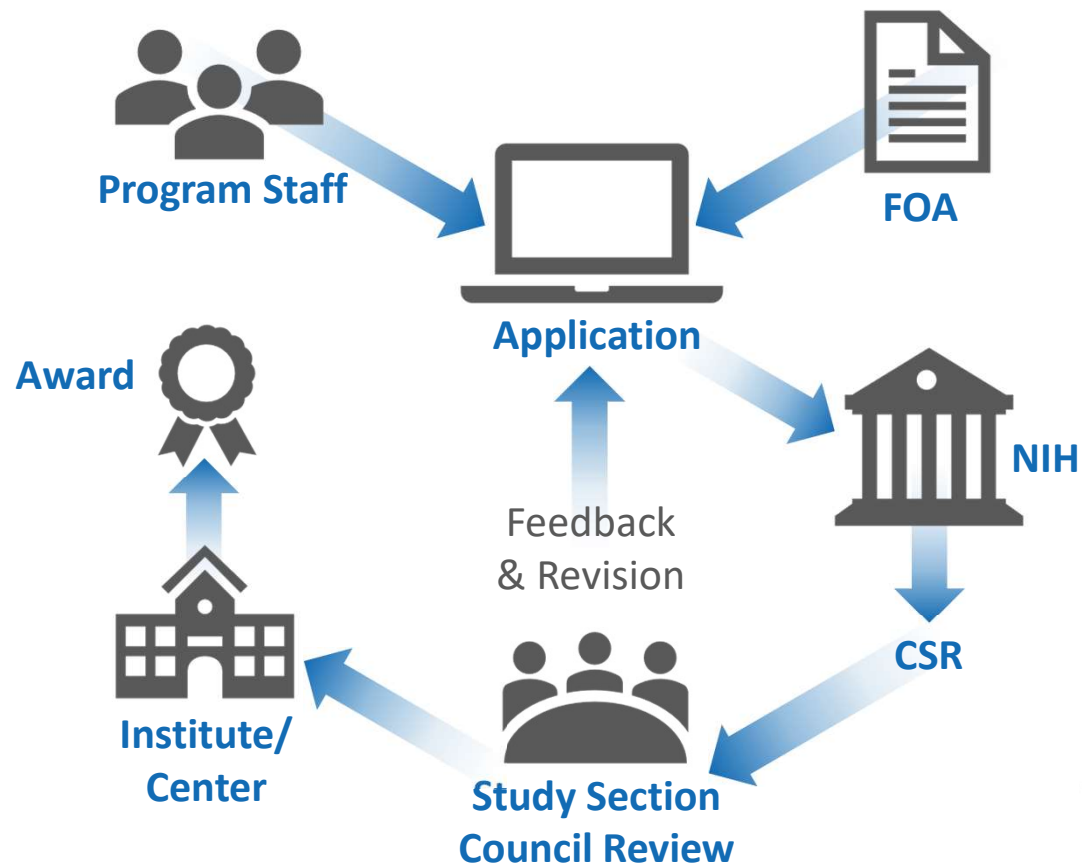
Pre-Award Process



Post-Award Monitoring and Reporting



Brief Overview of Grant Process



Diversity Supplement

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

- Support candidates from diverse diverse backgrounds, including those from underrepresented groups, who “wish to develop research capabilities...participate in...career development experiences”
- Support many career stages from undergraduate to faculty
- **Could be a bridge to a K for postdoctoral researchers or early stage faculty**
- Add to ongoing research & career development
- Expectation of a subsequent application for NIH support
- Enhance workforce diversity

PA-20-222: <https://grants.nih.gov/grants/guide/pa-files/PA-20-222.html>.

- Administratively reviewed by the Institute or Center (IC) funding the original grant
 - Note: different ICs have different deadlines and policies
 - https://grants.nih.gov/grants/guide/contacts/Diversity-Supp_contacts.html

