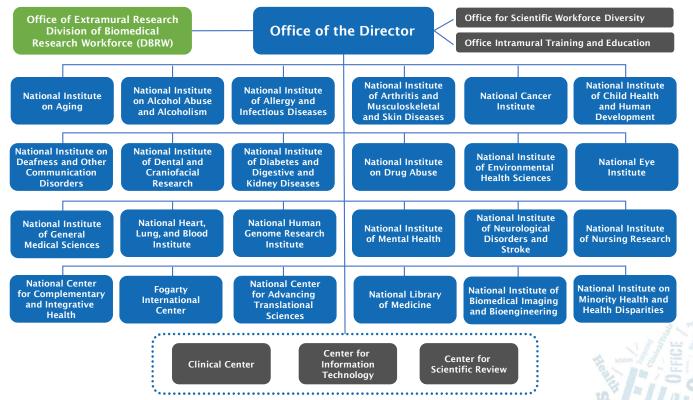
Writing an Effective K Application

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Office of the Director
National Institutes of Health



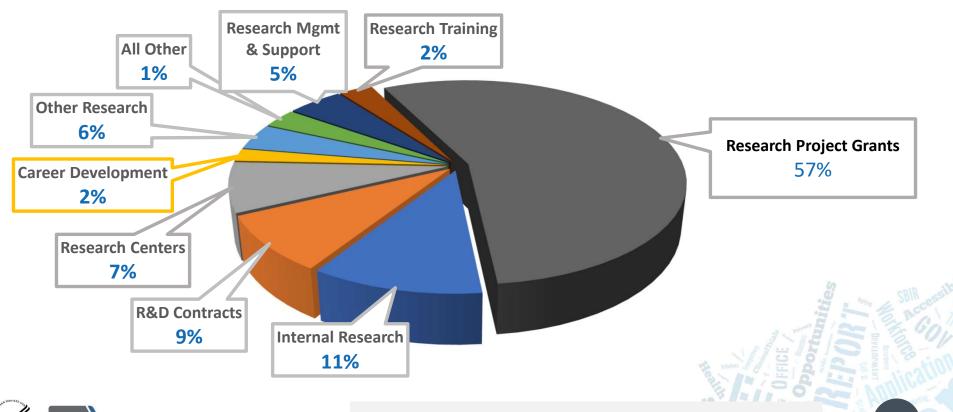
NIH includes 27 Institutes and Centers







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







Postdoctoral and Early Research Career Training

Graduate/ Clinical Training

Postdoctoral Training/ Clinical Residency Early Research Career

Established Investigator



- K25 is currently to support career development of investigators with quantitative/engineering backgrounds in biomedical research
- New K25 to provide biomedical researchers with quantitative skills is under discussion

Loan Repayment Programs https://www.lrp.nih.gov/

Diversity Supplements: PA-20-222







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.

Mentored Patient-Oriented Research Career Development Award

To provide support for the career development of clinically trained profession

K23

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)
- <u>PA-20-205</u> (K23; 19 IC)

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

Permit <u>Basic</u> <u>Experimental Studies</u> with Humans (BESH)

- <u>PA-20-191</u> (K01; 9 IC)
- PA-20-201 (K08; 13 IC)
- <u>PA-20-204</u> (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







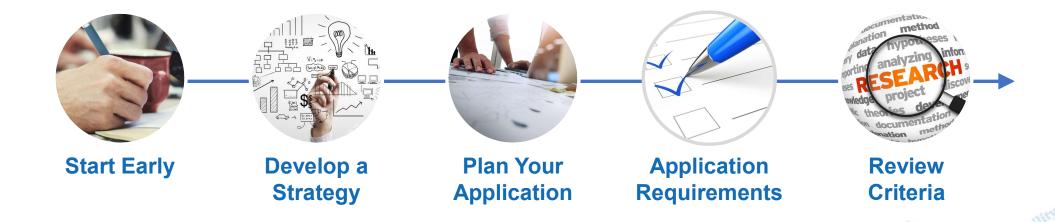


RECEIPT DATE	REVIEW	COUNCIL	AWARD DATE
Feb 12 Resubmission Mar 12	Jun/July	October	December
Jun 12 Resubmission Jul 12	Oct/Nov	January	April
Oct 12 Resubmission Nov 12	Feb/Mar	May	July





Writing an Effective K Application







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)







Develop a Strategy

- Assess your career situation and needs. Is there added value to a K award? Why not another funding mechanism?
- Check which NIH Institute or Center (IC) funds
 K awards in your research area
- Schedule a phone call with an NIH Program
 Officer to discuss & confirm that your research
 area, training needs & career development
 plans fit with the IC.
- Assess the field & the competition. See what is being funded by NIH: Research Portfolio Online Reporting Tools (RePORT: https://report.nih.gov)

- Identify mentor(s) and collaborators
- Discuss with them your plans, project & career development needs early to be sure they are on board
- Consider your strengths & areas for growth
- Can you fill any gaps & gain essential experiences with proposed mentor, collaborators or consultants?
- Identify essential resources & support needed & consider if this is available within your organization – or must be obtained elsewhere





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







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)







Career Goals & Objectives of the K Award

- New or enhanced research skills you will gain
- Other activities to enhance your research career, e.g. courses, workshops, techniques, teaching, mentoring (including 'soft skills' management, leadership)
- If you have changed research direction, discuss the reasons & justify how it will enhance research career development
- Provide a career development timeline, including plans to apply for subsequent grant support
- Career development can include a visit to another laboratory, to learn new technologies or approaches (network for the future!)







Sponsor/Mentor(s), Collaborators, Consultants

- Primary/Key Sponsor/Mentor(s) must explain how they will tangibly contribute to the applicant's career development
- Discuss research & career development activities:
 - Regular interactions with applicant, how interactions & proposed activities advance applicant's research and career
- Document sources/amounts of anticipated support for the applicant's research project
- Mentor(s) should discuss the plans for transitioning the candidate to independence by the end of the K award & convey clear support for the pathway to independence
- Provide details of previous experience as a mentor & outcomes of mentees







Institutional Environment & Commitment

- Document a strong, well-established research program related to the candidate's interests
- Experienced faculty, facilities & resources
- Opportunities for intellectual interactions, e.g., journal clubs, seminars & presentations
- Research Centers or Program Projects which may provide resources & interactions to promote candidate's success
- Commitment to the candidate's career development
- Adequate office space, lab space, time & support to the candidate for the period of K award



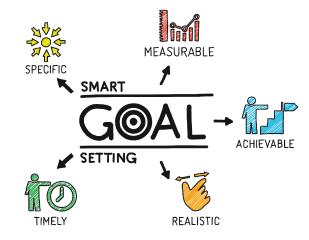




Specific Aims of the Project

- 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







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.







Career Award Scored Review Criteria

1. Candidate:

- Research, academic and/or clinical record
- Commitment & potential to develop as an independent & productive researcher
- Quality of letters of reference (referees should know you!)

2. Career Development Plan, Goals, Objectives:

- Contribute substantially to the scientific development of candidate
- Content, scope, phasing, & duration of the plan in the context of prior experience







Career Award Scored Review Criteria

3. Research Plan:

- Scientific & technical merit of the research question, design & methodology
- Strong premise, rigorous experimental design & statistical analyses, unbiased approach, addresses relevant biological variables
- Relevance of the proposed research to the candidate's career objectives
- Is the research plan appropriate to the stage of research development & developing the research skills described in the career development plan?





Career Award Scored Review Criteria

4. Mentor(s), Consultants(s), Collaborator(s):

- Qualifications, funding, & statement by Mentor(s), Collaborators, and/or Consultants
- Clear commitment & plan for career development & pathway to independence
- Mentors & collaborators must have real roles, i.e. be clearly involved & have the time to commit

5. Environment and Institutional Commitment to the Candidate:

- Assurance that minimum 75% effort will be devoted to research & related activities
- Capable faculty & research facilities
- Assurance that the candidate is considered an integral part of the institutional research program







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?
Scientific Premise	Research Strategy	Significance	N/A	Yes
Scientific Rigor		Approach	N/A	Yes
Consideration of Relevant Biological Variables Such as Sex		Approach	N/A	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	N/A	Adequate or Inadequate	No





THANK YOU! QUESTIONS?

Keep the Joy in Research
Writing a Grant is Fun (really!)
Trainees and Mentees Provide a
Scientific Family Forever

Websites: https://grants.nih.gov/grants/oer.htm

Contact us: NIHTrain@mail.nih.gov





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

- To enhance career tracking, NIH will require <u>Open Researcher</u>
 <u>Contributor Identifiers</u> (ORCID iDs) for trainees, fellows & career development (K) appointees/awardees, beginning in FY 2020
- Required as part of the <u>appointment</u> process for trainees, scholars, and participants supported by the following activities, <u>beginning in October 2019</u>:
 - T15, T32, T34, T35, T37, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, RL9
- Required at the time of <u>application</u> 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



Receipt & Referral



Grants Process Overview



Peer Review



Plan Your Application



Pre-Award Process



How to Apply



Post-Award Monitoring and Reporting





K-Awardees or Appointees

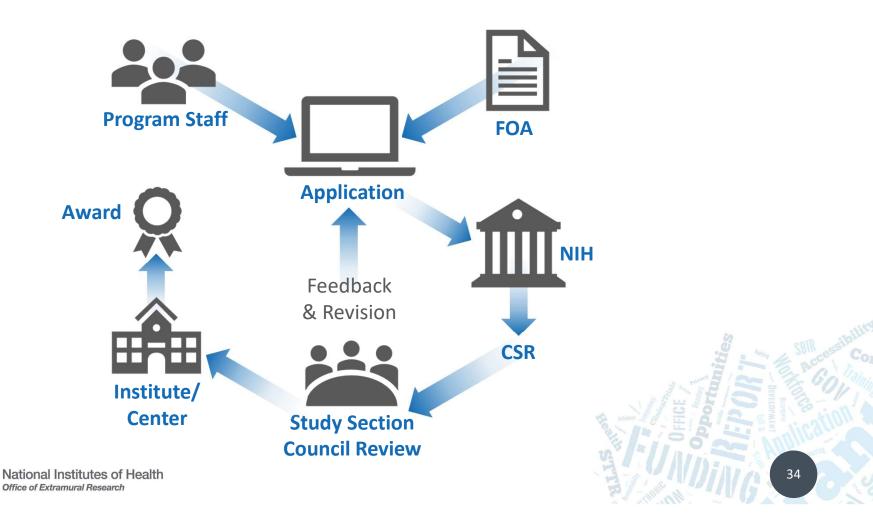
- Must be citizens, non-citizen nationals, or lawfully admitted for permanent residence in the U.S. at the time of award/appointment (except for some K99-R00 awards)
- Must have a research or clinical doctoral degree from an accredited domestic (U.S.) or foreign institution
- Must have a full-time appointment at the institution, and commit a minimum of 9 person-months (75% of full-time professional effort) to research career development
- Cannot be former PD/PIs on major NIH research grants (e.g. R01 equivalent), or other individual career development (K) awards.
- Appointees to institutional K12/KL2 awardees are eligible to apply for individual K

K-Kiosk: https://researchtraining.nih.gov/programs/career-development





Brief Overview of Grant Process



Responsible Conduct of Research

- Discuss the five components outlined in the NIH Policy:
 - (1) Format, (1) Subject Matter,
 - (3) Faculty Participation, (4) Duration, and (5) Frequency
- Is the plan appropriate for your career stage, and will it enhance your understanding of ethical issues related to research?
- Document any prior participation in RCR training and/or propose plans to receive additional instruction





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



