NIH K99/R00 Pathway to Independence Funding Program - Overview -

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Dept. of Medicine
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Course: “Funding and Grantsmanship for Research and Career Development Activities”
http://grantscourse.columbia.edu/
Topics to be Discussed

- National Institutes of Health
- K99/R00 Career Transition Funding Mechanism - Overview
- K99/R00 Career Transition Funding Mechanism - Application Components
- NIH Grant Review
  - Process
  - Scoring System
  - K99/R00 Specific Review Criteria
- Approaches for Competitive Applications
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- **National Institutes of Health**
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Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

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TOTAL NIH BUDGET AUTHORITY: FY 2015 ENACTED

- Research Project Grants: $16,333,000,000 (55%)
- Intramural Research: $3,426,000,000 (12%)
- Research Mgmt & Support: $1,561,000,000 (5%)
- R&D Contracts: $2,899,000,000 (10%)
- Research Training: $762,000,000 (3%)
- Other Research Grants: $1,844,000,000 (6%)
- Research Centers: $2,699,000,000 (9%)
- All Other: $72,000,000 (0%)
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  - K99/R00 Career Transition Funding Mechanism - Application Components
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Timeline of Funding for Junior Investigators

Graduate School
- Individual Fellowship Training Grant
- Mentor’s Research Grant

Post-doctoral Years
- Individual Post-doc Fellowship
- Institutional T32 Post-doc Training Grant slot
- Mentor’s Research Grant

Instructor/Assistant Professor

Career Transition Awards
Timeline of Funding for Junior Investigators

Short term Training
Medical School
Year-long Enhancement Programs
MD/PhD Fellowship or Institutional T32

Research Support
Internship/Residency

Fellowship – Research Years
Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot

Instructor/Assistant Professor
Career Transition Awards
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R01 Research Award

Independent Investigator

Funds research project
- Salaries of PI and other research personnel
- Supplies, reagents, etc
- Animal costs
- Patient care costs
- Core facilities
- Page charges for publications

Multi-Year (4yrs – 5yrs)
Renewable (e.g. original grant + 2 renewals = 15yrs)
Pathway to Independence Award

- Career Transition Award \((K99/R00)\)
- No citizenship requirement
- Applicants must:
  - Have earned a clinical or research doctorate
  - Have no more than 4 years of research experience since completing the requirements of the doctoral degree
  - Have not been the principal investigator of an NIH research grant (e.g., R01, R03, R21), career development award (e.g., K01, K07, K08, K23, K25), other peer-reviewed NIH or non-NIH research grant over $100,000 direct costs per year, or have been a project leader on a sub-project of a program project (P01) or a center (P50) grant.

1-2 years as a mentored K award for “post-docs”

- Funding level is Institute-specific
  - Salary and Research Support
- 75% effort

3 years as a Research award for independent investigators

- Total/year:=$249,000 (salary and research expenses)
  - D.C. + institution’s I.C. rate
- Must have an independent research position
Research Career Development Awards

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<table>
<thead>
<tr>
<th>NHLBI</th>
<th>Year</th>
<th>Category</th>
<th>Type</th>
<th>Success Rate</th>
<th>Awards - Number</th>
<th>Applications - Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLBI</td>
<td>2012</td>
<td>Success Rate</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 30%</td>
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<td>2012</td>
<td>Awards - Number</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 39%</td>
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<td>NHLBI</td>
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<td>Applications - Number</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 130%</td>
<td></td>
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<tr>
<td>NHLBI</td>
<td>2013</td>
<td>Success Rate</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 112%</td>
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<tr>
<td>NHLBI</td>
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<td>Awards - Number</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 22%</td>
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<tr>
<td>NHLBI</td>
<td>2013</td>
<td>Applications - Number</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 25%</td>
<td></td>
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<tr>
<td>NHLBI</td>
<td>2014</td>
<td>Awards - Number</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 40%</td>
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</tr>
<tr>
<td>NHLBI</td>
<td>2014</td>
<td>Success Rate</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 24.1%</td>
<td></td>
</tr>
<tr>
<td>NHLBI</td>
<td>2014</td>
<td>Applications - Number</td>
<td>Research Grants - Career Awards</td>
<td>K99</td>
<td>New 166</td>
<td></td>
</tr>
</tbody>
</table>


Topics to be Discussed

- National Institutes of Health
- K99/R00 Career Transition Funding Mechanism - Overview
- **K99/R00 Career Transition Funding Mechanism** - Application Components
- NIH Grant Review
  - Process
  - Scoring System
  - K99/R00 Specific Review Criteria
- Approaches for Competitive Applications

The purpose of the NIH Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented, NIH-supported, independent investigators. This program is designed to facilitate a timely transition of outstanding postdoctoral researchers with a research and/or clinical doctorate degree from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions. The program will provide independent NIH research support during this transition in order to help awardees to launch competitive, independent research careers.

Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific programmatic and budgetary information. Table of IC-Specific Information, Requirements and Staff Contacts.

5. NIH should establish a new physician-scientist-specific granting mechanism to facilitate the transition from training to independence. This program should be similar to the K99/R00 program whose funding currently goes almost exclusively to individuals holding a PhD degree. This new grant program could serve either as a replacement or transition from existing K Awards for physician scientists, and should provide a longer period of support, potentially lengthening the R00 phase to 5 years (with an interim staff review at year 3). This new grant series, as well as K and all other training awards, should rigorously enforce protected time of at least 75 percent effort and provide sufficient salary support to make that possible.
Additional Information for Physician-Scientists

For the purposes of this program, physician-scientists include individuals with an MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees who devote the majority of their time to biomedical research. The K99/R00 is intended for those physician-scientists who already have substantial research training and are dedicated to initiating a strong, research-intensive career as physician-scientists. The K99/R00 program is designed to facilitate a timely transition of outstanding physician-scientists from mentored, research positions to independent, tenure-track or equivalent faculty positions, and to provide independent NIH research support during the transition. Individuals who need a longer period of mentored career development before they are prepared to begin the transition to research independence should consider the K08 or K23 program (see: K Kiosk).
CAREER DEVELOPMENT INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES
SF424 (R&R) APPLICATION PACKAGES

Guidance developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)
<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Page Limits * (if different from FOA, FOA supersedes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Resubmission or Revision Application (when applicable)</td>
<td>1</td>
</tr>
<tr>
<td>Candidate Information and Goals for Career Development and Research Strategy</td>
<td>12 (for both attachments combined)</td>
</tr>
<tr>
<td>Specific Aims</td>
<td>1</td>
</tr>
<tr>
<td>Training in the Responsible Conduct of Research</td>
<td>1</td>
</tr>
<tr>
<td>Candidate's Plan to Provide Mentoring (Include only when required by the specific FOA, e.g., K24 and K05)</td>
<td>6</td>
</tr>
<tr>
<td>Plans and Statements of Mentor and Co-mentor(s)</td>
<td>6</td>
</tr>
<tr>
<td>Letters of Support from Collaborators, Contributors, and Consultants</td>
<td>6</td>
</tr>
<tr>
<td>Description of Institutional Environment</td>
<td>1</td>
</tr>
<tr>
<td>Institutional Commitment to Candidate's Research Career Development</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>12 pages total</td>
</tr>
<tr>
<td>Candidate Section</td>
<td>1 page</td>
</tr>
<tr>
<td>Research Plan Section</td>
<td>12 pages total</td>
</tr>
<tr>
<td>Other Candidate Information Section</td>
<td>1 page</td>
</tr>
<tr>
<td>Mentor, Co-Mentor, Consultant, Collaborators Section</td>
<td>6 pages</td>
</tr>
<tr>
<td>Environment and Institutional Commitment to Candidate Section</td>
<td>1 page</td>
</tr>
</tbody>
</table>

1 + 12 Pages Combined

- **Candidate Information**
  - Section 2

- **Research Plan**
  - 3. Specific Aims (1 page)
  - 4. Research Strategy
2. Candidate Information

- Candidate’s Background
- Career Goals and Objectives: Scientific Biography
- Career Development/Training Activities During Award Period
Candidate’s Background

- Personal background for this career path
- Other training experiences
- Other research experiences
- Reasons for basic, clinical, translational, behavioral, multidisciplinary research, relevant publications
Career Goals and Objectives

- Unique expertise/Scientific history
  - Previous work
    - Consistent themes, or
    - Why research interests have changed direction
  - e.g. Joint appointments, Multidisciplinary

- Skills that are lacking
  - Identification of specific modules to address areas for growth, provides justification of award
  - Role of specific Mentor(s) and Advisory Committee member(s)
Justify award

- Fits into past and future research career

Short-term Career Goals

- Timeline for funded period

**Year 1:** Preliminary data

**Year 2:** Submit publications (possible journals),
   Presentations at national meetings (examples),
   Formulation of project to submit for R00 application

**Year 3-5:** By the end of the funded period, applicant will be an independent investigator near to R01 funding
Long-term Career Goals

Scientific goals
- Basic science, translational, clinical, epidemiologic, behavioral

Mentoring goals
- How mentoring has been important to you
- Previous/current mentoring responsibilities

Networking goals
- Multidisciplinary activities, grants, etc
Career Development/Training Activities During Award Period

- Review of didactic courses, training, and research experiences to date
- New research skills/ knowledge required
- Identification of training modules required to fill gaps in knowledge in order to reach long term goals
  - Rational for each of the modules

New Section on each Module

- **Reason for module**
- **Specific Description of each “Mode of Learning”**
  - Role of Mentors and Advisors
  - Specific courses, workshops, and other didactics
  - Details on research meetings

- **Module: Career skills**
  - Grantsmanship
  - Becoming a mentor
  - Laboratory management

Table: Career Development/Training Activities During Award Period
<table>
<thead>
<tr>
<th>Module</th>
<th>Mentor(s)</th>
<th>Mode of learning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Area (1-3)</td>
<td>Specific names</td>
<td>Coursework (completed and new) 1-on-1 meetings (schedule? e.g. weekly) Guided readings Research meetings (schedule? e.g. weekly) Applied training Clinical experience</td>
</tr>
<tr>
<td>Career skills</td>
<td>All mentors</td>
<td>Improving communication skills Grant writing course Professional workshops/seminars Collaborations Abstracts and manuscripts Small grant application submission</td>
</tr>
<tr>
<td>Dissemination of Research Results</td>
<td></td>
<td>Supervising technical support personnel, organizing lab meetings, journal clubs</td>
</tr>
<tr>
<td>Research management</td>
<td></td>
<td>e.g. training new lab members, undergraduate, summer students</td>
</tr>
<tr>
<td>Mentorship</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mentors/Advisory Committee

- Scientific area per mentor/committee member
- Schedule of meetings

<table>
<thead>
<tr>
<th>Faculty Member</th>
<th>Role</th>
<th>Area of Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name (Title)</td>
<td>Mentor</td>
<td></td>
</tr>
<tr>
<td>Name (Title)</td>
<td>Co-Mentor</td>
<td></td>
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<tr>
<td>Name (Title)</td>
<td>Advisory Board Member</td>
<td></td>
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<tr>
<td>Name (Title)</td>
<td>Advisory Board Member</td>
<td></td>
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<tr>
<td>Name (Title)</td>
<td>Advisory Board Member</td>
<td></td>
</tr>
<tr>
<td>Name (Title)</td>
<td>Collaborator</td>
<td></td>
</tr>
<tr>
<td>Name (Title)</td>
<td>Consultant</td>
<td></td>
</tr>
</tbody>
</table>

Summary of coursework

- List previous relevant coursework
- Proposed coursework
  - Course number and description
  - Include courses on grant writing and responsible conduct of research
- Additional didactic activities
  - e.g. Those offered by professional societies, workshops, symposiums
Clinical and/or Teaching activities

- Be specific, mention hrs. per week, restate % of time dedicated to research

Percentage of time for each activity

Timetable
<table>
<thead>
<tr>
<th>Career Development Activities</th>
<th>K99</th>
<th>R00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mentorship</td>
<td></td>
<td></td>
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<tr>
<td>Mentor (name) – frequency (e.g. weekly) of individual meetings, frequency of lab meetings, frequency and listing of specific journal clubs, seminars, and other recurring relevant programs</td>
<td>X</td>
<td></td>
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<tr>
<td>Co-Mentor (name) – frequency (e.g. weekly) of individual meetings, frequency of lab meetings, frequency and listing of journal clubs, seminars, and other recurring relevant programs</td>
<td>X</td>
<td></td>
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<tr>
<td>Advisory Group – frequency (e.g. quarterly) of meetings</td>
<td>X</td>
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</table>

<table>
<thead>
<tr>
<th>Career Development Activities</th>
<th>K99</th>
<th>R00</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year 1</td>
<td>Year 2</td>
</tr>
<tr>
<td><strong>Experimental Training</strong></td>
<td></td>
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<tr>
<td>Mentor (name) – Specific area of research and/or methodology</td>
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<td>X</td>
</tr>
<tr>
<td>Co-Mentor (name) – Specific area of research and/or methodology</td>
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<td>X</td>
</tr>
<tr>
<td>Co-Investigator 1 (name) – Specific area of research and/or methodology</td>
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<tr>
<td>Co-Investigator 2 (name) – Specific area of research and/or methodology</td>
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<tr>
<td>Collaborator 1 (name) – Specific area of research and/or methodology</td>
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<td>X</td>
</tr>
<tr>
<td>Collaborator 2 (name) – Specific area of research and/or methodology</td>
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<tr>
<td><strong>Formal Coursework – e.g. Graduate School, School of Public Health</strong></td>
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<tr>
<td>Course #1: Specific Course # / Formal Title</td>
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<tr>
<td>Course #1: Specific Course # / Formal Title</td>
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</tr>
<tr>
<td>Course #3: Specific Course # / Formal Title</td>
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<tr>
<td>Responsible Conduct of Research</td>
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## Career Development Activities

### Workshops & Additional Training Programs

<table>
<thead>
<tr>
<th>Activity</th>
<th>K99 Year 1</th>
<th>K99 Year 2</th>
<th>R00 Year 3</th>
<th>R00 Year 4</th>
<th>R00 Year 5</th>
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<tbody>
<tr>
<td>Cold Spring Harbor Course on......</td>
<td>X</td>
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<tr>
<td>Woods Hole Workshop on.....</td>
<td>X</td>
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<tr>
<td>American Association for.... Junior Investigators Training on.....</td>
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<tr>
<td>CTSA “K to R” Program</td>
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<td>X</td>
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<tr>
<td>IRB 101 Course</td>
<td></td>
<td>X</td>
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<tr>
<td>NYAS Science Alliance Sessions on......</td>
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</table>

### Scientific Conferences - Communication Skills (Oral / Poster Presentations)

<table>
<thead>
<tr>
<th>Activity</th>
<th>K99 Year 1</th>
<th>K99 Year 2</th>
<th>R00 Year 3</th>
<th>R00 Year 4</th>
<th>R00 Year 5</th>
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<tbody>
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<td>Symposium of the NY Academy of....(annual)</td>
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<td>Society of...... (biannual)</td>
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<td>Career Development Activities</td>
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<td>R00</td>
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<tr>
<td>Mentoring Skills</td>
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<tr>
<td>Students (summer, undergraduate, medical)</td>
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<td>Communication Skills (Written)</td>
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<td>Preparation of manuscripts for peer reviewed journals</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Grant Writing</td>
<td></td>
<td></td>
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<tr>
<td>Pilot award for junior investigator (to supplement K award)</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Center for...... award for new investigators</td>
<td></td>
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<td>X</td>
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<tr>
<td>R01 preparation and submission (on research funded by K award)</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
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</tr>
</tbody>
</table>
6. Training in the Responsible Conduct of Research

- Format, Subject Matter, Faculty Participation, Duration, and Frequency of Instruction
- Role of Mentor
- Prior instruction in RCR
- Once every four years requirement
- Don’t do the minimum
- Additional IRB-related programs?

http://grants.nih.gov/training/responsibleconduct.htm

No more than 1 page
8. Plans and Statements of Mentor and Co-Mentor(s)

- Mentor’s Assessment of the Candidate
- Mentor’s Research and Career Development Plans for the Candidate
  - Research
  - Developmental activities
    - Seminars, scientific meetings, presentations, becoming a mentor, RCR
- Expectations for Publications

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- What Aspect of the Research will the Candidate be Allowed to Take to Start their Own Independent Research Career

- Mentor’s Plans for Providing Guidance and Counseling
  - How this will promote candidate’s development

- Plan for Candidate’s Transition from Mentored Stage to Independent Investigator

- Candidate’s Additional Responsibilities
  - Courses, seminars, lab meetings
  - Teaching, clinical, administrative
- **Source of Support for Candidate’s Research Project**
  - Grants
  - Core/shared facilities
  - Technical support

- **Previous Experience as a Mentor**
  - Mentor’s Past and Current Trainees [table]
    - Name, position (e.g. graduate student, post-doctoral fellow, junior faculty) and date when mentored by sponsor, mentee’s current position (title and institution), mentee’s awards/ grants

- **No more than 6 pages**
9. Letters of Support from Collaborators, Contributors, and Consultants

- Advisory Committee
  - Purpose
    - Reviews research progress, publications, R01 submission, career development activities, didactic program
    - Provides scientific guidance
    - Documents meetings with an annual report
  - Name, title, and short paragraph on each member
  - Each should provide a letter and Biosketch
Collaborators and Consultants

- Name, title, and short paragraph on each individual
- Each should provide a letter and Biosketch

Director of Core Facility

No more than 6 pages
Environment and Institutional Commitment to the Candidate

- 10. Description of Institutional Environment
- 11. Institutional Commitment to the Candidate’s Research Career Development
Environment and Institutional Commitment to the Candidate

10. Description of Institutional Environment

- Information relevant to Candidate’s research and career development activities
  - Institution, Dept/Division
  - Other institutions, schools, centers, shared resources, core facilities, CTSA, etc.
  - Degree programs, courses, seminars
  - Institution/Dept’s formal mentoring program

- No more than 1 page
11. Institutional Commitment to the Candidate’s Research Career Development

- Letter from Dept. Chair/Institute Director
  - Specifics on protected time
  - Statement that appointment and salary are not contingent on award
  - Statement on availability of research resources, personnel, office space, etc. required for project
  - Statement that sponsors will be able to provide time and support for mentoring responsibilities
  - Signed and dated on letterhead stationery

No more than 1 page
Letters of Reference: 3-5

- From individuals not directly involved in the application or proposed research project, not mentor
- Familiar with candidate’s qualifications, training, and interests
- Should address candidate's competence, professional training and qualifications, and potential to develop into an independent investigator
- Where possible, not from the candidate's current department or organization
- Submitted electronically through NIH Commons

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R&R Other Project Information:

10. Facilities & Other Resources

- Facilities to be used for the conduct of the proposed research
  - Laboratory
  - Animal
  - Computer
  - Office
  - Clinical
  - Other: Core facilities [e.g. research pharmacy, biostatistics, technical cores (microscopy, biomarkers)]

- Discuss ways in which the proposed studies will benefit from unique features of the scientific environment, subject populations, or unique collaborative arrangements.
R&R Other Project Information:

10. Facilities & Other Resources

Career Development Resources - also mentioned in “main body” of grant (table) and Mentor’s section

- Career development programs
  - Institution
  - Department/Institute
  - Professional societies

- Formal degree programs and other didactics
  - Scientific courses: e.g., Statistics
  - Career Development course: e.g., Funding & Grantsmanship

- Workshops, webinars, other training programs
**NIH K99/R00 Sites of Interest**

- **Funding Announcement: NIH Pathway to Independence Award (Parent K99/R00)**

- **IC-Specific Information, Requirements and Contacts**

- **K99/R00 FAQ’s**
  [http://grants.nih.gov/grants/new_investigators/QsandAs.htm](http://grants.nih.gov/grants/new_investigators/QsandAs.htm)

- **Application Page Limits**
NIH K99/R00 Sites of Interest

- Guidance for K applications (Forms-D)

- K application Review criteria (updated)
  https://grants.nih.gov/grants/policy/review_templates.htm

- Instructions to Provide to Referees and Reference Letter Submission Process

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Topics to be Discussed

- National Institutes of Health
- K99/R00 Career Transition Funding Mechanism - Overview
- K99/R00 Career Transition Funding Mechanism - Application Components

- NIH Grant Review
  - Process
  - Scoring System
  - K99/R00 Specific Review Criteria

- Approaches for Competitive Applications

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## Application Due Dates

<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</th>
<th>Application Instructions</th>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Research Grants</td>
<td>SF424 (R&amp;R)</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td>U01</td>
<td>Research Grants - Cooperative Agreements</td>
<td>SF424 (R&amp;R)</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td><strong>K series</strong></td>
<td>Research Career Development</td>
<td>SF424 (R&amp;R)</td>
<td>February 12</td>
<td>June 12</td>
<td>October 12</td>
</tr>
<tr>
<td>R03, R21, R33, R21/R33, R34, R36</td>
<td>Other Research Grants</td>
<td>SF424 (R&amp;R)</td>
<td>February 16</td>
<td>June 16</td>
<td>October 16</td>
</tr>
<tr>
<td>F Series Fellowships</td>
<td>Individual National Research Service Awards (Standard) (see NRSA Training Page)</td>
<td>SF424 (R&amp;R)</td>
<td>April 8</td>
<td>August 8</td>
<td>December 8</td>
</tr>
<tr>
<td>F31 Diversity Fellowships</td>
<td>Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research (see NRSA Training Page)</td>
<td>SF424 (R&amp;R)</td>
<td>April 13</td>
<td>August 13</td>
<td>December 13</td>
</tr>
</tbody>
</table>

All Activity Codes Cited Above new, renewal, resubmission, revision

**AIDS and AIDS-Related Applications**

NOTE: See Key Dates section of funding opportunity announcement to determine if AIDS dates apply.

<table>
<thead>
<tr>
<th>Based on Activity Code</th>
<th>May 7</th>
<th>September 7</th>
<th>January 7</th>
</tr>
</thead>
</table>

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

# Application Due Dates

<table>
<thead>
<tr>
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<th>Program Description</th>
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</tr>
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<tbody>
<tr>
<td>R01 renewal, resubmission, revision</td>
<td>Research Grants</td>
<td>SF424 (R&amp;R)</td>
<td>March 5</td>
<td>July 5</td>
<td>November 5</td>
</tr>
<tr>
<td>U01 renewal, resubmission, revision</td>
<td>Research Grants - Cooperative Agreements</td>
<td>SF424 (R&amp;R)</td>
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[http://grants.nih.gov/grants/funding/submissionschedule.htm](http://grants.nih.gov/grants/funding/submissionschedule.htm)

<table>
<thead>
<tr>
<th>Review and Award Cycles</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Merit Review</td>
<td>June - July</td>
<td>October - November</td>
<td>February - March</td>
</tr>
<tr>
<td>Advisory Council Round</td>
<td>August or October *</td>
<td>January</td>
<td>May</td>
</tr>
<tr>
<td>Earliest Project Start Date</td>
<td>September or December *</td>
<td>April</td>
<td>July</td>
</tr>
</tbody>
</table>

http://grants.nih.gov/grants/funding/submissionschedule.htm
**Overall Impact** Write a paragraph summarizing the factors that informed your Overall Impact score.
## NIH's Evaluation System

9-point rating scale (1=exceptional; 9=poor)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td></td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
<td>Strengths</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Weakeness</td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td></td>
</tr>
</tbody>
</table>


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<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

**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
Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications

Notice Number: NOT-OD-16-012

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.
## Reviewer Guidance on Rigor and Transparency: Research Project Grant and Mentored Career Development Applications

### OVERVIEW: MENTORED CAREER DEVELOPMENT AWARD (K) APPLICATIONS

<table>
<thead>
<tr>
<th>Element of Rigor and Transparency</th>
<th>Section of Application</th>
<th>Criterion Score</th>
<th>Additional Review Consideration</th>
<th>Contribute to Overall Impact Score?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Premise</td>
<td>Research Strategy</td>
<td>Research Plan</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td>Scientific Rigor</td>
<td>Research Strategy</td>
<td>Research Plan</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td>Consideration of Relevant Biological Variables, such as Sex</td>
<td>Research Strategy</td>
<td>Research Plan</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td>Authentication of Key Biological and/or Chemical Resources</td>
<td>New Attachment</td>
<td>NA</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Topics to be Discussed

- National Institutes of Health
- K99/R00 Career Transition Funding Mechanism - Overview
- K99/R00 Career Transition Funding Mechanism - Application Components
- NIH Grant Review
  - Process
  - Scoring System
  - K99/R00 Specific Review Criteria
- Approaches for Competitive Applications

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Approaches for Competitive Applications

- Identify Funding
- Prepare to Write the Grant Application
- Complete the Grant Application
Identify Funding

- Identify appropriate funding agencies
  - Government
  - Non-government

- Identify appropriate funding mechanisms
  - Research
  - Training

- Create a calendar of application deadlines for identified funding programs
Approaches for Competitive Applications

- Identify Funding
- Prepare to Complete the Grant Application
- Complete the Grant Application
It’s not the will to win, but the will to prepare to win that makes the difference.

Bear Bryant, University of Alabama
Prepare to Complete the Grant Application

- Speak with Agency Program Officer
- Speak with colleagues who are/were awardees
- Review funded applications if possible
- Review agency’s review criteria
- Identify what will make the application more competitive
  - Research and/or career development arrangements
  - Access to core facilities/research resources
- Strengthen “Preliminary Work/ Pilot Data”
- Who will write confidential letters of reference?

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Research and Career Development Arrangements

- Multiple Principle Investigators (research awards)
- Multiple Mentors (mentored awards)
- Advisors (mentored awards)
- Co-investigators/Collaborations
- Subcontracts to other institutions
- Multidisciplinary/Interdisciplinary

Prepare to Complete the Grant Application

- Identify and meet with Co-investigators, Collaborators, Consultants, Advisors
  - Identify roles and responsibilities
  - Administrative requirements
    (e.g. if other countries/institutions are involved)

- Identify necessary core facilities and other research resources

- Meet with research administrators

- Human subjects, lab animals, and any other regulatory issues?

Approaches for Competitive Applications

- Identify Funding
- Prepare to Complete the Grant Application
- Complete the Grant Application
Complete the Grant Application

- Review the application instructions
- Identify the different components
- Create a checklist
- Identify and delegate responsibilities for the different components
  - Technical/Scientific
  - Administrative – e.g. budget
  - Regulatory
  - Draft letters of collaboration/support

Complete the Grant Application

- Confirm page limits for each component
- Create a schedule for any required meetings
- Determine:
  - Shared computer drive/folders
  - Naming of files (dates?)
  - Track changes?
  - Font, margin, format of literature citation
- Set a **firm** time-line for each responsibility
  - Writing milestones
  - Absolute deadline date for final compilation

Complete the Grant Application

- Read instructions
- Never assume that reviewers “will know what you mean”
- Refer to literature thoroughly and thoughtfully
- Explicitly state the rationale of the proposed investigation
- Discuss “challenges” and how these will be addressed (e.g., alternate approaches)
- Include well-designed tables and figures
- Present an organized, lucid write-up
- Ask colleagues to review and comment

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# Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

<table>
<thead>
<tr>
<th>Benchmarks / Milestones</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of Specific Aim 1a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 1b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 2a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 2b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Elements of a Good Proposal

- Feasible
- Relevant
- Unique
- Innovative
- Clear
- Brief
- Consistent
Investigator

- Competent
- Enthusiastic
- Thorough
- Professional
Anticipate Questions
and
Answer them before
they are asked
Possible Problems Specific for Mentored Career Development Awards

Mentor

- Too many other responsibilities
  (e.g. administrative, clinical)
- Too many other mentees
  (e.g. students, post-docs)
- Not appropriate scientifically
- Too junior
- Limited experience as a mentor
- Limited funds to support proposed research

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Possible Problems Specific for Mentored Career Development Awards

**Institution**

- Limited scientific/technical resources
- Limited career development opportunities
- Limited opportunities for career advancement
Common Problems with Grant Applications from New Investigators

- Does not address/follow funding agency’s mission, specific instructions, budget limits, etc.
- Overly ambitious
- Not independent of previous mentor’s research
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- Unfocussed
- No or insufficient preliminary data
- Unrealistic budget
- Methodologies beyond the expertise of investigator or research team

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NIH: one round of applications
Pink Sheet: Reviewers’ Comments
Bell Curve of Reviewer’s Grant Applications

Definitely do not fund

Fine

Definitely fund

Great

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Poor Statistics
Research Resources not Adequately Described
Career Development/Research Training Plan not Comprehensive

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
All Components of the Application are as Strong as Possible
Good Luck!