Overview of the NIH Career Development Programs

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FY 2009 actual:
$823M (2.7%) - Training
$686M (2.3%) - Career
$1.509B (5%) - Combined

FY 2010 Budget: ~$31 Billion

Research Mgmt & Support: 5%
All Other: 2%
Other Research: 6%
Research Centers: 10%
R&D Contracts: 11%
Intramural Research: 10%
Research Training: 3%
Research Project Grants: 53%

NIH New Investigators Programs

- NRSA Individual and Institutional Training Awards
- Career Development Awards
- Pathways to Independence Award (K99/R00): facilitate receiving an R01 award earlier in an investigator's research career
- Fellowship and Career Award Review Criteria
- NIH Director's New Innovator Award
- NIH Loan Repayment Programs
- Enhancing Peer Review
**Training and Career Timetable**

**Approx. Stage of Research Training/Career Awards**

- **Pre-Bac**
  - Pre-Bac Institutional Training Grant (T34)

- **GRADUATE/ MEDICAL STUDENT**
  - Predoctoral Institutional Training Grant (T32)
  - Predoctoral Individual NRSA (F31)
  - Predoctoral Individual MD/PhD NRSA (F30)

- **POST DOCTORAL**
  - Postdoctoral Institutional Training Grant (T32)
  - Postdoctoral Individual NRSA (F32)
  - NIH Pathway to Independence (PI) Award (K99/R00)
  - Mentored Research Scientist Development Award (K01)
  - Mentored Clinical Scientist Development Award (K08)
  - Mentored Patient-Oriented RCDA (K23)
  - Mentored Quantitative RCDA (K25)

- **EARLY**
  - Independent Scientist Award (K02)

- **MIDDLE**
  - Midcareer Investigator Award in Patient-Oriented Research (K24)

- **SENIOR**
  - Senior Scientist Award (K05)

- **Small Grant (R03)**
- Research Project Grant (R01)
- Exploratory/Development Grant (R21)

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**Research Career Development Authority**

- Authorized by Sections 301 and 405 of PHS Act.
  - 42 U.S.C. 241 and 284; Regulations at 45 CFR 74 & 92
- K-Awards provide “protected time” to engage in research and enhance research capabilities.
- Early, mid, & senior level awards.
- Majority require 75% of full time research effort.
- Applicants must hold a research or health professional doctoral degree.
- U.S. citizenship or permanent residency required.
- 2 types of awards:
  - Individual, e.g. K01, K02, K08, K18, K22, K23, K24, K25, K99/R00
  - Institutional, e.g. K12, CTSA (KL2)
Career Development Award Eligibility

- U.S. Citizens, Non-Citizen Nationals, Permanent Residents (except K99/R00).
- Research doctoral degree (K01, K02), but some require clinical doctoral degree (K08, K23, K24).
- Must devote a minimum of 75% effort to research and career development activities. There are exceptions.
- Previous NIH Principal Investigators may be Ineligible.
- Principal Investigators on R03 or R21 are eligible to apply (except K99/R00).
- Principal Investigators on R01 or subproject Principal Investigators on a P01 are not eligible to apply.

Selected Career Development Awards

Individual Mentored:
- K01: Mentored Research Scientist Development Award
- K08: Mentored Clinical Scientist Development Award
- K23: Mentored Patient-Oriented Research Development Award
- K25: Mentored Quantitative Research Development Award
- K99/R00: NIH Pathway to Independence (PI) Award

Institutional Mentored:
- K12: Institutional Mentored Research Scientist Development Program

Individual Non-Mentored (Independent):
- K02: Independent Scientist Research Development Award
- K24: Mid-Career Patient-Oriented Research Development Award
Mentored Research Scientist Career (K01)

- Provides an intensive, mentored research experience for a period of up to 5 years.
- Minimum of 75% full-time professional effort is required (based on 12 person months appointment).
- Candidates must have a research doctorate and postdoctoral experience.
- Caution: Not an extension of postdoctoral training!
- Varied and limited NIH Institute and Center participation:
  - Some ICs use for re-entry
  - Some ICs use to pursue new research area
- Requires plan for independence.

Mentored Clinical Scientist Career (K08)

- Supervised research experience for individuals with health professional degree who are committed to a career in laboratory research.
- Phased award periods: didactic experience followed by hands-on research experience.
- Provides up to five years of salary and Research support and protected time.
- Must demonstrate need for a period of intensive research focus to enhance career.
- Must commit a minimum of 9 person-months (75% of full-time professional effort) to award.
Mentored Patient-Oriented Research (K23)

- Supervised research for clinically trained professionals with a commitment to focus on patient-oriented research (POR).
- Must have completed clinical training, including specialty/sub-specialty, if applicable, prior to award.
- Provides up to five years of salary and Research support and protected time.
- Must demonstrate need for a period of intensive research focus to enhance career.
- Must commit a minimum of 9 person-months (75% of full-time professional effort) to award.

Patient-Oriented Research (POR) is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes:

- Mechanisms of human disease;
- Therapeutic interventions;
- Clinical trials, and;
- The development of new technologies.
Mentored Quantitative Scientist (K25)

- Mentored experiences for scientists from quantitative and engineering backgrounds interested in pursuing health-related research.
- Minimum of 75% full-time professional effort is required (based on 12 person months appointment).
- Candidates must have a research doctorate and ideally some postdoctoral experience.
- Unique among NIH K awards in that eligibility spans the postdoctoral to senior faculty levels, although some Institutes have exceptions to this general rule.

Pathway to Independence Award (K99/R00)

- K99: Mentored research experience for up to 2 years.
- R00: Transition to research independence as junior faculty for up to 3 years.
- Applicants: no more than 5 years of postdoctoral research training at the time of initial application or resubmission.
- Non-U.S. citizens may apply, but institution must be domestic.
- Transition to R00 phase requires offer and acceptance of tenure-track, full-time assistant professor position (or equivalent).
Projected Funding for K99/R00 Awards

NIH Institutes and Centers have committed to 171 awards in the first year, assuming budget permits and sufficient numbers of quality applications are received.

| 171 K/R awards per year for 5 years |
|-------------------|---|---|---|---|---|
|                   | 2007 | 2008 | 2009 | 2010 | 2011 |
| 2007 cohort       | 15.4M | 15.4M | 42.6M | 42.6M | 42.6M |
| 2008 cohort       | 15.4M | 15.4M | 42.6M | 42.6M |    |
| 2009 cohort       | 15.4M | 15.4M | 42.6M |    |    |
| 2010 cohort       | 15.4M | 15.4M |    |    |    |
| 2011 cohort       |    |    |    |    | 15.4M |
| Totals:           | 15.4M | 30.8M | 73.4M | 116.0M | 158.6M = 394.2M |

Notes: Phase I, K portion total cost per year, per award = $90K (salary-$50K + fringe-25% + $20K research support = ~$83K x 8% F&A)
Phase II, R portion total cost per year, per award = $249K (salary + fringe + research support = ~$175K x 42% estimated F&A).

Institutional Career Development Program (K12)

- Institutional Mentored Research Scientist Development Program—Award is made to the institution.
- Enhance research career development for individuals, selected by the institution, who are training for careers in specified research areas.
- Provides institutions with a greater capacity and flexibility for mentoring junior investigators.
- All other provisions of individual K awards apply to the award recipient.
- Not transferable to another institution.
- Usually solicited by a Funding Opportunity Announcement.
Independent Scientist Award (K02)

- Foster development of outstanding scientists who can make significant contributions to their field of research.
- Provides up to five years of salary support and “protected time” for newly independent scientists.
- Must demonstrate need for a period of intensive research focus to enhance career.
- Must have independent peer-reviewed research support at the time of award.
- Must commit a minimum of 9 person-months (75% of full-time professional effort) to award.

Midcareer Investigator Award in POR (K24)

- Attract and retain talented individuals to the challenges of patient-oriented research (POR).
- Provides up to five years of salary support and “protected time” for mid-career scientists.
- Enable mid-career clinician scientists to devote more time to POR, and serve as mentors to new clinical investigators.
- Provides protected time to investigators who have their own independent peer-reviewed research support.
- Must commit between 3 and 6 person-months (25% to 50% of full-time professional effort) to award.
Career Award Review Criteria (1 of 3)

Candidate:
- Quality of research, academic and/or clinical record.
- Potential to develop as an independent and productive researcher.
- Qualifications and statement by Sponsor/Mentor and collaborators/Consultants.
- Quality of the letters of reference.

Career Development Plan:
- Likelihood that plan will contribute substantially to the scientific development of candidate.
- Content, scope, phasing, and duration of the plan in the context of prior experience and stated career objectives.

Career Award Review Criteria (2 of 3)

Research Plan:
- Scientific and technical merit of the research question, design and methodology.
- Relevance of the proposed research to the candidate's career objectives.
- Appropriateness of the research plan to the stage of research development and as a vehicle for developing the research skills described in the career development plan.
Environment and Institutional Commitment to the Candidate:

- Commitment of institution to ensure that the candidate's effort will be devoted to research.
- Adequacy of research facilities and training opportunities, including capable faculty.
- For “K” awards, assurance that institution intends for the candidate to be an integral part of its research program.

Training in the Responsible Conduct of Research:

- Quality and appropriateness of the proposed training in the responsible conduct of research.

Career Award Application and Due Dates

- Use SF 424 – Part I, Section 7: Supplemental Instructions for Preparing an Individual Research Career Development Award (CDA) Application.
- Submission dates for new applications: February 12, June 12, October 12.
- For resubmissions: March 12, July 12, November 12.
- Institutes and Centers use of career awards is highly variable. Read announcement and instructions carefully and call the NIH staff!
- In K announcements, see contact Webtable for participating Institutes and Centers.
Research Career Development Awards

Individual & Institutional Positions on Ks: FY 2009
### Percent of Institute Funds for K Awards: FY 2009

The chart shows the percent of institute funds for K awards for various NIH Institutes and Centers. The data for FY 2009 is presented.

### Career (K) Policies

- **NOT-OD-08-065**: Revision of NIH Policy Concerning Concurrent Support from Mentored Career Development (K) Award and a Research Grant (April 10, 2008).
- **Length of Support**: As a general rule, allow up to 6 years of mentored K support (combination of institutional and individual K award). An IC may make exceptions to this 6-year guideline up to a limit of 8 years.
Resources:

- NIH Extramural Training Mechanisms: http://grants1.nih.gov/training/extramural.htm
- Ruth L. Kirschstein National Research Service Award (NRSA): http://grants1.nih.gov/training/nrsa.htm

NIH Office of Extramural Research

Support creative new investigators with highly innovative research ideas at early career stages.
- No preliminary data required.
- Evaluate pre-application—Invite full application.
- Potential for significant impact on an important biomedical or behavioral research problem.
- Applicants must hold independent research position at a domestic institution.
- Doctoral degree or completed internship/residency within past 10 years.
- Must commit at least 25% of research effort.
- There are no citizenship or residency requirements.
Extramural Loan Repayment Program

- Clinical Research
- Pediatric Research
- Health Disparities Research
- Contraception and Infertility Research
- Clinical Research for Individuals from Disadvantaged Backgrounds

Researchers at 50% effort or more at non-profit organizations with qualifying educational debt.

Payments to loaning institution up to $35,000 per year.

Tax liability on the loan payments partially offset.

Concurrent service requirement.


Application Period: September 1 – December 1.
Enhancing Peer Review, New Investigator Policies and Funding Opportunities

Revisit NIH Peer Review Process

- Collaboration between NIH extramural staff and scientific community.
- Facilitates changing nature of science.
- Encourages New and Early Stage Investigators.
- Eases burden on research enterprise.
- Streamlines time to award.
Enhancing Peer Review at NIH

**Changes Implemented**

- Phase out of A2 applications
- Identification of Early Stage Investigator (ESI) applications
- New scoring system
- Criterion scoring
- Templates for structured critiques
- Clustering of New Investigator applications
- Score order of review
- Alignment of applications & review criteria
- Shorter Research Plans

**Limited Resubmission of Applications to NIH**

**Phase Out of A2 Applications**

**PURPOSE:**
- Ensure largest number of high-quality meritorious applications receive funding earlier.
- Improve system efficiency.
- Enhance success rates of new and resubmitted applications.

**POLICY:**
- Applications submitted for 1/25/09 and beyond allowed a single resubmission.
- Applications submitted for due dates prior to 1/25/09 are allowed two amendments. Last date NIH will accept the second amendment is 1/7/2011.
- All activity codes, and new, renewal (competing continuation) and revision (competing supplement) applications.
**Goals for New & Early-Stage Investigators**

**Identification of ESI Applicants**

**PURPOSE:**
- Encourage earlier transition to research independence.
- Counter trend of increasing time spent in training phase of career.
- Strongly encourage New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding.
- Identify applications from ESIs and New Investigators for reviewers.
- Apprise NIH staff of ESI and New Investigator status.
- Support New Investigators (majority expected to be ESIs) at success rates equivalent to that of established investigators submitting new applications.

**Definition of New Investigator**

- New Investigator (NI) is a PD/PI who has not yet *competed successfully* for a substantial NIH research grant.
- Receipt of the following awards does not remove new investigator status: R00, R03, R15, R21, R34, R36, R41, R42, R55, R56, SC2, SC3, all Fs, most Ks, all Loan Repayment contracts, G07, G08, G11, G13, G20, S10, S15, S21, S22.
- For multiple PD/PIs: all PD/PIs must meet definition of NI.
Definition of Early-Stage Investigator

- A New Investigator who is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency (or equivalent).
- For multiple PD/Pis, all PD/Pis must meet requirements for ESI status.
- Status applies only to R01s.
- ESIs are also eligible for the Shortened Review Cycle option available to NIs.

Enhancing Peer Review at NIH

New Scoring System

- 9-point scale
  1 = Exceptional
  9 = Poor
- Reduces number of rating discriminations.
- Provides rating descriptors:
  - To improve reliability.
  - To encourage use of the entire range.
- Will be used for:
  - Overall impact/priority scores.
  - Individual criterion scores.
- Will be implemented for applications submitted for:
  - FY2010 funding consideration.
  - Recovery Act FOAs.
**New Scoring System**

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Guidance on strengths &amp; weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td>Strengths</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
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<tr>
<td>Moderate Impact</td>
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<td>Very Good</td>
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<td></td>
<td>5</td>
<td>Good</td>
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<td></td>
<td>6</td>
<td>Satisfactory</td>
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<tr>
<td>Low Impact</td>
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<td>Fair</td>
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<tr>
<td></td>
<td>8</td>
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</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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**Restructured Research Plan**

<table>
<thead>
<tr>
<th>Current Application</th>
<th>New Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background and Significance</td>
<td>Research Strategy</td>
</tr>
<tr>
<td>Research Design and Methods</td>
<td>a. Significance</td>
</tr>
<tr>
<td>Preliminary Studies/Progress Report</td>
<td>b. Innovation</td>
</tr>
<tr>
<td></td>
<td>c. Approach:</td>
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<tr>
<td></td>
<td>o Preliminary Studies for New Applications</td>
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<tr>
<td></td>
<td>o Progress Report for Renewal/Revision</td>
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</tbody>
</table>
### Biographical Sketch Changes

- Personal Statement: Experience and qualifications for role in the project.
- Publications: No more than 15 based on chronology, importance to the field, and/or relevance to the application.
- Page limit remains at 4.

### Facilities and Resource Changes

- Description of how the scientific environment will contribute to the probability of success of the project.
- For Fs and Ks description of the institutional commitment to the success of the investigator.
- Select Agent Research: Description of the bio-containment resources available at the performance site.

### Application Page Limits

<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Activity Codes</th>
<th>Pages</th>
</tr>
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<tbody>
<tr>
<td>Introduction to Revision</td>
<td>All Activity Codes</td>
<td>1 page</td>
</tr>
<tr>
<td>Introduction to Resubmission</td>
<td>Institutional T, D, K12, R25</td>
<td>3 pages</td>
</tr>
<tr>
<td>Specific Aims</td>
<td>All Activity Codes</td>
<td>1 page</td>
</tr>
<tr>
<td>Research Strategy</td>
<td>Individual F, R15, R36</td>
<td>6 pages</td>
</tr>
<tr>
<td>Research Strategy + Candidate Information: Background, Career Goals, Activities During Award, and Training in RCR</td>
<td>Individual K</td>
<td>12 pages</td>
</tr>
<tr>
<td>Research Training Program Plan: Items 2-5</td>
<td>Institutional T, D, K12</td>
<td>25 pages</td>
</tr>
<tr>
<td>Research Education Program Plan (Research Strategy)</td>
<td>R25</td>
<td>25 pages</td>
</tr>
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</table>
Enhanced Review Criteria for FY2010

Additional Information:

- Enhancing Peer Review Website: http://enhancing-peer-review.nih.gov/index.html
- Side-by-side comparison of enhanced and former review criteria: http://grants.nih.gov/grants/peer_review_process.htm