The R21, R03, and K99 Grant Mechanisms

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NIH Exploratory/Developmental Research Grant Award (R21))
(Funding Opportunity Number (FOA): PA-20-195)

Purpose: intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development

- High risk/high reward studies
- No risk is required but risk is tolerated
- No preliminary data is required
- Any preliminary data provided will be evaluated
- Rationale needs to be supported
- “fishing expedition” criticism is relatively mutated

The combined budget for direct costs for the two year project period may not exceed $275,000. Typically requests are $125,000 year 1 and $150,000 for year 2.

R21s can not be renewed
Proposal SECTIONS

- Project Summary/abstract
- Project Narrative (2-3 sentence description for public and Congress)
- Facilities, equipment, and Resources
- Biosketches
- Budget and budget justification
- Introduction to application
- Specific aims
- Research Strategy
- Vertebrate Animals
- Human Subjects
- Resource Sharing
- Letters of Support

The Science Sections

Project Summary/abstract (up to 1 page)

Introduction to application (if resubmission)

Specific Aims (1 page)

Research Strategy (up to 6 pages)

- Background and Significance
- Innovation
- Preliminary data (if any)
- Approach
SCORED REVIEW CRITERIA

- **Significance**: Why do this?
- **Investigator**: Why you?
- **Innovation**: Has this been done before?
- **Approach**: How would you do this?
- **Environment**: Where will this be done?

Studies that may lead to a **breakthrough** in a particular area, or result in **novel** techniques, agents, methodologies, models or applications

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**NIH Small Research Grant Program (Parent R03)**
(Funding Opportunity Number (FOA): **PA-16-162**)

**Purpose**: The NIH R03 funding opportunity announcement (FOA) supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding, such as:

- Pilot or feasibility studies
- Secondary analysis of existing data
- Small, self-contained research projects
- Development of research methodology
- Development of new research technology

The combined budget for direct costs for the two year project period may not exceed $100,000. No more than $50,000 in direct costs may be requested in any single year.

Tend to be institute specific in terms of targeted areas. Not all institutes have general R03 mechanisms. NIAID has this mechanism and they are reviewed along with the R01s.
The Science Sections

Project Summary/abstract (up to 1 page)

Introduction to application (if resubmission)

Specific Aims (1 page)

Research Strategy (up to 6 pages)

• Background and Significance
• Innovation
• Preliminary data
• Approach

OTHER SECTIONS

• Project Summary/abstract
• Project Narrative (2-3 sentence description for public and Congress)
• Facilities, equipment, and Resources
• Biosketches
• Vertebrate Animals
• Human Subjects
• Resource Sharing
• Letters of Support
SCORED REVIEW CRITERIA

- Significance
- Investigator
- Innovation
- Approach
- Environment

NIH Pathway to Independence Award (Parent K99/R00)

(Funding Opportunity Announcement (FOA): PA-20-188)

Purpose: Transition from mentored postdoctoral research to independent research as a tenure-track faculty member.

K99: 1-2 years. Provides mentored postdoctoral research training toward a specific project designed to lead to independence for the candidate. Salary support = $75,000 (+fringe). Research support = $25,000. NOTE: These numbers vary slightly depending on institute.

R00: 3 years. Provides research and salary support up to $249,000.
ELIGIBILITY

• No more than 4 years postdoc experience at time of submission (or resubmission).
  • Whey do they start counting...

• Need to have rationale for requiring 1-2 years additional postdoctoral training.
  • I am great but...

• Need to be in a mentored postdoctoral position.

• Must not be in independent research position when the award is made.

• Must have a tenure-track faculty position by the end of the 2-year K99 phase for the R00 award to be made.

• Must devote at least 75% effort to career development and research during K99 phase and at least 75% effort to research during R00 phase.

• Not sure? Contact your Program Officer:

Writing Instructions

PA-20-188: NIH Pathway to Independence Award (Parent K99/R00 - Independent Clinical Trial Not Allowed)

PAR-21-271: Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed)

SF424 (R&R) instructions

https://grants.nih.gov/grants/how-to-apply-application-guide.html#inst
Grant Components

**Similar to other grants**
- Project summary/abstract
- Project narrative
- Facilities. Equipment and other resources
- Candidate biosketch
- Budget and Budget justification
- Specific aims
- Research plan
- References cited
- Support letters from Collaborators
- Resource sharing plan
- Authentication plan of key resources
- Human or vertebrate animal research
- Select agents

**Specific to K99/R00**
- Candidate's background
- Career goals and objectives
- Career development/training activities
- Mentor's biosketch (one for each co-mentor, if multiple)
- Training in the Responsible Conduct of Research
- Description of Institutional Environment
- Institutional Commitment to Candidate's Research Career Development
- Plans and Statements of Mentor and Co-mentor(s)
- Reference letters (submitted directly by references)

A really good idea to make a list and check things off as you go

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<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Page Limits * (if different from FOA, FOA supersedes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Summary/Abstract</td>
<td>30 lines of text</td>
</tr>
<tr>
<td>Project Narrative</td>
<td>Three sentences</td>
</tr>
<tr>
<td>Introduction to Resubmission or Revision Application (when applicable)</td>
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</tr>
<tr>
<td>First three items of Candidate Information (Candidate's Background, Career Goals and Objectives, and Candidate's Plan for Career Development/Training Activities During Award Period and Research Strategy)</td>
<td>12 (for all sections combined)</td>
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<tr>
<td>Specific Aims</td>
<td>1</td>
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<tr>
<td>Training in the Responsible Conduct of Research</td>
<td>1</td>
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<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>
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<tr>
<td>Description of Institutional Environment</td>
<td>1</td>
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<tr>
<td>Institutional Commitment to Candidate's Research Career Development</td>
<td>1</td>
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<tr>
<td>Biographical Sketch</td>
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</tr>
</tbody>
</table>
## CANDIDATE

**Candidate Background**
- Commitment to biomedical research
- Potential for independence

**Career Goals and Objectives**
- Short and long term research/career goals
- Research training history
- Plans to separate from mentor

**Candidate’s Plan for Career Development/Training Activities During Award Period**
- Describe plan and activities to promote research and career development
- Describe how the research and training proposed will lead to a new avenue of research that is independent of the mentor.
- Describe plan for evaluation of progress including milestones.
- Describe transition plan.

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## MENTOR, CO-MENTOR, CONSULTANT, COLLABORATORS SECTION

**Plans and Statements of Mentor and Co-mentor(s)**
- Prior research and mentoring experience
- Supervision plan
- Description of training elements of research
- Plans to facilitate transition to independence

**Letters of Support**
- Collaborators, Contributors and Consultants

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## ENVIRONMENTAL AND INSTITUTIONAL COMMITMENT TO THE CANDIDATE

**Description of Institutional Environment**
- Facilities and resources available for the candidate
- Intellectual environment

**Institutional Commitment to the Candidate’s Research Career Development**
- Commitment of resources
- Assurance of minimum effort (≥ 75% effort)
RESEARCH PLAN

Research Strategy
• Divide into sections: Significance, Innovation, and Approach
• Need to cover all the aspects of a good research strategy including, but not limited to
  ➢ Significance of proposed work (why is it important?)
  ➢ Preliminary Data (something worth following up and/or feasibility)
  ➢ Rigor of experimental design
  ➢ Justification of parametric choices (sample size, drug dose, etc.)
  ➢ Discussion of sex as a biological factor
  ➢ Feasibility
  ➢ Potential Outcomes and their meaning
  ➢ Potential complications and contingencies for dealing with them.
• Include discussion of training/independence transition elements
• Describe how the research proposed will lead to a new avenue of research that is independent of the mentor.

Training in The Responsible Conduct of Research

SPECIFIC AIMS
• This focuses on the research proposed, but work in some training/independence-transition text too.

LETTERS OF REFERENCE

OTHER SECTIONS
• Project Summary/Abstract
• Project Narrative
• References Cited
• Biosketches
• Current and Pending Support
• Facilities and Resources
• Equipment
• Vertebrate Animals
• Human Subjects
• Select Agent Research
• Authentication of Key Biological and/or Chemical Resources
• Consortium/Contractual
• Resource Sharing Plan
SCORED REVIEW CRITERIA

• Candidate
• Career Development Plan/Career Goals and Objectives
• Research Plan
• Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
• Environment & Institutional Commitment to the Candidate

Additional Review Criteria and Considerations
• Human subjects protection and inclusions
• Vertebrate animals
• Biohazards
• Resubmissions
• Training in responsible conduct in research
• Select agent research
• Resource sharing plan
• Budget and period of support

Common Score-lowering Issues

• Poor writing
• Mediocre idea
• Lack of feasibility
• Poor research design
• Flawed or missing interpretation of potential outcomes
• Poor funding for mentor (K99)
• Lack of institutional commitment
• Poor or modest productivity
• Insufficient rationale for need for training (K99)
• Concern about independence from mentor (K99)
**TIPS**

- Start writing at least 2 MONTHS before deadline
- READ and FOLLOW INSTRUCTIONS.
- If you are struggling to write research strategy, it probably means that you do not have a well developed idea.
- Work closely with your mentor.
- Talk to your program officer (get on their radar screen).
- BE PRODUCTIVE.
- Write grant proposal using the style of the magazine *Scientific American*.
- Graphs and tables are excellent.
- Have others with experience read your grant. However, give them a finished draft and do so with ample time to modify your grant to address their criticisms. DO NOT use them as proof-readers!