"Perfecting and Integrating the Career Development Components
of an NIH K Grant Application"
Emory University – May 10, 2021

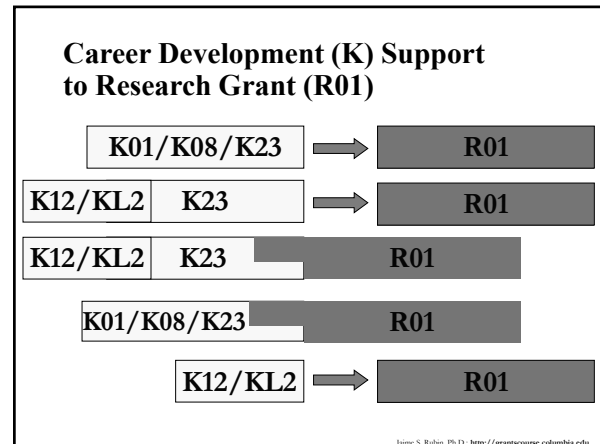**Slide 1**

Perfecting and Integrating the Career Development Components of an NIH K Grant Application

Emory University
May 10, 2021

Jaime S. Rubin, Ph.D.
Dept. of Medicine
College of Physicians and Surgeons
Columbia University

Course: "Funding and Grantsmanship for Research and Career Development Activities"
http://grantscourse.columbia.edu/

Slide 2

Career Development (K) Support to Research Grant (R01)

K01/K08/K23	→	R01
K12/KL2 · K23	→	R01
K12/KL2 · K23	R01	
K01/K08/K23	R01	
K12/KL2	→	R01

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Topics to be Discussed

NIH Career Development (K) Applications

- NIH Review
  - Process
  - Scoring System
  - Criteria
- Components of the NIH Application
  - Non-Technical/Scientific Sections
  - Best Practices for Addressing the Review Criteria

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Topics to be Discussed

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NIH's Evaluation System

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

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	Strengths
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	Weaknesses

http://enhancing-peer-review.nih.gov/docs/scoring_and_critique_overview_June2009.pdf

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

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

http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

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Initial Review Group or Study Section Actions

- **Discussed applications:**
  - Receives Impact/Priority Scores
  - Receives Scores for individual core review criteria
- **Not Discussed:**
  - Receives Scores for individual core review criteria
- Not Recommended for Further Consideration (NRFC)
- Other: e.g. Deferred

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Impact Score

- <u>Preliminary Impact Scores</u> determine which applications discussed at study section
- <u>Impact Score given by each member</u> of the study section
- <u>Overall Impact Score</u> (for discussed applications): Mean of reviewers' Impact Scores <u>x10</u>
- 81 possible overall Impact Scores (10 – 90, whole numbers)

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K awards Payline: NHLBI

Payline			
Grant Program	Grant Program Description	Percentile	Priority Score
R01	Research Project Grant	16	N/A
R01 ESI	Early Stage Investigators	26	N/A
K awards	Career Development Awards	N/A	32

FY20

https://www.nhlbi.nih.gov/current-operating-guidelines

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NIH's Review Criteria

- **Overall Impact Score**
  - "assessment of the likelihood that the <u>proposed career development and research plan</u> will enhance the candidate's potential for a productive, <u>independent</u> scientific research career in a health-related field…"
- **Core Review Criteria**
  A separate score is given for each

For Mentored Patient-Oriented Research Career Development Award
(Parent K23 – Independent Clinical Trial Not Allowed) (PA-20-205)
Check individual funding announcement if applying to another

https://grants.nih.gov/grants/guide/pa-files/PA-20-205.html

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Overall Impact *Write a paragraph summarizing the factors that informed your Overall Impact score.*

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Separate Scores for the Individual Criteria
- All applications receive scores
  (even those not discussed at study section)
- Individually reported in summary statement
- Major strengths and weaknesses that influenced the
  overall impact/priority score - ¼ page per criterion

http://enhancing-peer-review.nih.gov/docs/ReviewerVideoslides030609_Modified.ppt

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1. Candidate
Strengths
-
Weaknesses
-

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
Strengths
-
Weaknesses
-

3. Research Plan
Strengths
-
Weaknesses
-

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4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
Strengths
-
Weaknesses
-

5. Environment and Institutional Commitment to the Candidate
Strengths
-
Weaknesses
-

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1. Candidate

- "Does the candidate have the potential to develop
  as an independent and productive researcher?
- Are the candidate's prior training and research
  experience appropriate for this award?
- Is the candidate's academic, clinical (if relevant),
  and research record of high quality?
- Is there evidence of the candidate's commitment
  to meeting the program objectives to become an
  independent investigator in research?"

https://grants.nih.gov/grants/guide/pa-files/PA-20-205.html

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1. Candidate

- "Do the reference letters address the above
  review criteria, and do they provide evidence that
  the candidate has a high potential for becoming
  an independent investigator?"

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2. Career Development Plan/Career Goals & Objectives
- "What is the likelihood that the plan will contribute substantially to the <u>scientific development</u> of the candidate and lead to <u>scientific independence</u>?
- Are the candidate's <u>prior training and research experience</u> appropriate for this award?
- Are the <u>content, scope, phasing, and duration</u> of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving <u>research independence</u>?"

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2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- "Are there adequate plans for <u>monitoring and evaluating</u> the candidate's research and career development progress?"
- If proposed, will the <u>clinical trial experience</u> contribute to the applicant's research career development?

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3. Research Plan
- "Are the proposed <u>research questions, design, and methodology</u> of significant scientific and technical merit?
- Is the <u>prior research</u> that serves as the key support for the proposed project <u>rigorous</u>?
- Has the candidate included plans to address <u>weaknesses in the rigor of prior research</u> that serves as the key support for the proposed project?
- Has the candidate presented strategies to ensure a <u>robust and unbiased approach</u>, as appropriate for the work proposed?

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3. Research Plan
- Has the candidate presented adequate plans to address <u>relevant biological variables</u>, such as sex, for studies in vertebrate animals or human subjects?"
- "Is the research plan <u>relevant</u> to the candidate's <u>research career objectives</u>?
- Is the research plan <u>appropriate</u> to the candidate's <u>stage of research development</u> and as a vehicle for <u>developing the research skills</u> described in the career development plan?"
- If proposed, will the <u>clinical trial</u> experience contribute to the proposed research project?

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NIH Review criteria – changes
- For applications with deadlines on or after January 25, 2019

Section	Criteria	Current language	Revised language
Scored Review Criteria	Research Plan	Is there a strong scientific premise for the project?	Is the prior research that serves as the key support for the proposed project rigorous?
Scored Review Criteria	Research Plan	Not Applicable	Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-229.html   Jaime S. Rubin, Ph.D.; **http://grantscourse.columbia.edu**

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4. Mentor(s), Co-mentor(s), Consultant(s), Collaborator(s)
- "Are the <u>qualifications</u> of the mentor(s) in the area of the proposed research appropriate?
- Do(es) the mentor(s) adequately address the <u>candidate's potential</u> and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing <u>guidance and advice</u> to the candidate?
- Is the mentor's description of the elements of the research <u>career development activities</u>, including formal course work adequate?"

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4. Mentor(s), Co-mentor(s), Consultant(s), Collaborator(s)

- "Is there evidence of the mentor's, consultant's and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?"

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4. Mentor(s), Co-mentor(s), Consultant(s), Collaborator(s)

- "If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?"

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5. Environment and Institutional Commitment to the Candidate

- "Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort [usually 75%] will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?"

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5. Environment and Institutional Commitment to the Candidate

- "Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate, adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?"

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Additional Review Criteria

Evaluated for the overall impact score, but not given an individual score

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan (as of Jan 25, 2019)
- Vertebrate Animals
- Biohazards
- Resubmissions
  - Response to previous reviewers' comments and subsequent changes made to the proposal

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Additional Review Considerations

Not given an individual score and not considered for the overall impact score

- Training in the Responsible Conduct of Research
  - Address required components (training faculty involvement)
- Select Agent Research
- Resource Sharing Plans
  - 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genomic Data Sharing Plan
- Authentication of Key Biological and/or Chemical Resources
  - Plans for identifying and ensuring the validity of resources
- Budget and Period of Support

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Guidance for NIH Reviewers

https://grants.nih.gov/grants/policy/review/rev_prep/applications.htm

- Rigor and Transparency
- Sex as a Biological Variable
- Vertebrate Animals
- Human Subjects Section
- Clinical Trials
- Single IRB for multi-site studies
- Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research
- Human Embryonic Stem Cells
- Authentication of Key Biological and/or Chemical Resources
- Select Agents
- Resource Sharing Plans
- Budget Information
- Revision Applications

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Guidelines for NIH Reviewers

https://grants.nih.gov/grants/policy/review-guidelines.htm

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Guidelines for NIH Reviewers

https://grants.nih.gov/grants/policy/review-guidelines.htm

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Topics to be Discussed

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For Individual Career Development Award (K, excluding K12) Applications	
Section of Application	Page Limits * (if different from FOA, FOA supersedes)
Project Summary/Abstract	30 lines of text
Project Narrative	Three sentences
Introduction to Resubmission or Revision Application (when applicable)	1
Candidate Information and Goals for Career Development and Research Strategy	12 (for both attachments combined)
Specific Aims	1
Training in the Responsible Conduct of Research	1
Candidate's Plan to Provide Mentoring (Include only when required by the specific FOA, e.g., K24 and K05)	6
Plans and Statements of Mentor and Co-mentor(s)	6
Letters of Support from Collaborators, Contributors, and Consultants	6
Description of Institutional Environment	1
Institutional Commitment to Candidate's Research Career Development	1
Biographical Sketch	5

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#cat   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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1 + 12 Pages Combined

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

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2. Candidate Information

- Candidate's Background
- Career Goals and Objectives
- Candidate's Plan for Career Development/ Training Activities During Award Period

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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Not everything that can be counted counts.
Not everything that counts can be counted.

Research Plan Section
3. Specific Aims
4. * Research Strategy

Candidate Section
2. Candidate Information and Goals for Career Development

Quote Investigator suggests crediting sociologist William Bruce Cameron
http://quoteinvestigator.com/2010/05/26/everything-counts-einstein/

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2. Candidate's Background

- Scientific history/Unique expertise
  - Previous work
    - Consistent themes, or
    - Why research interests have changed direction
  - Relationship to career path described in application
- Other didactic/training experiences
  - e.g., Master's degree
- Other research experiences
  - e.g., MD/PhD, Medical school, Fellowship
- Reasons for basic, clinical, translational, epidemiology, behavioral, multidisciplinary research, relevant publications

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Personal Statement/ Candidate's Background

When describing a previous research experience:

- Why?
  - This Area of Research
  - This Mentor/Lab Group
  - This Institution
- What was the hypothesis/scientific question?
- Why was the study important?
- What were the findings and conclusions?
- What were your role and responsibilities?

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Personal Statement/ Candidate's Background

When describing a previous research experience:

- What did you learn and accomplish?
  - "Intellectual aspects"
  - Do not focus on technical aspects
- Why the transition from one research project/area/mentor/institution to the next?
- How/Why did your interests change or evolve?
- Cite any resulting publications/abstracts
- Describe any honors, awards and resulting conference/workshop presentations

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Career Goals and Objectives

- Justify award
  - Fits into past and future research career
- 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)

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Career Development and Research Arrangements

- <u>Multiple Mentors (mentored awards)</u>
- <u>Advisors (mentored awards)</u>
- Co-investigators/Collaborations
- Subcontracts to other institutions
- Multidisciplinary/Interdisciplinary

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- **Mentors/Advisory Committee**
  - Scientific area per Mentor/Committee member
  - Schedule of meetings

Career Development and Research Training Mentors and Advisors		
Faculty Member	**Role**	**Area of Expertise**
Name (Title)	Mentor	
Name (Title)	Co-Mentor	
Name (Title)	Advisory Board Member	
Name (Title)	Advisory Board Member	
Name (Title)	Advisory Board Member	
Name (Title)	Collaborator	
Name (Title)	Consultant	

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- Short-term Career Goals
  - Timeline for funded period

  <u>Year 1</u>: Preliminary data

  <u>Year 2</u>: Submit publications (possible journals), Presentations at national meetings (examples), Formulation of R01 application

  <u>Years 3-5</u>: By the end of the funded period, applicant will be an independent investigator near to R01 funding

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- 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.

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Career Development/Training Activities During Award Period

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

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NIH and AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for Research Training Grant, Fellowship, and Career Development Award Applications

Notice Number: NOT-OD-20-033

• In describing their <u>career development plans</u> in the Program Plan attachment, candidates for career development awards will be expected to address, as applicable, any <u>new research skills</u> they plan to acquire in the areas of <u>rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation</u>.

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- **New Section on each Module**
  - Reason for module
  - Specific description of each "Mode of Learning"
    - Role of Mentor(s) and Advisor(s)
    - Specific courses, workshops, and other didactics
    - Details on research meetings
  - Module: Career skills
    - Grantsmanship
    - Becoming a mentor
    - Research Group/Laboratory management

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Module	Mentor(s)	Mode of learning
Scientific Area (1-3)	Specific names	Coursework (completed and new) 1-on-1 meetings (schedule? e.g. weekly) Guided readings Research meetings (schedule? e.g. weekly) Applied training Clinical experience
Career skills	All mentors	
Dissemination of Research Results		Improving communication skills Grant writing course Professional workshops/seminars Collaborations Abstracts and manuscripts R01/Small grant application submission
Research management		Supervising technical support personnel, organizing lab meetings, journal clubs
Mentorship		e.g. training new lab members, undergraduate, summer students

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- **Summary of coursework**
  - List previous relevant coursework
  - Proposed coursework
    - Course number and description
    - Include career development courses (e.g., grant writing) and responsible conduct of research
    - Additional didactic activities
    - e.g., Those offered by professional societies, workshops, symposiums

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- Clinical and/or Teaching activities
  - Relationship to proposed research and career development activities
  - Be specific, mention hrs. per week (cal months)
  - Percentage of time for each activity
- Restate % of time dedicated to research
- Timetable
- **Table: Career Development/ Training Activities During Award Period**

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Career Development Activities	Year 1	Year 2	Year 3	Year 4	Year 5
Mentorship					
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	X	X	X	X	X
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	X	X	X	X	X
Advisory Group – frequency (e.g. quarterly) of meetings	X	X	X	X	X

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Career Development Activities	Year 1	Year 2	Year 3	Year 4	Year 5
Experimental Training					
Mentor (name) – Specific area of research and/or methodology	X	X	X	X	X
Co-Mentor (name) – Specific area of research and/or methodology	X	X	X		
Co-Investigator 1 (name) – Specific area of research and/or methodology		X	X		
Co-Investigator 2 (name) – Specific area of research and/or methodology			X	X	
Collaborator 1 (name) – Specific area of research and/or methodology		X	X	X	
Collaborator 2 (name) – Specific area of research and/or methodology			X	X	X
Formal Coursework					
Course #1: Specific Course # / Formal Title	X				
Course #1: Specific Course # / Formal Title		X			
Course #3: Specific Course # / Formal Title			X		
Responsible Conduct of Research and Related Policy Issues		X			
Funding for Research Activities			X		

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Career Development Activities	Year 1	Year 2	Year 3	Year 4	Year 5
Workshops & Additional Training Programs					
Cold Spring Harbor Course on......	X				
Woods Hole Workshop on.....	X	X			
American Association for.... Junior Investigators Training on.....			X		
CTSA "K to R" Program				X	
IRB 101 Course		X			
NYAS Science Alliance Sessions on......	X	X	X	X	X
Scientific Conferences-Communication Skills (Oral / Poster Presentations)					
Symposium of the NY Academy of....(annual)	X	X	X	X	X
Congress of........ (annual)		X	X	X	X
American Association for........ (annual)		X	X	X	X
Society of...... (biannual)	X		X		X

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Career Development Activities	Year 1	Year 2	Year 3	Year 4	Year 5
Mentoring Skills (responsibility shared with K mentors)					
Students (summer, undergraduate, medical)		X	X	X	X
Communication Skills (Written)					
Preparation of manuscripts for peer reviewed journals			X	X	X
Grant Writing					
CTSA pilot award for junior investigator	X	X			
Center for...... award for new investigators			X	X	
R01 preparation and submission (on research funded by K award)				X	X

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PHS 398 Career Development Award Supplemental Form

View Burden Statement

OMB Number: 0925-0001
Expiration Date: 2/28/2023

Introduction

1. Introduction to Application
   (for Resubmission and Revision applications)

Candidate Section

2. Candidate Information and Goals for
   Career Development

Research Plan Section

3. Specific Aims

4. *Research Strategy

5. Progress Report Publication List
   (for Renewal applications)

6. Training in the Responsible Conduct
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    Research Career Development

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    Program Goals

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1 + 12 Pages Combined

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

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3. Specific Aims (1 page)
4. Research Strategy

- Not overly ambitious
- Appropriate for the career level and of the applicant
- Appropriate for the length of the K award
- Achievable research goals
- Appropriate for the Mentor's expertise/background
- Appropriate for the Mentor's available funding
- Appropriate of the Institution's resources

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Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

Benchmarks/ Milestones	Year 1	Year 2	Year 3
Summary of Specific Aim 1a	→		
Summary of Specific Aim 1b	→		
Summary of Specific Aim 2a		→	
Summary of Specific Aim 2b		→	
Summary of Specific Aim 3			→

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Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

Benchmarks/ Milestones	Year 1	Year 2	Year 3
Summary of Specific Aim 1a	(M)→		
Summary of Specific Aim 1b	(M) (M)→		
Summary of Specific Aim 2a		(M) (M)→	
Summary of Specific Aim 2b		(M) (M)→	
Summary of Specific Aim 3			(M)→

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Specific Aims: Milestones

- (M) Specific Aim 1a Milestone:
- (M) Specific Aim 1b Milestone #1:
- (M) Specific Aim 1b Milestone #2:
- (M) Specific Aim 2a Milestone #1:
- (M) Specific Aim 2a Milestone #2:
- (M) Specific Aim 2b Milestone #1:
- (M) Specific Aim 2b Milestone #2:
- (M) Specific Aim 3 Milestone:

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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.

Updates include:

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-012.html
https://grants.nih.gov/grants/peer/critiques/k.htm
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Guidance: Rigor and Reproducibility in Grant Applications

NIH research grant and career development award application instructions and review language focus on four key areas:

1. The rigor of the prior research
2. Rigorous experimental design for robust and unbiased results
3. Consideration of relevant biological variables
4. Authentication of key biological and/or chemical resources

https://grants.nih.gov/policy/reproducibility/guidance.htm
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Reviewer Guidance on Rigor and Transparency: Research Project Grant and Mentored Career Development Applications

OVERVIEW: MENTORED CAREER DEVELOPMENT AWARD (K) APPLICATIONS

Element of Rigor and Transparency	Section of Application	Criterion Score	Additional Review Consideration	Contribute to Overall Impact Score?
Rigor of the Prior Research	Research Strategy	Research Plan	NA	Yes
Scientific Rigor	Research Strategy	Research Plan	NA	Yes
Consideration of Relevant Biological Variables, such as Sex	Research Strategy	Research Plan	NA	Yes
Authentication of Key Biological and/or Chemical Resources	New Attachment	NA	Yes	No

https://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf
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PHS 398 Career Development Award Supplemental Form

OMB Number: 0925-0001
Expiration Date: 2/28/2023

View Burden Statement

Introduction
1. Introduction to Application (for Resubmission and Revision applications)

Candidate Section
2. Candidate Information and Goals for Career Development

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3. Specific Aims
4. *Research Strategy
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Environment and Institutional Commitment to Candidate Section
10. Description of Institutional Environment
11. Institutional Commitment to Candidate's Research Career Development
12. Description of Candidate's Contribution to Program Goals

https://grant.nih.gov/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplement-form.htm
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6. Training in the Responsible Conduct of Research

- 1) Format, 2) Subject Matter, 3) Faculty Participation, 4) Duration, and 5) Frequency of Instruction
- Role of Mentor
- Prior instruction in RCR
- Once every four years requirement
- Don't do the minimum
- Additional IRB or IACUC-related programs?
- http://grants.nih.gov/training/responsibleconduct.htm
- No more than 1 page

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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
  - Career development activities
    - Seminars, scientific meetings, presentations, becoming a mentor, RCR
- Expectations for publications

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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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 mentoring and supervision
  - How this will promote candidate's development
- Plan for Candidate's <u>Transition from Mentored Stage to Independent Investigator</u>
- Candidate's additional responsibilities
  - Courses, seminars, lab meetings
  - Teaching, clinical, administrative

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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- Source of support for Candidate's research project
  - Grants
  - Core/shared facilities
  - Technical support
- Previous experience as a Mentor
  - Previous mentees - Type (e.g., graduate student, post-doctoral fellow, junior faculty), Number, Career Outcomes
- Mentor and Co-Mentors
  - How mentorship responsibilities will be shared
  - How different areas of expertise enhance mentorship
  - Past collaborative research/co-mentorship activities
- Addition instructions if clinical trials proposed
- <u>No more than 6 pages</u>

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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Possible Problems Specific for Mentored Fellowship & Career Development Awards

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

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PHS 398 Career Development Award Supplemental Form

View Burden Statement	OMB Number: 0925-0001 Expiration Date: 2/28/2023

Introduction
1. Introduction to Application (for Resubmission and Revision applications)   Add Attachment Delete Attachment View Attachment

Candidate Section
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Research Plan Section
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6. Training in the Responsible Conduct of Research   Add Attachment Delete Attachment View Attachment

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11. Institutional Commitment to Candidate's Research Career Development   Add Attachment Delete Attachment View Attachment
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https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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9. Letters of Support from Collaborators, Contributors, and Consultants

- Advisory Committee (described in Section 2)
  - 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 in Section 2
  - Each should provide a letter and NIH Biosketch

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.410-phs-398-career-development-award-supplemental-form.htm   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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- Collaborators and Consultants (described in Section 2)
  - Name, title, and short paragraph on each individual in Section 2
  - Each should provide a letter and NIH Biosketch
- Director of Core Facility
- Source of "special" research resource (e.g., data set, patient samples, unique animal model/cell line/reagent)
- <u>No more than 6 pages</u>

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Environment and Institutional Commitment to the Candidate

- 10. Description of Institutional Environment
- 11. Institutional Commitment to the Candidate's Research Career Development
- 12. Description of Candidate's Contribution to Program Goals

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Slide 82:

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, Institute
    - Other schools, centers, shared resources, core facilities, CTSA, etc.
    - Degree programs, courses, seminars, journal clubs
    - Institution's/Dept.'s formal mentoring program
- <u>No more than 1 page</u>

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Possible Problems Specific for Mentored Career Development Awards
Institution

- Limited scientific/technical resources (e.g., core facilities, biostatistical support, patient population)
- Limited career development opportunities (e.g., courses, workshops)
- Limited opportunities for career advancement

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Environment and Institutional Commitment to the Candidate

- 11. Institutional Commitment to the Candidate's Research Career Development
  - Letter from Dept. Chair/Institute Director
    - Specifics on protected time (most K awards: 75%)
    - Specifics on faculty appointment (full-time)
    - Statement that appointment and salary are not contingent on award
    - Statement on availability of research resources, personnel, office and research space, equipment, etc. required for project
    - Statement that mentors and collaborators will be able to provide time and support for mentoring/research responsibilities
    - Signed and dated on letterhead stationery
  - <u>No more than 1 page</u>

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Environment and Institutional Commitment to the Candidate

- 12. Description of Candidate's Contribution to Program Goals
  - Required for applicants to "diversity-related" career development funding programs
    - e.g., Diversity-related K01's and K22's
  - Institutional letter
    - Addresses how the applicant's participation in this funding program "to promote diversity in health-related research"

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R&R Other Project Information:
10. Facilities & Other Resources

Scientific/Technical Resources

- Facilities to be used for the conduct of the proposed research
  - Laboratory
  - Animal
  - Computer
  - Office
  - Clinical [patient/research subject populations]
  - Other: Core facilities [e.g., research pharmacy, biostatistics, technical cores (microscopy, biomarkers), biohazards]
- Discuss how the proposed studies will benefit from the unique features of the scientific environment, subject populations, or collaborative arrangements

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R&R Other Project Information:
10. Facilities & Other Resources

Career Development Resources

- More complete descriptions of programs referenced in:
  - 2. Career Development/Training Activities During Award Period
  - 8. Plans and Statements of Mentor and Co-Mentor(s)
  - 10. Description of Institutional Environment
  - 11. Institutional Commitment to the Candidate's Research Career Development
- Cannot be used to avoid page limitations of other application sections

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R&R Other Project Information:
10. Facilities & Other Resources

Career Development Resources - also referenced in "main body" of the grant (Table) and Mentor's section

- Career development programs
  - Institutional (e.g., Office of Faculty Affairs)
  - Department/Institute
  - Professional societies
- Formal degree programs and other didactics
  - Degree program
  - Scientific courses: e.g., Statistics
  - Career Development courses: e.g., Funding & Grantsmanship
- Workshops, webinars, other training programs

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PHS Assignment Request Form

List individuals who should not review your application and why *(optional)*   *Entry is limited to 1000 characters.*

Provide sufficient information (e.g., name organization affiliation) to correctly identify each individual.
Provide specific reason why an individual should not review your application. Information will be
considered, but listing an individual does not guarantee they will not be on review panel.

Identify scientific areas of expertise needed to review your applic...
Note: Do not provide names of individuals   Identify scientific areas of expertise needed to review your application *(optional)*
                                                                Note: Do not provide names of individuals

Expertise:
Each entry is limited to 40 characters
                                                                Limit your answers to expertise. DO NOT enter the names of individuals you'd like to review your application.

https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-F.pdf   Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu

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Common Problems with Grant Applications from New Investigators

- Does not address/follow funding agency's mission, specific instructions, budget limits, etc.
- Overly ambitious
  - e.g., $, time, expertise, career level, resources
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- No or insufficient preliminary data
  - Demonstrates feasibility of project, scientifically as well as by investigator's team

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Common Problems with Grant Applications from New Investigators

- Study design
  - e.g., Control groups(s), Unfocussed
- Issues with Statistical aspects/Power analysis/ Data analysis
- Does not adequately describe access to "research resources"
- Unrealistic budget (too large or too small)
- Methodologies beyond the expertise of investigator or research team
- Not independent of previous mentor's research

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NIH "K" Sites of Interest

- K Kiosk – includes Program Announcements for K01, K07, K08, K22, K23, K25, and K99 grant mechanisms
  https://researchtraining.nih.gov/programs/career-development
- Career Development (K) Applications Instructions
  https://grants.nih.gov/grants/how-to-apply-application-guide.html
  https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.100-how-to-use-the-application-instructions.htm

  Reference Letters
  http://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/reference-letter.htm

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NIH "K" Sites of Interest

- Application Page Limits
  https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm
- NIH Biosketch Format Pages, Instructions and Samples
  https://grants.nih.gov/grants/forms/biosketch.htm
- Instruction in the Responsible Conduct of Research
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

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NIH "K" Sites of Interest

- NIH Research Training and Career Development Programs
  https://researchtraining.nih.gov/
- Research Training and Career Development Programs at Specific Institutes
  https://researchtraining.nih.gov/institute

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Good Luck!

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