

Transitioning to Research Independence

Part 3: Review Processes

December 14, 2020

K-Club

Sponsored by:



Department of Pediatrics



Children's[™]
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Georgia CTSA
Georgia Clinical & Translational Science Alliance



EMORY
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MEDICINE

Department of Medicine

Survey Drawing



Today's Panelists



Jaime Rubin, PhD

Vice Chair for Investigator Development
Department of Medicine
Columbia University Medical Center



Mandy L. Ford, PhD

Prof, Division of Transplantation
Dept of Surgery, School of Medicine
Scientific Director
Emory Transplant Center, Emory
University



Claudia Morris, MD, FAAP

Co-Director, Center for Clinical &
Translational Research
Prof. of Pediatrics & Emergency Medicine
Research Director for Div. of Pediatric
Emergency Medicine
Dept. of Pediatrics, Emory University

K-Club Special: CTSA TL1 (T32-like): Clinical and Translational Research Training

- Innovative didactic and mentored research training to individuals interested in careers that encompass clinical and/or translational research
- Predoctoral and postdoctoral trainees (medical and PhD students, resident and fellow physicians, PhD postdocs, and residents)
- Award includes stipend, travel, and tuition for the Master of Science in Clinical Research (MSCR) degree or Certificate Program in Translational Research (CPTR)
- Deadlines
 - Predoctoral: February 15, 2021
 - Postdoctoral: March 15, 2021

<http://georgiactsa.org/training/tl1/index.html>

K-Club Special: CTSA KL2 Clinical & Translational Research Career Development Program

- To support and enhance career development for junior clinical faculty (MD, PhD, MD/PhD, or PharmD) committed to a career in clinical and/or translational research.
- Award includes salary support, a technical budget and tuition for the Master of Science in Clinical Research (MSCR) degree or Certificate Program in Translational Research (CPTR)
- **Deadline: March 1, 2021**

<http://georgiactsa.org/training/kl2/index.html>

K-Club Special: Free Online Trainings for Clinical Research Professionals

- Georgia CTSA & Southern California CTSI
- Earn continuing education (CE) contact hours
- Currently available programs:
 - Legal Aspects for Conducting Clinical Trials (6.5 CE hours)
 - Clinical Trials with Medical Devices (7 CE hours)
 - Quality by Design (QbD) in Clinical Trials (5.5 CE hours)
- Coming soon:
 - Patient Centered Drug Development and Real-World Evidence/Data, a five (5) course program

<https://twd.ce.emorynursingexperience.com/>

National Research Mentoring Network

Transitioning to Research Independence: Funding & Grantsmanship for Newly Independent Investigators

Jaime S. Rubin, PhD

Vice Chair for Investigator Development

Professor of Medical Sciences (in Medicine) at CUIMC

Department of Medicine, Columbia University

Funding and Grantsmanship for Research and Career
Development Activities

<http://grantscourse.columbia.edu/>

Transitioning to Research Independence

Part 1 – October 19: Types of NIH Awards

Go to K-Club page for video and slides

Part 2 – November 9: Grantsmanship

Go to K-Club page for video and slides

Part 3 – TODAY: Review Processes

- After You Submit Your Application: Sequence of Events
- Review Scores and Criteria
- Rigor and Reproducibility

After You Submit Your Application: Sequence of Events

Resource Center

TRANSITIONING TO RESEARCH INDEPENDENCE:
FUNDING AND GRANTSMANSHIP

NRMN WEBINAR

#Funding #Grantsmanship #Grants

Date: 12/5/2019
Time: 1-2:30p CT

Dr. Jaime Rubin of Columbia Medical School will share her best practices and techniques for submitting NIH Research (R) and Career Development (K) Awards, and other helpful tips for transitioning to research independence.



Jaime S. Rubin, Ph.D.
Vice Chair for Investigator Development
Professor of Medical Sciences (in Medicine) at
CUMC Department of Medicine
Columbia University

#ThatsNIH #RepresentationMatters #NRMNmentoringMatters

PHS Assignment Request Form

PHS Assignment Request Form OMB Number: 0925-0001
Expiration Date: 02/28/2023

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Suggestions (optional) **Awarding Component Assignment Suggestions (optional)**

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components: Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Study Section Assignment Suggestions (optional) **Study Section Assignment Suggestions (optional)**

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for "Suggested Study Sections." Remove all hyphens, parentheses, and spaces. All suggestions will be considered; however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections: Suggestions are considered with other assignment factors. Not all suggestions can be honored.
Only 20 characters allowed

Rationale for assignment suggestions (optional) *Entry is limited to 1000 characters.*

Up to 1000 characters.

NIH Office of Extramural Research FORMS-F Series (Updated May 13, 2020) Page 38

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

PHS Assignment Request Form

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 application (optional) Entry is limited to 1000 characters.

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

1

Expertise:
Each entry is limited to 40 characters

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Limit your answers to expertise. DO NOT enter the names of individuals you'd like to review your application.

http://grants.nih.gov/grants/ElectronicReceipt/Files/Annotated_Forms_General_FORMS-F.pdf Jaime S. Rubin, Ph.D.; <http://grantcourse.columbia.edu>

Success Rates on NIH RePORT

The screenshot displays the NIH RePORT website interface. At the top left is the NIH logo and the text "Research Portfolio Online Reporting Tools (RePORT)". A search bar is located at the top right. Below the search bar is a navigation menu with links for HOME, ABOUT RePORT, FAQs, GLOSSARY, and CONTACT US. A secondary navigation bar contains tabs for QUICK LINKS, RESEARCH, ORGANIZATIONS, WORKFORCE, FUNDING, REPORTS, and LINKS & DATA. The main content area is titled "FUNDING" and features a left-hand sidebar with a list of categories: NIH Budget and Spending, Funding Facts, NIH Categorical Spending, Awards by Location, NIH Data Book, Success Rates (highlighted), NIH Recovery Act Sites, Federal Funds for R&D, and Federal Funds for Health R&D. The main content area shows a breadcrumb trail: Home > Funding > Success Rates. Below this is a large heading "Success Rates" with a graphic of three blue arrows pointing right. A list of four links is provided, each with a file icon and a size in parentheses: 1. NIH Success Rate Definition (~68KB), 2. Research Project Grants and Other Mechanisms: Competing applications, awards, success rates, and funding, by Institute/Center, mechanism/funding source, and activity code (~480KB), 3. SBIR and STTR: Competing applications, awards, success rates, and funding, by phase and state (~28KB), and 4. SBIR and STTR: Competing applications, awards, success rates, and funding, by phase (~188KB). Below this list is a section titled "Research Project Grants" with a single link: 1. Competing applications, awards, success rates, and total funding, by Institute/Center, FY 1997-2018.

https://report.nih.gov/success_rates/index.aspx

Success Rates on NIH RePORT

NHLBI K23 Application Success Rate

Fiscal Year	Activity Code	NIH Institute / Center	Number of Applications Reviewed	Number of Applications Awarded	Success Rate ¹	Total Funding ²
2010	K23	NHLBI	90	38	42%	\$5,466,560
2011	K23	NHLBI	89	39	44%	\$5,486,852
2012	K23	NHLBI	86	18	21%	\$2,635,891
2013	K23	NHLBI	107	32	30%	\$4,639,354
2014	K23	NHLBI	77	29	38%	\$4,147,948
2015	K23	NHLBI	94	36	38.3%	\$5,393,783
2016	K23	NHLBI	101	45	44.6%	\$8,086,510
2017	K23	NHLBI	138	52	37.7%	\$9,311,596
2018	K23	NHLBI	137	50	36.5%	\$8,957,091
2019	K23	NHLBI	127	43	33.9%	\$7,613,342

After You Submit Your Application: Sequence of Events



Type your
questions in
Chat!

Review Scores and Criteria for Research Grants

The graphic is a dark-themed poster for a webinar. At the top, it says 'Resource Center' in white. Below that, the main title 'TRANSITIONING TO RESEARCH INDEPENDENCE: FUNDING AND GRANTSMANSHIP' is in white, followed by 'NRMN WEBINAR' in large yellow letters. A teal diagonal shape on the left contains the text about Dr. Jaime Rubin. On the right, the date and time are listed. A circular portrait of Dr. Rubin is shown. At the bottom, several hashtags are listed: #Funding, #Grantsmanship, #Grants, #ThisIsNIH, #RepresentationMatters, and #MentoringMatters. A DNA double helix is visible in the top left corner.

Resource Center

TRANSITIONING TO RESEARCH INDEPENDENCE:
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#MentoringMatters

Comparison of Review Criteria for Research Grants and K Awards

Research Grants	K Awards
<p>Overall Impact “likelihood for the project to exert a sustained, powerful influence on the research fields involved”</p>	<p>Overall Impact “likelihood that the proposed <u>career development and research plan</u> will enhance the candidates’ potential for a productive, <u>independent</u> scientific research career in a health-related field”</p>
Significance	Candidate
Innovation	Career Development Plan/Career Goals & Objectives
Investigators	Mentor(s), Co-Mentor(s), Collaborator(s), and Consultant(s)
Approach	Research Plan
Environment	Environment & Institutional Commitment to the Candidate

Review Criteria for K Applications: Candidate

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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Review Criteria for K Applications: Candidate

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?”

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

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Review Criteria for K Applications: Candidate



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Review Criteria for K Applications: Career Development Plan

2. Career Development Plan/Career Goals & Objectives

- “What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?”
- Are the candidate's prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration 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 research independence?”

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

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Review Criteria for K Applications: Career Development Plan

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

- “Are there adequate plans for monitoring and evaluating the candidate’s research and career development progress?”
- If proposed, will the clinical trial experience contribute to the applicant’s research career development?

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

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Review Criteria for K Applications: Career Development Plan



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Review Criteria for K Applications: Research Plan

3. Research Plan

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

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

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Review Criteria for K Applications: Research Plan

3. Research Plan

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

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

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Review Criteria for K Applications: Research Plan



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Review Criteria for K Applications: Mentor, Co-mentor, Consultant, Collaborator

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

- “Are the qualifications of the mentor(s) in the area of the proposed research appropriate?”
- Do(es) the mentor(s) adequately address the candidate’s potential 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 guidance and advice to the candidate?
- Is the mentor’s description of the elements of the research career development activities, including formal course work adequate?”

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

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Review Criteria for K Applications: Mentor, Co-mentor, Consultant, Collaborator

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?”

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

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Review Criteria for K Applications: Mentor, Co-mentor, Consultant, Collaborator

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?”

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

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Review Criteria for K Applications: Mentor, Co-mentor, Consultant, Collaborator



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Review Criteria for K Applications: Environment and Institutional Commitment

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?”

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

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Review Criteria for K Applications: Environment and Institutional Commitment

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?”

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

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Review Criteria for K Applications: Environment and Institutional Commitment



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Rigor and Reproducibility

Resource Center

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Rigor and Reproducibility

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 <u>prior research</u> that serves as the key support for the proposed project <u>rigorous</u> ?
Scored Review Criteria	Research Plan	Not Applicable	Has the candidate included plans to <u>address weaknesses</u> in the <u>rigor of prior research</u> that serves as the key support for the proposed project?

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-229.html>

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Rigor and Reproducibility

- Rigor of the prior research
- Rigor of experimental design for robust and unbiased results
- Consideration of relevant biological variables
- Authentication of key biological and/or chemical resources

Thank You!