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/
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
PHS Assignment Request Form

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.html#AwardingComponent

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 "ZRG1-HDMP" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SRIR/STTR panel for informatics.

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

Rationale for assignment suggestions (optional)

Entry is limited to 1000 characters.

Up to 1000 characters.
PHS Assignment Request Form

List individuals who should not review your application and why (optional)

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 the review panel.

Identify scientific areas of expertise needed to review your application (optional)

Note: Do not provide names of individuals.

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


Jaimie S. Rubin, Ph.D.; http://grantsofcourse.columbia.edu
Success Rates on NIH RePORT

### NHLBI K23 Application Success Rate

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Activity Code</th>
<th>NIH Institute / Center</th>
<th>Number of Applications Reviewed</th>
<th>Number of Applications Awarded</th>
<th>Success Rate</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>K23</td>
<td>NHLBI</td>
<td>90</td>
<td>38</td>
<td>42%</td>
<td>$5,466,560</td>
</tr>
<tr>
<td>2011</td>
<td>K23</td>
<td>NHLBI</td>
<td>89</td>
<td>39</td>
<td>44%</td>
<td>$5,486,652</td>
</tr>
<tr>
<td>2012</td>
<td>K23</td>
<td>NHLBI</td>
<td>86</td>
<td>18</td>
<td>21%</td>
<td>$2,635,891</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NHLBI</td>
<td>107</td>
<td>32</td>
<td>30%</td>
<td>$4,639,354</td>
</tr>
<tr>
<td>2014</td>
<td>K23</td>
<td>NHLBI</td>
<td>77</td>
<td>29</td>
<td>38%</td>
<td>$4,147,948</td>
</tr>
<tr>
<td>2015</td>
<td>K23</td>
<td>NHLBI</td>
<td>94</td>
<td>36</td>
<td>38.3%</td>
<td>$5,393,783</td>
</tr>
<tr>
<td>2016</td>
<td>K23</td>
<td>NHLBI</td>
<td>101</td>
<td>45</td>
<td>44.6%</td>
<td>$8,086,510</td>
</tr>
<tr>
<td>2017</td>
<td>K23</td>
<td>NHLBI</td>
<td>138</td>
<td>52</td>
<td>37.7%</td>
<td>$9,311,596</td>
</tr>
<tr>
<td>2018</td>
<td>K23</td>
<td>NHLBI</td>
<td>137</td>
<td>50</td>
<td>36.5%</td>
<td>$8,957,091</td>
</tr>
<tr>
<td><strong>2019</strong></td>
<td><strong>K23</strong></td>
<td><strong>NHLBI</strong></td>
<td><strong>127</strong></td>
<td><strong>43</strong></td>
<td><strong>33.9%</strong></td>
<td><strong>$7,613,342</strong></td>
</tr>
</tbody>
</table>

[Source](https://report.nih.gov/success_rates/index.aspx)

[Jaime S. Rubin, Ph.D.](http://grantcourse.columbia.edu)
After You Submit Your Application: Sequence of Events

Type your questions in Chat!
TRANSITIONING TO RESEARCH INDEPENDENCE:
FUNDING AND GRANTSMANSHIP

NRMN WEBINAR

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

#Funding  #Grantsmanship  #Grants
#RepresentationsMatters  #ThisIsNIH
#NRMNmentoringMatters
# Comparison of Review Criteria for Research Grants and K Awards

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


Joane S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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?”


Jaime S. Rubin, Ph.D.; http://granteecourse.columbia.edu
Review Criteria for K Applications: Candidate

Type your questions in Chat!
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?”


Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
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?


Review Criteria for K Applications:
Career Development Plan

Type your questions in Chat!
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?


Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
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?


Review Criteria for K Applications: Research Plan

Type your questions in Chat!
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?”


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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?”


Jaime S. Rubin, Ph.D.; http://grants.columbia.edu
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?”


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Review Criteria for K Applications: Mentor, Co-mentor, Consultant, Collaborator

Type your questions in Chat!
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?”


James S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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?”


Jaime S. Rubin, Ph.D.; http:// grantscience.columbia.edu
Review Criteria for K Applications:
Environment and Institutional Commitment

Type your questions in Chat!
Rigor and Reproducibility

TRANSITIONING TO RESEARCH INDEPENDENCE: FUNDING AND GRANTSMANSHP

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Rigor and Reproducibility

NIH Review criteria – changes

For applications with deadlines on or after January 25, 2019

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


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!