Transitioning to Research Independence

Part 3: Review Processes

December 14, 2020

K-Club

Sponsored by:

EMORY UNIVERSITY SCHOOL OF MEDICINE
Department of Pediatrics

Children's Healthcare of Atlanta

CFAR

Georgia CTSA
Georgia Clinical & Translational Science Alliance

EMORY UNIVERSITY SCHOOL OF 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/

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

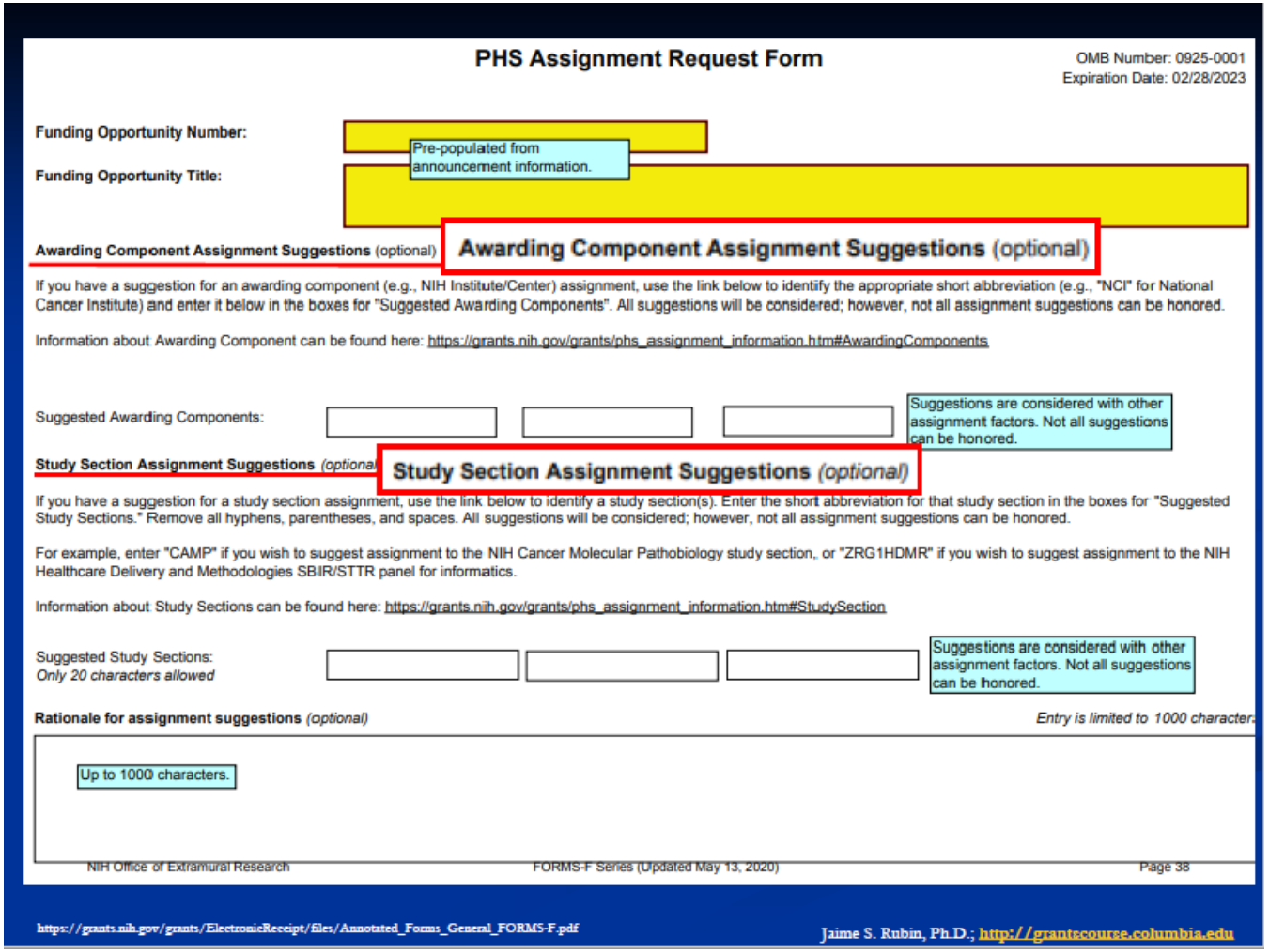
Go to K-Club page for video and slides

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



PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Funding Opportunity Number:

Funding Opportunity Title:

Pre-populated from announcement information.

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 "ZRG1HDMR" 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:
Only 20 characters allowed

Suggestions are considered with other assignment factors. Not all suggestions can be honored.

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

https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-F.pdf

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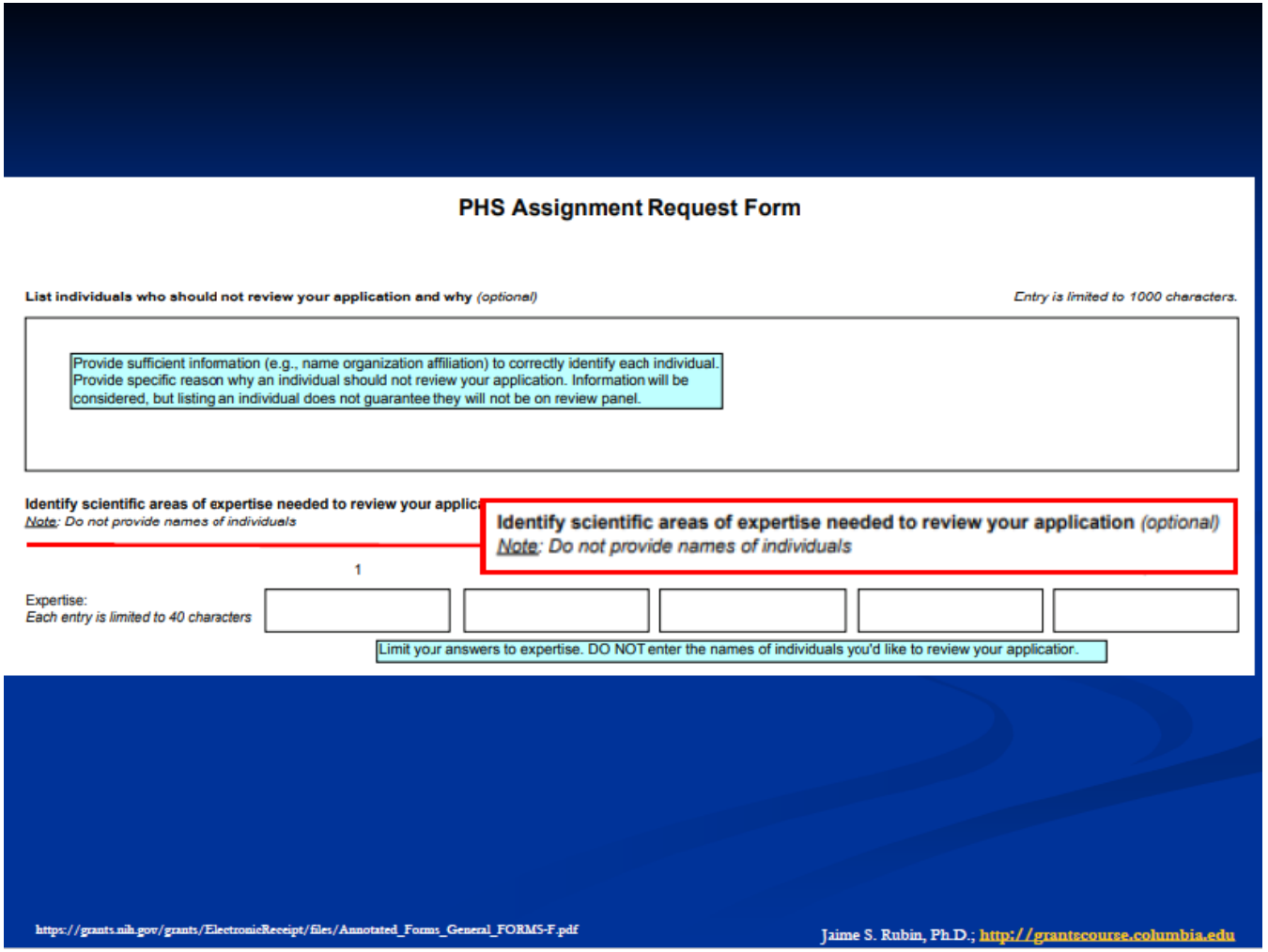
PHS Assignment Request Form



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 applica

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

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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

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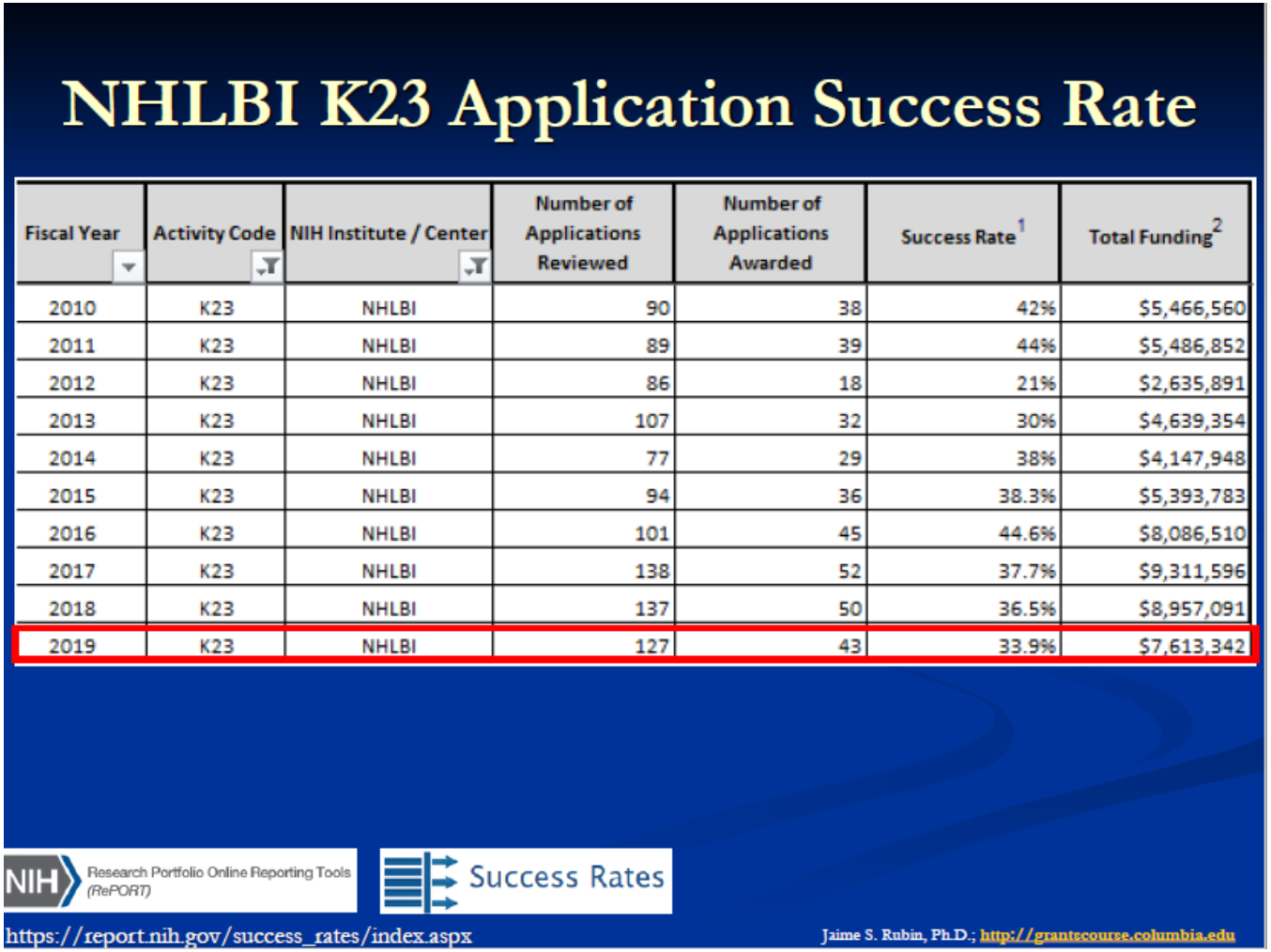
Success Rates on NIH RePORT

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

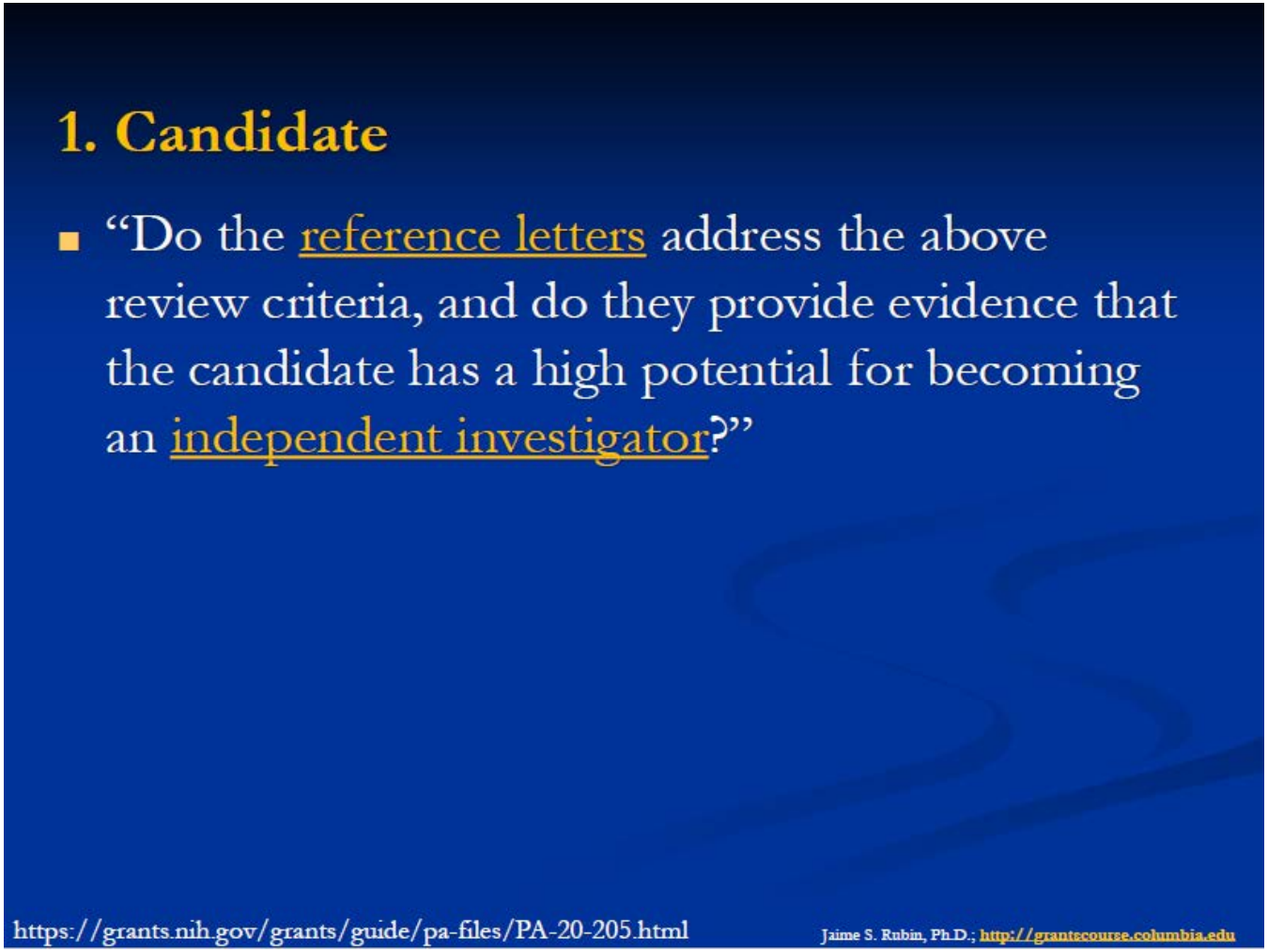
Review Scores and Criteria for Research Grants

Comparison of Review Criteria for Research Grants and K Awards

Research Grants	K Awards
Overall Impact "likelihood for the project to exert a sustained, powerful influence on the research fields involved"	**Overall Impact** "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"
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

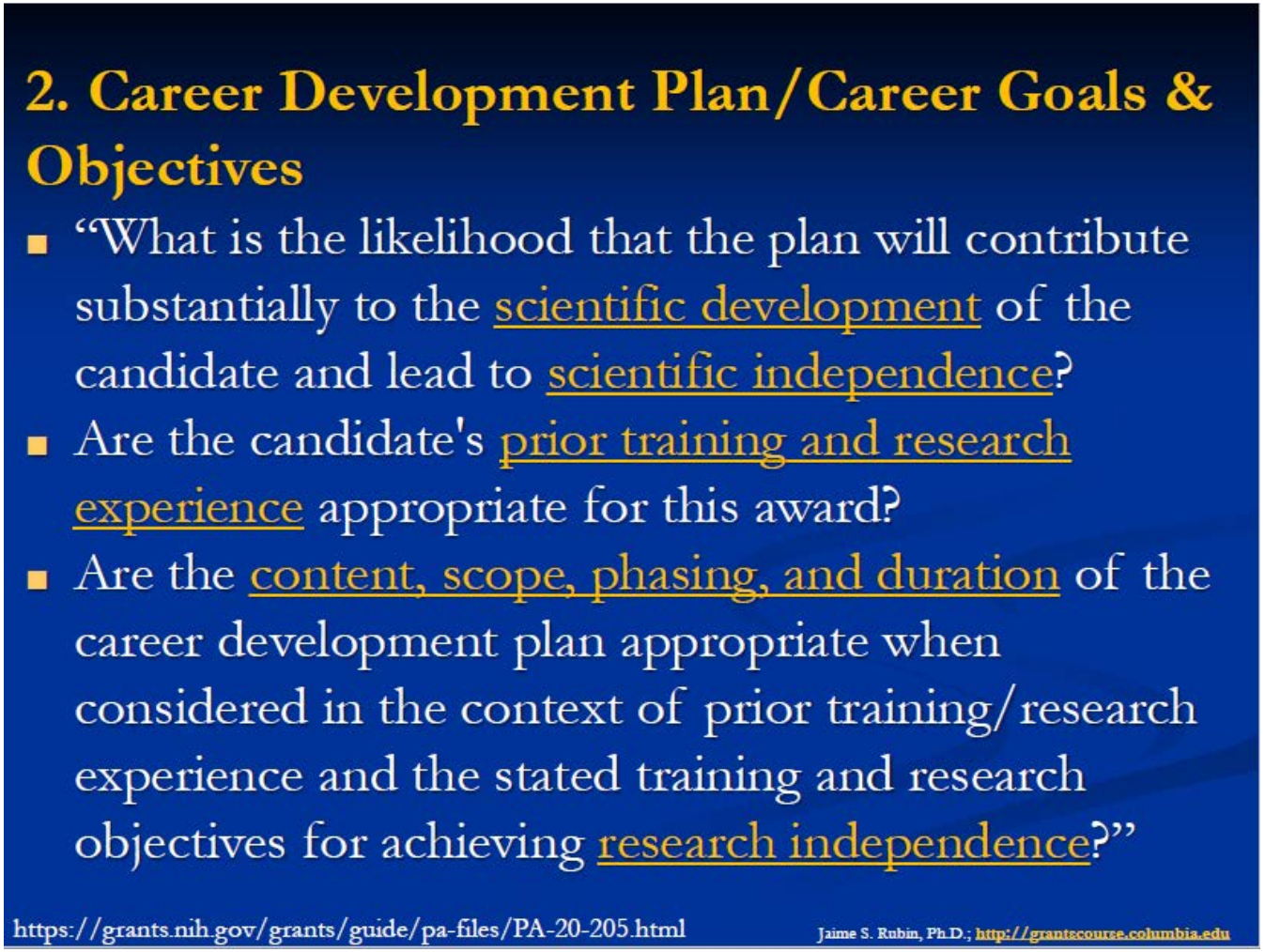
Review Criteria for K Applications: Candidate

Review Criteria for K Applications: Candidate

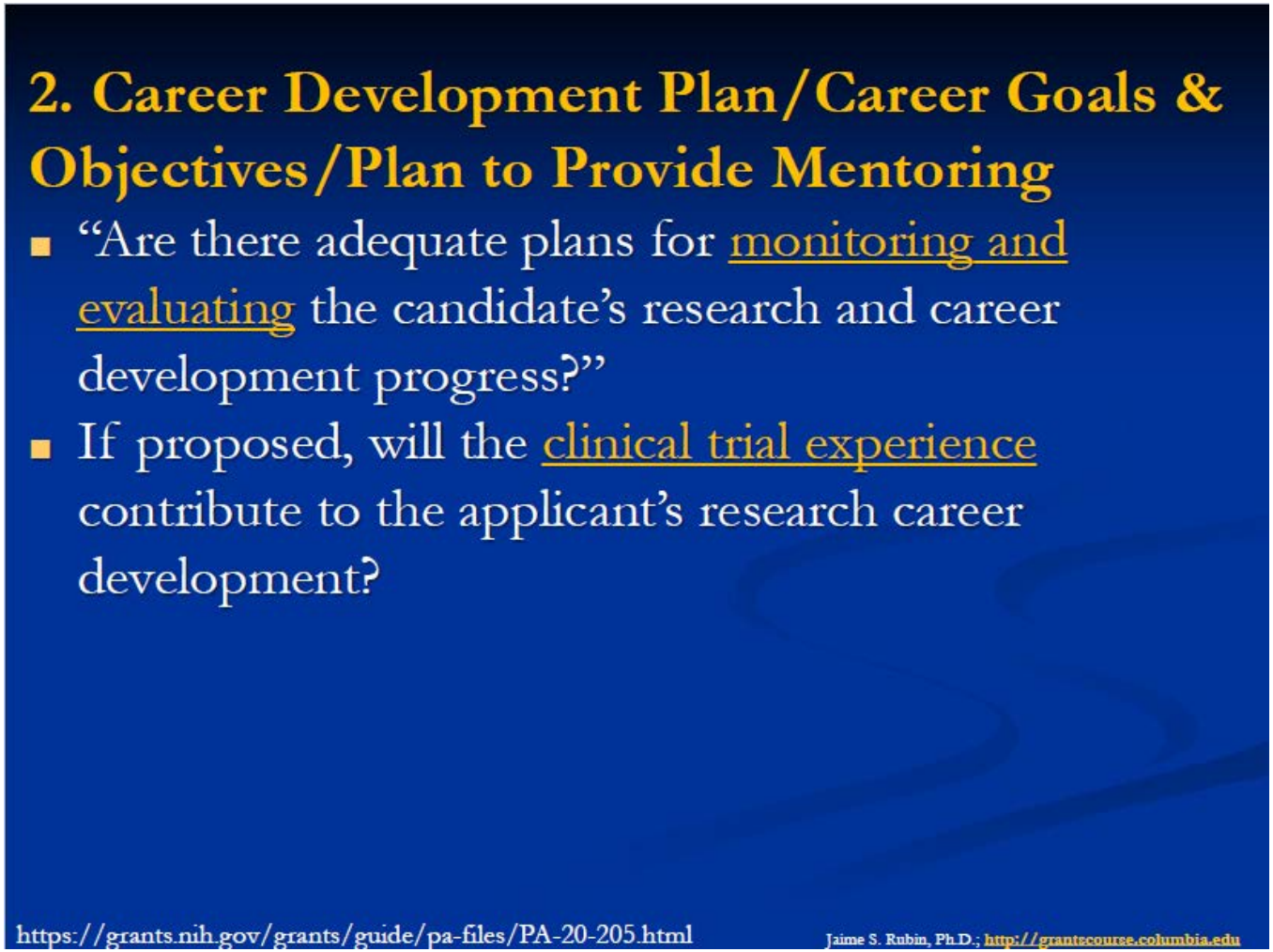


Review Criteria for K Applications: Candidate

Review Criteria for K Applications: Career Development Plan

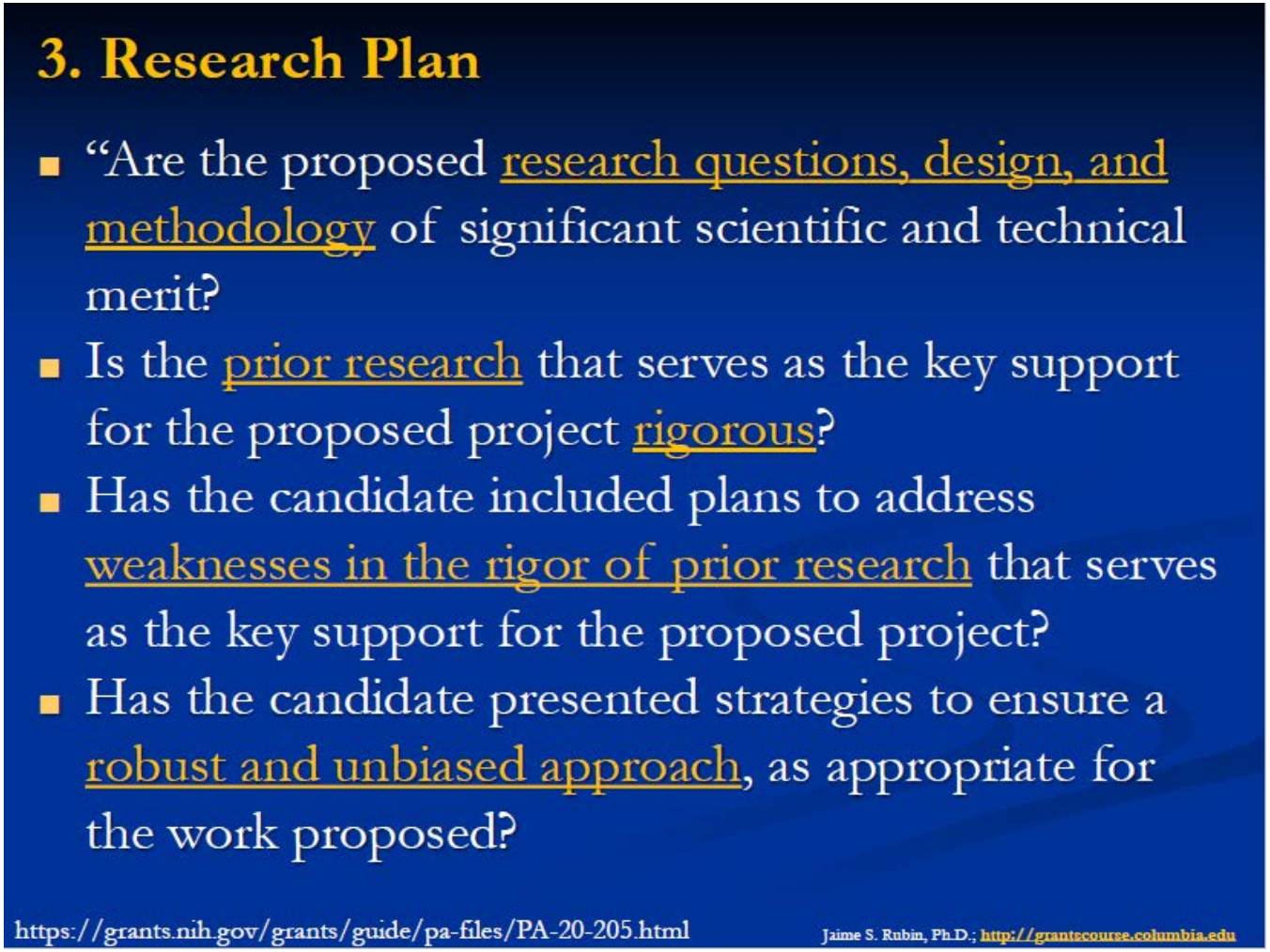


Review Criteria for K Applications: Career Development Plan

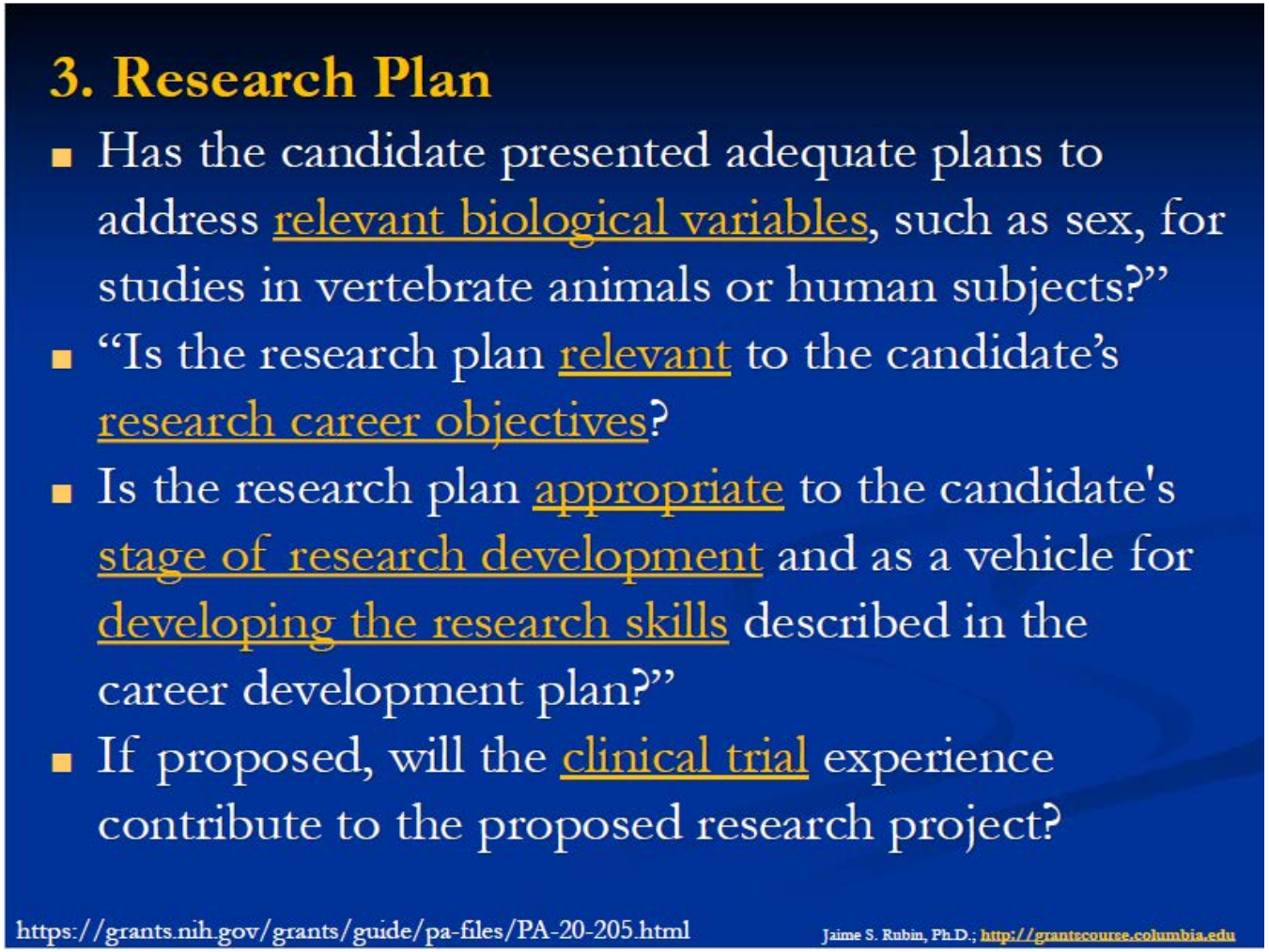


Review Criteria for K Applications: Career Development Plan

Review Criteria for K Applications: Research Plan

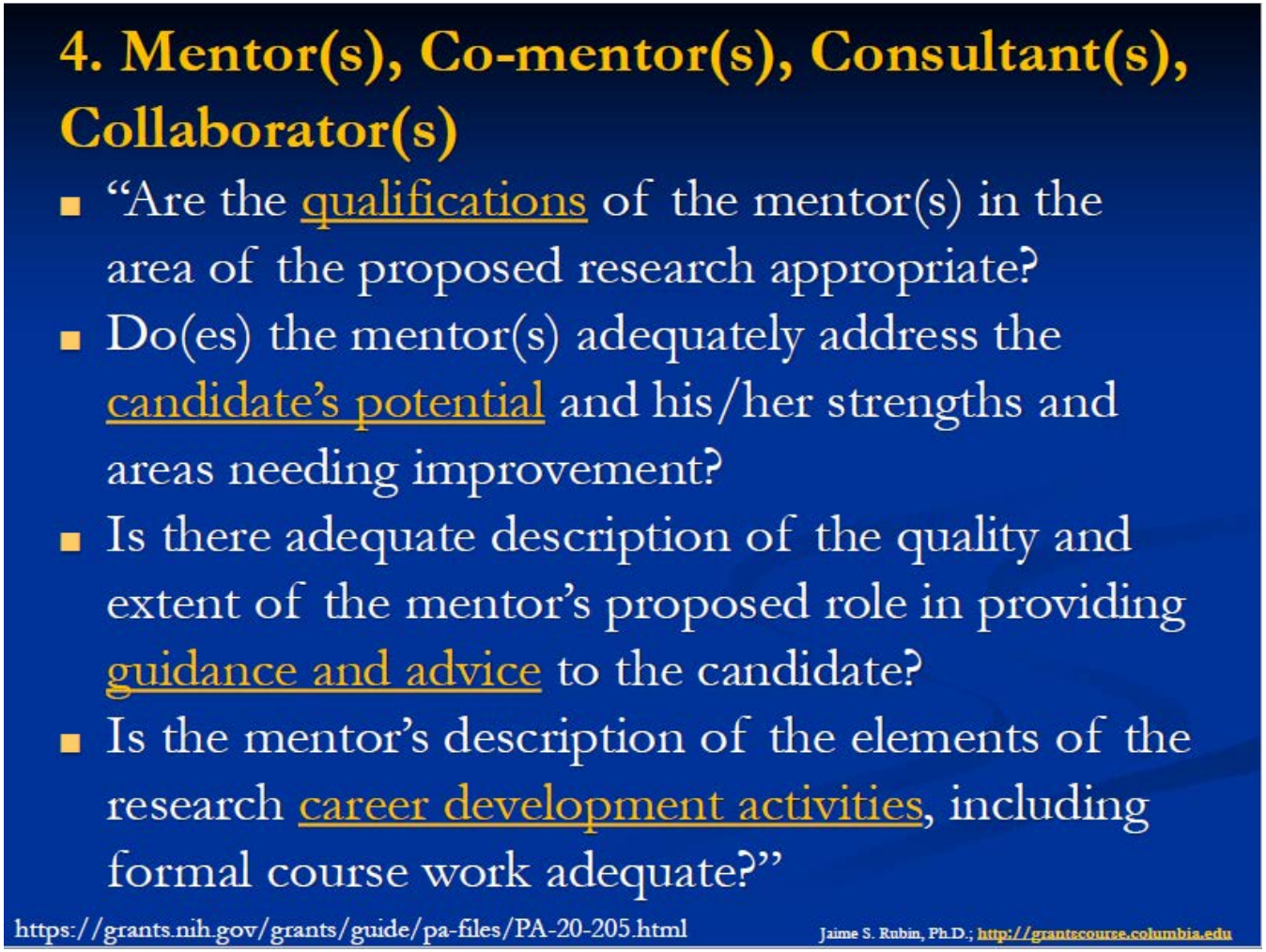


Review Criteria for K Applications: Research Plan

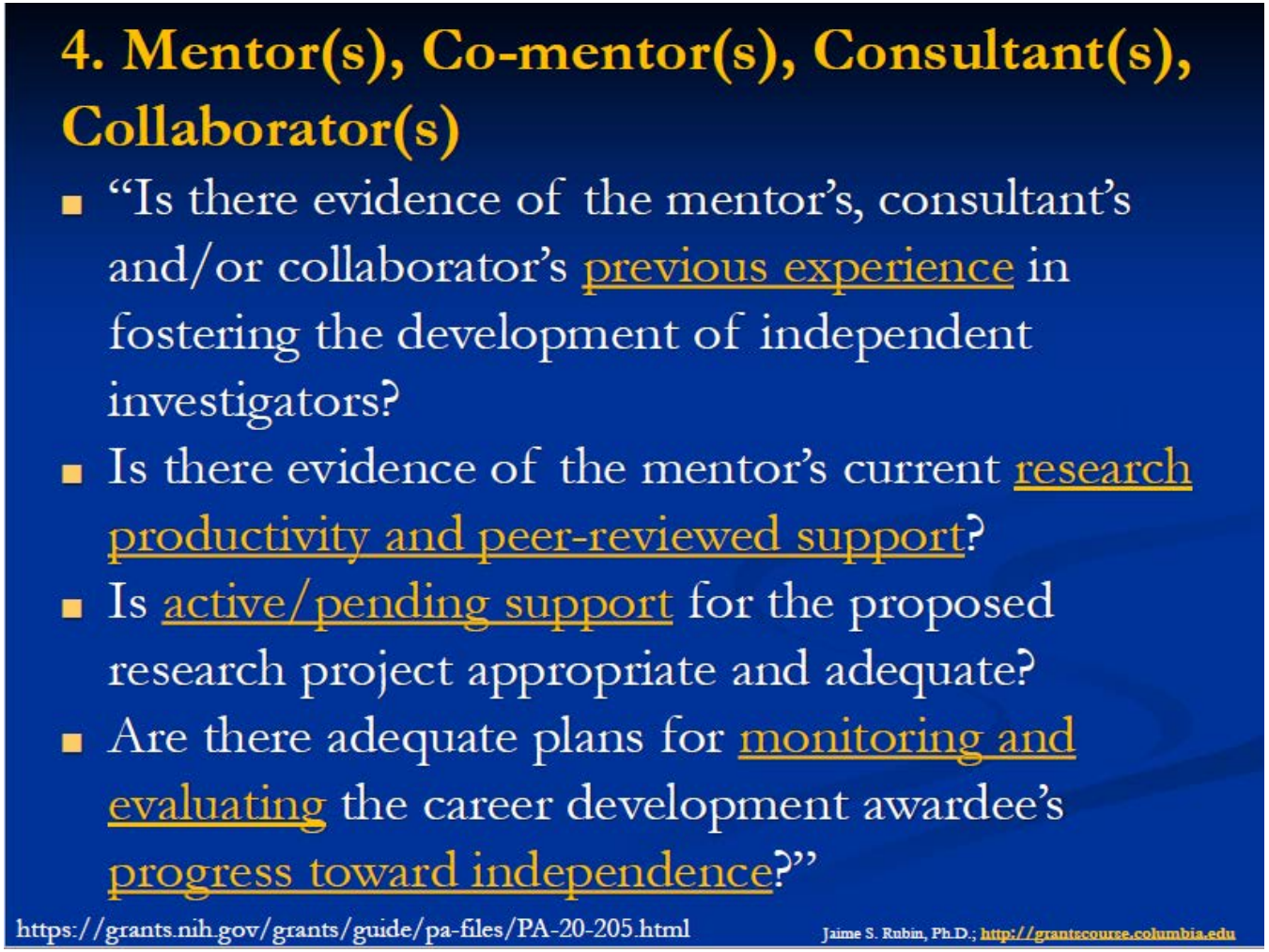


Review Criteria for K Applications: Research Plan

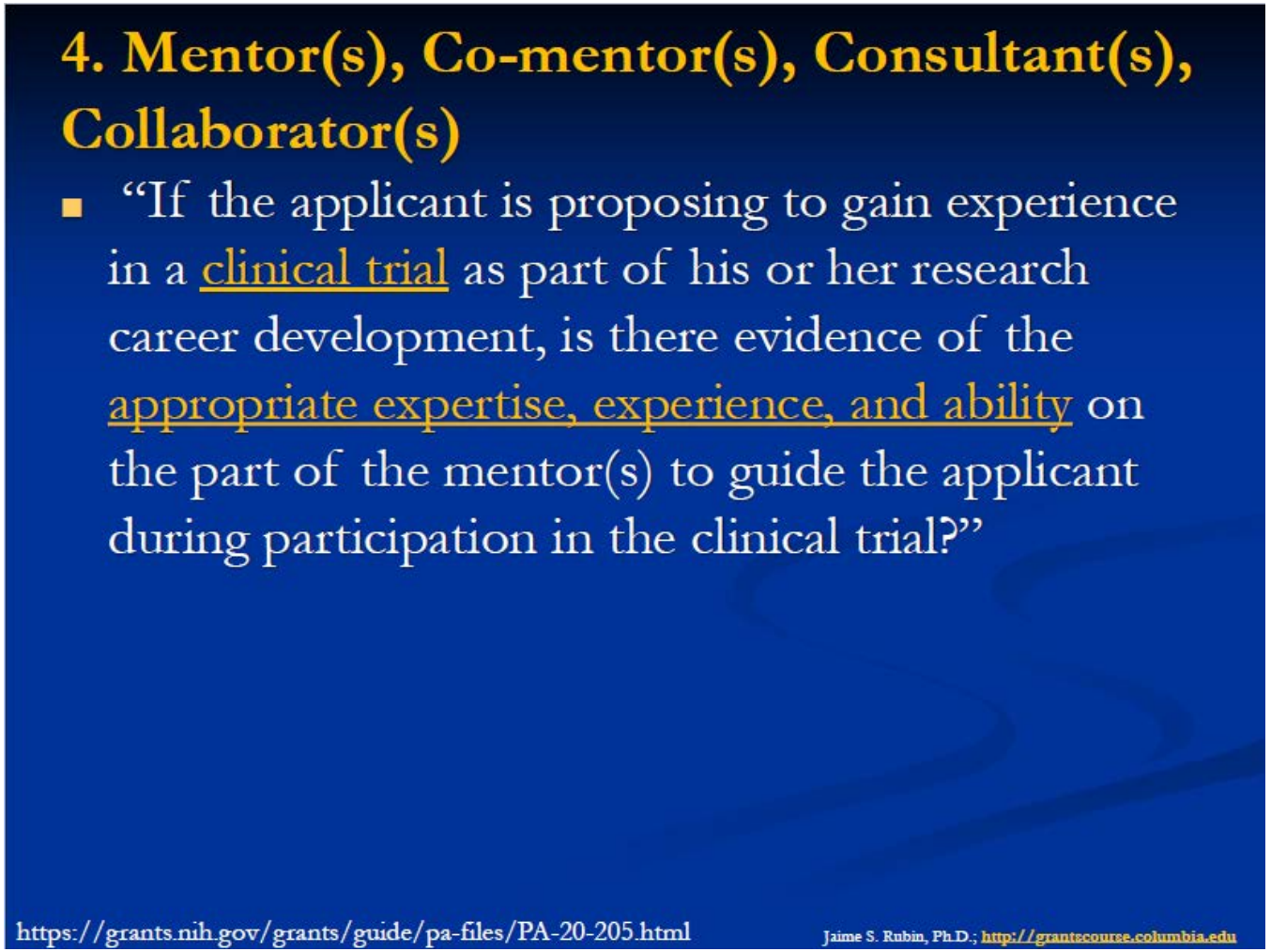
Review Criteria for K Applications: Mentor, Co-mentor, Consultant, Collaborator



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



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



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

Review Criteria for K Applications: Environment and Institutional Commitment

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Review Criteria for K Applications: Environment and Institutional Commitment

Rigor and Reproducibility

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 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

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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!