K Award Info Session for Clinicians

March 25, 2022

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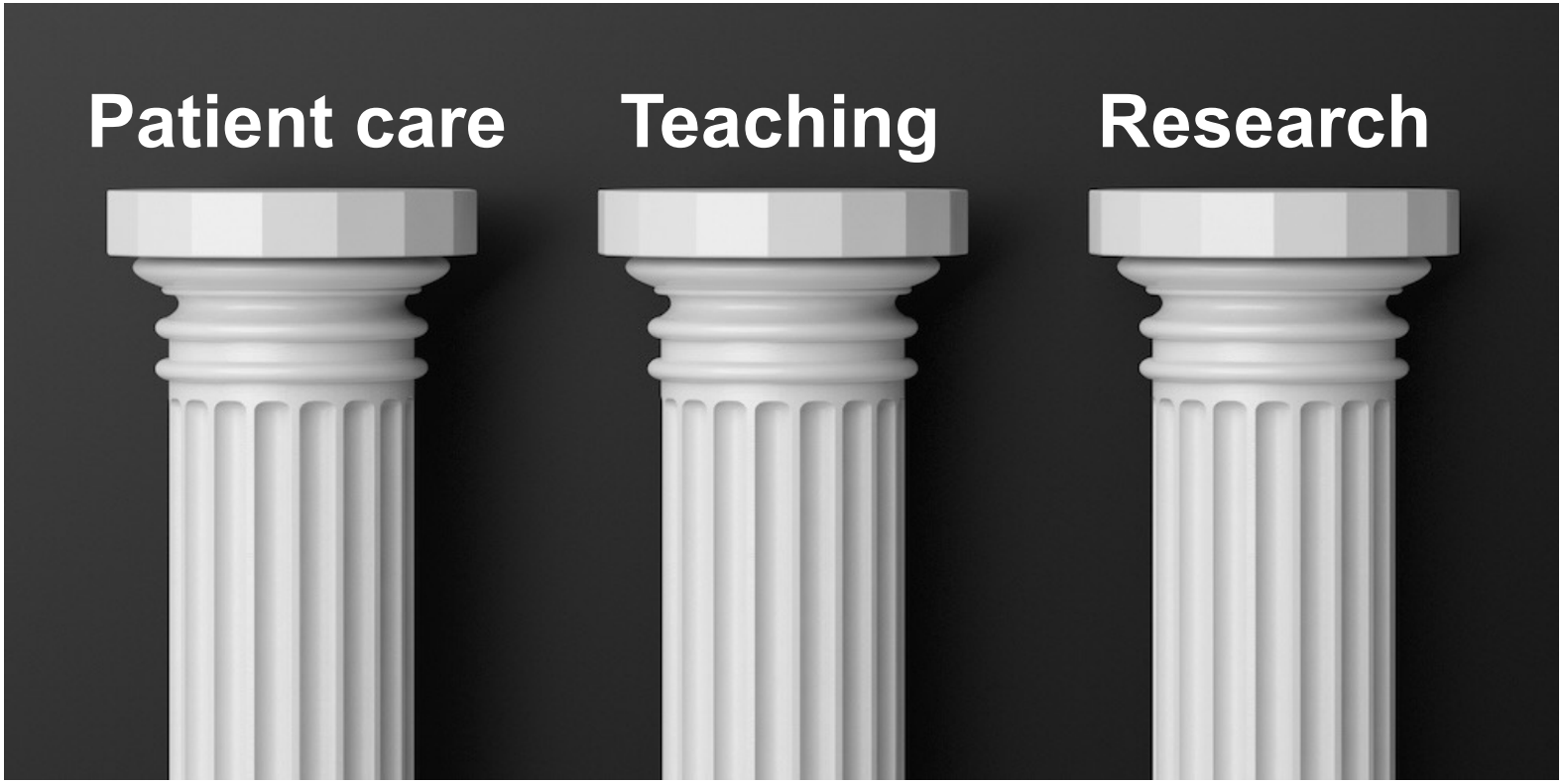
COLUMBIA | VAGELOS COLLEGE OF PHYSICIANS AND SURGEONS
OFFICE FOR RESEARCH

Clinician-Scientist



Famous clinician-scientist

- **I am thinking about doing research.**
- **I am thinking of spending my career in research.**
- **I would like to become an independent researcher.**
- **I am an independent researcher.**

Independent Researcher

R01 grant award (NIH)
High impact papers
World-renown expert

NIH

King's Landing - Westeros

NIH

Bethesda, MD

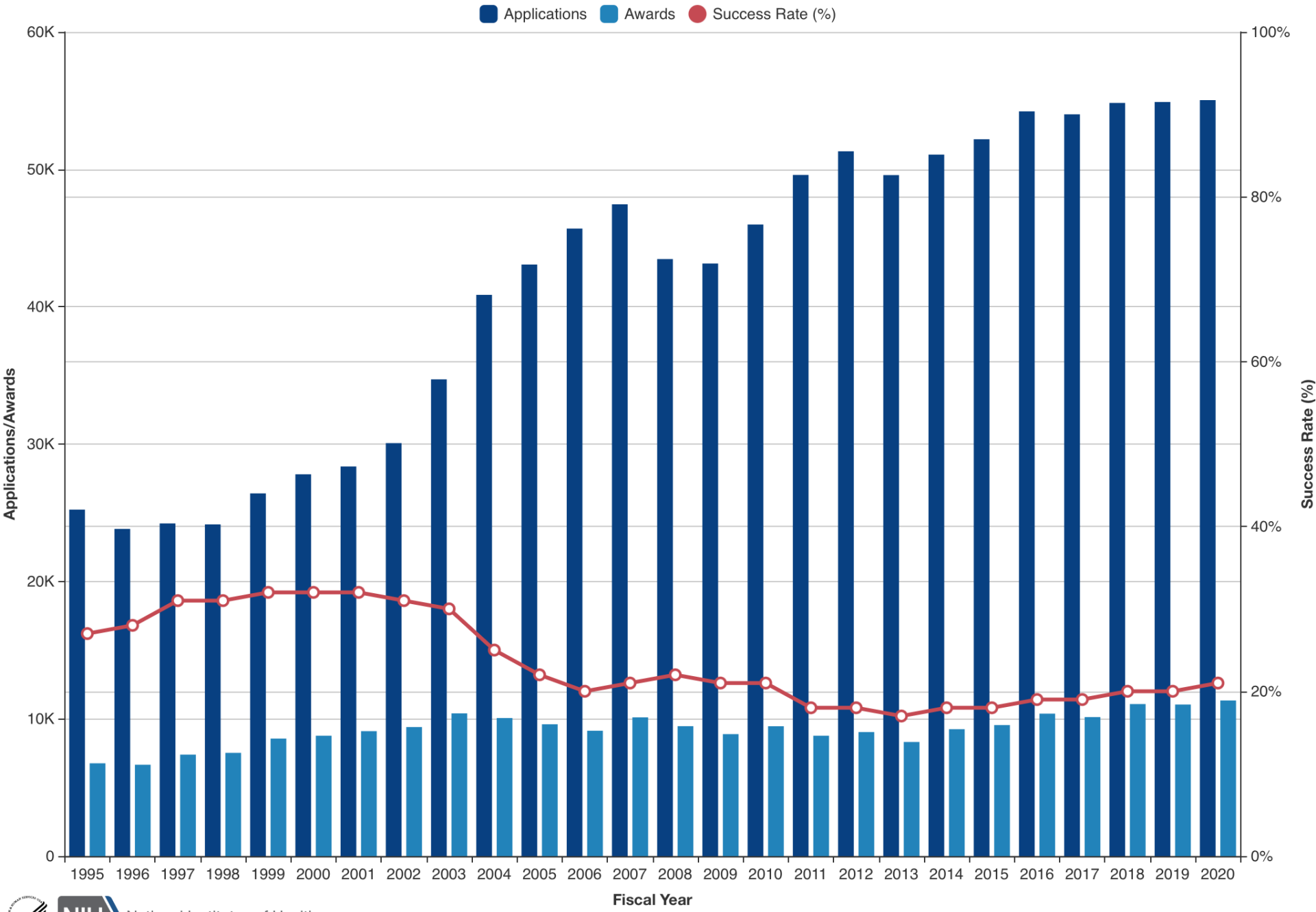
NIH Structure and Resources

- Part of the US Department of Health and Human Services
- Comprised of 27 institutes and centers
- Close to 20,000 employees
- More than 80% of the budget goes to more than 300,000 research personnel at 2,500 universities and research institutions through more than 50,000 grants
- About 10% of its budget goes to 6,000 NIH scientists are conducting intramural research

NIH Institutes

1. National Cancer Institute (NCI)
2. National Eye Institute (NEI)
3. National Heart, Lung, and Blood Institute (NHLBI)
4. National Human Genome Research Institute (NHGRI)
5. National Institute on Aging (NIA)
6. National Institute on Alcohol Abuse and Alcoholism (NIAAA)
7. National Institute of Allergy and Infectious Diseases (NIAID)
8. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
9. National Institute of Biomedical Imaging and Bioengineering (NIBIB)
10. National Institute of Child Health and Human Development (NICHD)
11. National Institute on Deafness and Other Communication Disorders (NIDCD)
12. National Institute of Dental and Craniofacial Research (NIDCR)
13. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
14. National Institute on Drug Abuse (NIDA)
15. National Institute of Environmental Health Sciences (NIEHS)
16. National Institute of General Medical Sciences (NIGMS)
17. National Institute of Mental Health (NIMH)
18. National Institute of Neurological Disorders and Stroke (NINDS)
19. National Institute of Nursing Research (NINR)
20. National Library of Medicine (NLM)
21. National Institute on Minority Health and Health Disparities (NIMHD)

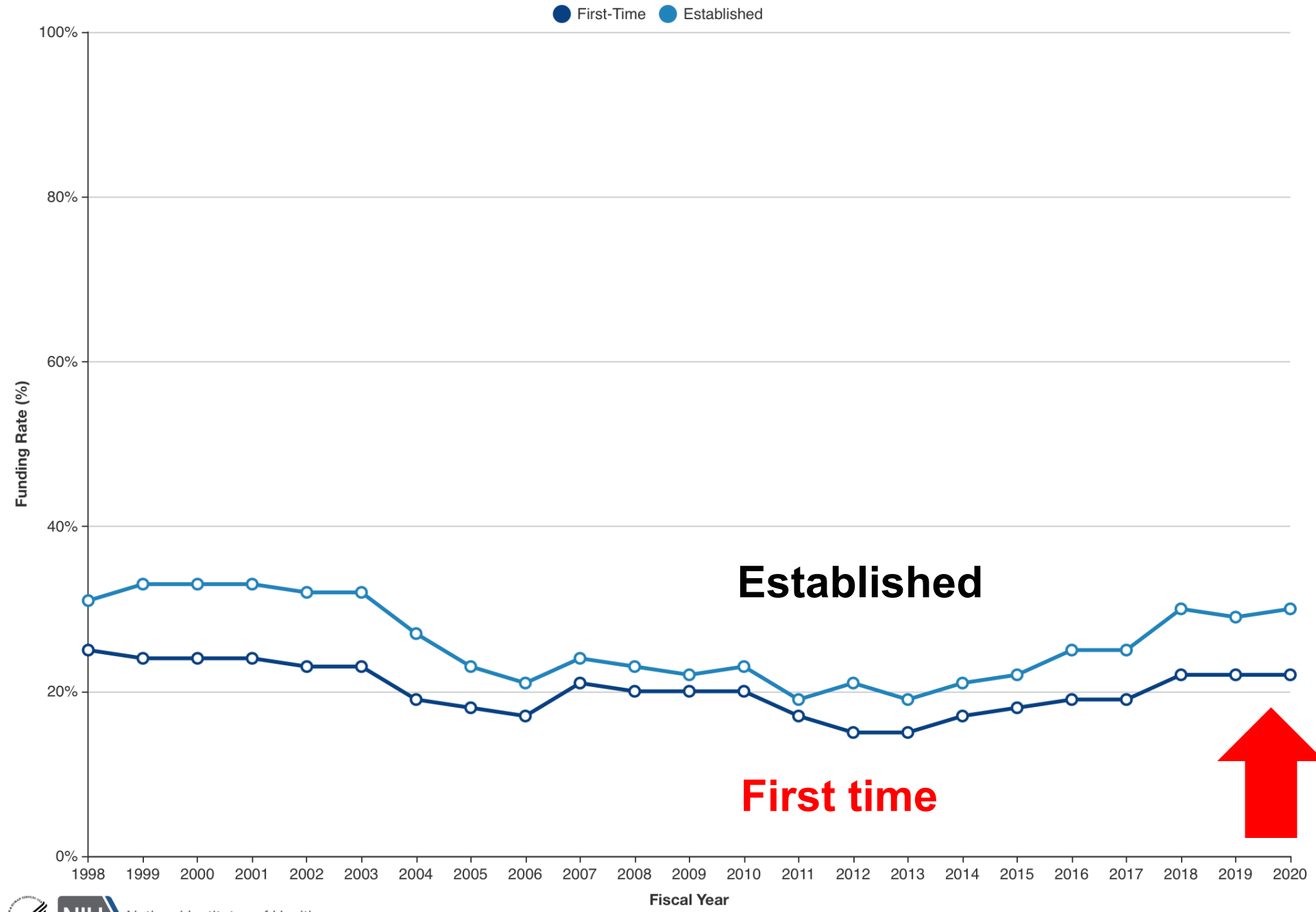
Research Project Grants: Competing Applications, Awards, and Success Rates

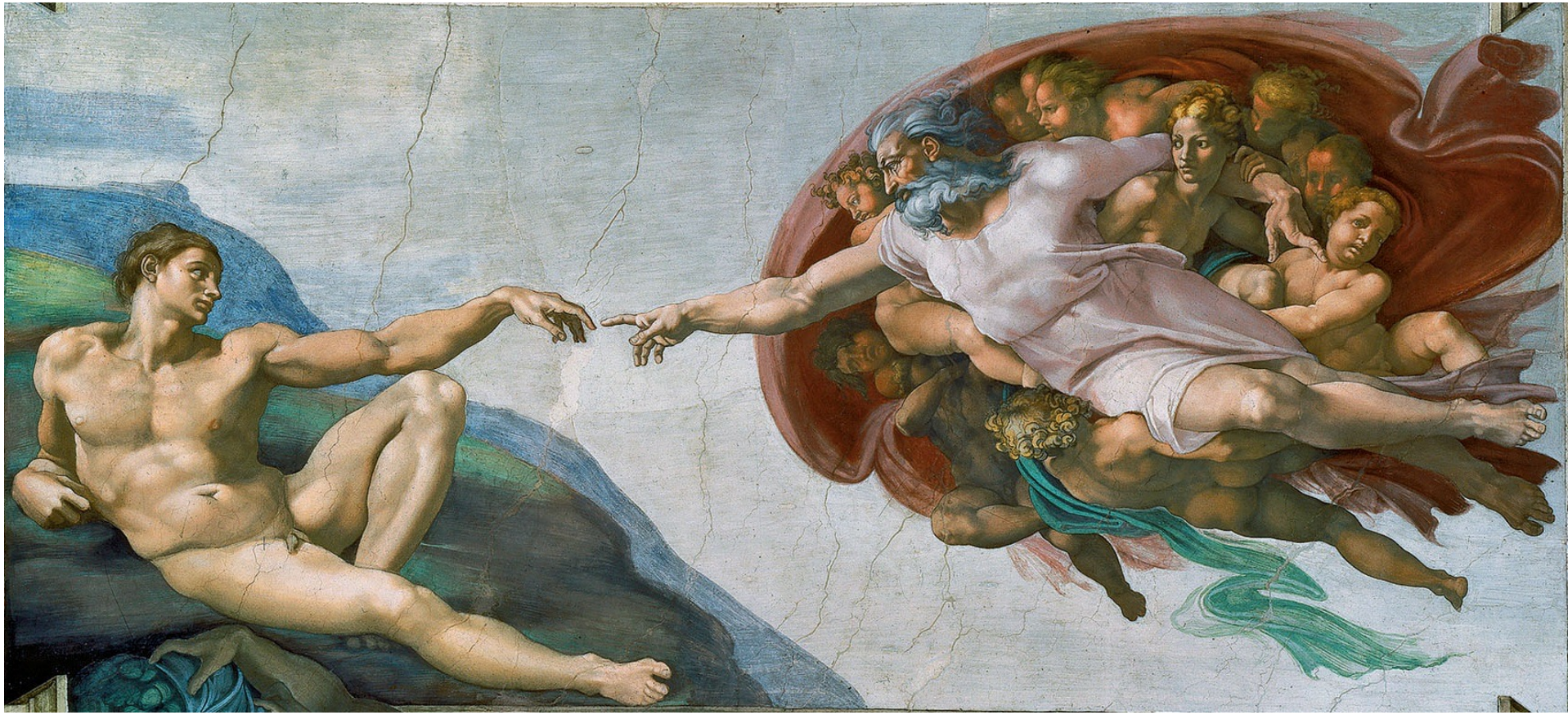


NIH National Institutes of Health
Office of Extramural Research

Data for this report are available at NIH Data Book - https://report.nih.gov/nihdatabook/report/20

R01-Equivalent Investigators, New (Type 1): Funding Rates, by Career Stage of Investigator

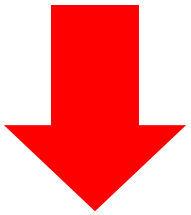




K Award

Grant support of an early career scientist, committed to research and a demonstrated aptitude do develop into an independent investigator.

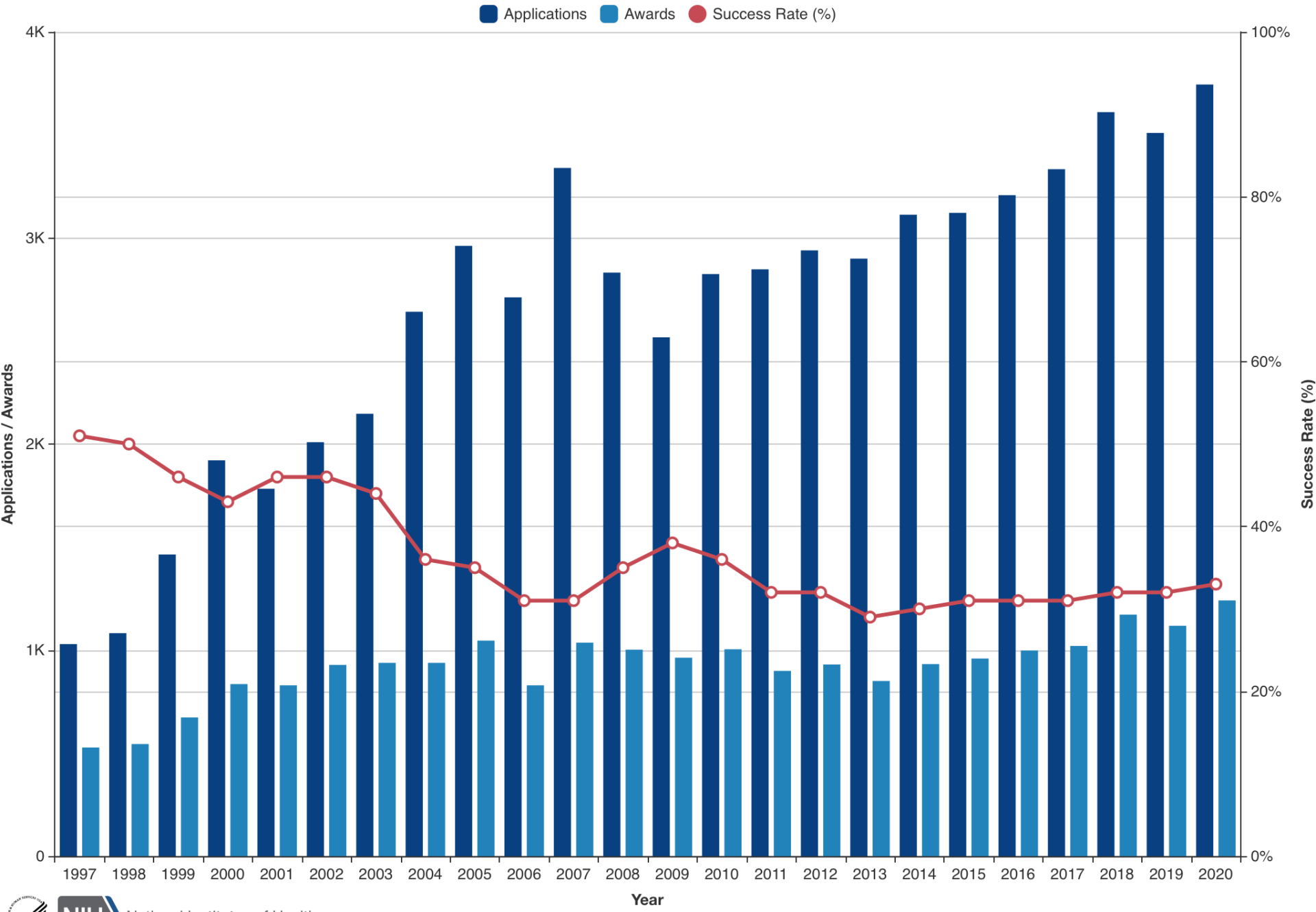
- **I am thinking about doing research.**
- **I am thinking of spending my career in research.**
- **I would like to become an independent researcher.**



K award

- **I am an independent researcher.**

Research Career Development Awards: Competing Applications, Awards, and Success Rates



NIH National Institutes of Health
Office of Extramural Research

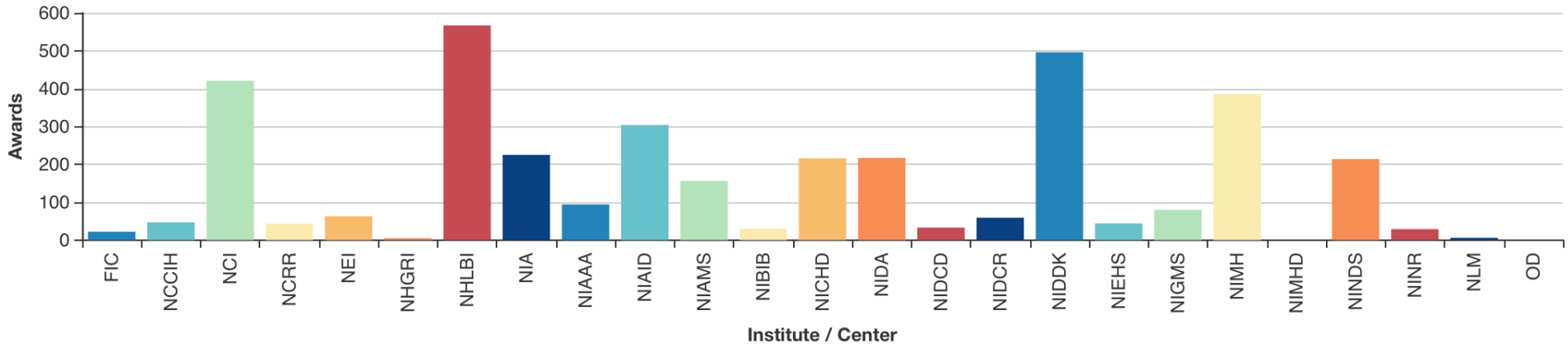
Data for this report are available at NIH Data Book - https://report.nih.gov/nihdatabook/report/211

K Award Funding Rates

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Success Rates	51%	50%	46%	43%	46%	46%	44%	36%	35%	31%	31%	35%	38%	36%	32%	32%	29%	30%	31%	31%	31%	32%	32%	33%
K01	35%	34%	39%	36%	43%	42%	43%	32%	31%	28%	32%	39%	36%	40%	34%	32%	33%	34%	34%	32%	31%	31%	32%	35%
K02	53%	57%	71%	54%	56%	46%	48%	47%	38%	35%	42%	38%	36%	29%	38%	26%	23%	40%	19%	22%	56%	29%	24%	29%
K07	49%	44%	43%	41%	36%	39%	36%	20%	22%	24%	26%	34%	39%	22%	25%	7%	27%	18%	25%	27%	14%	28%	25%	67%
K08	55%	58%	52%	50%	50%	52%	47%	40%	39%	34%	36%	44%	47%	44%	42%	42%	36%	40%	40%	38%	44%	40%	44%	41%
K12	100%	45%	36%	24%	43%	35%	46%	31%	28%	34%	45%	53%	52%	49%	32%	47%	45%	26%	44%	45%	46%	55%	35%	46%
K22		0%	9%	19%	38%	40%	33%	32%	29%	29%	27%	23%	26%	25%	30%	24%	20%	15%	23%	24%	19%	19%	14%	20%
K23		100%	42%	49%	46%	47%	42%	36%	34%	27%	33%	38%	44%	38%	34%	37%	32%	38%	35%	36%	34%	38%	37%	38%
K24			44%	45%	45%	44%	45%	42%	51%	44%	47%	50%	47%	61%	45%	46%	39%	49%	48%	57%	40%	52%	52%	48%
K25				42%	56%	52%	42%	30%	33%	31%	35%	48%	22%	30%	23%	25%	29%	27%	23%	25%	24%	17%	34%	34%
K99										100%	20%	23%	29%	25%	22%	23%	22%	22%	22%	23%	23%	26%	24%	25%
All Other Ks	66%	70%	54%	49%	51%	59%	56%	49%	60%	48%	49%	67%	66%	47%	47%	42%	53%	33%	36%	44%	41%	41%	33%	37%

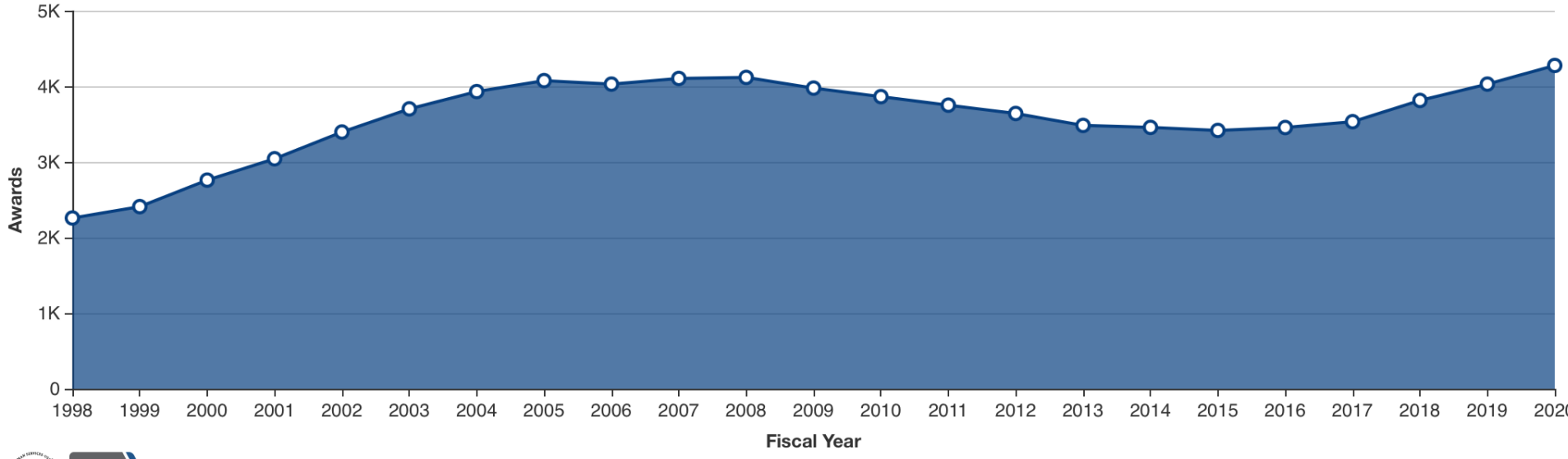
Individual Research Career Development Awards: Awards, by Institute / Center

Awards for 2011



Awards Trend NIH Total

Show T204 document



Types of K Award

- **K08**: To provide the opportunity for promising clinician scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research, and aid in filling the academic faculty gap in health profession's institutions.
- **K23**: To provide support for the career development of clinically trained professionals who have made a commitment to patient-oriented research, and who have the potential to develop into productive, clinical investigators.
- **K01**: For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.
- **K99/R00**: To support both an initial mentored research experience (K99) followed by independent research (R00) for highly qualified, postdoctoral researchers, to secure an independent research position. Award recipients are expected to compete successfully for independent R01 support during the R00 phase.

K Components

- Cover letter
- Project summary
- Project narrative
- Facilities and other resources
- Equipment

K Components

- **Candidate information and goals**
  - **Candidate background**
  - **Career goals and objectives**
  - **Candidate's plan for career development/training activities**

K Components

- Specific aims page
- Research plan
  - Significance, Innovation, Approach
  - Pilot data?

K Components

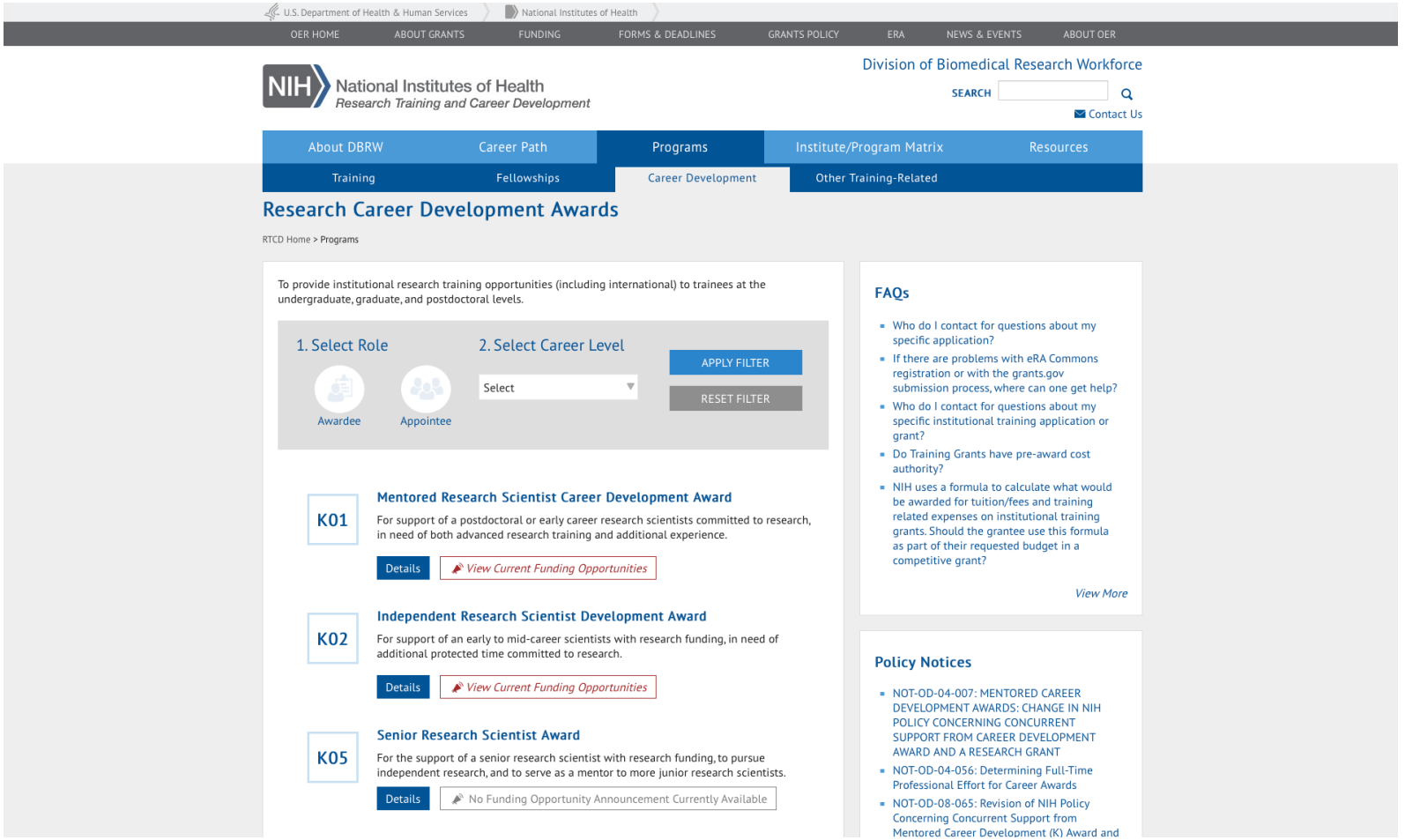
- Plans and statements from mentors and co-mentors
- Letters of support (collaborators, contributors, and consultants)
- References letters (3-5)

K Components

- Institutional environment description
- Institutional commitment
- NIH biosketches (key personnel)
  - Training, focus, no. of publications, etc.
- Human subjects section
  - Trials (additional sections)
- Budget and budget justification

Some Specifics on Applying for Each Career Development Award (K Award)

Visit the NIH website for research career development awards: https://researchtraining.nih.gov/programs/career-development



NIH Review Process

Center for Scientific Review

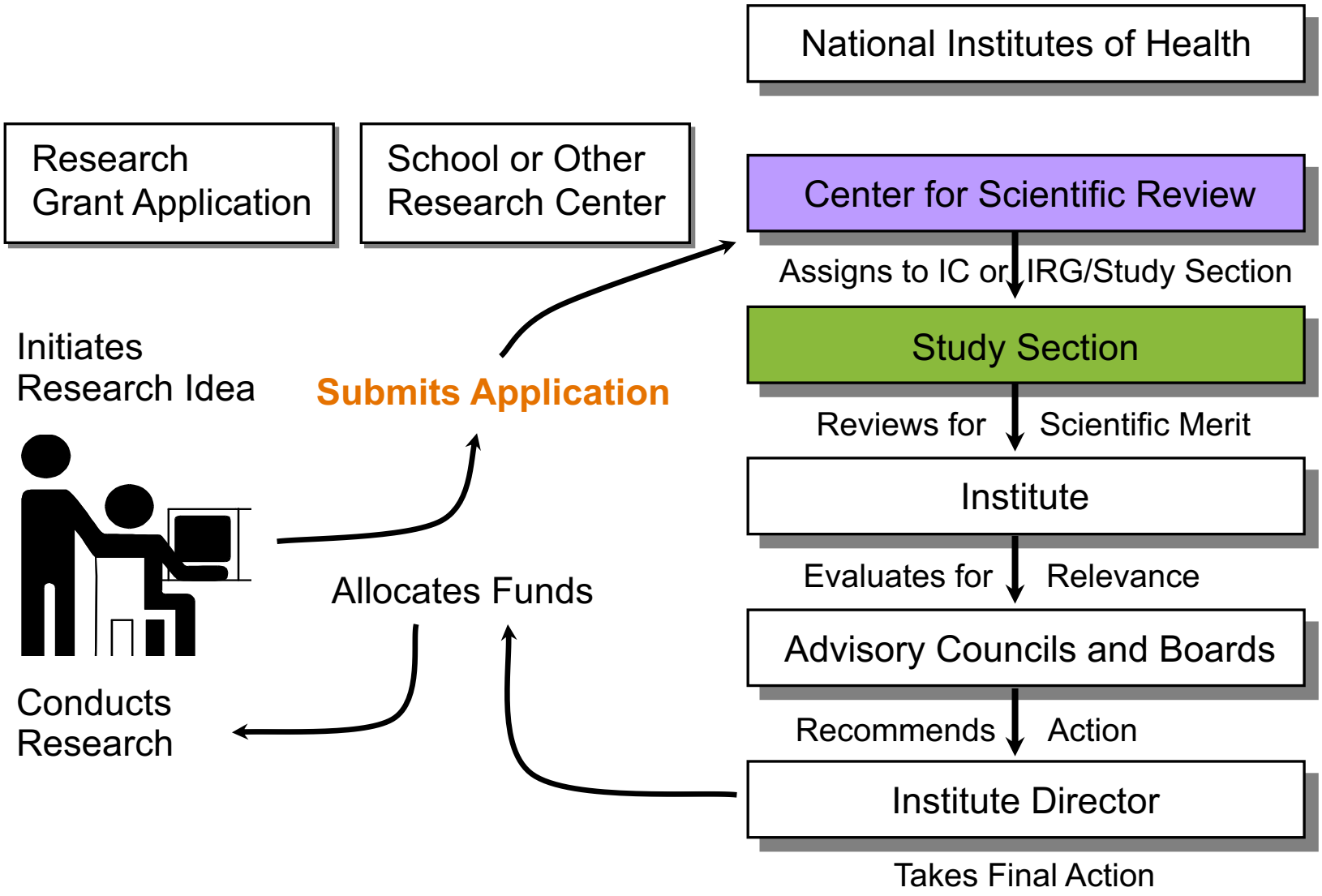
- **Center for Scientific (CSR) Review** http://public.csr.nih.gov/Pages/default.aspx
- **"Portal for NIH grant applications and their review for scientific merit"**

The Gateway for NIH Grant Applications

The Center for Scientific Review (CSR)

- Receives all NIH applications
- Refers them to NIH Institutes or Centers (IC) or to CSR Integrated Review Groups (a group of study sections) and then specific study sections

Review Process for a Research Grant



IC = Institute or Center; IRG = Integrated Review Group

STEP 1: Assignment

- Your proposal is submitted to the CSR.
- The CSR makes 2 assignments:
  - **Funding**: assigned to a NIH IC (INSTITUTE or CENTER), for example, the NCI or NHLBI; they dole out the money
  - **Review**: assigned to the Integrated Review Group (group of study sections) / study sections in the CSR or an IC review group.
  - Study section reviews includes most R01s, fellowships, and small business applications.
  - IC review groups handle applications that have institute-specific features (e.g., K-type career development awards).

Scientific Review Officer (SRO)

- PhD or equivalent
- Assigns applications to reviewers and organizes the conduct of the study section review.
- Invites standing vs. temporary reviewers

What Your SRO Looks for When Recruiting Reviewers

- Demonstrated scientific expertise/research support
- Doctoral degree or equivalent
- Mature judgment
- Work effectively in a group context
- Breadth of perspective
- Impartiality
- Diversity
- Geographic distribution
- Have a broad range of scientific expertise and background
- Likely experts in the field, but may not be in exact area of your application

STEP 2: The Review Process

- **Several months later, your application is delivered to reviewers serving on your assigned study section.**
- **Your application is reviewed by study section members (and NOT by NIH staff) before the meeting**
  - **R1, R2, R3; sometimes R4**
- **The study section convenes for a 2 day meeting in DC/Bethesda area (sometimes on the west coast)**

NIH Scoring System

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
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
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

Review Criteria

Before the study section meeting

- **Overall impact score**
  - **Candidate**
  - **Career development plan, career goals and objectives, plan to provide mentoring**
  - **Research plan**
  - **Mentors, Consultants, Collaborators**
  - **Environment and institutional commitment**
- **Protection of human subjects**
- **Inclusion of women, minorities and children**
- **Budget and budget justification**

Study Section Procedures

- Overall score = average of individual scores?
- Example:
  - Candidate (4)
  - Career development plan, career goals and objectives, plan to provide mentoring (1)
  - Research plan (2)
  - Mentors, Consultants, Collaborators (3)
  - Environment and institutional commitment (2)

  - What is the overall score???

Study Section Procedures

Before the study section meeting

- **Reviewers submit their scores**
- **For each application, the SRO averages the reviewer's overall scores.**
  - **R1 = 4 R2 = 3 R3 = 2**
  - **Average of overall scores = 3**
- **All of the reviews and scores of the assigned applications are posted online to reviewers.**
- **Applications are then categorized by SRO into "discussed" and "not discussed" categories.**

Study Section Procedures

At the study section meeting

- **SRO, Chairperson, Other NIH staff, Reviewers**
- **SRO goes over list of discussed and not discussed applications, and asks if anyone wants to "rescue" an application**
- **Discussion**
  - **For not discussed applications, only individual scores (not overall score) are given to applicants.**
  - **FALSE: "not discussed" applications are "bad".**

Study Section Procedures

- At the end of all the discussion, the reviewers(R1, R2, R3) re-state their scores.
- Then, all study section members score the application on the online score sheets, within the upper and lower limits set by the main reviewers (R1, R2, R3).
- EVERYBODY in the room votes – your final score is the average of all study section members' scores.
- Written reviews are supposed to revised if the discussion changed the scores of the main reviewers (R1, R2, R3).

Study Section Procedures

- Gender/Children/Race-ethnicity
- Ethical issues
- Budget considerations

Aftermath

Days to weeks after the meeting

- **You will receive your final "score".**
- **Mean overall score → multiply by 10 to get the priority score**
- **Payline determined by each institute and their budget**

NHLBI

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

Aftermath

6 to 8 weeks later after the meeting

- **You will receive a Summary Statement. This will include the reviewers' written critiques and summary of the group discussion.**

What about funding decision?

- **Review of your proposal (with score and percentile) are forwarded to the Advisory Council of your assigned IC for a second level of peer review – good enough to get funded? Consistent with IC's goals?**
- **Main contact now is your Program Officer (PO).**

NIH submission, review, and funding dates

K Series Career Development Award	Cycle I	Cycle II	Cycle III
New submission due date	**February 12**	**June 12**	**October 12**
Resubmission deadline	**March 12**	**July 12**	**November 12**
HIV new & resubmission deadlines	May 7	September 7	January 7
Scientific Merit Review (Study Section)	**June – July**	**October – November**	**February - March**
Summary statement sent to applicant	July – August	November – December	March - April
Advisory Council Round (Funding decision)	August or October*	January	May
Earliest Project Start Date	**September or December***	**April**	**July**

*Council may be held the month before or after so the project start date may adjust accordingly

https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

Timeline for application preparation

TASK	TIMELINE (MONTHS BEFORE SUBMISSION)											
	12	11	10	9	8	7	6	5	4	3	2	1
Identify skills gaps and conceptualize the training aims												
Identify mentorship team												
Obtain application forms and instructions												
Review previously funded K award applications												
Identify the training modules need to address training aims												
Specific aims page (research plan)												
Study design												
Biostatistician input												
Determine budget and budget justification												
Determine pilot data (need for a pilot study?)												
Write research plan												
Finalize budget and budget justification												
Ask for letters of support and references letters												
Complete drafts of all components												
Feedback and revision												

Contacting the NIH Program Officer (PO)

- Find out who the NIH Scientific Program Officer is for the institute to which you are applying
- Why contact them?
  - Important to establish NIH contacts
  - Whether the mechanism is appropriate and if your research aligns with the institute's mission
  - If you're eligibility for the mechanism
- Email first, do not call!
- Attach a NIH Biosketch and Specific Aims page
- They may need to be nudged in a 1-2 weeks. Follow-up via email.

Top five tips

- A clean, clear, well-written application
- A clean, clear, well-written application
- A clean, clear, well-written application
- A clean, clear, well-written application
- A clean, clear, well-written application

Common problems cited by reviewers

- Unclear rationale for training.
- Why this training will move you on the pathway to independence.
- Overqualified candidate.
- Underqualified candidate (publications, current training, etc)
- You are proposing training in what you are already doing now (nothing new).
- Mentorship team not interdisciplinary
- Mentorship team is missing expertise
- Training and research too close to mentor's
- No strong evidence of institutional support

Common problems cited by reviewers

- **Problem not important enough.**
- **Lack of focus in hypotheses, aims, and or research plan.**
- **Problem more complex than investigator appears to realize.**
- **Methods unsuited to the objective.**
- **Issue is scientifically premature.**

Common problems cited by reviewers

- **Too little detail in the research plan to convince reviewers the investigator knows what he or she is doing, i.e., no recognition of potential problems and pitfalls.**
- **Has several “trust me” statements**
- **Lack of pilot data**

Resources for Applying to a K Award

	July	August	September	October	November	December	January	February	March	April	May	June
Funding and Grantsmanship Course								Weekly				
K Award Seminar (Psychiatry)				Monthly								
MSPH Research Resources	Indiividual help as needed											
K-POPP	5 sessions + indivdiual assistance				5 sessions + indivdiual assistance				5 sessions + indivdiual assistance			
Specific Aims Workshops												
NIH new submission deadlines				12th				12th				12th
NIH new resubmission deadlines	12th				12th				12th			
NIH HIV deadlines			7th				7th				7th	

- **Funding and Grantsmanship for Research and Career Development Activities** (Jamie Rubin, Medicine)
  - Overview of various grants: http://grantscourse.columbia.edu
- **K Award Seminar** (Harold Pincus and Catherine Monk, Psychiatry)
  - Guidance for developing a K Award: https://rfmh.nyspi.org/kad/ - must be onsite to access link
- **Research Resources Office** (Pam Factor-Litvak, Mailman School of Public Health)
  - Individual help: https://www.mailman.columbia.edu/information-for/faculty-staff/research-resources-r2
- **K Award Program for On-time Proposal Preparation (K-POPP)** (VP&S Office for Research)
  - Info, guidance, and project management to the deadline: https://research.ps.columbia.edu/content/k-award-program-time-proposal-preparation-k-popp
- **Grant Starter Kit**: Templates, checklists and examples of K Award components
  - https://research.ps.columbia.edu/content/grant-starter-kit

Funding and Grantsmanship Course

Funding and Grantsmanship for Research and Career Development Activities

- **Purpose:** A course for students, postdoctoral scientists, clinical fellows, new investigators, faculty, and administrators.
- **Instructor:** Jamie Rubin, Department of Medicine
- **Website:** http://grantscourse.columbia.edu
- **Duration**: Once a year in the Spring semester
- **Structure**: 7 sessions
  - Session 1: Types of support and review processes: Government Agencies
  - Session 2: Types of support and review processes (non-governmental funding) and identifying funding
  - Session 3: Planning and organizing a research proposal (i.e., NIH R01)
  - Session 4: Planning and organizing a fellowship/career development proposal
  - Session 5: Experiences of a peer review
  - Session 6: Practice of seeking grant support
  - Session 7: Writing Specific Aims

Career Development K Award Seminar

- **Purpose:** Provide structured, longitudinal assistance to fellows and faculty interested in applying for Career Development Award grants.
- **Instructors:** Harold Pincus and Catherine Monk, Department of Psychiatry
- **Website:** https://rfmh.nyspi.org/kad/ -- must be on NYSPI/RFMH computer/server to access
- **Duration**: Once a year, from October to May
- **Structure**: 8 sessions
  - Session 1: Overview
  - Session 2: Reviewer's Panel
  - Session 3: Personal Statement
  - Session 4: Career Plan
  - Session 5: Research Plan
  - Session 6: Administrative Process
  - Session 7: Funded Applicants' Panel
  - Session 8: Mock Review

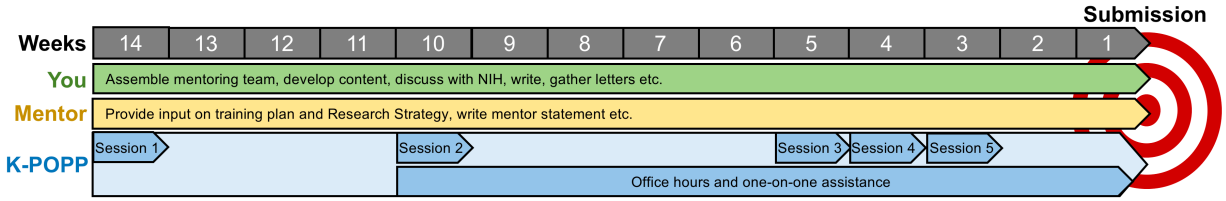
Research Resources (R2) Office

- **Purpose:** Support Mailman school researchers in the development and preparation of grant applications.
- **Instructor:** Pam Factor-Litvak (Mailman School of Public Health)
- **Website:** https://www.mailman.columbia.edu/information-for/faculty-staff/research-resources-r2
- **Duration**: Ongoing
- **Structure**: One-on-one grant planning and preparation meetings can be scheduled

K-POPP

NIH K Award Program for On-time Proposal Preparation (K-POPP)

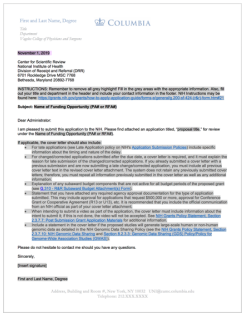
- **Purpose:** Provide provide practical resources (i.e. checklists, timelines, helpdesk etc.) to ensure applicants are staying on target to meet the submission deadline.
- **Instructors:** Daichi Shimbo, Yinghui Mao, Walter Bockting, Pam Factor-Litvak, and Danielle Matsushima
- **Website:** https://research.ps.columbia.edu/content/k-award-program-time-proposal-preparation-k-popp
- **Duration**: Three times a year coinciding with new submission deadlines
- **Structure**: 5 sessions – Next course begins on **Monday, March 22nd, 2021**
  Contact ps-officeforresearch@cumc.columbia.edu to register
  - Session 1: Intro to the K Award
  - Session 2: Specific Aims (co-sponsored by CUIMC Academic Affairs)
  - Session 3: Candidate Section and Research Strategy
  - Session 4: All the Other Components
  - Session 5: NIH Rigor and Reproducibility Webinar

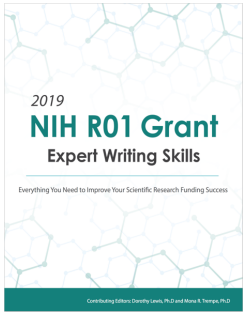


Other helpful resources…

Grant Starter Kit

- Checklists
- Templates
- Examples of attachments
- Helpful links

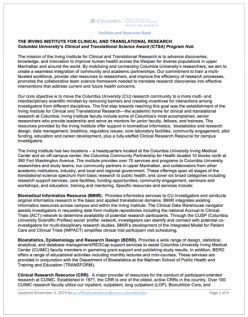


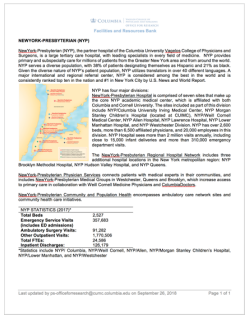


Facilities & Resources Bank

Descriptions of:

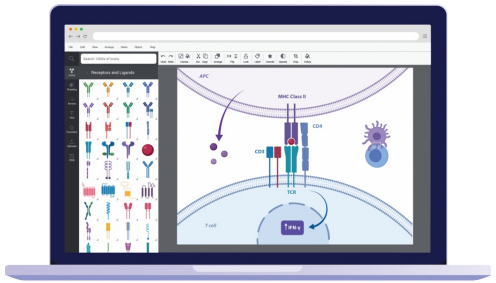
- Institutional resources
- Departments
- School offices
- Core facilities





BioRender

Easy way to create scientific figures for presentations, grants, and papers

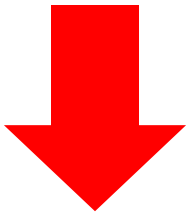


https://research.ps.columbia.edu/content/grant-starter-kit

https://research.ps.columbia.edu/content/facilities-and-resources-bank

https://research.ps.columbia.edu/content/biorender

- **I am thinking about doing research.**
- **I am thinking of spending my career in research.**
- **I would like to become an independent researcher.**



K award

- **I am an independent researcher.**

Q & A