

A painting depicting a medical examination. A woman is lying down, partially nude, while a man in a dark blue military-style uniform with gold epaulettes examines her abdomen. The scene is set in a room with wood-paneled walls. The text 'FEDERALLY-FUNDED CLINICAL RESEARCH' is overlaid in white, bold, sans-serif font across the lower middle of the image.

**FEDERALLY-FUNDED  
CLINICAL RESEARCH**

Nina Gentile, MD  
Professor, Emergency Medicine  
Lewis Katz School of Medicine

# Historical perspective of the academic medical center

- 1910 Flexner Report - Scientific knowledge and its advancement as the defining ethos of a modern physician.
- 1960 Medicare/Medicaid - drive changes in priorities of AMCs
- 1990 Managed Care - creates a funding crisis for AMCs slowing growth of clinical revenues
  - AMCs responded by having their faculty increase their clinical duties at the expense of research activities.

Characteristic	1960–1961	2008–2009	% Change
No. of medical schools	86	126	47
No. of medical students	30,288	76,202	251
No. of residents/fellows	14,417	108,176	750
No. of full-time faculty	11,224	128,683	1,146
Expenditures in millions	\$437	\$78,856	2,492*

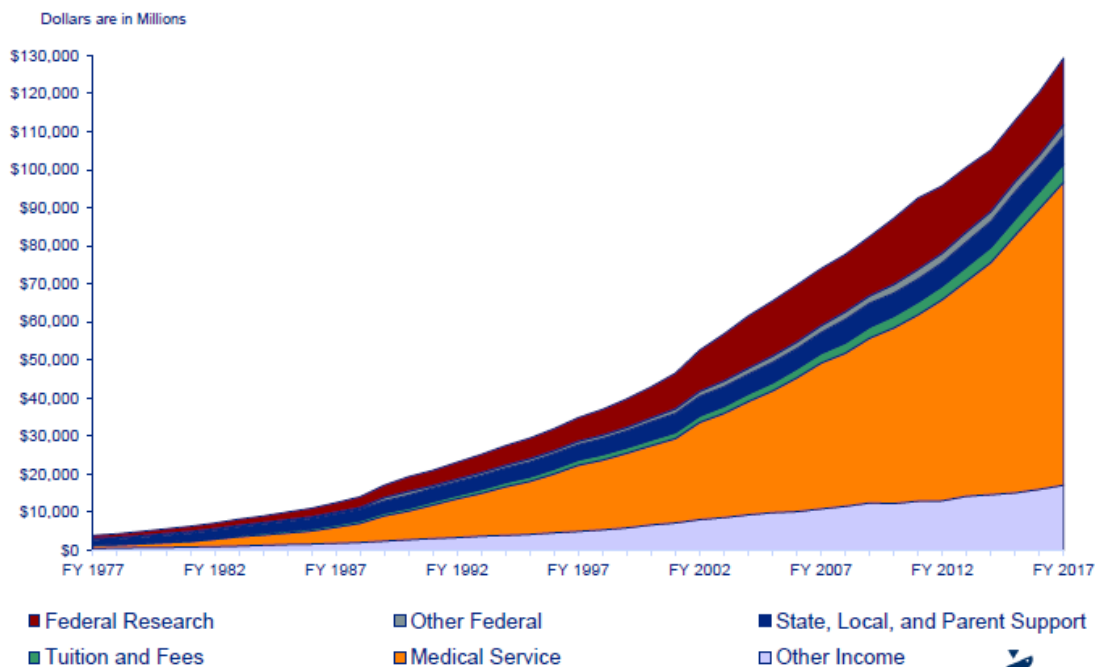
\*Consumer Price Index adjusted.

ACADEMIC MEDICINE

Source	% of Total, 1960–1961	% of Total, 2007–2008
Federal research funding	31	19
Other federal funding	10	3
State/local funding	17	8
Tuition/fees	6	3
Clinical service	6	52
Other income source	30	15

ACADEMIC MEDICINE

**Figure 8: Revenue by Source for Medical Schools with Full Accreditation, FY 1977 through FY 2017**

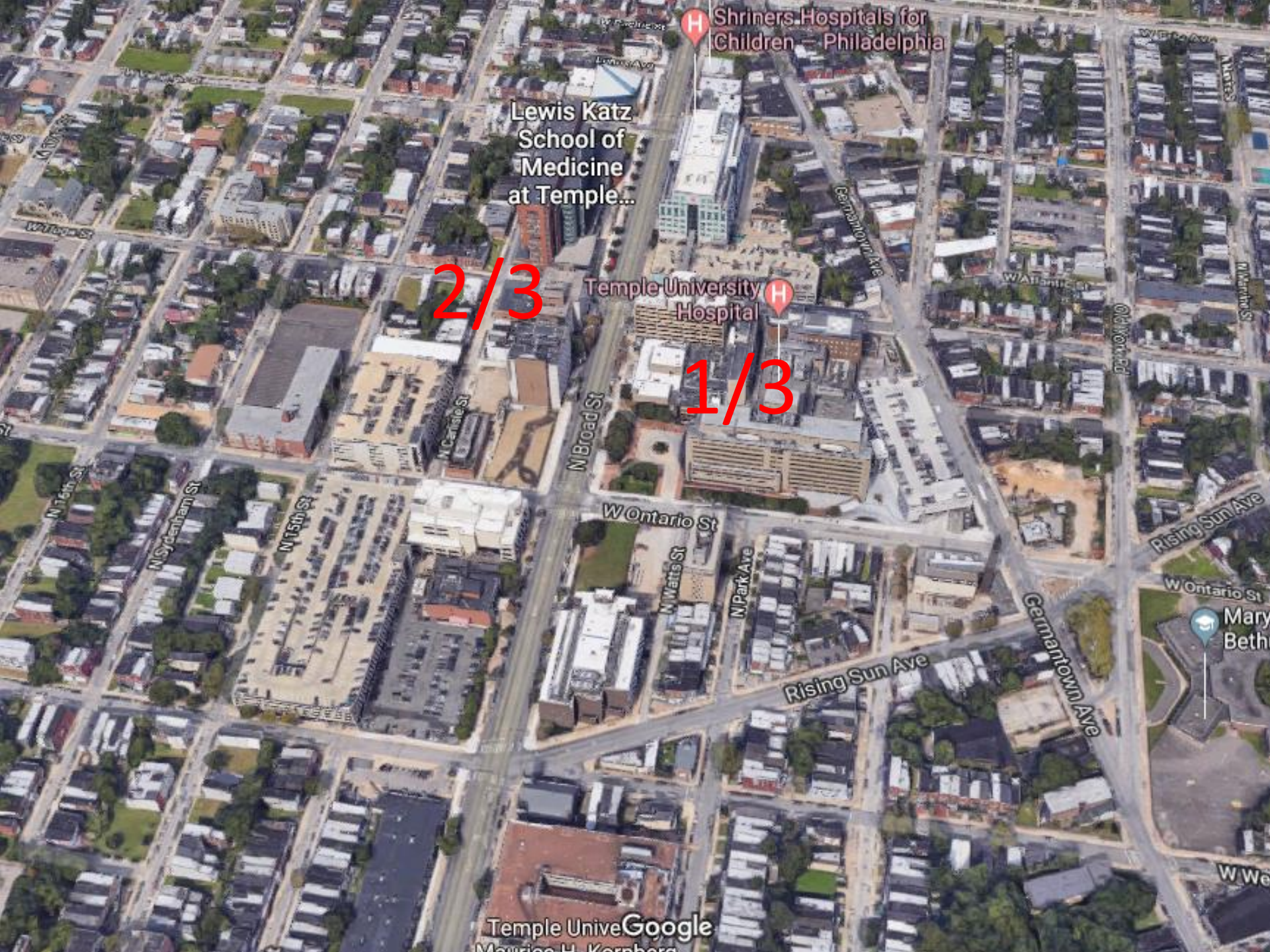


Source: LCME I-A Annual Financial Questionnaire  
 © Association of American Medical Colleges 2018. All rights reserved.



**Perspective: Follow the Money: The Implications of Medical Schools' Funds Flow Models.**

\_Miller, Jeffrey C.; Andersson, George E.; Cohen, Marcia; Cohen, Stephen M.; Gibson, Scott; Hindery, Michael A.; Hooven, Martha; Krakower, Jack; Browdy, David H. Academic Medicine87(12):1746-1751, December 2012. U.S. medical schools' annual revenues in millions by source, 2007–2008. Total revenue was \$78.9 billion. U.S. Medical School Growth, 1960–1961 to 2008–20093



Shriners Hospitals for Children - Philadelphia

Lewis Katz School of Medicine at Temple...

2/3

Temple University Hospital

1/3

Mary Beth

# Fallout of this trend:

- AMC behave more and more like community hospitals
- Research only at select, largely private medical schools and universities
- Resident research de-emphasized
  - Shrinking potential for young faculty to achieve successful academic careers.
- Minorities/ patients from larger geographic areas underrepresented in clinical research
- We lack the ability to inform decisions on health care policy

# Expectations for AMCs

- Transforming local practices
- Informing healthcare leaders and providers through presentations and publications
- Informing health policy driven by private and public (states and federal) organizations



**Table 2****Outline of recommendations to improve clinical research**

1. Clear public policies by medical universities to monitor and improve clinical research
2. Medical universities should provide training in clinical research methodology and require research by medical students **Early research training**
3. Research training and projects should be required components of residency training
4. Accreditation Council for Graduate Medical Education fellowship programs should require research training in clinical research methodology
5. Mentoring programs and protected time for young clinical faculty to develop their clinical research **Protected time for research**
6. Increased national and foundation funding for clinical research, especially in regards to clinical research fellowships and mentors
7. Financial incentives at medical universities for clinical research
8. Improved use of indirect grant funding to support clinical research
9. Philanthropic efforts focused on advancing the development of clinical research careers **Augment research development and funding**
10. Routine monitoring of clinical research on departmental, university, and national levels in order to direct interventions to improve the existing status
11. Improved efficiency of central support by medical universities for clinical research and routine assessment to determine its impact
12. Improved efficiency of clinical service support to improve patient care and income and to increase faculty time for clinical research and other academic activities



# Clinical Research Funding

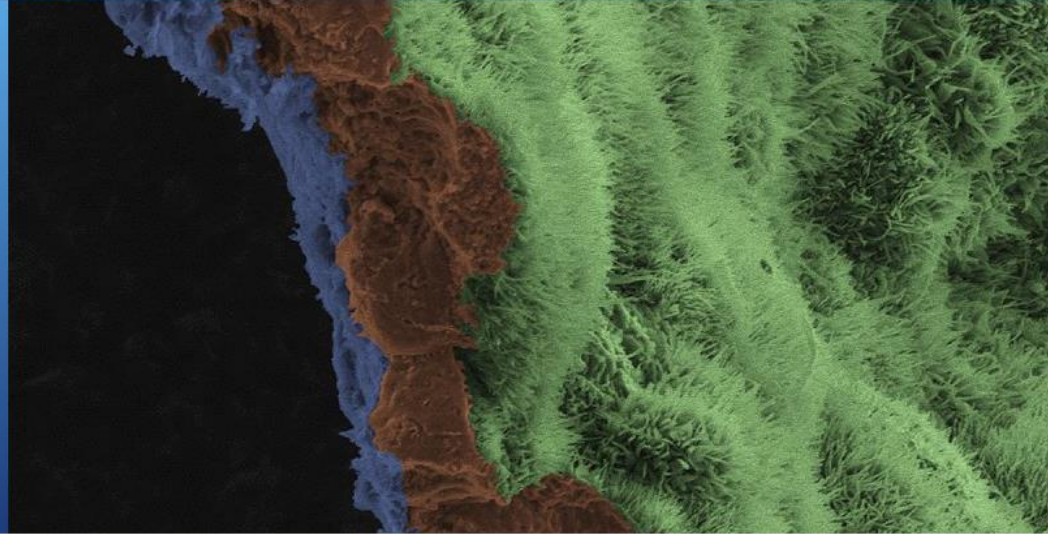
- Internal
- Foundations
- Organizations eg AHA
- DoD
- NIH

## 2019 Research Highlights

A sampling of notable NIH-supported research accomplishments in 2019

[Learn more »](#)

● ● ● ● ●



### In the News



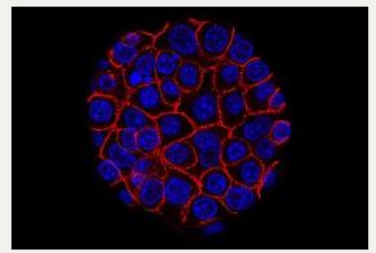
**Physical Activity**  
Increased exercise may be linked to reduced cancer risk.



**Suicide Risk**  
Research examined suicide risk in the year after an emergency department visit.



**Vaping**  
Study finds teens prefer mint and mango flavors.



**Pancreatic Cancer**  
The latest research and clinical advances.

# Learn the Language—grants & applications

Grant mechanism = kind of grant (R01, K22, P01, new investigator)

Investigator initiated (unsolicited) application = your idea + a general grant mechanism

Application in response to an FOA = your idea + an FOA

# Learn the Language—information

FOA = funding opportunity announcement

RFA = request for applications

PA = program announcement

RFP = request for proposals

Notice = information about an FOA

# Learn the Language—your new best friends

Funding agency = organization that awards grants

IC = National Institutes of Health (NIH) Institute or Center

Program officer = funding agency employee managing an FOA

Study section = reviewers of your grant application

# What do you want to do?

- Get or Promote research education
  - Student training programs (Ts)
  - MD PhD program (Fs)
  - Mentored programs (Ks)
- Conduct research
  - Independent research funding (Rs)
  - Research project cooperative agreements (Us)

# Learn the Language--investigators

New investigator = has no major (R01-type )  
funding

Early stage investigator = new investigator within  
10 years of completing terminal research  
degree or medical residency

# Individual Research Grants

One project

F, K, R = NIH Individual research grants

R01—Research Project Grant

R03—Small Grant

R21—Exploratory/Developmental Grant

R41/R42—Small Business Technology

Transfer Research Grants

R43/R44—Small Business Innovation

Research Grants



# Multiproject Grants

Several related projects, sometimes with supporting cores and programs for career development and for funding pilot projects (you could get a grant from a multiproject grant)

## Examples

P = NIH multiproject grants

P01—Research Program Project Grant

P30—Center Core Grant

P50—Specialized Center Grant

# Training Grants (Ts and Fs)

- Most are for students and post-doc fellows
- For the development of researchers
- Typically no salary support and limited research funds

# [http://grants1.nih.gov/training/F\\_files\\_nrsa.htm](http://grants1.nih.gov/training/F_files_nrsa.htm)

Acrobat download and installati... Individual Fellowships | Resea... x

x Convert Select

x McAfee

F30

## Ruth L. Kirschstein Individual Predoctoral NRSA for MD/PhD and other Dual Degree Fellowships

Individual fellowships for predoctoral training which leads to the combined MD/PhD and other dual Clinical/Research degrees.

Details

[View Current Funding Opportunities](#)

F31

## Ruth L. Kirschstein Predoctoral Individual National Research Service Award

To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research doctoral degree (e.g., PhD).

Details

[View Current Funding Opportunities](#)

F32

## Ruth L. Kirschstein Postdoctoral Individual National Research Service Award

To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

Details

[View Current Funding Opportunities](#)

## Policy Notices

- NOT-OD-18-175: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2018
- Summary of Leave, Part-Time and Extension Policies Available to Ruth L. Kirschstein National Research Service Awards (NRSA) Trainees and Fellows
- NOT-OD-17-095: Additional Guidance on Full-Time Training for Ruth L. Kirschstein National Research Service Awards
- NOT-OD-17-084: Revision: Ruth L. Kirschstein National Research Service Awards (NRSA) Predoctoral Stipends, Training Related Expenses, Institutional Allowance, and Tuition/Fees Effective for Fiscal Year 2017
- NOT-OD-15-048: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2015
- NOT-OD-14-101: NIH Announces Change in Policy Requirements for Activation Notices for Fellows Sponsored by Foreign and Federal Institutions

# <https://www.nichd.nih.gov/grants-contracts/training-careers/extramural/institutional>

ms | grants x Institutional Training Grants (T32) x +

reers/extramural/institutional

## Institutional Training Grants (T32/K12)

These awards are made to institutions to support groups of pre- and/or postdoctoral fellows, including trainees in basic, clinical, and behavioral research.

### T32 Institutional Training Programs

- **Purpose:** Ensures that a diverse and highly trained workforce is available to assume leadership roles in biomedical, behavioral, and clinical research
  - Issued to eligible institutions to support research training for groups of pre- and/or postdoctoral fellows. The number of positions or "slots" varies with each award.
  - The maximum duration of support for pre- and postdoctoral fellows under any National Research Service Award (NRSA) program is 5 years and 3 years, respectively (6 years for students in formal M.D./Ph.D. programs).
- **Eligibility:** U.S. citizens, non-citizen U.S. nationals, or those lawfully admitted for permanent residence
- NICHD participates in the Parent T32 announcement, as well as other T32 announcements that promote training in priority [scientific](#), [health-related research fields relevant to the NICHD mission](#).

[Specific T32 Announcements](#) ▼

### K12 Institutional Career Development Programs

NICHD uses the **Mentored Clinical Scientist Award (K12) Program** to provide support to domestic institutions that mentor clinical fellows and scientists and help them become independent research investigators.

NICHD only accepts K12 applications in response to active Requests for Applications (RFAs). Receipt deadlines are listed in the RFA.

[Specific K12 Announcements](#) ▼

[Support for Training at Universities and Other Institutions](#)

[Individual Research Fellowships \(E\)](#)

[Career Development \(K\) Awards](#)

**Institutional Training Grants (T32/K12)**

[Education Grants \(R25\)](#)

[FAQs About Extramural Training](#)

**Learn More**

[NICHD News & Features](#)

[Contacts for NICHD Funding Information](#)

[Division of Extramural Research \(DER\)](#)

[National Center for Medical Rehabilitation Research \(NCMRR\)](#)

[Sample Applications](#)

[Find a Program Officer](#)

[Forms](#)

# Career Development (Ks)

- Most are for fellows and assistant professors but some are for more senior faculty
- For the development of researchers
- Some salary support and research funds
- Many are limited to certain career periods (e.g., first 3 years of assistant professorship) and to US citizens or resident aliens
- Investigators with other career development awards or R01-type funding are not eligible

# <http://grants1.nih.gov/training/careerdevelopmentawards.htm>

s://researchtraining.nih.gov/programs/career-development

## 1. Select Role



Awardee



Appointee

## 2. Select Career Level

Early Career

APPLY FILTER

RESET FILTER

K01

### Mentored Research Scientist Career Development Award

For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.

Details

[View Current Funding Opportunities](#)

K07

### Academic Career Development Award

To support either a mentored or independent investigator to develop or enhance curricula, foster academic career development of promising young teacher-investigators, and to strengthen existing teaching programs.

Details

[View Current Funding Opportunities](#)

K08

### Mentored Clinical Scientist Research Career Development Award

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.

Details

[View Current Funding Opportunities](#)

K12

### Clinical Scientist Institutional Career Development Program Award

To provide support for newly trained clinicians appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

Details

[View Current Funding Opportunities](#)

which involves human subjects, do I need a study record for each phase?

- Who do I contact for questions about my specific application?
- If there are problems with eRA Commons registration or with the grants.gov submission process, where can one get help?
- Who do I contact for questions about my specific institutional training application or grant?
- Do Training Grants have pre-award cost authority?
- NIH uses a formula to calculate what would be awarded for tuition/fees and training related expenses on institutional training grants. Should the grantee use this formula as part of their requested budget in a competitive grant?

[View More](#)

## Policy Notices

- NOT-OD-18-175: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2018
- Summary of Leave, Part-Time and Extension Policies Available to Ruth L. Kirschstein National Research Service Awards (NRSA) Trainees and Fellows
- NOT-OD-17-095: Additional Guidance on Full-Time Training for Ruth L. Kirschstein National Research Service Awards
- NOT-OD-17-084: Revision: Ruth L. Kirschstein National Research Service Awards (NRSA) Predoctoral Stipends, Training Related Expenses, Institutional Allowance, and Tuition/Fees Effective for Fiscal Year 2017

# <http://grants1.nih.gov/training/careerdevelopmentawards.htm>

://researchtraining.nih.gov/programs/career-development

K22

## Career Transition Award

To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial mentored research experience, followed by a period of independent research.

Details

[View Current Funding Opportunities](#)

K23

## Mentored Patient-Oriented Research Career Development Award

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.

Details

[View Current Funding Opportunities](#)

K25

## Mentored Quantitative Research Career Development Award

To support the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have made a commitment to focus their research endeavors on basic or clinical biomedical research.

Details

[View Current Funding Opportunities](#)

K99/  
R00

## Pathway to Independence Award

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.

Details

[View Current Funding Opportunities](#)

K43

## Emerging Global Leader Award

To provide research support and protected time to a junior scientist with a faculty position at an LMIC institution leading to an independently funded research career.

Details

[View Current Funding Opportunities](#)

- NOT-OD-15-048: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2015
- NOT-OD-14-101: NIH Announces Change in Policy Requirements for Activation Notices for Fellows Sponsored by Foreign and Federal Institutions

[View More](#)

## NIH Resources

- Clarifying Percent Effort and Support for Career Development
- Institutional Research Training Grant Data Tables
- Individual Fellowship Activation Notice
- Statement of Appointment Forms
- Payback Agreement and Annual Payback Activities Certification Forms
- SF424 Individual Fellowship Application Guide for NIH and AHRQ
- SF424 Application Guide
- General Resources on the Responsible Conduct of Research
- Evaluation of the NIH Individual Mentored Career Development Awards Program (2011)

# Establishing a long term Career

- Academicians often move to build on prior experiences
- When de novo - need to tap into what available resources
  - Basic scientists, peers with similar interests, other services who cover the same ground
  - Be willing to collaborate
- Build a team



# The Big Ideas In Medicine Often Come From The Front Lines, Not The Ivory Tower



EMAIL



FACEBOOK



LINKEDIN



TWITTER



REDDIT



PRINT



By Jamie Wells, M.D. — February 6, 2018



The storming of a castle seemed humorously apropos. (Credit: Wikimedia Commons)

Understanding why there is an ever-increasing job dissatisfaction rate among doctors (see [here](#)) isn't difficult to comprehend. Loss of autonomy, erosion of the ability to practice medicine (as expected and trained to do) and bureaucratic regulations that impede actual care (click [here](#)) top the list. Perverse incentives, ballooning of paperwork and physicians providing glorified data entry for electronic medical records need be included. Electronic medical records, pitched as panaceas. designed and vetted by

## Related articles

[New Budget Bill Gets It Right Relaxing 'Meaningful Abuse' -- Oops, 'Use'-- Requirements](#)

[Patient's Tattooed Directive is Stark Reminder to Plan Your Demise](#)

[All I Want For Christmas Is Truth In Medical Advertising](#)

[A frustrated doctor s call for help](#)

[Rating Doctors Like PCs: Bad Idea Needing a Reboot](#)

# Special Challenges to studying Neurological Emergencies

- Urgency: recruitment in minutes not hours
- Multiple disciplinary involvement:
  - EMS, emergency medicine, neurology, pediatrics, neurosurgery, radiology, traumatology, rehabilitation, others
  - Research encompassing a continuum of care that starts in the ambulance or in the emergency department and continues in the ICU, in the OR, on the stroke unit, or in the clinic.
  - Network leadership, Hub PI's, and Trial PI's represent a range of specialties.
- Conditions complicate informed consent

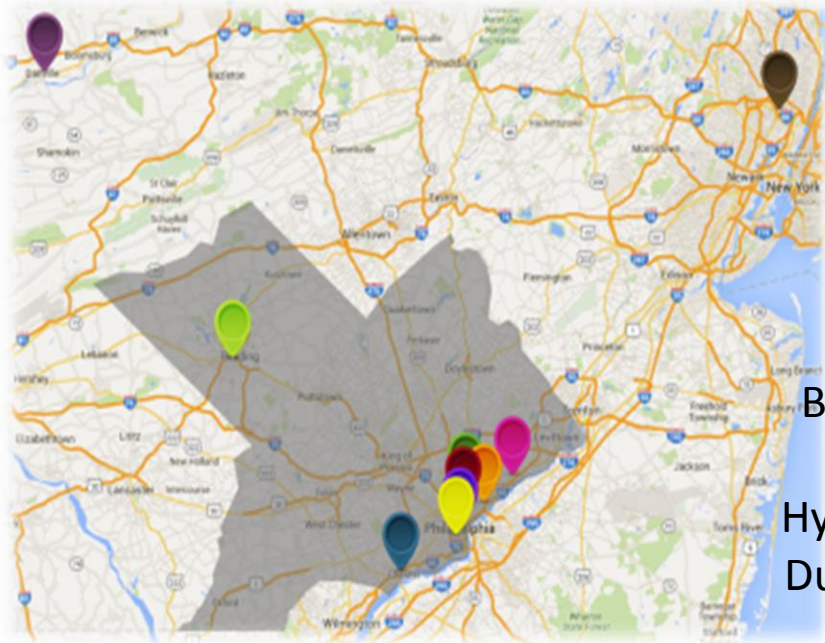
# NET\*2 creates NETT

- Started with 6 investigators doing surveillance studies
- Recognized need for a multi-center collaborative to study these (relatively uncommon) conditions
- Neurological Emergencies Treatment Trials
  - A new clinical trials network dedicated to:
    - Cross-disciplinary cooperation
    - Interventions in minutes not hours
    - Stroke, TBI, status epilepticus studies

# NETT to SIREN (NIH/U24-NS100681)

## Temple-NETT/SIREN clinical research Hub

- 12 hospitals, 6 EMS systems
- Support to study sites' subject enrollment, protocol adherence



A screenshot of a web browser displaying the Grantome website. The browser address bar shows the URL: grantome.com/grant/NIH/U24-NS100681-03. The website header includes the Grantome logo and navigation links: Home, Search, Services, Blog, Contact, About. Below the header is the NIH logo and the text: Temple SIREN Emergency Care Clinical Research Hub, Gentile, Nina T., Temple University, Philadelphia, PA, United States. The main content area features a search bar, a list of related grants (e.g., 'See 18 grants from Nina Gentile'), social media sharing options, and an abstract section. The abstract text describes the Temple-led Emergency care research network, its growth since 2007, and its focus on serving diverse populations in the Philadelphia area. It also mentions the network's commitment to translational research and its role in SIREN studies.

## SIREN STUDIES

- Brain Oxygen Optimization in Severe Traumatic Brain Injury—Phase 3 (BOOST 3)
- Hyperbaric Oxygen for Brain Injury Treatment (HO<sub>2</sub>BIT)
- Duration of Hypothermia after Cardiac Arrest (ICECAP)

http://grants1.nih.gov/grants/oer.htm

File Edit View Favorites Tools Help

Google Search

bing News Entertainment Video Sports Money

OER Home Page - Grants Web Site

U.S. Department of Health & Human Services

www.hhs.gov

Office of Extramural Research  
National Institutes of Health

Contact Us | Print Version

Search:

Advanced Search | Site Map

Home About Grants Funding Forms & Deadlines Grants Policy News & Events About OER NIH Home

### About Grants

#### Grants Process

- Grant Application Basics
- Grants Process Overview
- Types of Grant Programs
- How to Apply
- Peer Review Process
- Award Management
- Foreign Grants Information
- NIH Financial Operations (w/Funding Strategies)

#### Electronic Grants

- Electronic Research Admin (eRA)
- eRA Commons
- Applying Electronically

### Funding

#### Funding Opportunities

Search Funding Opportunities:  
*NIH Guide for Grants and Contracts*

- Funding Opportunities (RFAs, PAs) & Notices
- Unsolicited Applications (Parent Announcements)

- Recovery Act Grant Information
- Research Training & Career Development
- Small Business (SBIR/STTR)
- Contract Opportunities

#### NIH-Wide Initiatives

- New and Early Stage Investigators
- Stem Cell Information
- NIH Common Fund
- OppNet (Behavioral & Social Sciences)

#### Award Data



- Search NIH Awards (RePORTER)

#### Global OER Resources

### News & Events

#### News Flashes

- New Podcasts Available
- December 2010 NIH Extramural Nexus Now Available
- New Podcast Series

#### Get Connected

- Nexus (Monthly News)
- Workshops & Training
- Listservs & Feeds



## Research Grants

The following represent frequently used research grant programs. A [comprehensive list of all activity codes](#) is also available.

Important note: NIH Institutes and Centers (ICs) may vary in the way they use activity codes; not all ICs accept applications for all types of grant programs or they apply specialized eligibility criteria. Look closely at funding opportunity announcements (FOAs) to determine which ICs participate and the specifics of eligibility.

### [R01](#)

#### NIH Research Project Grant Program (R01)

- Used to support a discrete, specified, circumscribed research project
- NIH's most commonly used grant program
- No specific dollar limit unless specified in FOA
- Advance permission required for \$500K or more (direct costs) in any year
- Generally awarded for 3 -5 years
- All ICs utilize

### [R21](#)

#### NIH Exploratory/Developmental Research Grant Award (R21)

- Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. Sometimes used for pilot and feasibility studies.
- Limited to up to two years of funding
- Combined budget for direct costs for the two year project period usually may not exceed \$275,000.
- No preliminary data is generally required
- Most ICs utilize
- See parent FOA: [PA-10-069](#)

# Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs

- Supports R&D and financing of cutting edge technologies
- ~\$2.5 billion annual set aside
- ~160,000 awards granted
- ~10 patents per day

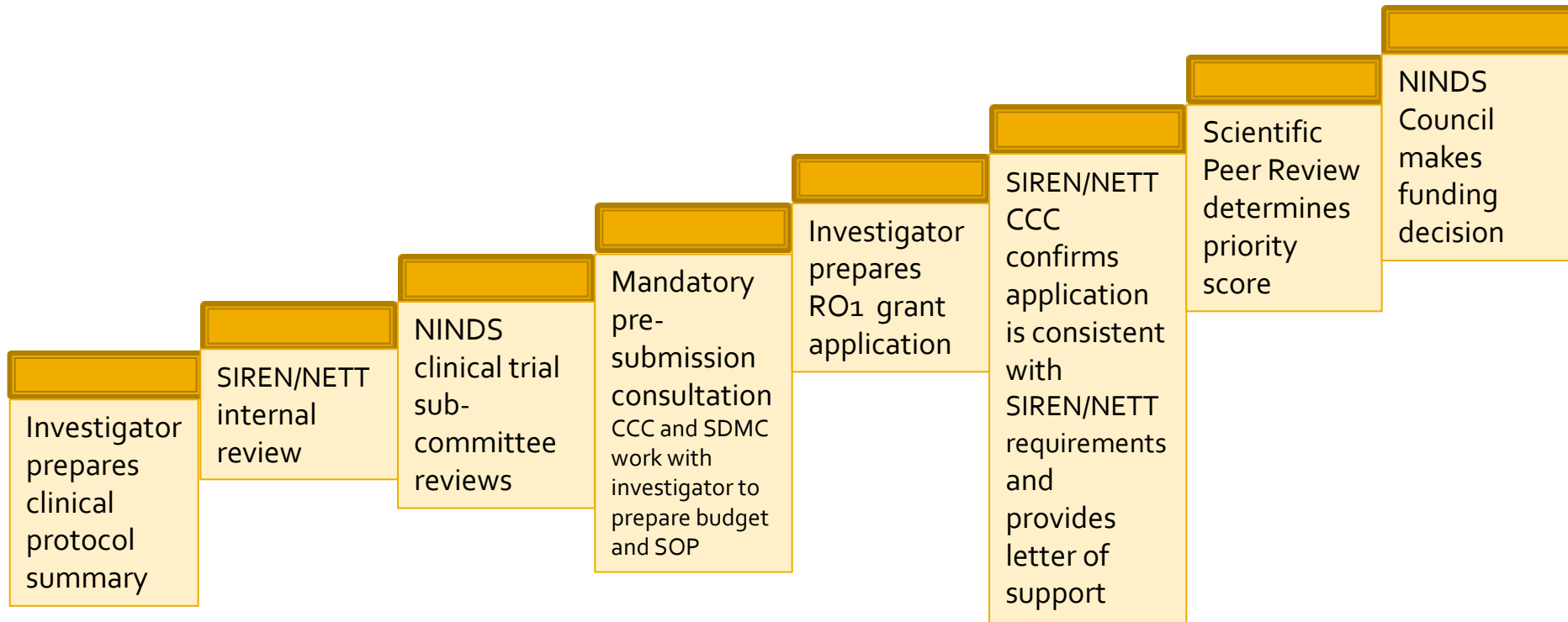
**Research  
Development**

**The I-SPOT Experience**

---



# Steps to New Study Development



# I-SPOT TIMELINE



# Lessons I learned through my journey

- Be open to opportunities
- Expect hard work and be patient
- Be willing to collaborate
- Use available clinical research network infrastructures

# Temple SIREN-NETT Investigators' meeting

