Overview of U.S. NIH and Research Grant Funding

Aaron Neal, D.Phil.
Clinical Research Specialist
NIAID/DCR Country Lead for Indonesia

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National Institutes of Health
U.S. Department of Health and Human Services

National Institute of Allergy and Infectious Diseases

aaron.neal@nih.gov

Presentation Overview

- Organization of Public Health in U.S.
- U.S. National Institutes of Health (NIH)
- National Institute of Allergy and Infectious Diseases (NIAID)
- U.S. NIH Research Grant System Overview

- Throughout the presentation:
  - I refer to NIAID specifically, but much of the information applies to other ICs
  - There are many URLs that will link you to helpful resources
  - I focus mostly on navigating the NIH system, not on general grantsmanship
- This a condensed, simplified overview of a complicated system
  - I am not a grants specialist, but NIH has many staff who are and can help you

U.S. Health and Human Services

- **$1.765 trillion USD budget for 2023**
  - **6.18% for NIH, CDC, FDA**
- **12 Operating Divisions and 15 Offices**
- **Workforce of over 83,000**

https://www.hhs.gov/

Sister Agencies of the U.S. Public Health Service

Public Health

- Protects the public health of the nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions
- Provides guidance, tools, and services for laboratory testing
- Responds to public health emergencies within the U.S. and abroad

https://www.cdc.gov/

Research

- Supports biomedical and behavioral research within the U.S. and abroad
- Conducts research in its own laboratories and clinics
- Trains promising young researchers
- Promotes collecting and sharing medical knowledge

https://www.nih.gov/

Regulatory

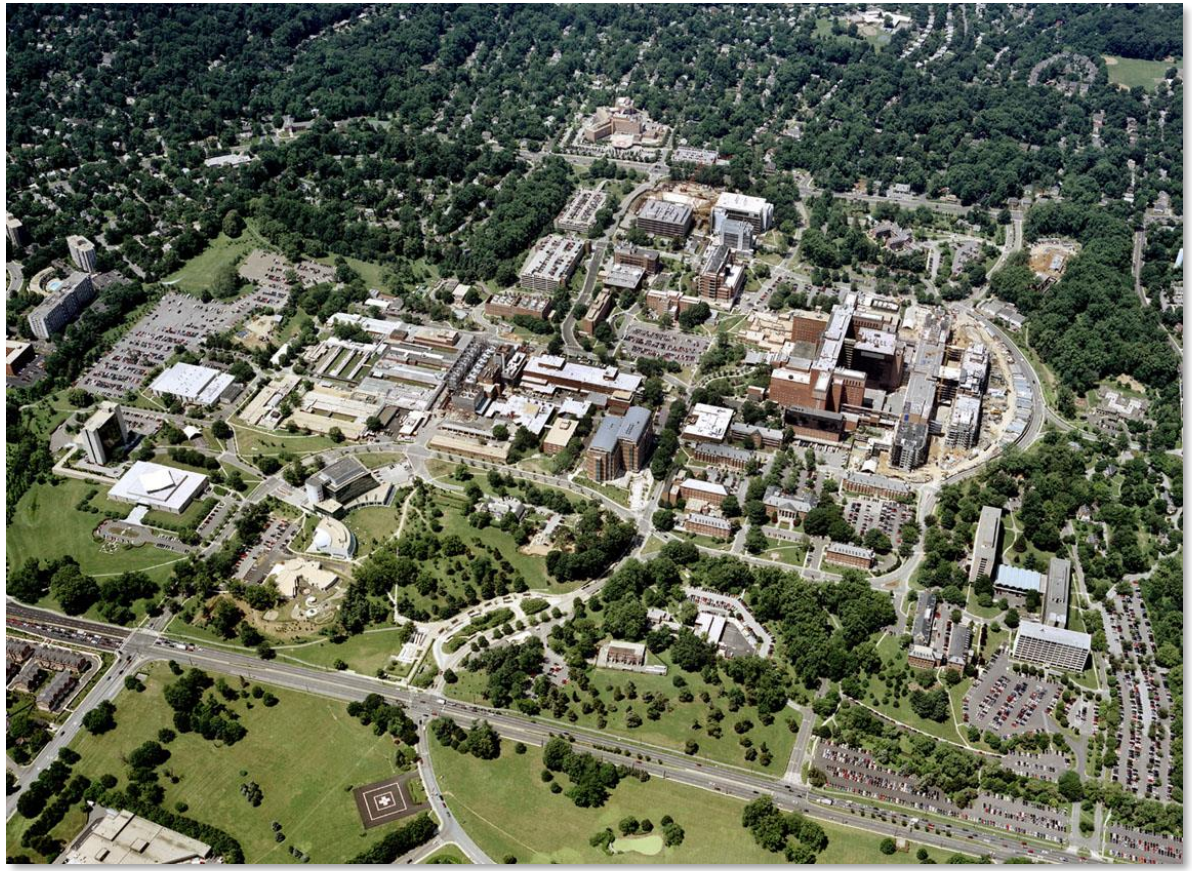
- Ensures that food is safe, pure, and wholesome
- Ensures that human and animal drugs, biological products, and medical devices are safe and effective
- Ensures that electronic products that emit radiation are safe

https://www.fda.gov/

U.S. National Institutes of Health

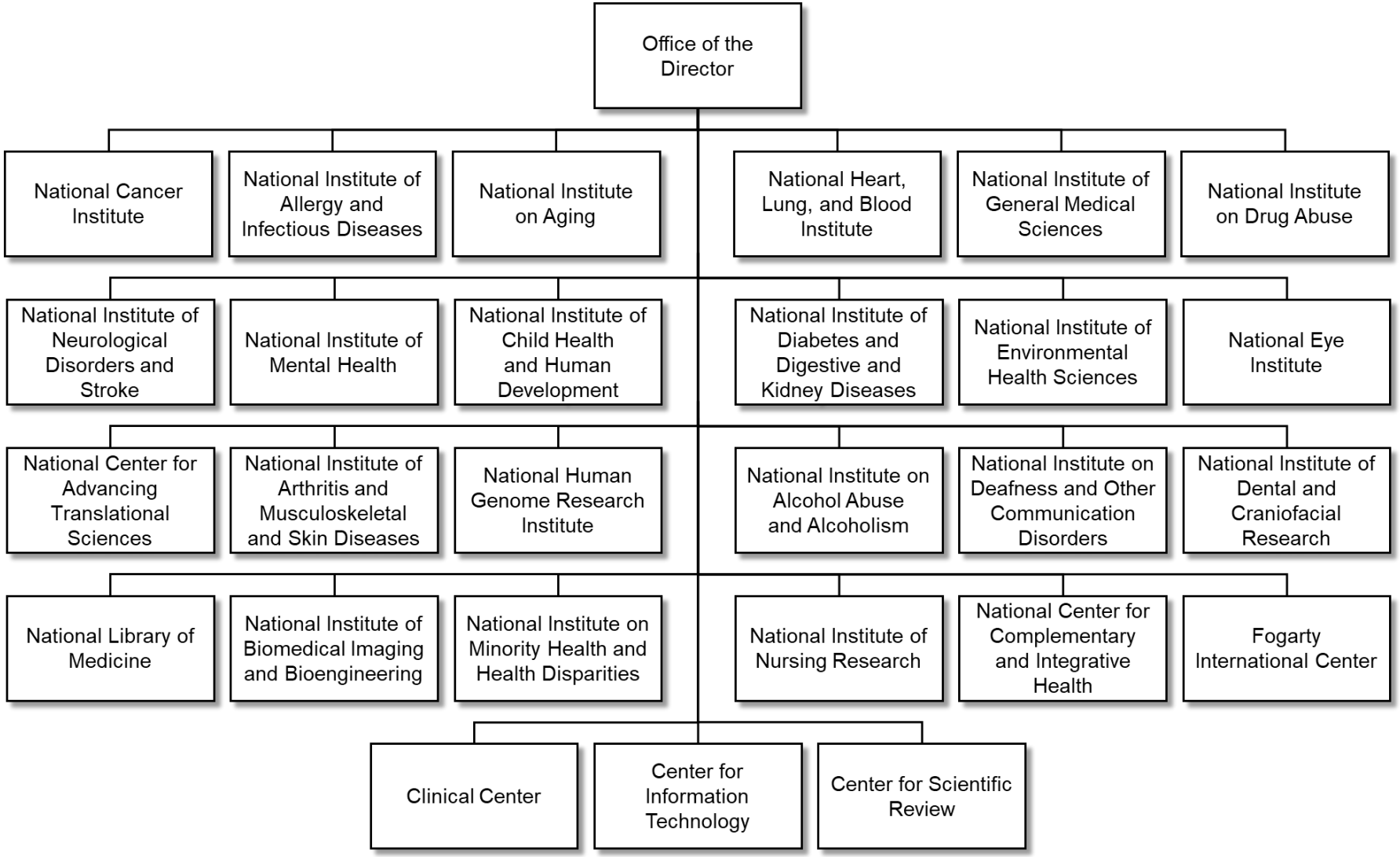
"The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability."

- **Officially established in 1930**
- **World's largest funder of biomedical research**
- **$45.178 billion USD budget for 2023**
- **In FY 2022: 61,912 active projects; 7,816 new R01s**
- **18,478 employees (8,655 scientific, 2,139 health)**
- **Large trainee population in NIH labs:**
  - **2,196 Postdoctoral Fellows (65% international)**
  - **431 Graduate Students (14% international)**
  - **1,648 Postbaccalaureate Fellows**
- **27 Institutes and Centers, 309 research areas**

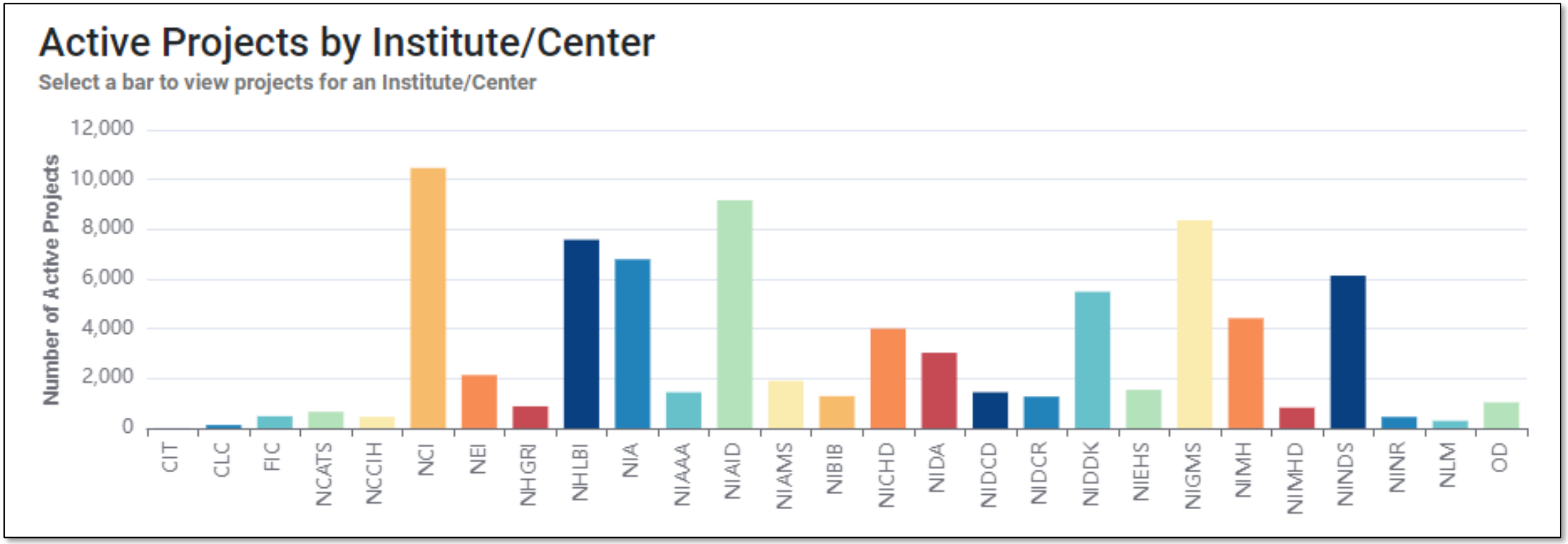


https://reporter.nih.gov/

U.S. NIH Institutes and Centers



U.S. NIH Institutes and Centers



https://reporter.nih.gov/

Accessed 10 March 2023

- **Note: Projects include all funded activities, not just competitive grants**

U.S. NIH Budget and Research

NIH Budget Comparison by Institute/Center
(USD in thousands)

Institute/Center	FY 2021	FY 2022	% Change
NCI	$ 6,559,852	$ 6,912,522	+5.4%
NIAID	6,069,619	6,322,728	+4.2%
NIA	3,899,227	4,219,936	+8.2%
NHLBI	3,664,811	3,808,494	+3.9%
NIGMS	2,991,417	3,092,373	+3.4%
NIDA	1,479,660	1,595,474	+7.8%
NCATS	855,421	882,265	+3.1%
NHGRI	615,780	639,062	+3.8%
Other ICs	14,072,003	14,681,016	+4.3%
Subtotal	$ 40,207,790	$ 42,153,870	+4.8%
OD	2,532,710	2,779,120	+9.7%
B&F	200,000	250,000	+25.0%
NIH Program Level	$ 42,940,500	$ 45,182,990	+5.2%

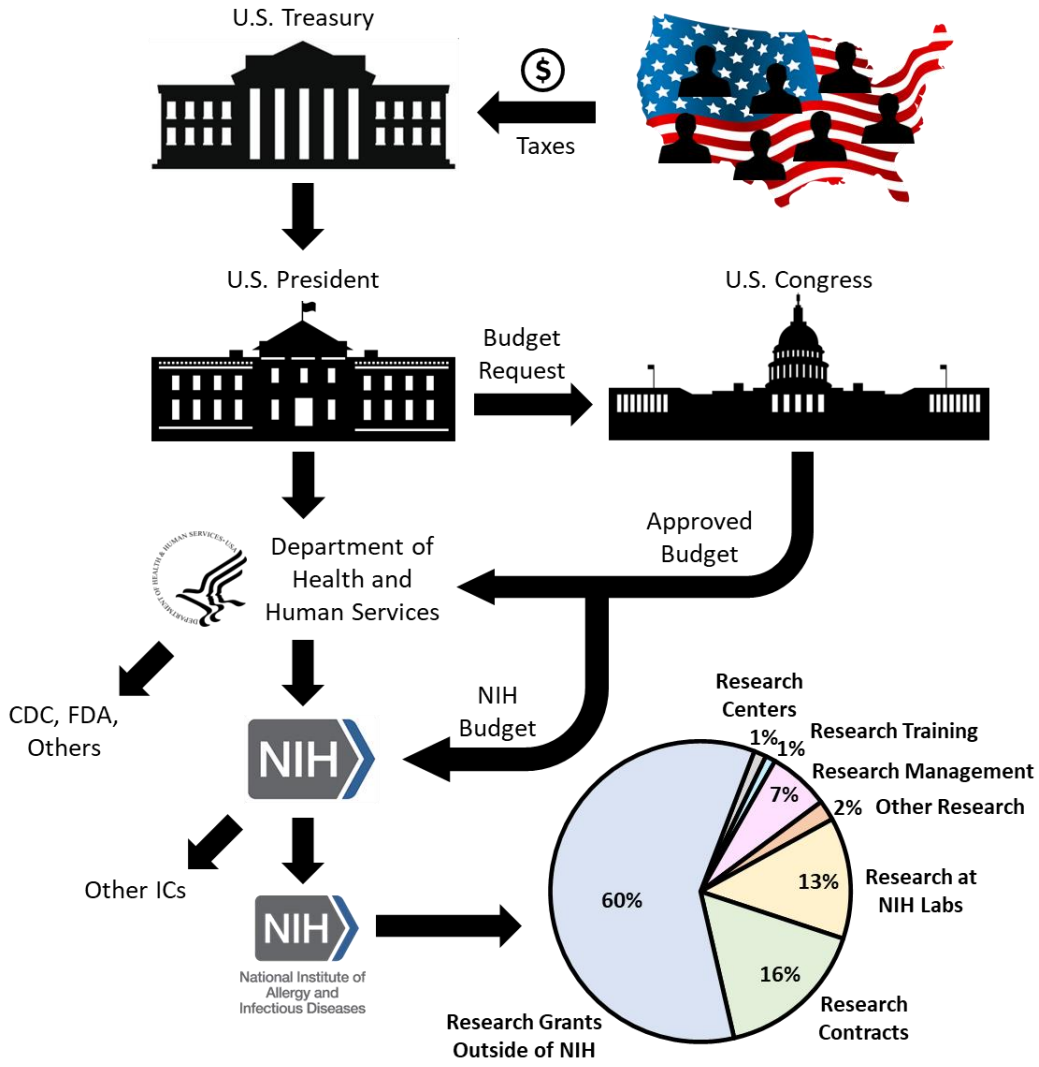
Top Research Areas by Funding
(USD in millions and rounded)

Research Area	FY 2022
Clinical Research	$ 18,405
Genetics	11,480
Neurosciences	11,163
Prevention	10,973
Infectious Diseases	8,324
Brain Disorders	8,313
Biotechnology	8,142
Behavioral and Social Science	7,650
Cancer	7,644
Clinical Trials and Support	6,832
Rare Diseases	6,482
Aging	6,069
Bioengineering	5,866

https://officeofbudget.od.nih.gov/index.htm
https://report.nih.gov/funding/categorical-spending#/

U.S. Research Funding Model

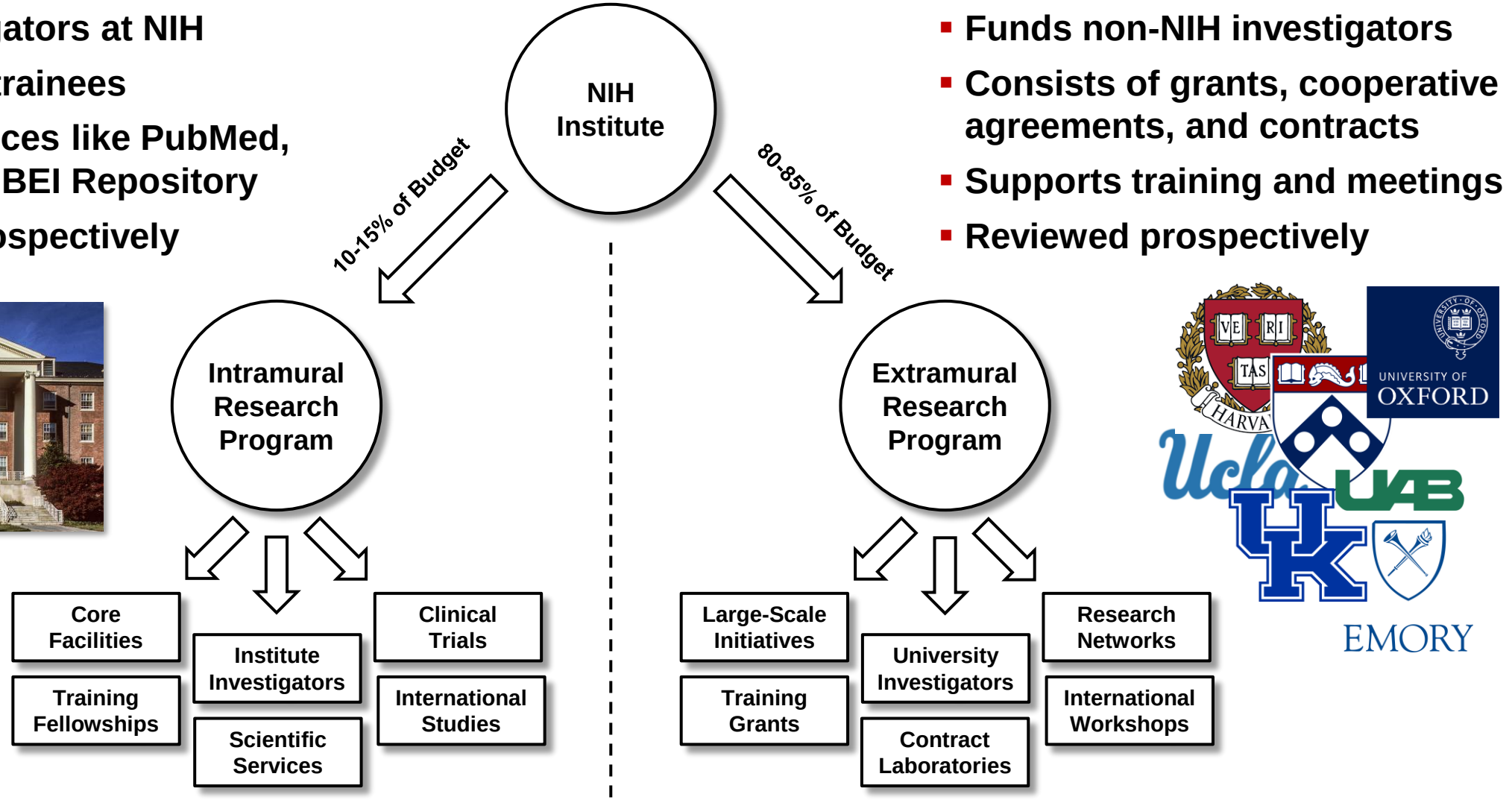
- Budgets are appropriated by Congress every fiscal year (FY)
  - Year-to-year fluctuations in appropriations directly affect grant numbers awarded by NIH
  - Less funding = more competition
    - “Paylines” directly represent this since they indicate the top percentiles of funded applications from all received
- NIH reports use of funds to Congress
  - NIH cannot petition Congress for more funding or funding for particular research
- Congress can specify how funds must be used



https://www.niaid.nih.gov/about/budget-planning

U.S. NIH Research Funding Model

- Funds investigators at NIH
- Supports NIH trainees
- Supports services like PubMed, GenBank, and BEI Repository
- Reviewed retrospectively



- Funds non-NIH investigators
- Consists of grants, cooperative agreements, and contracts
- Supports training and meetings
- Reviewed prospectively

https://irp.nih.gov/

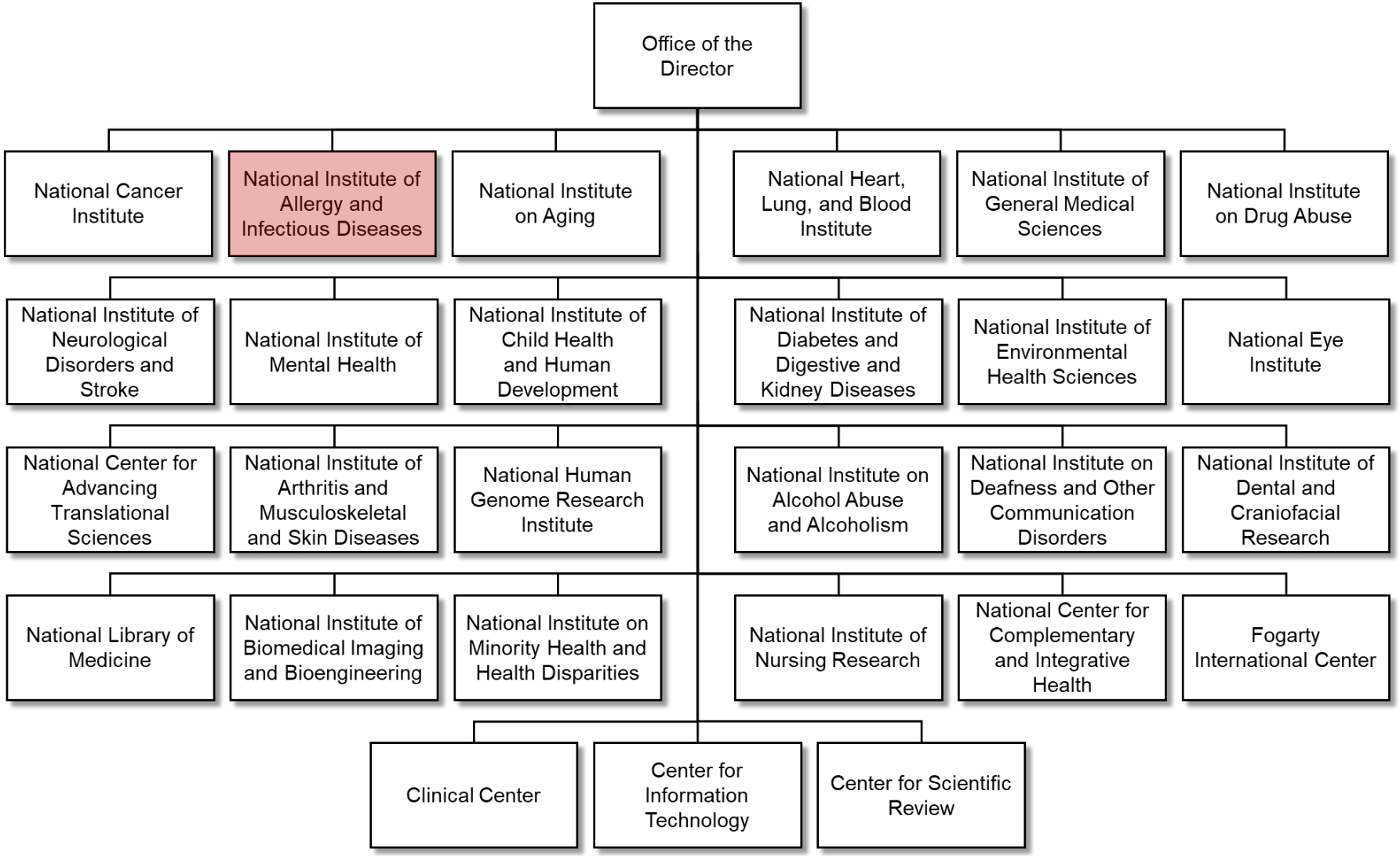
NIH Direct Funding: ASEAN Countries 2012-22

Country	Projects	Funding	Sub-Projects	Funding	NIH ICs
Thailand	66	$ 29,897,819	20	$ 1,577,547	NIAID, FIC, NIMH, NIDCR
Vietnam	19	$ 4,576,516	0	$ 0	FIC, NHLBI, NIDA, NIAID
Malaysia	7	$ 952,073	0	$ 0	NIAID
Philippines	5	$ 1,923,748	25	$ 1,923,748	NIAID
Singapore	2	$ 286,838	0	$ 0	NIAID
Indonesia	0	$ 0	0	$ 0	-
Cambodia	0	$ 0	0	$ 0	-
Laos	0	$ 0	0	$ 0	-
Brunei	0	$ 0	0	$ 0	-
Myanmar (Burma)	0	$ 0	0	$ 0	-
Total	99	$ 37,636,994	45	$ 3,501,295	-
China	96	$ 22,176,424	0	$ 0	NIAID, FIC, NIA, NIMH, NIDA
India	77	$ 21,307,262	68	$ 6,067,867	FIC, NIAID, NHLBI, NCI, NICHD, NIMH
Japan	15	$ 7,314,249	0	$ 0	NCI, NIAID, NIDCR, NIGMS
Korea	8	$ 10,818,835	0	$ 0	NCI, NHLBI, NIA

- Note: Indirect NIH funding is not shown here, so actual project numbers and dollar amounts may be higher

https://reporter.nih.gov/

U.S. NIH Institutes and Centers



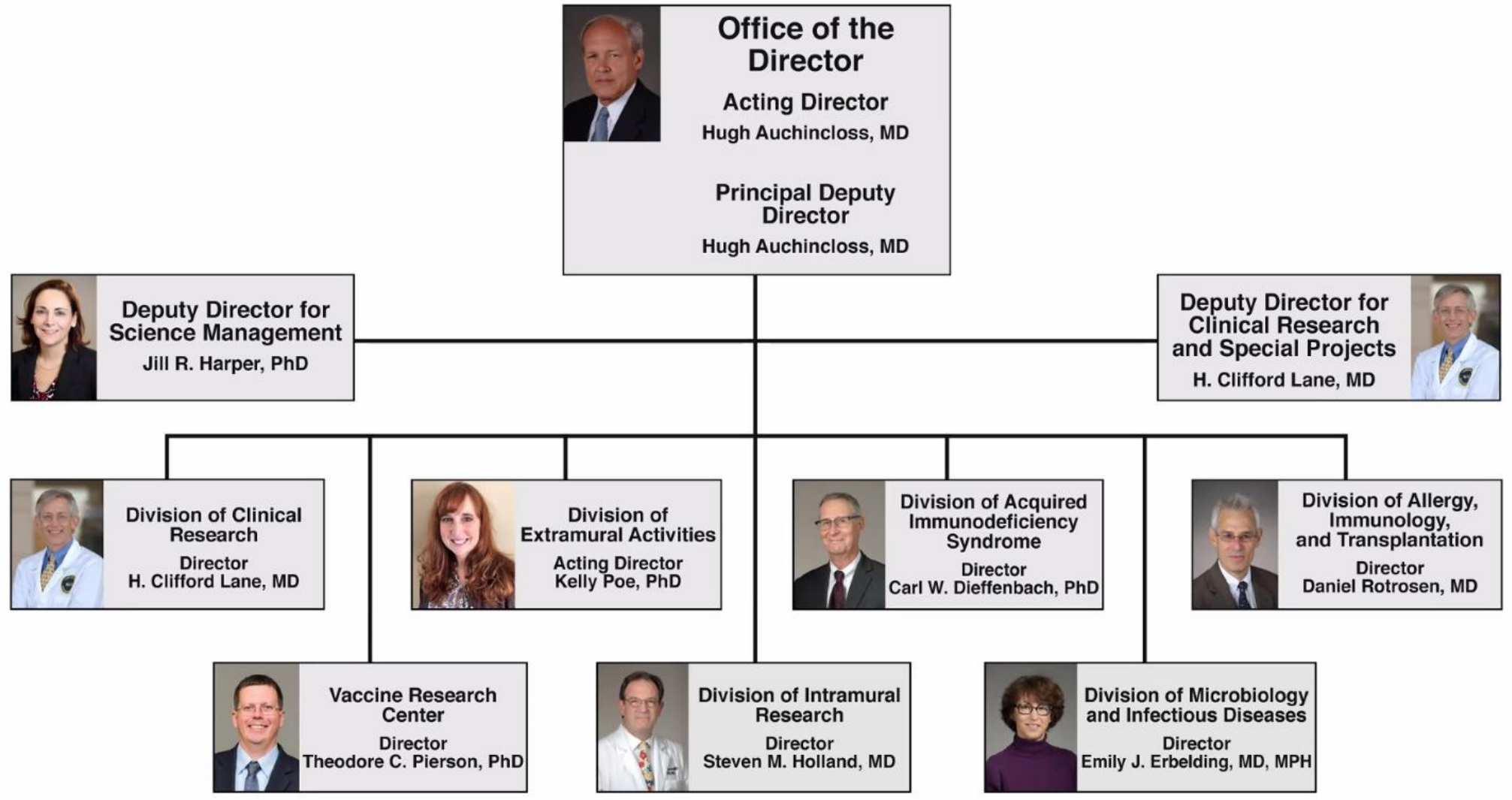
National Institute of Allergy and Infectious Diseases

"The NIAID mission is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. NIAID has a unique mandate, which requires the Institute to respond to emerging public health threats."

- **Second largest NIH institute/center (IC)**
- **Annual budget of $6.33 billion**
  - **5,609 research project grants ($4.66 billion) in 2022**
- **3,496 employees and contractors**
  - **854 research fellows and trainees**
- **Only NIH IC with dual-mandate responsibilities:**
  - **Maintain and "grow" basic and applied research portfolio**
  - **Respond rapidly to emerging and re-emerging infectious disease threats**

https://www.niaid.nih.gov/

NIAID Organization and Leadership



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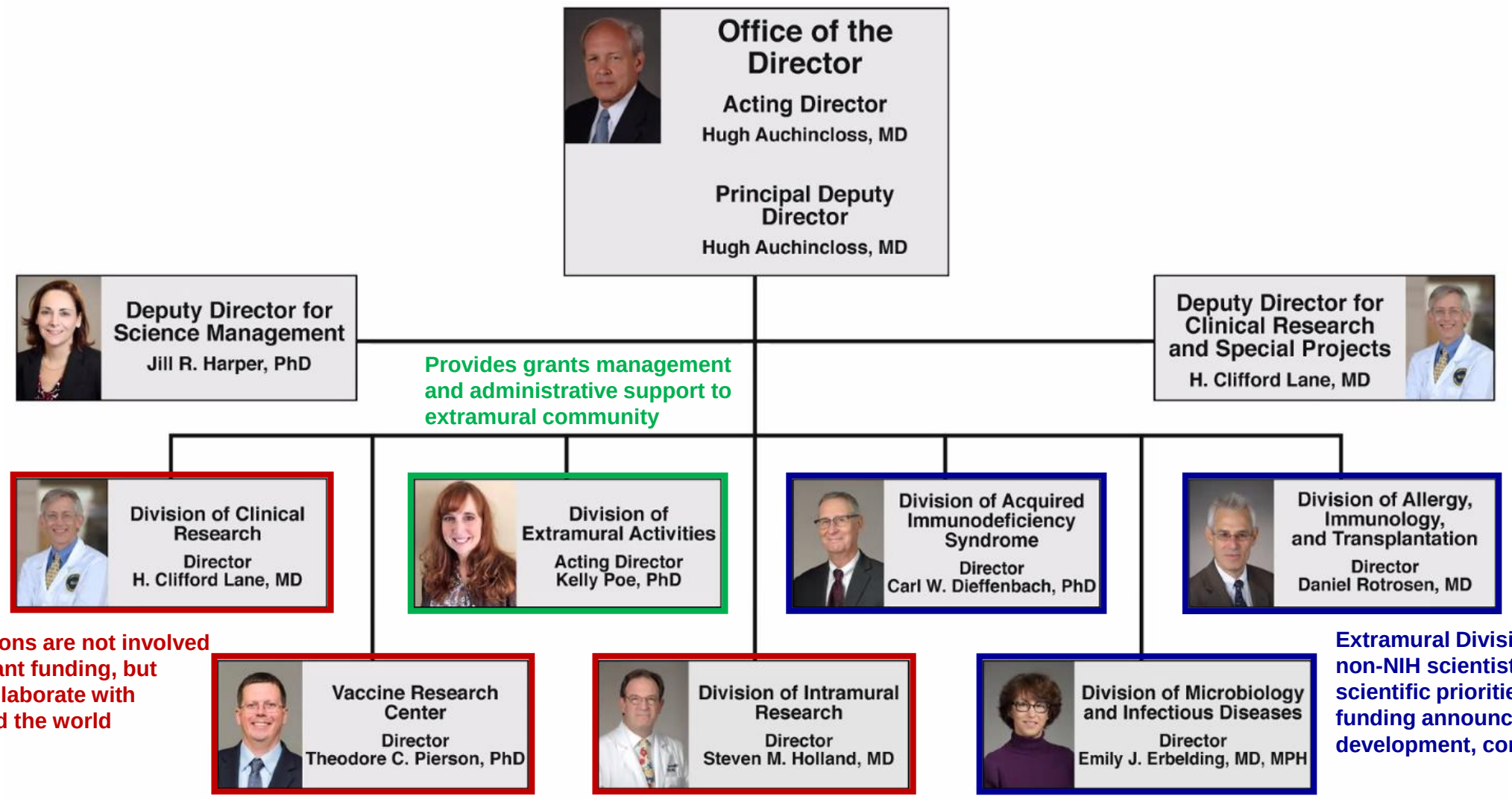
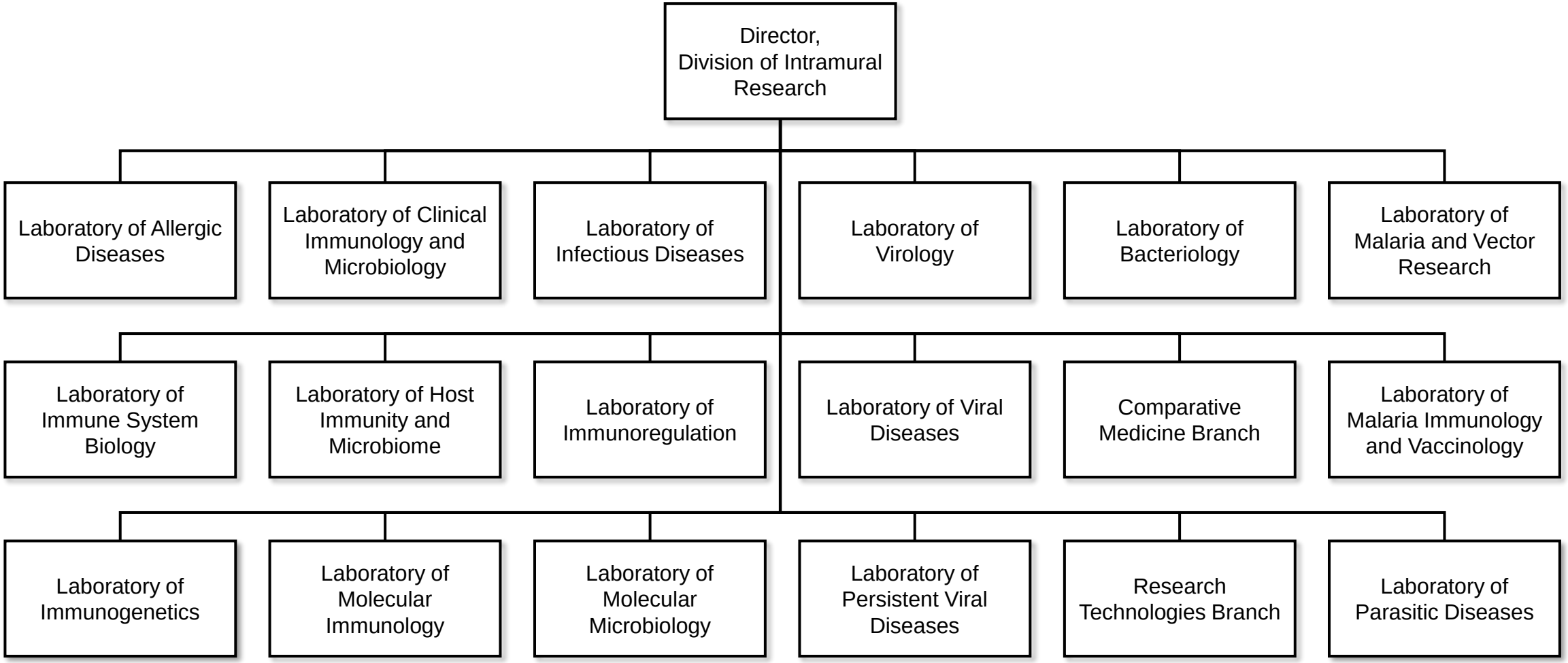


Intramural Divisions are not involved in extramural grant funding, but investigators collaborate with scientists around the world

Extramural Divisions support non-NIH scientists and drive scientific priorities through funding announcements, program development, conferences, etc.

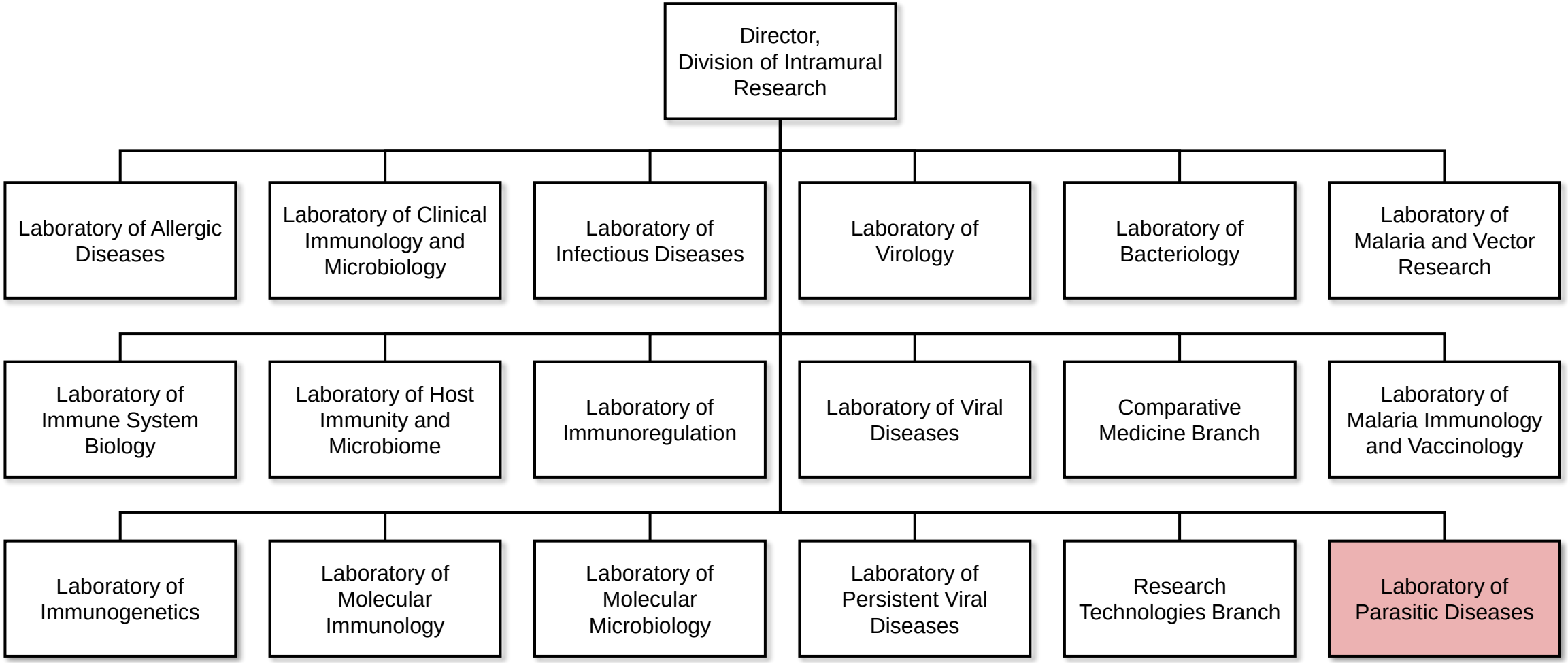
https://www.niaid.nih.gov/

NIAID Div. of Intramural Research



https://www.niaid.nih.gov/about/dir

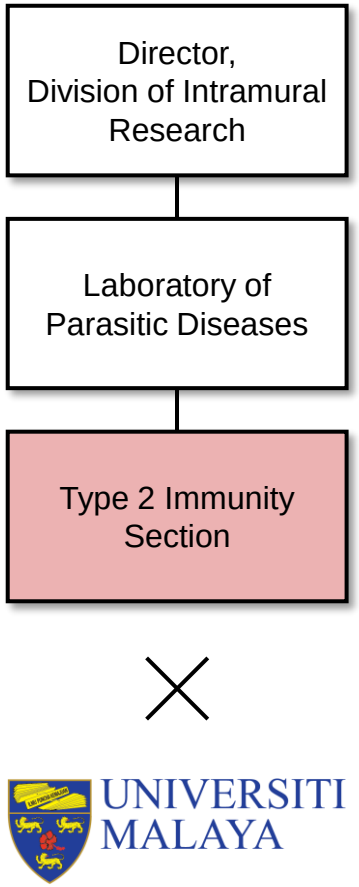
NIAID Div. of Intramural Research



https://www.niaid.nih.gov/about/dir

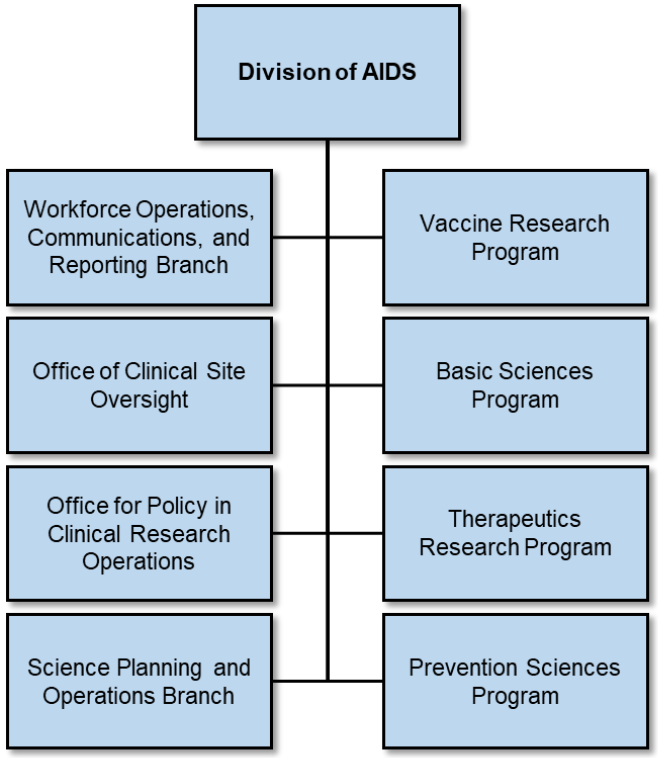
NIAID Div. of Intramural Research

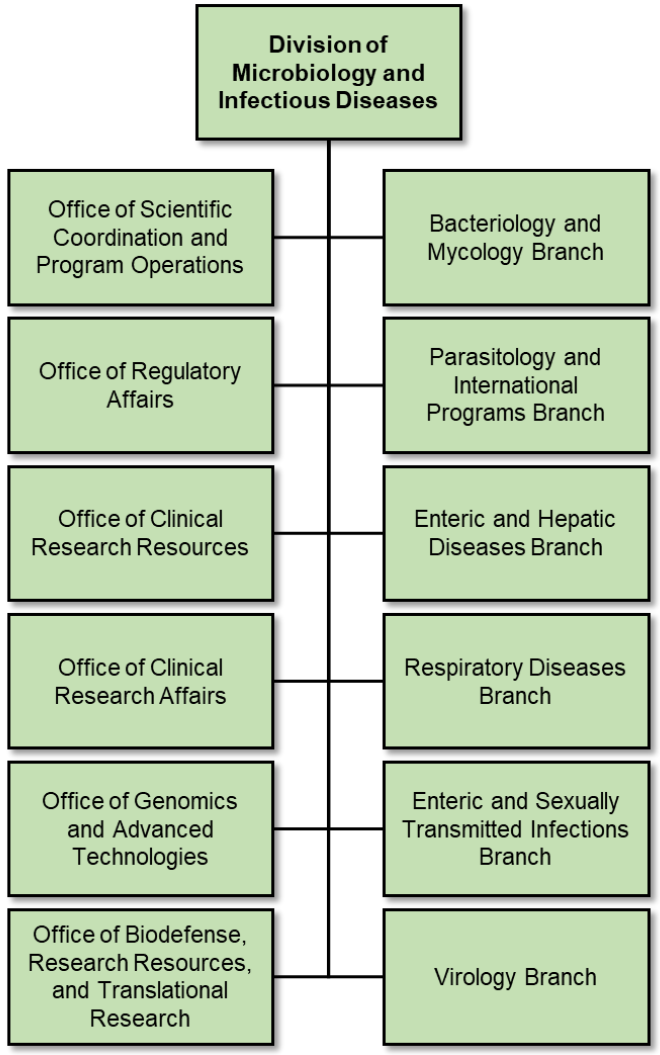
- Dr. P'ng Loke joined NIAID as a Senior Investigator and Section Chief in 2020
  - Studying heterogeneity of type-2 immune responses during helminth infections
    - Type-2 immunity induced by helminth infections may be therapeutically beneficial for improving symptoms of inflammatory bowel diseases and metabolic syndrome
- While an extramural researcher at NYU, began collaboration with Prof. Yvonne Lim at UM
  - Used NIH grant to fund collaborative work in Malaysia (indirect funding) looking at helminth infection within the indigenous Orang Asli community
  - Continuing collaboration as intramural investigator
    - Hosted Prof. Lim at NIAID through Fulbright program
    - Prof. Lim's former student is now NIAID postdoc fellow

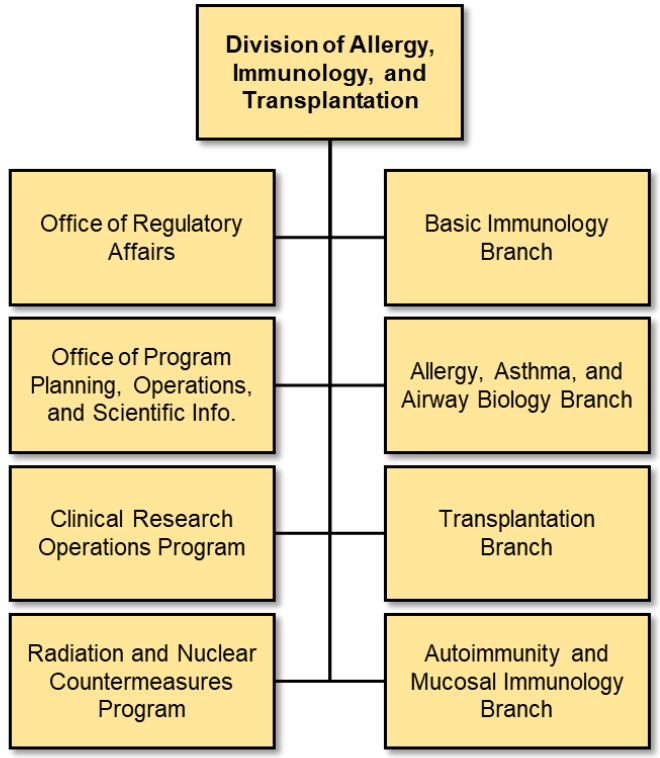


https://irp.nih.gov/pi/png-loke

NIAID Extramural Divisions







- **Staffed with scientific experts who support the entire research enterprise**
- **Support grantees scientifically and conduct research through cooperation**
- **Grantees work closely with Program Officers**

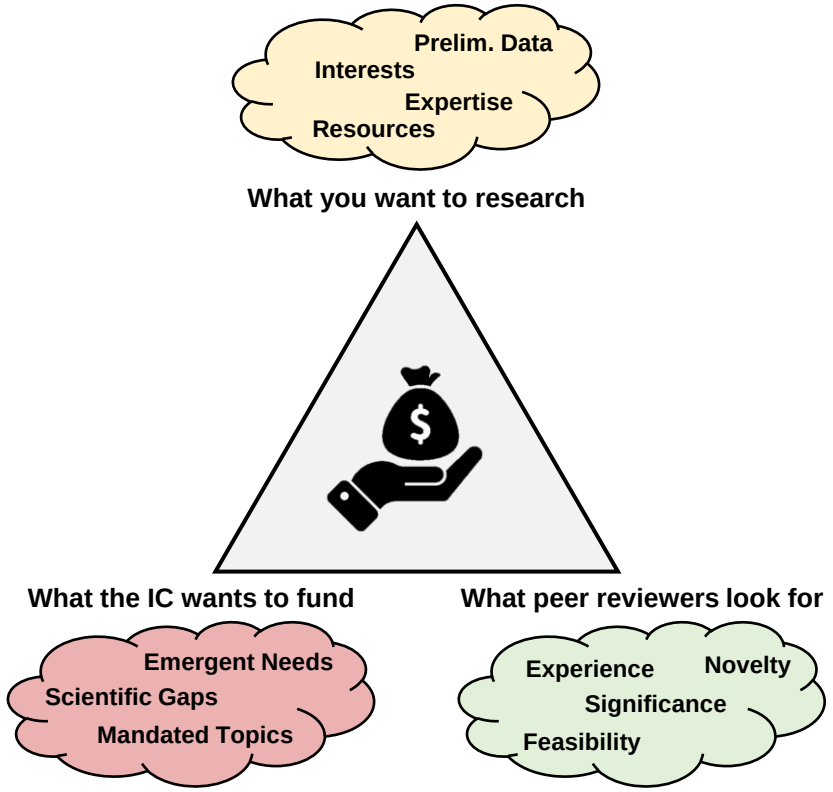
https://www.niaid.nih.gov/about/daids

https://www.niaid.nih.gov/about/dmid

https://www.niaid.nih.gov/about/dait

NIAID Research Considerations

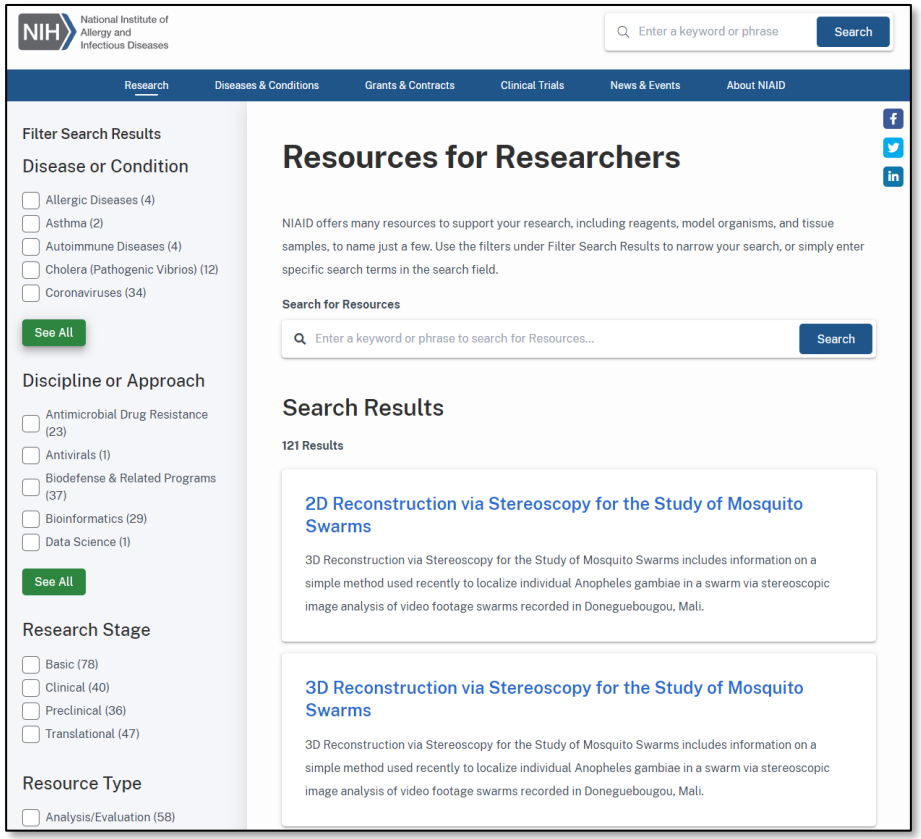
- Developing a research proposal is a balancing act
- All proposals **must** align with IC research priorities
  - Know the NIH and know your target IC
  - NIAID and other ICs routinely identify research priorities, which can be found through a variety of sources:
    - Advisory Council-approved research concepts
    - Solicited research initiatives
    - NIAID strategic plans
    - Recently funded research proposals
    - Discussions with Program Officers
- NIAID's dual-mandate can mean sudden opportunities
  - December 2015: No active extramural research on Zika
  - End of 2016: 65 grant supplements, 40 grants, 26 contracts



https://www.niaid.nih.gov/grants-contracts/research-priorities

Resources for Researchers

- Some NIH ICs, like NIAID, offer scientific resources for investigators whether or not they receive NIH grant funding
  - Many of the resources are free and can help strengthen your research toward a successful grant application
  - Some resources require informal or formal communication with NIH Program Officers



https://www.niaid.nih.gov/research/resources Accessed 10 March 2023

Resources for Researchers

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  - Many of the resources are free and can help strengthen your research toward a successful grant application
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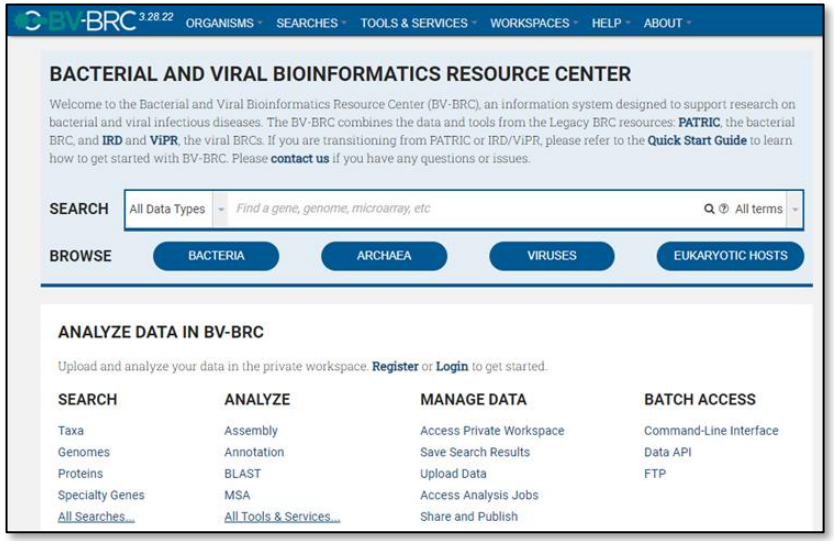
- Examples include:
  - BEI Resources Repository
  - Bacterial and Viral Bioinformatics Resource Center
  - ACTG/IMPAACT Specimen Repositories (HIV)
  - Bioinformatics@NIAID

https://www.beiresources.org/ Accessed 10 March 2023



https://www.bv-brc.org/ Accessed 10 March 2023

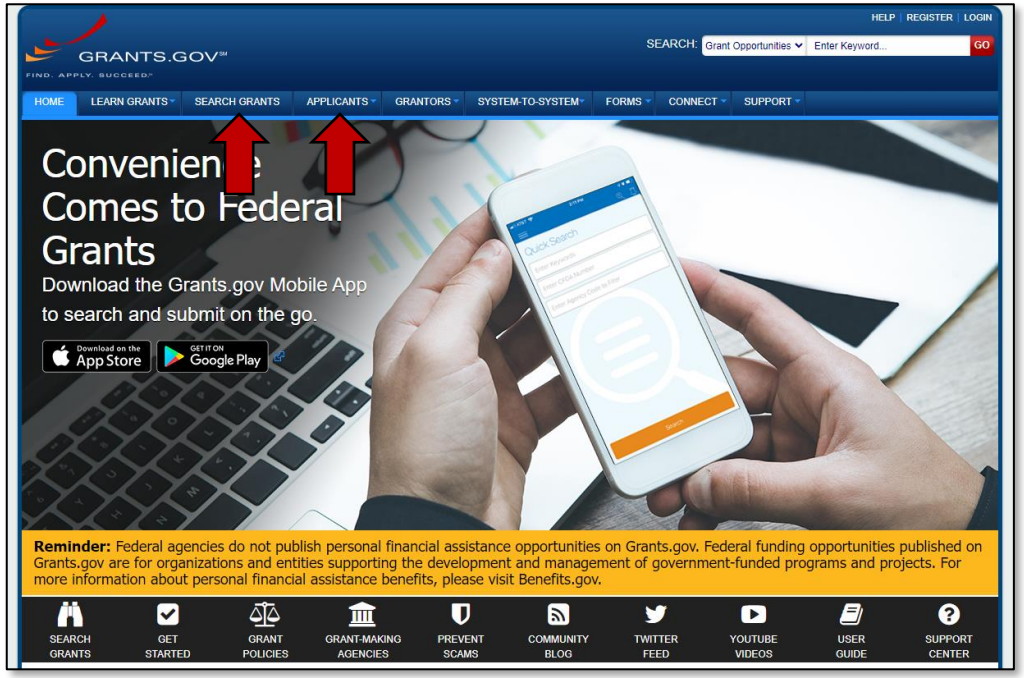
U.S. NIH Grant Funding

Things to Know

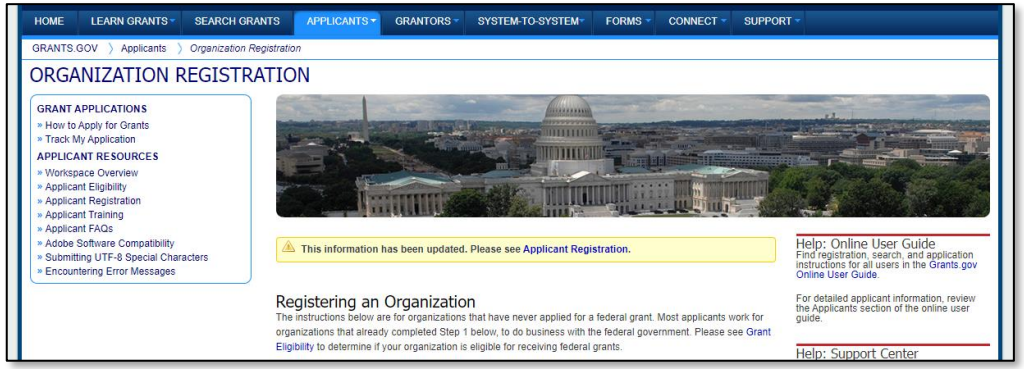
- Most NIH grants go to U.S. institutions, but you do not need U.S. affiliation or citizenship to become either a grantee institution or a PI for most grants
  - Application should include talent, resources, populations, or other resources **not found in U.S.**
- The Federal grant process can feel overwhelming, and that is normal
  - Many U.S. universities/institutions have dedicated grants management offices and staff
- Virtually all investigators submit and resubmit their research proposals several times before receiving funding
  - Each scientific review provides valuable feedback to improve the quality of the proposal
  - Collaborations with successful grant recipients can build experience for your own success
  - **Persistence is key!**
- U.S. Federal grants are awarded to an **institution**, not an **individual investigator**
  - Most registrations must be completed by an institution's authorized official (AO)

Finding Grant Funding

- **Grants.gov**
  - THE source for all U.S. government funding
  - Lists grant opportunities from 26 grant-making agencies
- No matter where you find the grant posting, all applications are routed through grants.gov
- Organizations/Institutions must complete several registrations in order to submit applications
  - 1. System for Award Management (SAM)
    - https://sam.gov/content/entity-registration
  - 2. Grants.gov registration
    - https://www.grants.gov/web/grants/register.html
  - 3. NATO Commercial and Gov. Entity (NCAGE) Code
    - https://eportal.nspa.nato.int/Codification/CageTool/home
  - 4. eRA Commons account (Signing Official and PI separate)
    - https://www.era.nih.gov/register-accounts/register-in-era-commons.htm
  - 5. HHS Payment Management System (PMS) (post-award)
    - https://pms.psc.gov/about-us.html



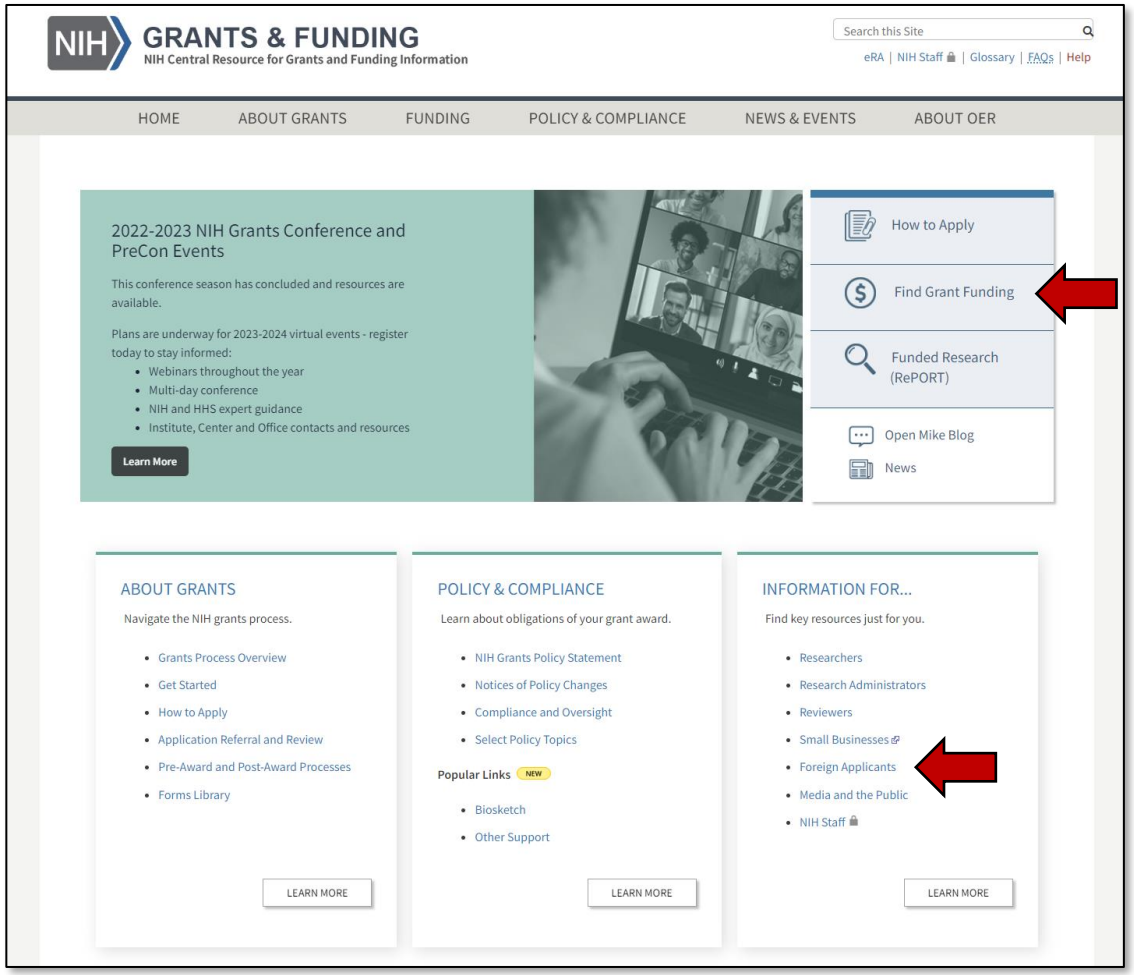
https://www.grants.gov/ Accessed 10 March 2023



https://www.grants.gov/web/grants/applicants/organization-registration.html

Finding Grant Funding

- **Grants.nih.gov**
  - THE source for all NIH and associated funding
  - Funding opportunities found on Grants.nih.gov are also listed on Grants.gov
- NIH Guide for Grants and Contracts
  - Official publication of notices of grant policies, guidelines, and funding opportunity announcements (FOAs)
  - Published daily and available online, by email listserv, or both
- Helpful information for foreign applicants
  - https://www.niaid.nih.gov/grants-contracts/international-applications



https://grants.nih.gov/ Accessed 10 March 2023

Examples of NIH Research Grants

R01: Research Project Grant Program

- Supports a discrete, specified research project
- Most common grant at NIH; supported by all ICs
- No specific USD limit, but usually <$500K USD/year for 3-5 years

U01: Research Project Cooperative Agreement

- Supports discrete, specified projects to be performed by investigator(s) in an area representing specific interests and competencies
- Substantial NIH staff involvement
- No specific dollar limit; amount/time specified in FOA

R21: Exploratory/Developmental Research Grant Award

- Supports new, exploratory and developmental research projects in early stages; sometimes used for pilot and feasibility studies
- No preliminary data is generally required
- Usually <$275K USD total over 1-2 years

R03: Small Grant Program

- Supports variety of projects, such as pilot/feasibility studies, preliminary data collection, secondary analysis of existing data, etc.
- Usually <$50K USD/year for 1-2 years

R34: Clinical Trial Planning Grant Program

- Supports early peer review of the rationale for the proposed clinical trial and the development of essential elements of a clinical trial
- Usually $100K USD for 1 year

R24: Resource-Related Research Projects

- Used in a wide variety of ways to provide resources to research projects or to enhance research infrastructure

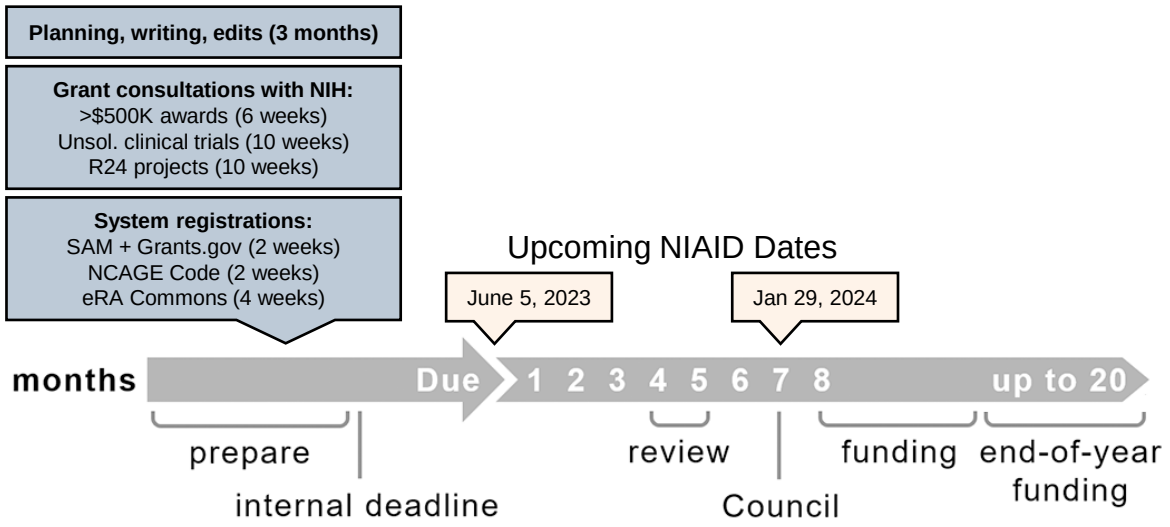
https://grants.nih.gov/grants/funding/funding_program.htm

Standard Application Cycle

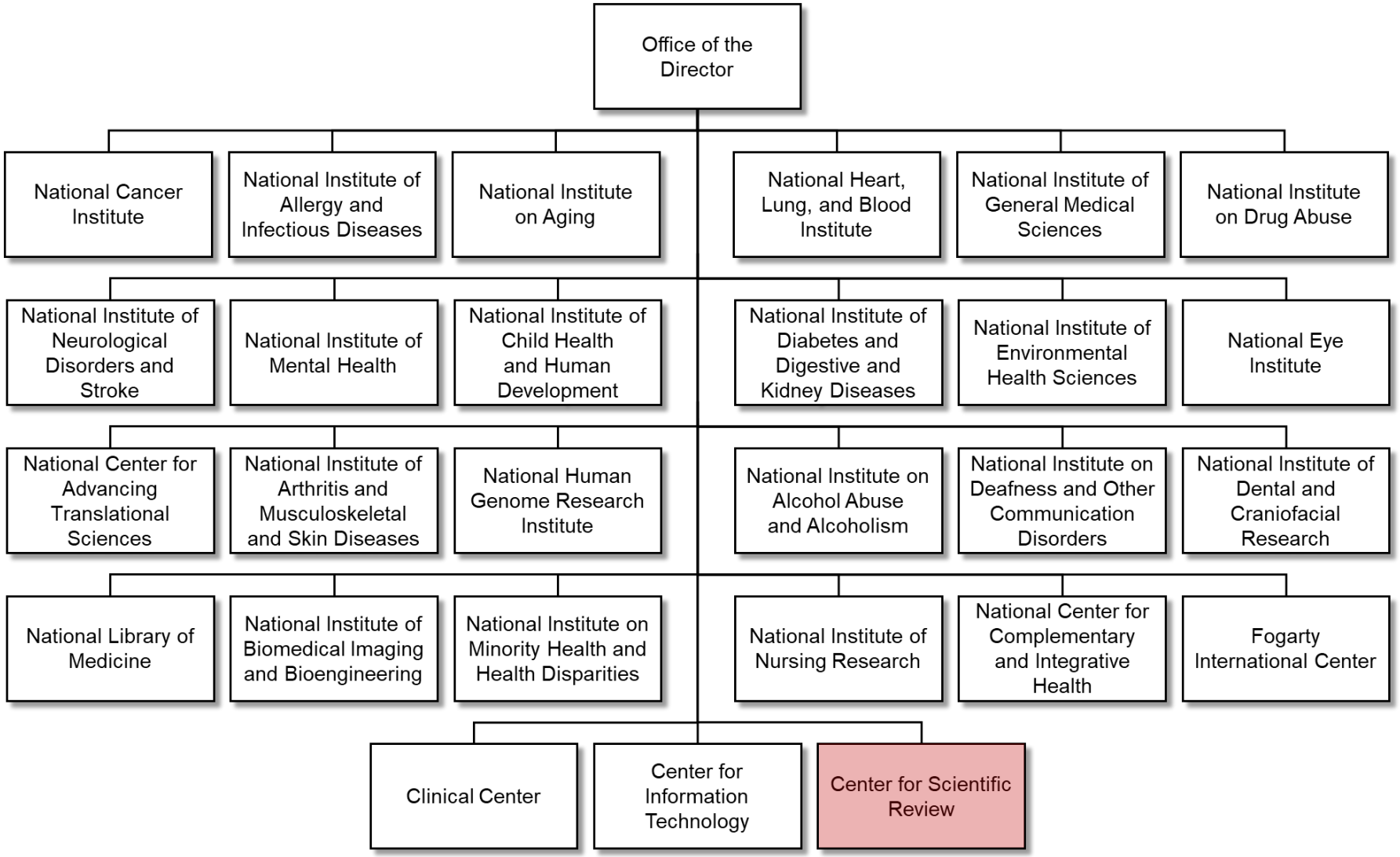
- Each FOA provides Key Dates
  - Open date
  - Due date
  - Earliest start date
- Many grants follow the “standard dates” for 3 application cycles per year
- Successful grants can take between 8-20 months from submission to funding
- Prior to submission:
  - Allow plenty of time for system registrations and organizational approvals
  - Some grant applications require consultation with NIH staff prior to submission
  - Plan to submit >2-3 days before the deadline

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October	January	May
Earliest Project Start Date	September or December	April	July
R01 (Research Grants)	February 5	June 5	October 5

https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm
Accessed 10 March 2023

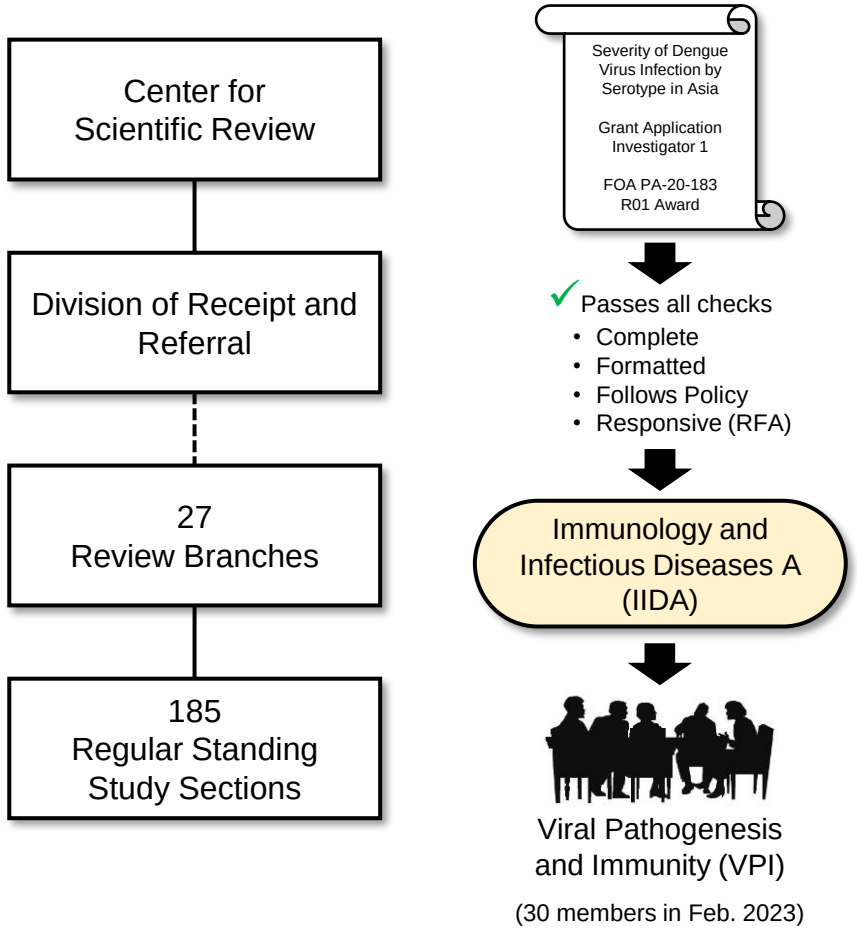


U.S. NIH Institutes and Centers



Center for Scientific Review

- CSR is the gateway for NIH grant applications and their review for scientific merit
- CSR Division of Receipt and Referral
  - Checks applications for completeness, formatting, and compliance with NIH policies
  - Assigns each application to a review group
    - CSR maintains 27 Review Branches consisting of 185 regular standing Study Sections
      - NIH Scientific Review Officers (SROs) are active at every step of the review process
    - In some cases, applications go to IC Scientific Review Panels (SRPs) for specialized review (i.e. RFAs)
- Two levels of NIH peer review:
  - Initial peer review
  - Council review



https://public.csr.nih.gov/ForApplicants/SubmissionAndAssignment
https://public.csr.nih.gov/StudySections/ReviewBranches
Accessed 10 March 2023

U.S. NIH Peer Review Process

Initial peer review (Scientific Review Group)

- SRG is composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas
- Each proposal is assigned at least 3 reviewers, but all SRG members may review and comment
  - Reviewers issue an **overall impact score**
    - Criteria scores range from 1 (best) to 9 (worst)
  - For Foreign Entities, reviewers also assess whether comparable work is being done in U.S.
  - Noncompetitive applications may not be reviewed (streamlined)
- SROs prepare a **summary statement** that summarizes the review, discussion, and more
- NIH Peer Review: "Live" Mock Study Section:
  - https://www.youtube.com/watch?v=Vx6qO8z9swQ

https://www.niaid.nih.gov/grants-contracts/scoring-summary-statements Accessed 10 March 2023

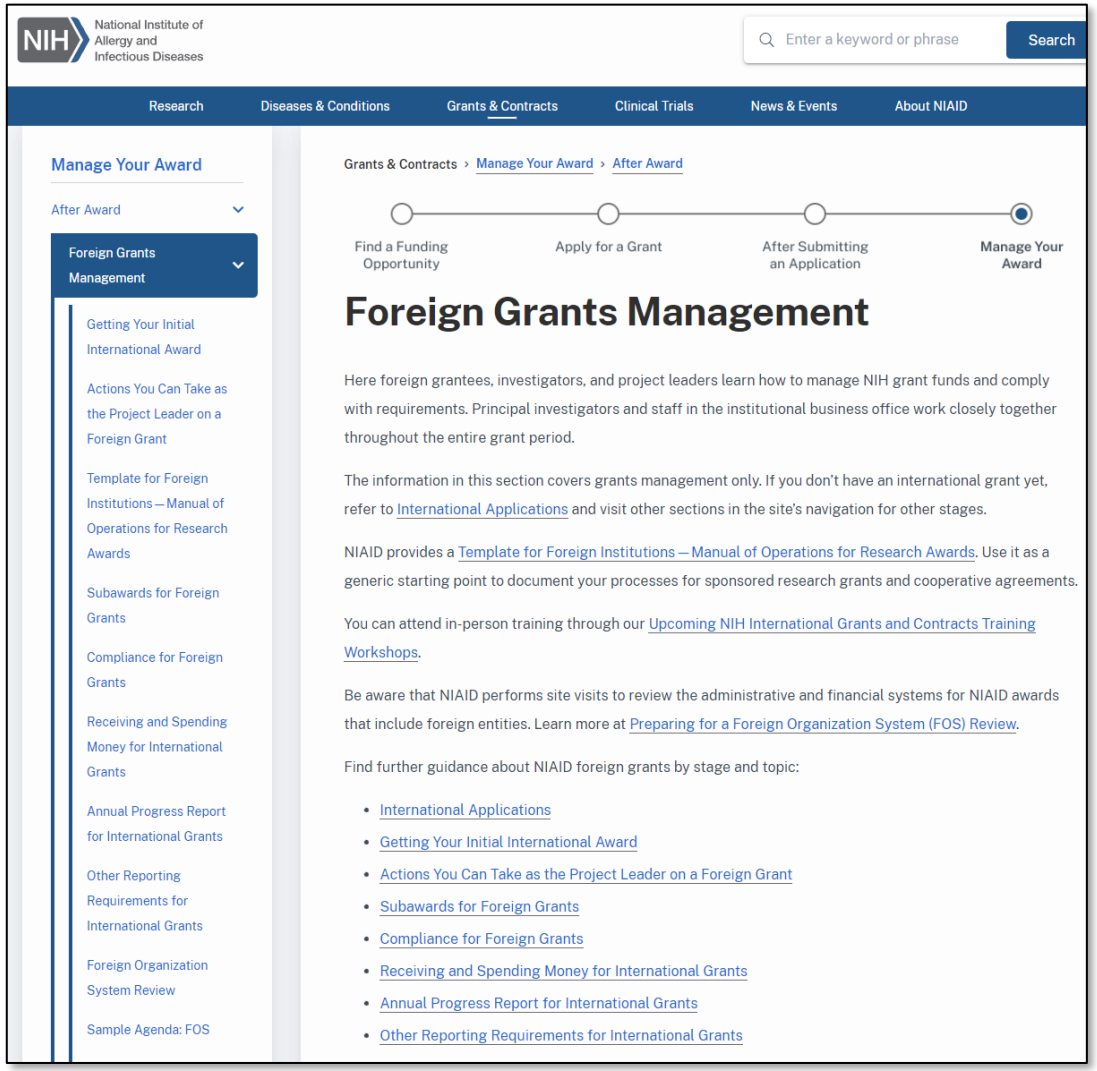
Council review (IC National Advisory Council)

- Much smaller hurdle than initial peer review
- Looks for potential barriers to funding
  - Human subjects and animal concerns
  - Special circumstances such as foreign applications and applications requesting money over the limit
- Not a second scientific review
- Council recommends an application for funding, but the IC makes the final decision
  - Recommended for funding
  - Not recommended for funding
  - Deferred for re-review by the study section
- Proposals recommended for funding may still not be funded due to external factors

https://www.niaid.nih.gov/grants-contracts/second-level-review Accessed 10 March 2023

After You Receive an NIH Grant

- If you receive a low (good) score from peer review, if Council recommends funding, and if the IC plans to fund your proposal:
  - Additional information is needed before a final decision is made (just-in-time (JIT) request)
    - Resolve queries or discrepancies
    - Provide certifications, IRB approvals, etc.
- **Notice of Award** is received from IC's Grants Management Officer
  - Register in HHS Payment Management System (PMS)
  - Funds are now yours to spend on research
- Grants are legally binding, so must comply with NIH grant policies, many of which are based on U.S. law
- NIAID assists foreign organizations build capacity to appropriately manage NIH funds
  - https://www.niaid.nih.gov/grants-contracts/preparing-foreign-organization-system-review

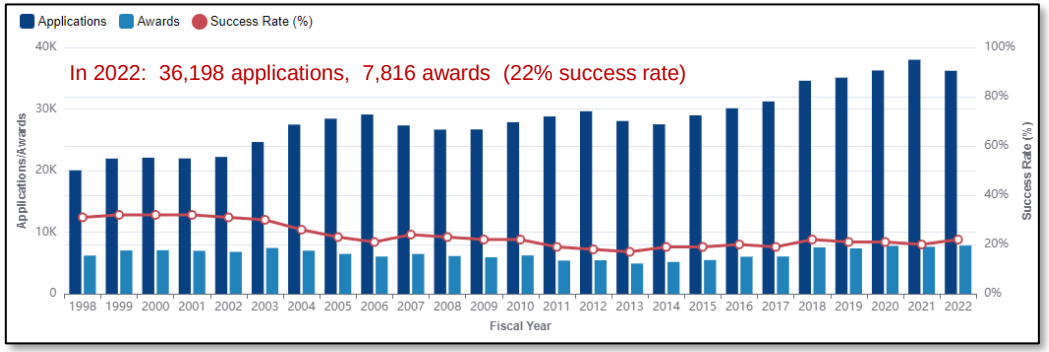


https://www.niaid.nih.gov/grants-contracts/foreign-grants-management Accessed 10 March 2023

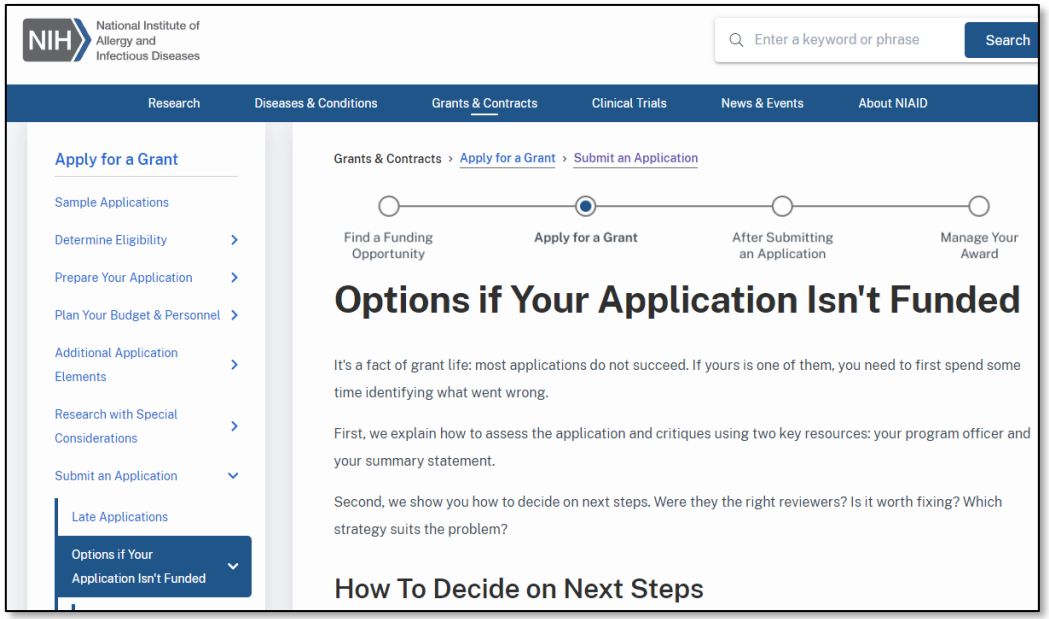
If Your Proposal is Rejected

- Most grant applications are unsuccessful
  - Current NIAID payline for R01 (new PI) is 15th percentile
- Rejected proposals are returned with feedback
  - Summary Statement provides reviewers' critiques
    - Can problems be readily fixed to meet their expectations?
    - Were some points misunderstood that can be easily clarified?
    - Is the proposed research viewed as significant?
    - Did they seem to be the right reviewers?
  - Program Officers can provide observations and advice
    - Did reviewers seem enthusiastic about the proposal?
    - Are there opportunities for special funding?
- If the problems are fixable, revise and resubmit
  - If the FOA expired, use most current version and forms
  - Explicitly address reviewers' critiques
  - Usually no harm in resubmitting

R01-Equivalent Grants: Competing Applications, Awards, and Success Rates



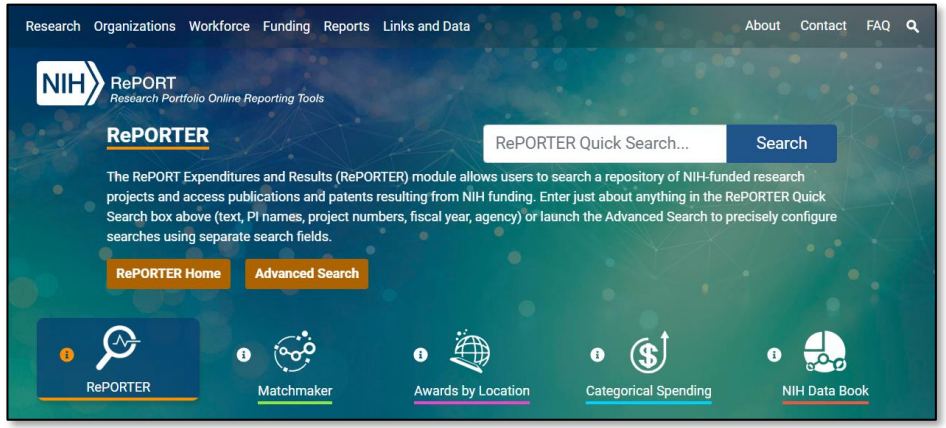
https://report.nih.gov/nihdatabook/report/29 Accessed 10 March 2023

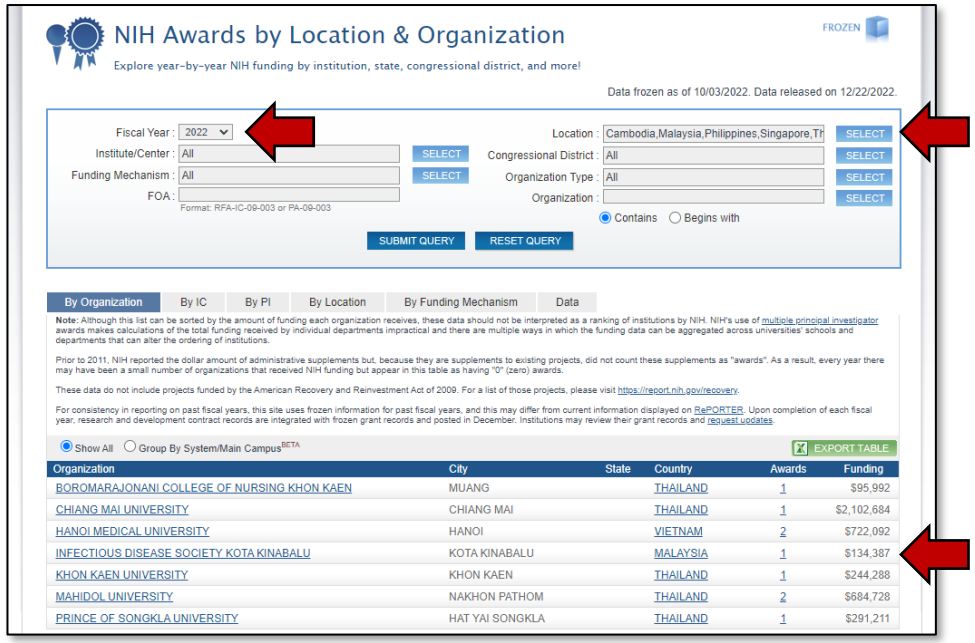


https://www.niaid.nih.gov/grants-contracts/options-if-application-not-funded
Accessed 10 March 2023

NIH RePORT

- Research Portfolio Online Reporting Tools (RePORT)
  - Publicly-accessible database with an incredible amount of information about NIH funding decisions
- When planning a research proposal, search RePORT to understand previous funding decisions
  - Which PIs in which countries received funding for which research proposals?
    - A quick search of active NIH awards in ASEAN countries in 2022 reveals 9 total awards across 7 Foreign Entities
  - Only funded awards (active or closed) are tracked
- Note that RePORT only captures direct awards and not “indirect” funding through foreign components

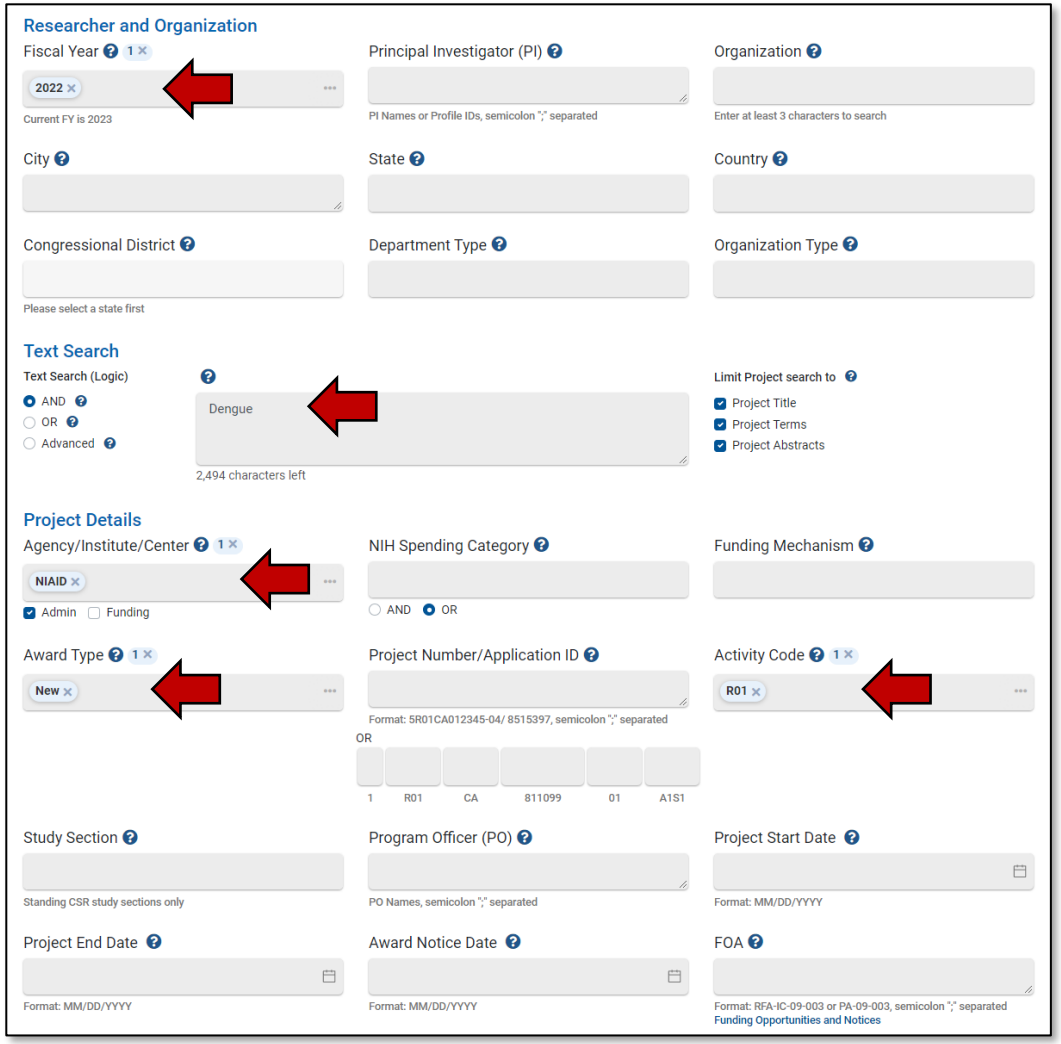




https://report.nih.gov/ Accessed 10 March 2023

NIH RePORTER

- RePORT Expenditures and Results (RePORTER)
  - Sophisticated search tool within RePORT
- Example search for a PI planning a dengue proposal:
  - New dengue R01 awards from NIAID in 2022

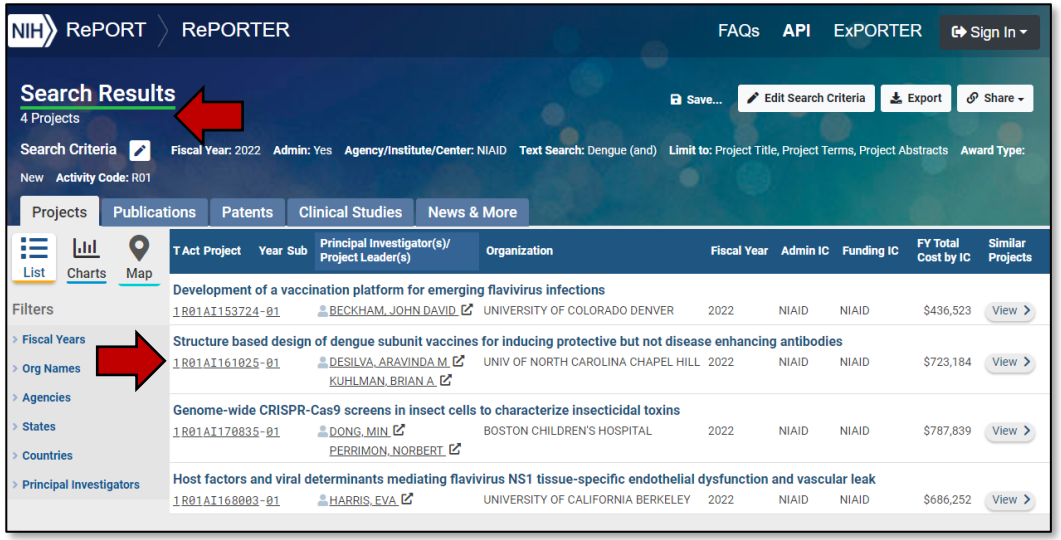


https://reporter.nih.gov/advanced-search

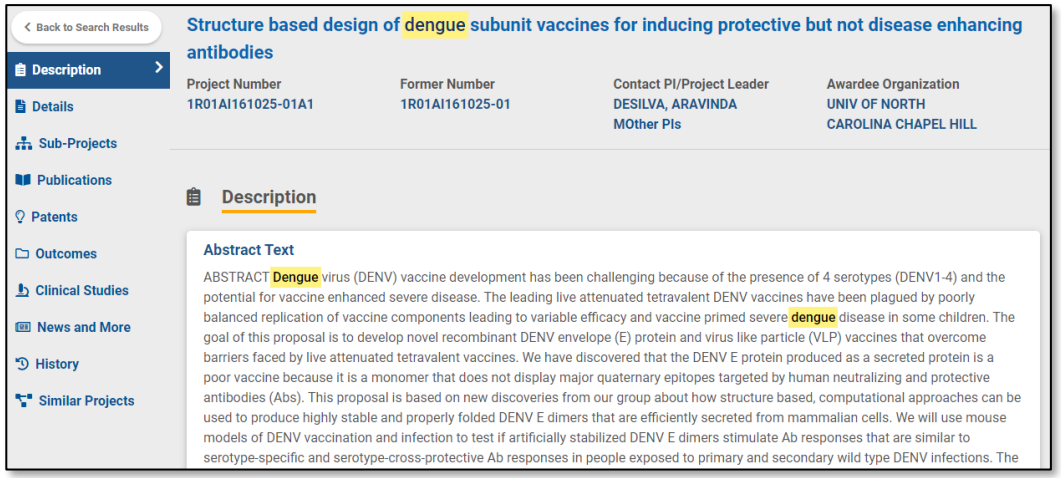
Accessed 10 March 2023

NIH RePORTER

- RePORT Expenditures and Results (RePORTER)
  - Sophisticated search tool within RePORT
- Example search for a PI planning a dengue proposal:
  - New dengue R01 awards from NIAID in 2022
    - 4 projects from U.S. investigators
    - Clicking project ID provides all details about the funded research project
- Searching RePORTER can help you understand NIH funding priorities and identify potential collaborators (or competitors)



https://reporter.nih.gov/advanced-search Accessed 10 March 2023



FOA of Interest: RFA-AI-23-023

- International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)
  - Applicant organizations **must** be headquartered in foreign resource-constrained countries (i.e. low-income, lower-middle-income, and upper-middle-income)
  - Funding up to $125K USD/year for up to 5 years
  - **Due dates: 02 August 2023; 02 August 2024; 01 August 2025**
- 38+ projects supported by related FOA (PAR-20-108)
  - 22 Principal Investigators
  - $5,166,803 USD total funding so far
  - South Africa, Brazil, Argentina, Kenya, Uganda, Mali, Ghana, Ecuador, Tanzania, Tunisia, Vietnam, Malaysia
- 96 projects supported by related FOA (PAR-17-142)
  - 24 Principal Investigators
  - $13,112,994 USD total funding
  - South Africa, Brazil, Peru, China, Argentina, Kenya, Mozambique, Uganda, Cameroon

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	International Research in Infectious Diseases (R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant
Announcement Type	New

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

- Non-domestic (non-U.S.) Entities (Foreign Institutions)

Applicant organizations must be headquartered in foreign (non-U.S.) resource-constrained countries (i.e. low-income economies, lower-middle-income economies, and upper-middle-income economies by World Bank Classification). Eligibility status of applicant organizations will be determined by this World Bank Classification list at application submission date.

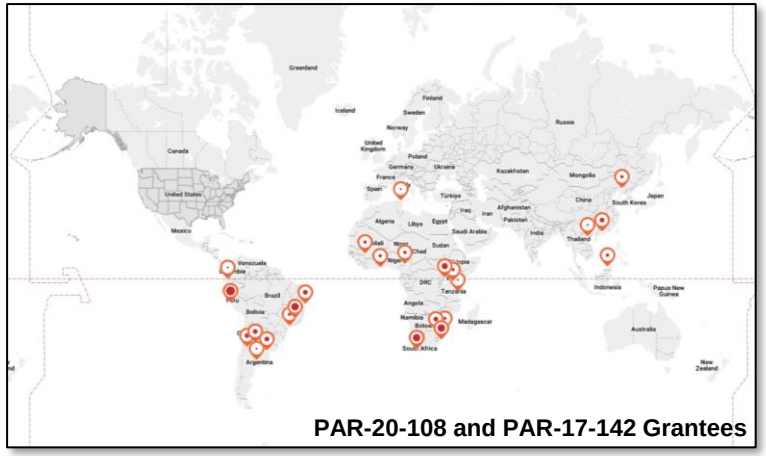
Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-23-023.html Accessed 10 May 2023



PAR-20-108 and PAR-17-142 Grantees

Alternative Sources of Funding

- US-Japan Cooperative Medical Sciences Program (USJCMSP) Collaborative Awards
  - Deadline: June 01, 2023
  - Funding: $60K total over 2 year period
  - Website: https://www.amed.go.jp/en/news/program/0301B_00027.html
- Centers for Research in Emerging Infectious Diseases (CREID) Network Pilot Grant Program
  - Deadline: Check during Fall 2023
  - Funding: $150K total over 1 year period
  - Website: https://creid-network.org/pilot-program
- Wellcome Trust: https://wellcome.org/grant-funding
- Gates Grand Challenges: https://www.grandchallenges.org/grant-opportunities
- Other funding sources: https://www.niaid.nih.gov/grants-contracts/find-foundation

Summary

- U.S. NIH is the largest funder of biomedical research globally
  - Will directly fund foreign investigators, sometimes exclusively, but more commonly funds U.S. investigators who collaborate internationally through a foreign component
- Get to know NIH and IC research through free resources like RePORT
- The entire grant process can be very complicated
  - This is only a general introduction but hopefully helpful enough to get you started
  - When you have questions, look to NIH websites, Grants Management Specialists, and Program Officers for guidance – they are there to help you!
  - Future seminars will cover various aspects of grant applications in more detail
- Persistence is key!

Preview of Future Topics

- Developing the scientific core of your proposal
  - **Specific Aims** (1 page limit)
    - Most important part of the application
    - Should teach the reviewers everything they need to know about the research objectives, central hypothesis, and significance of the proposed studies
    - 2-3 aims that are supportive but independent
  - **Research Strategy** (12 page limit)
    - Significance
      - Similar to manuscript introduction section
      - Usually 3-5 pages
    - Innovation
      - Conceptual, technical, and applicable innovations
      - Usually 0.5 pages
    - Approach
      - Similar to a methods section, with distinct blocks for each aim
      - Include rigorous methodologies to achieve unbiased results
      - Provide explanation of how biological variables (e.g. sex and ethnicity) are factored into research design and analyses
      - Consider all necessary controls
      - Discuss how data will be collected, analyzed, and interpreted

- All proposals are rigorously peer-reviewed and given a score from 1 (best) to 9 (worst)
  - **Significance**
    - Does the project address an important problem or critical barrier to progress?
    - If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
  - **Investigator(s)**
    - Are the PIs, collaborators, and other researchers well suited to the project?
    - If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training?
  - **Innovation**
    - Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
  - **Approach**
    - Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
    - Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
    - For **clinical research**, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
    - *Study design, data management, and statistical analysis*
  - **Environment**
    - Will the scientific research environment contribute to the probability of success?
    - Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

Terima Kasih

Aaron Neal, D.Phil.
aaron.neal@nih.gov