The NIH R01 Grant: A Foundation for Your Research Career

James Burroughs Program Coordinator, CAIRHE



Center for American Indian and Rural Health Equity



Why NIH?



Credit: NIH Data Book, FY19



Center for American Indian and Rural Health Equity For Healthy Communities Under the Big Sky www.montana.edu/cairhe



R01 Grants: The "Gold Standard"

Purpose of the Award

Provides funding to support research on a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the <u>mission of the NIH</u>.*

Details

- NIH's most-used grant program, and the largest and oldest
- No specific dollar limit unless specified in FOA
- Advance permission required for \$500,000 or more (direct costs) in any year
- Generally awarded for <u>3 to 5 years</u>; can be competitively renewed
- Preliminary data required/expected
- Can be investigator-initiated (most) or can be solicited via a Request for Applications
- Investigator-initiated proposals use standard due dates (Feb. 5, June 5, Oct. 5)

* 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.



What Can an R01 Grant Support?

- Salary and benefits (e.g., summer salary, course buyouts) for PI, key personnel, and other essential personnel
- Equipment and supplies
- Consultant costs
- Alterations and renovations
- Publications and miscellaneous costs
- Contracted services
- Consortium costs
- Travel expenses
- Facilities & Administrative costs (indirect costs)

Most importantly, it can help you build your <u>TEAM</u>!







By Comparison: R21 Grants

Purpose of the Award

Intended to encourage **exploratory/developmental research** by providing support for the early and conceptual stages of project development.

Details

- "Need not have preliminary data, extensive background material or preliminary information; however, they may be included if available." (This is, <u>in practice</u>, false.)
- Project period of <u>up to 2 years</u>; not renewable
- Combined budget for direct costs for the 2-year project period may not exceed \$275,000 (no more than \$200,000 in any single year)
- Novel, <u>high-risk/high-reward</u> proposals
- Investigator-initiated proposals use standard due dates (Feb. 5, June 5, Oct. 5)
- R21 ≠ "R01 Lite"



R01 vs. R21

Usually 3 to 5 years

Up to \$500,000 per year, or more

Pilot data needed

Special consideration for Early-Stage Investigators (ESI)

Offered by most (if not all) ICs

~20% overall success rate

Path to next R01 (*)

<u>2 years maximum</u>

Up to \$275,000 <u>total</u> maximum

Pilot data needed (for success)

<u>NO</u> special consideration for Early-Stage Investigators (ESI)

Offered by 1/2 to 2/3 ICs

~17% overall success rate

Not a proven path to R01

"Smaller and shorter does not equal easier."

Early-Stage Investigator (ESI) or New Investigator (NI)

Early-Stage Investigator (ESI): A PI who has completed their terminal research degree or end of post-graduate clinical training (whichever date is later) within the **past 10 years** and who has not previously competed successfully as PI for a substantial NIH independent research award (i.e., an R01).

- Designation matters for R01 applications
- ESI/NI applications clustered and reviewed together
- Institutes consider ESI status for funding decisions. All ICs are different. (*)
- Consider carefully if you are part of a multi-PI application!



Credit: NIH Office of Extramural Research



"OK, I'm sold. I want an R01. How do I get it?"

Start planning early

- Apply for the right opportunity
- Contact appropriate program staff early
- Present ideas clearly and directly



Preliminary Health Sciences Funding for MSU Faculty: Look No Further



Center for American Indian and Rural Health Equity



- <u>NIH funding</u> allocated, awarded, and administered locally by <u>MSU colleagues</u>.
- Designed to develop the research careers of early-stage investigators in Montana.
- Funding comparable to that of R03 or R21 grants, and MUCH EASIER to get!
- Comes with hands-on assistance and coaching to get you to an RO1 level.

Also: MWCTR-IN <u>ctrin.unlv.edu</u>



The Grant Life Cycle

FROM "PLAN" TO "APPLY" **COULD TAKE 8+ MONTHS**





For Healthy Communities Under the Big Sky www.montana.edu/cairhe

You Aren't Alone: R01-Level Awardees at MSU, Past 10 Years (partial list: see reporter.nih.gov)

Adams Carter Kominsky Swain Nygaard Kinion Voyich Cloninger Copie Dickensheets Stewart

McDermott Franklin Skewes Walk Held Harmsen Livinghouse Lefcort Kohout Brooker DuBois

Broderick June l ei Rink Pincus Schmidt Stowers John-Henderson Wiedenheft

and more ...



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27 Institutes & Centers (ICs), each with a different:

- Mission and priorities
- Budget
- Funding strategy and payline





Types of Funding Opportunity Announcements (FOAs)

Type of FOA	Description		
Program Announcements (PA, PAR, PAS)	Highlights areas of focus Usually ongoing (3+ yrs.) Often use standard receipt dates		
Requests for Applications (RFA)	 Narrowly defined scope Usually single receipt date Set-aside funds IC usually convenes review panel 		
Parent Announcements	 Type of program announcement Generally span the breadth of NIH mission By activity code (R01, R03, etc.) For "<u>investigator-initiated</u>" or unsolicited research ideas (~80% of all R01s) 		



Department of Health and Human Services

R01 Funding Opportunities

Part 1. Overview Information

	Network to the deal of the set of
Participating Organization(s)	
Components of Participating Organizations	NATIONAL INSTITUTES OF HEALTH (NIH) National Eye Institute (NEI)
	National Heart, Lung, and Blood Institute (NHLBI)
	National Human Genome Research Institute (NHGRI)
	National Institute on Aging (NIA)
	National Institute on Alcohol Abuse and Alcoholism (NIAAA)
	National Institute of Allergy and Infectious Diseases (NIAID)
	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
	National Institute of Biomedical Imaging and Bioengineering (NIBIB)
	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
	National Institute on Drug Abuse (NIDA)
	National Institute of Environmental Health Sciences (NIEHS)
	National Institute of General Medical Sciences (NIGMS)
	National Institute of Mental Health (NIMH)
	National Institute of Neurological Disorders and Stroke (NINDS)
	National Institute of Nursing Research (NINR)
	National Institute on Minority Health and Health Disparities (NIMHD)
	National Center for Complementary and Integrative Health (NCCIH)
	The following Institutes/Centers only accept mechanistic studies that meet NIH's definition of a clinical trial. See Related Notices section below.
	National Heart, Lung, and Blood Institute (NHLBI) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) National Institute of Neurological Disorders and Stroke (NINDS) National Center for Complementary and Integrative Health (NCCIH) National Institute of Mental Health (NIMH)
	Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the <u>R01 Clinical Trial Required IC-</u> <u>Specific Scientific Interests and Contact website</u> . Applicants should also carefully note which ICs accept only mechanistic trials. ICs that do not participate in this announcement will not consider applications for funding.
Funding Opportunity Title	Pesearch Project Grant (Parent P01 Clinical Trial Pequired)

Research Project Grant (Parent R01 Clinical Trial Required)

Activity Code

R01 Research Project Grant



PA-20-184

Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)

PA-20-185

NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)

Examples of Non-Parent R01 Funding Opportunities

PAR-20-238 ("R" means special receipt, referral, and/or review considerations) Intervention Research to Improve Native American Health (R01 Clinical Trial Optional)

RFA-EB-21-001 (National Institute of Biomedical Imaging and Bioengineering)

Technology Development to Reduce Health Disparities (R01 Clinical Trial Optional)



Clinical Trials Policy

A research study in which one or more **human subjects** are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **healthrelated biomedical or behavioral outcomes**.

R01 grants have 3 options (apply to the correct FOA):

- Clinical trials allowed/required
- Clinical trials not allowed
- Basic Experimental Studies with Humans (BESH)

More Info: https://grants.nih.gov/policy/clinical-trials.htm



Finding the Right NIH Funding Opportunity

New/Active FOAs publicized through:

- Grants.gov
- $_{\odot}~$ Weekly emails from individual ICs, or MSU ORD
- NIH Guide for Grants and Contracts (Go to grants.nih.gov >> "Funding")

Active Funding Opportunities and Notices	Funding Opportunities and Notices 👻 Search Terms				Search Advanced Search	
 Clear All Filters Reset Release Date Filter Displaying: 1 to 25 of 45 results 	Results Per Page 25	~		Ξ (Export to x	✤ Share Search	Save your Search
Title		FOA/Notice Number	Issuing Organization	Release Date 🔻	Expiration Date	Activity Code
Urgent Award: COVID-19 Mental Health Research	(R01 Clinical Trial Required)	PAR-22-112	NIMH	Jan 31, 2022	Dec 23, 2022	<mark>R01</mark>
Urgent Award: COVID-19 Mental Health Research	(R01 Clinical Trial Optional)	PAR-22-113	NIMH	Jan 31, 2022	Dec 23, 2022	<mark>R01</mark>
Integrative Research in Gynecologic Health (R01 C	Clinical Trial Optional)	RFA-HD-23-006	NICHD	Jan 31, 2022	Apr 18, 2022	<mark>R01</mark>
Notice of Special Interest (NOSI): Research on bar comorbidities among vulnerable population grou	riers to care and risk of HIV-associated ps	NOT-HL-22-010	NHLBI	Jan 31, 2022	May 7, 2025	<u>R01</u>



A More Targeted Approach: MATCHMAKER

https://reporter.nih.gov/matchmaker





Center for American Indian and Rural Health Equity Matchmaker Results

Top 500 Projects

American Indians (AI) disproportionately suffer from high rates of cardiovascular disease, type 2 diabetes,, and rising cancer rates.1-4 These large health inequities are in part due to rapidly increasing rates of obesity, secondary to unhealthy lifestyles. 5 Women Infant and Children (WIC) data show AI preschool obesity rates are, the highest nationally (21%) and AIs are the only ethnic group showing persistent increase.6 We contend that, effective obesity and chronic disease prevention can only be accomplished in Al communities when families, are empowered and

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2020

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Study Section

KABJZBBJ4B54

40

30

20



REEV

A Community-based ,family

5 R01MH110945-04

5 R01HD087407-05

5 R01DK109323-05



March-2020

555917996

Matchmaker Search Result Example



Not All ICs Are Equal Where R01s Are Concerned

Research Project Grants: Funding, by Institute / Center

NIH Data Book Report ID: 209 Share @

Click IC bars to filter trend data below. Hover over trend chart to set year for IC breakdown chart above.



Funding for 2020



Center for American Indian and Rural Health Equity C

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Data 🌐

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Important NIH People

Program Official (or Officer): NIH staff scientist responsible for developing research initiatives and for the programmatic, scientific, and/or technical aspects of assigned applications and grants. (Contact before application, after Summary Statement, during study.)

Scientific Review Officer: NIH staff scientist and the federal official responsible for ensuring that applications receive an objective and fair initial peer review. Convenes the SRG. (Contact before or after application, before review.)

Scientific Review Group (SRG, aka "Study Section"): Primarily non-federal scientists (i.e., your peers) who conduct the first level of review for grants in a particular subject area. They have expertise in relevant scientific disciplines and current research areas. (<u>NEVER</u> contact.)



Matchmaker Results

Top 500 Projects

American Indians (AI) disproportionately suffer from high rates of cardiovascular disease, type 2 diabetes,, and rising cancer rates.1-4 These large health inequities are in part due to rapidly increasing rates of obesity, secondary to unhealthy lifestyles. 5 Women Infant and Children (WIC) data show AI preschool obesity rates are, the highest nationally (21%) and AIs are the only ethnic group showing persistent increase.6 We contend that, effective obesity and chronic disease prevention can only be accomplished in Al communities when families, are empowered and

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Result Example

Other Information					
FOA PA-14-033 Study Section Psychosocial Risk and Disease Prevention Study Section[PRDP]		Administering Institutes or Centers NATIONAL HEART, LUNG, AND BLOOD INSTITUTE CFDA Code 837		Project Start Date	01-March-2016
				Project End Date	31-August-2022
				Budget Start Date	01-March-2020
				Budget End Date	31-August-2022
Fiscal Year 2020	Award Notice Date 06-March-2020	DUNS Number 555917996	UEI KABJZBBJ4B54		Ū.



For Healthy Communities Under the Big Sky www.montana.edu/cairhe

What to Discuss with Program Officers?

- Your ideas—provide a Specific Aims page.
- Fit—is your idea a good fit for Institute or Center (IC)?
- Priority—is your idea a research priority for IC?
- Funding mechanisms the IC currently supports.
- Specific Funding Opportunity Announcements (FOAs).
- After you're scored: Prospects for funding, next steps.

Don't be intimidated. It's their job to help you, and most *really enjoy it!*



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Getting your SPECIFIC AIMS right (the page <u>and</u> the Aims themselves) is CRITICAL to a successful proposal.

- Start writing *many months* before submission.
- Workshop this page with your study team.
- Get input from mentors and other colleagues.
- Get input from Program Officials at potential Institutes/Centers.
- Edit EXTENSIVELY (think # of revisions in <u>double digits</u>). *

* Hemingway revised the ending to A Farewell to Arms 47 times!



More Attributes of an Outstanding R01 Application

- Strong Significance; important problem in public health: IMPACT is high.
- High degree of novelty and innovation.
- Strong track record of a well-qualified applicant, with <u>team</u> to shore up individual weaknesses; compelling publications.
- Relevant, supportive preliminary data to ensure Aims can be done.
- <u>Clear</u> rationale.
- Focused approach that provides <u>unambiguous</u> results.
- Careful attention to details:
 - Spelling, punctuation, grammar, fonts, tables, figures, <u>budgets</u>.
 (Get professional help if these aren't your strengths.)



Some General Tips for Success

- Read every word of the FOA <u>multiple times</u>, especially the <u>Review Criteria</u>!
- Refer to the Application Form Instructions often.
- <u>https://grants.nih.gov/grants/how-to-apply-application-guide.html</u>. Your one-stop shop.
- Be realistic ... not overly ambitious. NIH wants high feasibility.
- Be <u>direct</u> and put yourself in the **Reviewer's seat:**
 - Tell them what they want to hear (<u>Review Criteria</u> in FOA).
 - Reviewers can't read your mind.
 - Reviewers won't read between the lines.
 - \circ Don't assume they know what you intend.



In the "Reviewer's Seat"

Typical Study Section:

- 20+ Reviewers
- 50 to 120 Applications
- 1 ¹/₂ days (about <u>15 minutes of discussion per application in upper half of scores</u>)

How Organized:

- Usually 3 assigned primary reviewers for your application, picked by SRO
- All other panel members hear discussion and engage
- Every panel member gets a vote and may only read your Specific Aims, if that

Will the proposed study have a strong and sustained impact on the scientific field? Two questions drive a Reviewer's decision:

<u>Should</u> they do it? <u>Can</u> they do it?



NIH Application Impact Score

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



Your Application's Impact Score Reflects ...

The likelihood of the project to exert a sustained, powerful influence on the research field(s) involved:

 in consideration of the 5 core review criteria (Significance, Innovation, Approach, Investigator, Environment);

and

 additional Review Criteria (as applicable for the project proposed). READ the FOA.

Address on your Specific Aims page!



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 (P.S.: To the right people)



The Peer Review Process: Quick Take

For more: https://public.csr.nih.gov/ForApplicants



Your preferences are considered, but CSR has the ultimate decision based on the best match.



Matchmaker Results

Top 500 Projects

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Another Way to Find Study Sections: The Assisted Referral Tool (ART)

https://art.csr.nih.gov/ART/

Center for Scientific Review	Assisted Referral Tool (ART)	Help Disclaimer User Guide
ART Home >> SRG		Animal Usage?
Enter application text and hit the Subm	it button to get a list of relevant study sections in two groups, "Strong" and "Possible". Within a group, study sections are listed alphabetical	lly by the SRG acronym
Title	Optional but strongly recommended, as title concepts receive full weight in the models	Sample Clear
Enter your application text here. Entering both A	bstract and Specific Aims is recommended. Section subheaders and delimiters (e.g. 'Abstract') will be ignored. At least 10 scientific concepts from the RCDC These	aurus must be detected for ART to submit your job.
Terms will be weighted by frequency of appearan For more information consult the User Guide.	nce in the text above. The process is automated and confidential. ART does not track or store submitted text.	
Submit		



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Turning Discovery Into Health

Study Section Example

Community Influences on Health Behavior Study Section – **CIHB**



We're hiring SROs!

CSR is a great place to work - interesting, collegial, and being an SRO is a great way to contribute broadly to science. Learn More

The Community Influences on Health Behavior (CIHB) Study Section reviews applications concerned with how community-level factors prevent or moderate health risks and behaviors. Community is defined in a variety of ways including geographically, by social unit or practices, virtual spaces, and group affiliations. Research approaches may include community based participatory research, mixed methods (quantitative and qualitative analyses), ethnographic studies, policy and document analysis, and other non-interventional study designs.

The List of Reviewers lists all present, whether standing members or temporary, to provide the full scope of expertise present on that date. Lists are posted 30 days before the meeting and are tentative, pending any last minute changes.

Review Dates

List of Reviewers on 02/15/2022
List of Reviewers on 10/26/2021

- List of Reviewers off 10/26/2021
- List of Reviewers on 06/02/2021

Membership Panel

CHAIRPERSON

RAMASWAMY, MEGHA, PHD PROFESSOR DEPARTMENT OF POPULATION HEALTH UNIVERSITY OF KANSAS SCHOOL OF MEDICINE KANSAS CITY, KS, 66160

MEMBERS

BLEAKLEY, AMY, PHD, MPH * PROFESSOR DEPARTMENT OF COMMUNICATION UNIVERSITY OF DELAWARE NEWARK, DE, 19716

BONAR, ERIN E, PHD ASSOCIATE PROFESSOR DEPARTMENT OF PSYCHIATRY UNIVERSITY OF MICHIGAN ANN ARBOR, MI, 48109

BROWN, ERIC C, PHD * ASSOCIATE PROFESSOR DEPARTMENT OF PUBLIC HEALTH SCIENCES MILLER SCHOOL OF MEDICINE UNIVERSITY OF MIAMI MIAMI, FL, 33136

CORLISS, HEATHER L, PHD PROFESSOR DIVISION OF HEALTH PROMOTION AND BEHAVIORAL SCIENCE SCHOOL OF PUBLIC HEALTH

+ 35 more

Dr. Pia Peltola Scientific Review Officer

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301-594-9295



Thank You! Questions?

Grateful acknowledgment to:

- Alex Adams, CAIRHE
- Allen Harmsen, MSU
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- Kathy Etz, NIDA
- Shobha Srinivasan, NCI
- Megan Columbus, NIH Office of Extramural Research
- Michelle Hamlet, NINR
- Kay Lund, NIH Office of the Director
- Nancy Whitesell, University of Colorado Anschutz Medical Campus



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