The National Institutes of Health

Institutes: NIH is made up of **27 Institutes and Centers**, each with a specific research agenda, often focusing on particular diseases or body systems – NCI (cancer), NIDDK (diabetes, digestive, kidney), NHLBI (heart, lung blood), etc

Scientific Review Groups: The initial step of the peer review process takes place in Scientific Review Groups (SRGs) that are managed by the Institutes and Centers that are components of the NIH. The Center for Scientific Review (CSR) is one of the NIH components that manage the scientific review groups that evaluate investigator-initiated applications. **There are LOTS of them!**

Finding the best "fit" for your application is critical

Program Announcement - A PA is a formal statement from the NIH about a new or ongoing extramural activity or **program**. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or **program**, and/or invite applications for grant support

PAR (Reviewed in an Institute) - **Program Announcement** with special receipt, referral and/or review considerations

<u>PAR-18-744</u>	NIDDK	Release date 04/04/2018	Opening Date 05/16/2018	Expiration Date 05/08/2021	R21	Pilot and Feasibility Clinical Research Grants in Kidney Diseases (R21 Clinical Trial Optional)
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The National Institutes of Health

Request for Applications (RFA) - An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s).

Applications submitted in response to an RFA are usually reviewed by a Scientific Review Group (SRG) specially convened by the awarding component that issued the RFA.

<u>RFA-DK-18-021</u>	NIDDK	Release Date 10/16/2018	Opening Date 01/21/2019	Expiration Date 02/22/2019	R01	Lymphatics in Health and Disease in the Digestive System (R01 Clinical Trial Not Allowed)
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NIH Small Grant Program (R03):

•Provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, development of new research technology, etc.

Limited to two years of funding

•Direct costs generally up to \$50,000 per year

Not renewable

R03

•Utilized by more than half of the NIH ICs

•See parent FOA: PA-18-488

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 FOAs: PA-18-489 and PA-18-344

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
 - •Utilized by all ICs
 - •See parent FOAs: PA-18-484 and PA-18-345

NIH Academic Research Enhancement Award (AREA)

•Support small research projects in the biomedical and behavioral sciences conducted by undergraduate and/or graduate students and faculty in institutions of higher education that have not been major recipients of NIH research grant funds

<u>R15</u> •Eligibility limited (see <u>https://grants.nih.gov//grants/funding/area.htm</u>)

- •Direct cost limited to \$300,000 over entire project period
- •Project period limited to up to 3 years
- •All NIH ICs utilize except FIC and NCATS
- •See parent FOA: PA-18-504

•NOT AVAILABLE FOR FACULTY IN THE UTHSC COM – UTK is eligible

Specialized NIH Grants

NIH Support for Conferences and Scientific Meetings (R13 and U13)

- •Support for high quality conferences/scientific meetings that are relevant to NIH's scientific mission and to the public health
- •Requires advance permission from the funding IC
- •Foreign institutions are not eligible to apply
 - •Award amounts vary and limits are set by individual ICs
 - •Support for up to 5 years may be possible
 - •See parent FOA: PA-18-648

NIH Clinical Trial Planning Grant (R34) Program

•Designed to permit early peer review of the rationale for the proposed clinical trial and support development of essential elements of a clinical trial

<u>R34</u>

•Usually project period of one year, sometimes up to 3

•Usually, allows for a budget of up to \$100,000 direct costs, sometimes up to \$450,000

•Used only by select ICs; no parent FOA

Other Awards are available:

- Small Business Innovative Research (SBIR R43/R44)
- Small Business Technology Transfer (STTR R41/R42)
- Research Project Cooperative Agreement (U01)
- NIH Pathway to Independence (PI) Award (K99/R00)
- Program Project/Center Grants (P01, P20. P30, P50)
- Resource-Related Research Projects (R24)
- Education Projects (R25)
- Resource Access Program (X01)

Components of R03, R21, and R01 NIH Grants

- Specific Aims
- Abstract
- Narrative
- Budget detailed
- Research Design
- Bibliography
- NIH Biosketch
- Authentication of Agents
- Equipment
- Facilities
- Cover page
- Resource sharing plan
- MyNCBI List of Publications (for Biosketch)

Components of R03, R21, and R01 NIH Grants

Section of Application	Activity Codes	Page Limits * (if different from FOA, FOA supersedes)				
Project Summary/Abstract	For all Activity Codes	30 lines of text				
Project Narrative	For all Activity Codes.	Three sentences				
Introduction to Resubmission and Revision Applications	For all Activity Codes (including each applicable component of a multi-component application)	1				
Specific Aims	For all Activity Codes that use an application form with the Specific Aims section (including each component of a multi-component application)	1				
	For Activity Codes <u>R03</u> , <u>R13</u> , <u>R21</u>	6				
Research Strategy	For Activity Codes <u>R01,R15</u> ,	12				
	For all other Activity Codes	Follow FOA instructions				
Biographical Sketch	For all Activity Codes	5				

Components of R03, R21, and R01 NIH Grants

Specific Aims Page – Often the only page that all but three reviewers will read

- You must quickly gain the reviewers' trust and confidence while simultaneously convincing them that your work is important to fund.
- You must also convey that you and your team are the best people to complete the work you've proposed.
- Introductory Paragraph:
- Introduce your research subject to the reviewers and quickly capture their attention.
- Describe the significant gap in knowledge that directly relates to the critical need the funding entity deals with.
- First sentence is the "hook".
- Then state what is known and the gap in the knowledge.
- Critical need (hypothesis driven).

Specific Aims Page

Second Paragraph:

- Introduce the solution that fills the gap in knowledge. Convince your reviewers that you
 (and your colleagues) have the solution to address the current knowledge gap and the
 expertise to accomplish this solution. Keep wording simple, relevant, and to the point.
- <u>Long-Term Goal</u> important to ensure that your long-term goals align with the mission of your funding entity.
- <u>Hypothesis and Objectives</u> State your central hypothesis clearly, specifically, and with simple language. You want to demonstrate to the reviewers that you have a hypothesis-driven proposal that is testable. Describe how your project addresses the critical need, and clearly state the proposed solution.
- <u>Rationale</u> Explain how you arrived at your central hypothesis (for example, using past studies and published literature). Briefly, state what your project's completion would make possible (e.g., new therapeutics).
- <u>Qualifications</u> state why your experimental design and your team are the best to accomplish the research goals.

http://www.biosciencewriters.com/NIH-Grant-Applications-The-Anatomy-of-a-Specific-Aims-Page.aspx

Specific Aims Page

Aims:

• Describe briefly each of the aims you will use to test your hypothesis. Ideally, the aims should be related, but not dependent, upon each other.

Final Summary Paragraph

- <u>Innovation</u> Plainly state what is innovative about your project.
- <u>Expected Outcomes</u> Specifically state your expected outcomes for this project. Use plain language. What do you expect to see at the completion of each aim?
- <u>Impact</u> State how your project would help those who need it, (i.e. the development of a new treatment, vaccine, disease model or diagnostic tool). Include a broad impact statement about how your proposal will benefit the people or other subjects that you mentioned in the opening paragraph

Research Plan – Probably only read by 2 or 3 reviewers

(a) Significance (R01~4 pages: R21~2 pages)
(b) Innovation (R01~1 page: R21~1 page)
(c) Approach (R01~7 Pages: R21~3 pages)

When writing your Research Strategy, your goal is to present a well-organized, visually appealing, and readable description of your proposed project. That means your writing should be streamlined and organized so your reviewers can readily grasp the information.

- When reviewers read your application, they'll look for the answers to three basic questions:Can your research move your field forward?
- Is the field important—will progress make a difference to human health?
- Can you and your team carry out the work?

Research Plan – Probably only read by 2 or 3 reviewers

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(b) Innovation (R01~1 page: R21~1 page)
(c) Approach (R01~7 Pages: R21~3 pages)

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Research Plan

Add Emphasis

- Emphasize the project's importance and highlight the team's expertise.
- Don't take a chance your reviewer will gloss over that one critical sentence buried somewhere in your Research Strategy. If it's a key point, repeat it, then repeat it again.
- Add more emphasis by putting the text in bold, or *bold italics*.
- While describing a method in the Approach section, state collaborators' experience with it.
- Point out that you have access to a necessary piece of equipment.
- When explaining the research field and the status of current research, weave in your own work and preliminary data.

Research Plan

Although you will emphasize your project's significance throughout the application, the Significance section should give the most details.

Don't skimp—the farther removed your reviewers are from your field, the more information you'll need to provide on basic biology, importance of the area, research opportunities, and new findings.

When you describe your project's significance, put it in the context of

- 1) the state of your field
- 2) your long-term research plans
- 3) your preliminary data.

Research Plan

Innovation - Be cautious about seeming too innovative. Not only is innovation just one of five review criteria, but there might be a paradigm shift in your area of science. A reviewer may take a challenge to the status quo as a challenge to his or her world view.

- Show how the proposed research is new and unique, e.g., explores new scientific avenues, has a novel hypothesis, will create new knowledge.
- Explain how the project's research can refine, improve, or propose a new application of an existing concept or method.
- Show how the research can shift a current paradigm.....BUT, must:
 - Have a very strong case for challenging the existing paradigm.
 - Have data to support the innovative approach.
 - Have strong evidence that I can do the work.

Research Plan

${\bf Approach-}$

- Enter a bold header for each Specific Aim.
- Under each aim, describe the first set of experiments.
- Outline the branching of next steps (omit detail if you don't have the space):
- If you get result X, you will follow pathway X; if you get result Y, you will follow pathway Y.
- Consider illustrating this with a flowchart.

Trim the fat—omit all information not needed to make your case. If you try to wow reviewers with your knowledge, they'll find flaws and penalize you heavily. Don't give them ammunition by including anything you don't need

Research Plan

Approach –

- If you are a new investigator, you need enough detail to convince reviewers that you understand what you are undertaking and can handle the method.
- Cite a publication that shows you can handle the method where you can, but give more details if you and your team don't have a proven record using the method—and state explicitly why you think you will succeed.
- If space is short, you could also focus on experiments that highlight your expertise or are especially interesting. For experiments that are pedestrian or contracted out, just list the method.
- Be sure to lay out a plan for **alternative experiments and approaches** in case you get negative or surprising results. Show reviewers you have a plan for spending the four or five years you will be funded no matter where the experiments lead.

NIH – Rigor and Transparency

1. The scientific premise of the proposed research

•The **scientific premise** for an application is the research that is used to form the basis for the proposed research question(s). NIH expects applicants to describe the general strengths and weaknesses of the prior research being cited by the applicant as crucial to support the application - include attention to the rigor of the previous experimental designs.

2. Rigorous experimental design for robust and unbiased results

•Scientific rigor is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. This includes full transparency in reporting experimental details so that others may reproduce and extend the findings.

3. Consideration of relevant biological variables

•Biological variables, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored.

NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.

4. Authentication of key biological and/or chemical resources

•Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics.

The quality of resources used to conduct research is critical to the ability to reproduce the results. Each investigator will have to determine which resources used in their research fit these criteria and are therefore key to the proposed research.

https://grants.nih.gov/reproducibility/index.htm

Biosketch

Along with any principal investigators, include a biographical sketch with research support information for everyone you designate as senior/key personnel or other significant contributors (OSCs). This includes consultants and technical staff with senior/key personnel or OSC designations, even if they are not paid a salary from the grant. OSCs who contribute at least one person month or more effort must be designated as senior/key personnel.

Reviewers check carefully to see whether the PI and others have enough experience with the techniques to execute the Research Plan. The personal statement and contributions to science can be big factors in how you rate on the Investigator review criterion.

- Your personal statement can be a big factor in how you the PI rate on the Investigator review criterion.
- All key personnel's biosketches must explicitly state how their experience qualifies them for **their role on your project**, including relevant education, expertise, and accomplishments.

Other Grantsmanship Considerations

Citations – "Use whatever format you want". Numbered references saves space.
Documents - Everything uploaded into the NIH grant package must be PDF format.
Font – Must be 11 point or larger. Figure legends can be smaller but must be legible. No more than 15 characters per linear inch and no more than six lines per linear inch. Use Arial or Helvetica font with 11 point font or larger.

Headers and Footers – No.

Subheadings – Yes.

Margins – Narrow (1/2" all around) is minimum and advised – creates more space.

Figures – Use lots of them to demonstrate preliminary data and capabilities. Use text

boxes with tight wrapping and add a figure legend to each.

Information for form pages

- All institutional information is pre-filled in Cayuse
- Kristen will help fill those in and create the package in Cayuse
- Most grants allow for a pending IRB or IACUC protocol

APPLICATION FOR FEDERAL ASSISTANCE			2. DATE SUBMITTED 06/28/2018		Applicant Ide	Applicant Identifier		
		-	3. DATE RECEIVED	BY STATE	State Applica	tion Identifier		
1. TYPE OF SUBMISSION Pre-application Application			4. a. Federal Identifier DK117966			b. Agency Routing Number		
Changed/Correl	cted Application					• •		
5. APPLICANT INFO	ORMATION					X 5		
	e University of Tennessee	Health Science Cer	n Organiza	tional DUNS: 9	41884009			
Department:			_	Division: Street2:				
	S. Dunlap, Suite 300			ounty/Parish: S				
-	emphis			Postal Code: 38				
	ennessee nited States of America		▼ ∠ip/	30	3163-0001			
Mrs Brev Position/Title: Street1: City: State/Province: Country: Phone Number: 3014484889	Director, Office of Sponso 910 Madison Ave, Suite 8	23	T	_	Shelby	.edu		
6. EMPLOYER IDEN or (TIN): 1-626001636-B3	ITIFICATION NUMBER(EIN)	7. TYPE OF APPLIC H: Public/State C Other (Specify):	Controlled Instituti	on of Higher E	Education	▼		
TYPE OF APPLIC New Resubmission Renewal	ATION:	Small Business Org	ganization Type	nomically Disad	vantaged			
Continuation Revision								

Budget

- Salary information will be provided by Kristen
- We will build a budget like this together and Kristen can input it into Cayuse

	Salary	% effort	Requested	Fringe	Total
Heidel, R. Eric		. 2	1,782.8	615.1	2,397.92
Kennel, Stephen J		. 2	2,645.0	912.5	3,557.55
Macy, Sallie D		5	3,510.7	1,579.8	5,090.44
Richey, Tina A		5	2,841.3	980.2	3,821.55
Wall, Jonathan S		7.5	10,784.5	3,720.6	14,505.12
Williams, Angela		10	5,861.3	2,022.1	7,883.45
				-	24.050.44
Gunnling				Total	34,858.11
Supplies					2 000 00
HPLC and CD supplies Radionuclides					3,000.00
					0.00
Chemicals (autoradiography reagents, slides, microplate	25)				5,000.00
Animals					8,000.00
60 Balb/c mice (purchase of mice and shipping costs)					0.00
Mouse housing					0.00
					0.00
Travel					3000.00
Total Direct UTMC					45,858.11
Indirect (F&A) - 40%					18,343.24
Total					64,201.35

Process for submitting a grant

- Contact Kristen as soon as you find a grant you want to apply for
- Grants submitted in Cayuse through Kristen 5-7 days prior to the agency deadline
- UTHSC will review it and submit it