

# NIH 102 (NIH 101: The sequel)

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# **NIH 101 outline:**

- **NIH mission as an agency**
- **NIH IC missions and budgets**
- **Success rates**
- **Common funding mechanisms and when they are appropriate**
- **NIH funding updates (Common Fund)**

# Funding Mechanisms

**Research Projects (R01, R03, R21)**

**Solicited vs. Unsolicited**

**Generally due three times per year:**

**Feb 5, June 5 and Oct. 5 for R01**

**Feb 15, June 15 and Oct 15 for  
R03 and R21 proposals**

**Program Projects (P01)**

**Cooperative Agreements (U01, U19)**

## **NIH 102 follow-up:**

- **Where should a grant proposal be targeted?**
- **How do I get it there?**
- **Whom do I contact to help me answer these questions?**
- **What should I do to help my proposal be reviewed well?**
- **What is in a summary statement and what does it mean?**

## **NIH 102 follow-up:**

- **Where should a grant proposal be targeted?**
  - **How do I get it there?**

**Is there a special call for  
your proposal?**

**If not: What is your problem?**

**What gap are you filling?**

## Targeting:

**What is the problem?**

**What has been done already to address this problem?**

**What is the gap that still remains (your north star)?**

**How do you propose to address this gap?**

### Quick Search



Enter just about anything to find NIH projects and funding information: text, PI names, project numbers, fiscal year, agency

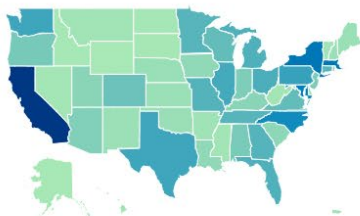
#### Welcome to the new NIH RePORTER

Rebuilt from the ground up, leveraging the latest technologies, to bring you an enhanced experience. Faster performance, mobile ready, and an intuitive, all-new Quick Search brings the power of NIH RePORTER to your fingertips.



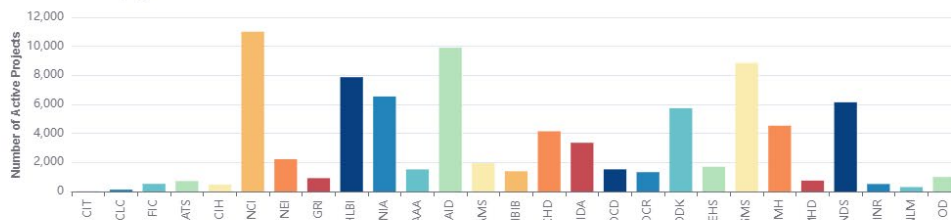
### Active Funding by State

Select a state to view projects



### Active Projects by Institute/Center

Select a bar to view projects for an Institute/Center



### Advanced Projects Search

Fiscal Year ?

Current FY is 2021

Agency/Institute/Center ?

Principal Investigator (PI) ?

PI Names or Profile IDs, semicolon ";" separated

Organization ?

Enter at least 3 characters to search

Project Number/Application ID ?




### Matchmaker

Find potential Program Officials, ICs, and review panels for your research.

### Publications Search



FIND PROGRAM OFFICIALS OR SIMILAR PROJECTS

QUERY

BROWSE NIH

MATCHMAKER

SEARCH PUBLICATIONS <sup>BETA</sup>

SUBMIT QUERY

CLEAR QUERY

Fiscal Year (FY):  
Current FY is 2019

Active Projects

SELECT

## RESEARCHER AND ORGANIZATION

Principal Investigator (PI) /  
Project Leader:  ,   
(Last Name, First Name) Use '%' for wildcard in PI names

[Enter several PI/Project Leader names OR PI Profile IDs](#)

City:

Use '%' for wildcard

Organization:  LOOKUP

Please enter at least 3 characters to use Lookup.

Contains  Begins with  Exact

State:  SELECT

Country:  SELECT

Department Type:  SELECT

Congressional District:  SELECT

Organization Type:  SELECT

DUNS Number:

## TEXT SEARCH

Text Search (Logic):   
 And  
 Or  
 Advanced

Characters left: 2500

Search in

- Projects
- Publications
- News

Limit Project search to

- Project Title
- Project Terms
- Project Abstracts

Limit Publication search to

Start Year

End Year

## PROJECT DETAILS

Project Number/  
Application ID:   
Format: 5R01CA012345-04/  
8515397 Use '%' for wildcard in project number, e.g. %R21%  
[Enter multiple project numbers/application IDs](#)

Agency/Institute/Center:  SELECT  
 Admin  Funding

NIH Spending Category:  SELECT





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**[MATCHMAKER](#)**

[SEARCH PUBLICATIONS](#) <sup>BETA</sup>

## Use Matchmaker to find similar projects and program officials

Enter abstracts or other scientific text and Matchmaker will return lists of similar projects from RePORTER or program officials associated with those projects. These matches are based on the terms and concepts used in the submitted text. Up to 15,000 characters are permitted. Matchmaker summarizes the projects by the program official, institute or center, review panel, and activity code.

[VIEW TUTORIAL](#)

Enter your Text:

Terms will be weighted by frequency of appearance in the text above. The process is automated and confidential. The Matchmaker system does not track and store submitted text.

Characters left: **15000**

[CLEAR](#)

[SIMILAR PROJECTS](#)

[SIMILAR PROGRAM OFFICIALS](#)

Matching Text

While significant evidence has demonstrated that obesity increases the risk of metastasis, the molecular mechanisms by which obesity contributes to the metastatic progression of breast cancer are unclear. Further, recent research in cancer development and progression has highlighted the role of metabolic reprogramming, which results in an increased supply of the cellular building blocks necessary for the increased cell proliferation and in adaptations required for cell survival in changing nutrient- and oxygen-containing environments. Research from our team and others demonstrates that the metabolic enzyme, pyruvate carboxylase, is upregulated during obesity and that this upregulation correlates strongly with breast cancer progression. Additional studies suggest that leptin, an adipokine whose expression is

Characters left: 12603

Fiscal Year (FY) ?

Active Projects

SELECT

Exclude Subprojects?

Select options begin with FY 2007.

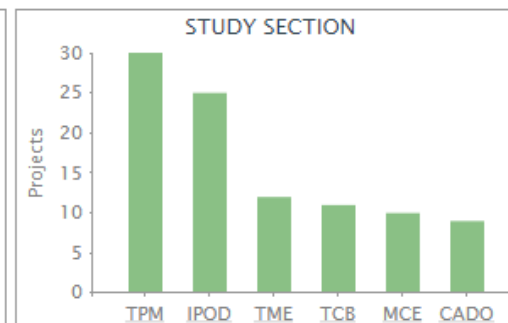
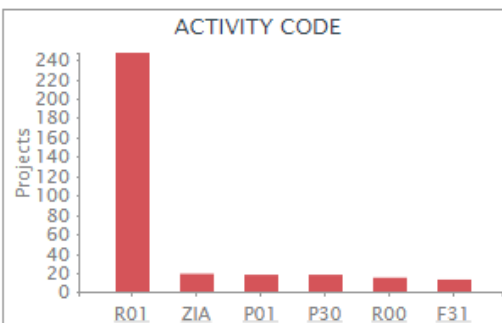
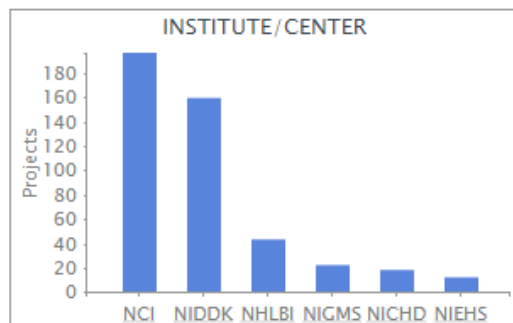
RESET

RESUBMIT

500 projects with similar concepts to the entered text. (500 maximum)

[Click here to view detailed Charts](#)

Click on chart labels to filter search results by the Institute/Center or Activity Code or Study Section



Click on the column header to sort the results

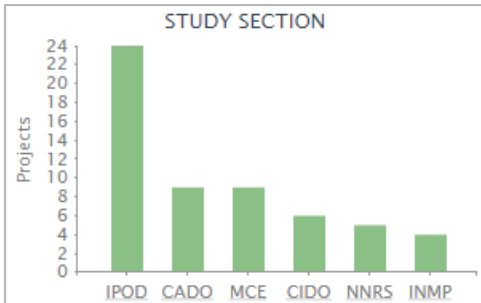
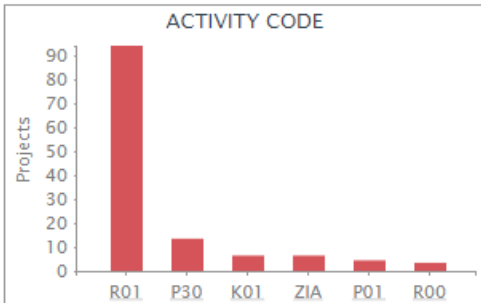
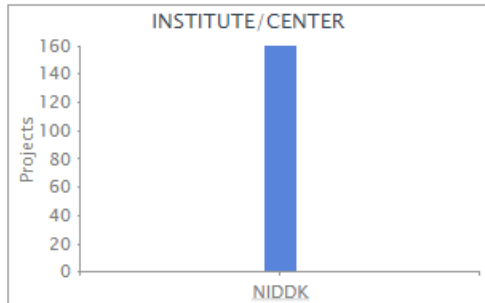
Records per page 25

1 2 3 4 ... 18 19 20

1 of 20 Next Last

T: Application Type; Act: Activity Code; Project: Admin IC, Serial No.; Year: Support Year/Supplement/Amendment

Match Score	T	Act	Project	Year	Sub #	Project Title	Contact PI / Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
<input type="checkbox"/> 1276	1	R01	CA232589	01A1		<a href="#">OBESITY, METABOLISM AND BREAST CANCER METASTASIS</a>	<a href="#">TEEGARDEN, DOROTHY et al.</a>	PURDUE UNIVERSITY	2019	NCI	NCI	\$472,530	
<input type="checkbox"/> 541	5	F30	CA225142	02		<a href="#">EVALUATING THE IMPACT OF OBESITY-ASSOCIATED INFLAMMATION ON BREAST CANCER HETEROGENEITY AND METASTASIS USING SINGLE-CELL RNA-SEQ</a>	<a href="#">MCDONELL, SHANNON BRUCE</a>	UNIV OF NORTH CAROLINA CHAPEL HILL	2019	NCI	NCI	\$35,564	



Click on the column header to sort the results

Records per page

1 2 3 4 5 6 7

1 of 7 Next Last

T: Application Type; Act: Activity Code; Project: Admin IC, Serial No.; Year: Support Year/Supplement/Amendment

Match Score	T	Act	Project	Year	Sub #	Project Title	Contact PI / Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
<input type="checkbox"/>	405	5	<a href="#">K24</a>	<a href="#">DK081913</a>	09	<a href="#">ADIPOKINE PHYSIOLOGY</a>	<a href="#">MANTZOROS, CHRISTOS S</a>	BETH ISRAEL DEACONES MEDICAL CENTER	2019	NIDDK	NIDDK	\$180,244	
<input type="checkbox"/>	379	5	<a href="#">R01</a>	<a href="#">DK076648</a>	10	<a href="#">EXPLORING THE FUEL-MEDIATED PROGRAMMING OF NEONATAL GROWTH</a>	<a href="#">DABELEA, DANA</a>	UNIVERSITY OF COLORADO DENVER	2018	NIDDK	NIDDK	\$642,943	
<input type="checkbox"/>	373	1	<a href="#">R01</a>	<a href="#">DK116872</a>	01A1	<a href="#">A NOVEL ADIPOKINE SUPPRESSES LEPTIN SIGNALING AND PROMOTES OBESITY</a>	<a href="#">WANG, YONG-XU</a>	UNIV OF MASSACHUSETTS MED SCH WORCESTER	2019	NIDDK	NIDDK	\$418,750	
<input type="checkbox"/>	369	5	<a href="#">R01</a>	<a href="#">DK108408</a>	04	<a href="#">DIETARY SALT HAS AN UNRECOGNIZED ROLE IN MODULATING ENERGY INTAKE AND METABOLIC SYNDROME</a>	<a href="#">JOHNSON, RICHARD JOSEPH</a>	UNIVERSITY OF COLORADO DENVER	2019	NIDDK	NIDDK	\$415,684	
<input type="checkbox"/>	366	5	<a href="#">R01</a>	<a href="#">DK084142</a>	07	<a href="#">LEPTIN AND THE NUTRITIONAL PROGRAMMING OF OBESITY AND DIABETES</a>	<a href="#">BOURET, SEBASTIEN G</a>	CHILDREN'S HOSPITAL OF LOS ANGELES	2019	NIDDK	NIDDK	\$520,924	
<input type="checkbox"/>	361	5	<a href="#">P30</a>	<a href="#">DK057521</a>	20	7732 <a href="#">ANIMAL METABOLIC PHYSIOLOGY CORE</a>	<a href="#">KAHN, BARBARA B.</a>	MASSACHUSETTS GENERAL HOSPITAL	2019	NIDDK		\$267,960	
<input type="checkbox"/>	342	5	<a href="#">R01</a>	<a href="#">DK100699</a>	05	<a href="#">CENTRAL MECHANISMS REGULATING ACUTE LEPTIN AND INSULIN SIGNALING</a>	<a href="#">WILLIAMS, KEVIN W</a>	UT SOUTHWESTERN MEDICAL CENTER	2018	NIDDK	NIDDK	\$357,750	

# Project Information?

1R01DK116872-01A1

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Project 3 of 160

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**PI PROFILE LINKS**

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**Project Number:** 1R01DK116872-01A1

**Title:** A NOVEL ADIPOKINE SUPPRESSES LEPTIN SIGNALING AND PROMOTES OBESITY

**Contact PI / Project Leader:** [WANG, YONG-XU](#)

**Awardee Organization:** UNIV OF MASSACHUSETTS MED SCH WORCESTER

**Contact PI / Project Leader Information:**

**Program Official Information:**

**Other PI Information:**

Profile Exists No Profile

**Name:** [WANG, YONG-XU](#)

**Name:** LAUGHLIN, MAREN R

Not Applicable

**Email:** [Click to view Contact PI / Project Leader email address](#)

**Email:** [Click to view PO email address](#)

**Title:** ASSOCIATE PROFESSOR

**Organization:**

**Department Type/ Organization Type:**

**Congressional District:**

**Name:** UNIV OF MASSACHUSETTS MED SCH WORCESTER

**City:** WORCESTER **Country:** UNITED STATES (US)

ANATOMY/CELL BIOLOGY

SCHOOLS OF MEDICINE

**State Code:** MA

**District:** 02

**Other Information:**

**FOA:** [PA-18-484](#)

**Study Section:** [Cellular Aspects of Diabetes and Obesity Study](#)

[Section \(CADO\)](#)

**Fiscal Year:** 2019 **Award Notice Date:** 14-DEC-2018

**DUNS Number:** 603847393

**Project Start Date:** 1-JAN-2019

**Budget Start Date:** 1-JAN-2019

**CFDA Code:** 847

**Project End Date:** 31-DEC-2022

**Budget End Date:** 31-DEC-2019

**Administering Institutes or Centers:**

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

**Project Funding Information for 2019:**

**Total Funding:** \$418,750

**Direct Costs:** \$250,000

**Indirect Costs:** \$168,750

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES	\$418,750

Download Readers:



# NIH 102 follow-up:

- **How to approach a potential program officer:**
  - **Never email on a Monday or Friday**
  - **Introduce yourself (briefly) and give a short description of your research program/proposal**
  - **Ask for a brief phone call**

## **NIH 102 follow-up:**

- **What should I do to help my proposal be reviewed well?**

**Preliminary/feasibility data**

**Judicious use of figures**

**Grammar and consistency of outline**

# The need for preliminary data

- Demonstrate that your proposed research is promising
- Demonstrate a credible ability to carry it out your proposal
- The more surprising the results the more data you will need to convince the reviewers
- Must convince the reviewers of a high likelihood of success
- Demonstrate that you can interpret or analyze data correctly
- The preliminary data must address your **north star\***. Do not include data that does not help you address the north star of the proposal
- Sometimes it is feasibility data
- Insert it in the proposal where it is relevant

**\*north star = the gap you are addressing**

# **NIH 102 follow-up:**

- **What should I do to help my proposal be reviewed well?**

**Judicious use of figures and white space**

**Grammar and consistency of outline**

**Know the mission and priorities of the IC(s) and address those**



# **What should I do to help my proposal be reviewed well?**

- **Co-PIs, co-investigators, consultants**
- **Early stage investigators and/or new investigators**
- **“A hammer in search of a nail” versus innovation or merging into a new field**

# NIH 102 follow-up:

- **What is in a summary statement and what does it mean?**

**SUMMARY STATEMENT**

**PROGRAM CONTACT:**



( Privileged Communication )

Release Date: 12/12/2016

Revised Date:

Application Number: 2 R01 AI098472-06

Principal Investigator

GANDHI, MONICA

Applicant Organization: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Review Group: BSCH  
Behavioral and Social Consequences of HIV/AIDS Study Section

Meeting Date: 11/15/2016  
Council: JAN 2017  
Requested Start: 04/01/2017

RFA/PA: PA16-160  
PCC: A23E

Dual IC(s): HD

Project Title: "Hair Extensions": Using Hair Levels to Interpret Adherence, Effectiveness and Pharmacokinetics with Real-World Oral PrEP, the Vaginal Ring, and Injectables

SRG Action: Impact Score:15 Percentile:1  
Next Steps: Visit [http://grants.nih.gov/grants/next\\_steps.htm](http://grants.nih.gov/grants/next_steps.htm)

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns  
Animal Subjects: 10-No live vertebrate animals involved for competing appl.  
Gender: 1A-Both genders, scientifically acceptable  
Minority: 5A-Only foreign subjects, scientifically acceptable  
Children: 1A-Both Children and Adults, scientifically acceptable  
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
6		
7		
8		
9		
10		
<b>TOTAL</b>		

**ADMINISTRATIVE BUDGET NOTE:** The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

## CRITIQUE 1:

Significance: 3  
Investigator(s): 2  
Innovation: 3  
Approach: 3  
Environment: 1



**Overall Impact:** The investigators hypothesize that the AAV-mediated T cell response is dependent on the capsid dose response. The investigation will evaluate these types of responses and determine if they can be mitigated by reducing the empty capsids present in rAAV vector preparations. In addition, these T cell responses are dependent on capsid proteasome interactions and capsid ubiquitination. The investigators will use AAV capsid libraries that will lead to the creation of vectors with optimized human hepatocyte transduction and reduced immunogenicity. To do this, the investigators will study AAV antigen (Ag) presentation after exposure to various doses of empty capsids and or empty/full capsids. They will establish class I vs. II Ag presentation via use of two different knockout mouse strains. The importance of proteasome inhibitors and capsid ubiquitination will be evaluated. Ultimately novel AAV capsids will be isolated in a humanized mouse models. Variants found to be robust at transducing human hepatocytes in these mouse models will be further evaluated in B6 mice for their antigenicity. There is enthusiasm for attempting to define the parameters that are responsible for the T cell-mediated response in humans infused with various AAV vectors. There is real concern that the immune responses observed in the mouse models will not accurately predict the human condition as mice or any other animal models tested to date do not stimulate similar responses. Nevertheless, this proposal may ultimately provide additional insights into this important yet unexplained process as well as provide new AAV vectors that may have reduced immunogenicity in humans.

### 1. Significance:

#### Strengths

- The cell-mediated immune response in humans treated with AAV vectors remains a challenge and a better understanding of how AAV induces such responses will be an important step forward in developing a means to overcoming this limitation.
- While it may be obvious to some, the value of removing empty capsids from clinical grade AAV vectors remains controversial. Thus, providing solid data to support the removal of empty capsids is important to the field.
- Evaluating the T cell response in mice may provide important insights with the caveat listed below.

#### Weaknesses

- Although there has been great effort, no one has created an animal model that recapitulates the events that occur in humans. Thus it is not possible to know whether the events studied will be relevant to humans.
- The parameters that reduce antigen presentation may be inherently linked to efficacy and if so, capsids that have reduced immunogenicity may have reduced transduction.

## 2. Investigator(s):

### Strengths:

- Dr. Samulski is a world leader in AAV vector biology. Dr. Li did two post docs, the last ended with Dr. Samulski in 2004. Together they have a strong publication record with Dr. Li as first author.

### Weaknesses

- Is Dr. Li has few senior author papers. He has been a faculty for 10 years yet most if not all of his publications are with Dr. Samulski– many of which Dr. Samulski is the senior author.

## 3. Innovation:

### Strengths

- Identifying effective humanized AAV variants that are resistant to ubiquitination result in a lower risk for activation of T cells is the most innovative feature of the proposal

### Weaknesses

- Most of the methods and approaches are not highly innovative because it involves approaches and methods that are relatively well established.

## 4. Approach:

### Strengths

- The experiments are well described and the logical progression through each of the aims is easy to follow.
- To provide experimental support to show the proportion of empty capsids may influence the immune response is important. This is especially true because, as the investigators point out, not all of the T cell responses are dose dependent.
- The use of two serotypes, AAV-2 and AAV-8, are important because they have very different transduction efficiencies in mice.

### Weaknesses

- The AAV-2 and AAV-8 variants, while having different transduction in mice, appear to have similar transduction in humans. The same may be true for the various capsid variants described herein.
- One mouse inbred strain is studied and the immune parameters measured may have nothing to do with the human condition.
- How is the capsid load ultimately removed from the cell if ubiquitination and other degradation pathways are blocked – especially in terms of alternate processing and ultimate alternative antigen loading processing?