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NIH 102
(NIH 101: The sequel)

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NIH 102 follow-up:

- **Where should a grant proposal be targeted?**
  - **Highlighted Topics**
  - **How do I get it there?**
  - **Is there a special call for your proposal?**
  - **If not: What is the problem you are addressing? IS IT SIGNIFICANT?**
  - **What gap are you filling?**

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Highlighted topics (https://grants.nih.gov/funding/find-a-fit-for-your-research/highlighted-topics):

National Institute of General Medical Sciences (NIGMS)

NIGMS prioritizes the discovery of generalizable principles related to the interaction of microbes with the human-built environment in the context of model systems and surrogate microbes rather than actual infectious agents. Areas of interest include but are not limited to:

Characterization of microbes interacting with the built environment (e.g., identities, numbers, interactions with other microbes)

Investigation of the physical and chemical principles governing interactions, release, and viability of microbes on/in solids, liquids and gases related to the built environment

Investigation of modes of interaction between humans/other model hosts and microbes in the built environment

Technology development/improvement for microbe detection, sampling, and culturing

Applications from multidisciplinary teams including architects, engineers, epidemiologists, microbiologists, physicists, chemists, data scientists, and physicians will also be a higher priority for funding.

IC may give special consideration to support meritorious applications in this topic area.

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- Research on the Transition from Pediatric to Adult Health Care
- Advancing Prevention and Treatment of Bacterial Sexually Transmitted Infections in HIV-Affected Populations
- Understanding the Impact of Immune Function on Neurocognition and Substance Use Disorder Risk Across the Lifespan (IMMUNE-LIFESPAN)
- Sleep, Circadian Rhythms, and Substance Use Disorders
- Research on Drowning Prevention
- Effects of Contraception as Treatment for Gynecologic Disorders
- School Mental and Behavioral Health: Expanding Access to Evidence-Based Interventions and Services
- Understanding and Combating Chronic Disease Burden: The Role of Trauma
- Priority Research Questions in Fundamental Cellular and Molecular Neuroscience
- Research on Short-Lived and Long-Lived Plasma Cells in Humans
- Accelerating Research in Celiac Disease
- Technology Development for Genomics
- Advancing the Use of Genomic Information Into Clinical Care
- Leveraging New Approach Methodologies and Non-Animal Technologies to Accelerate Osteoarthritis Research
- Supporting Research on Microbes and the Built Environment

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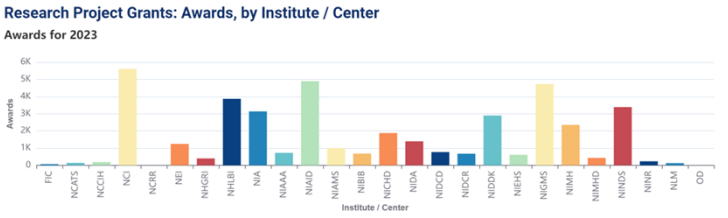

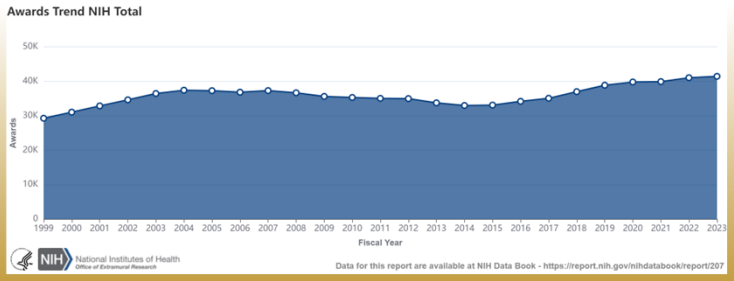

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Success rates by mechanism and institute

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Targeting:

What is the problem? Does it need to be addressed?

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?

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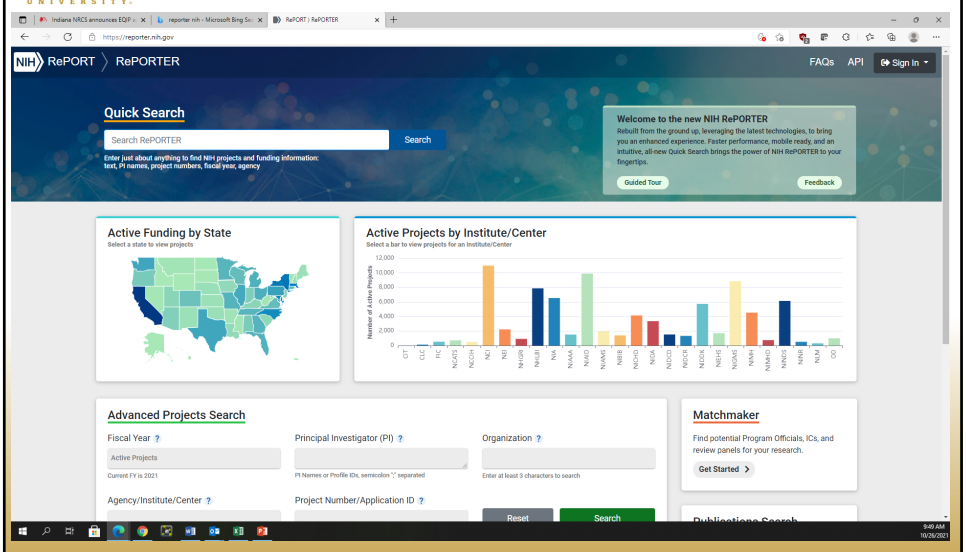

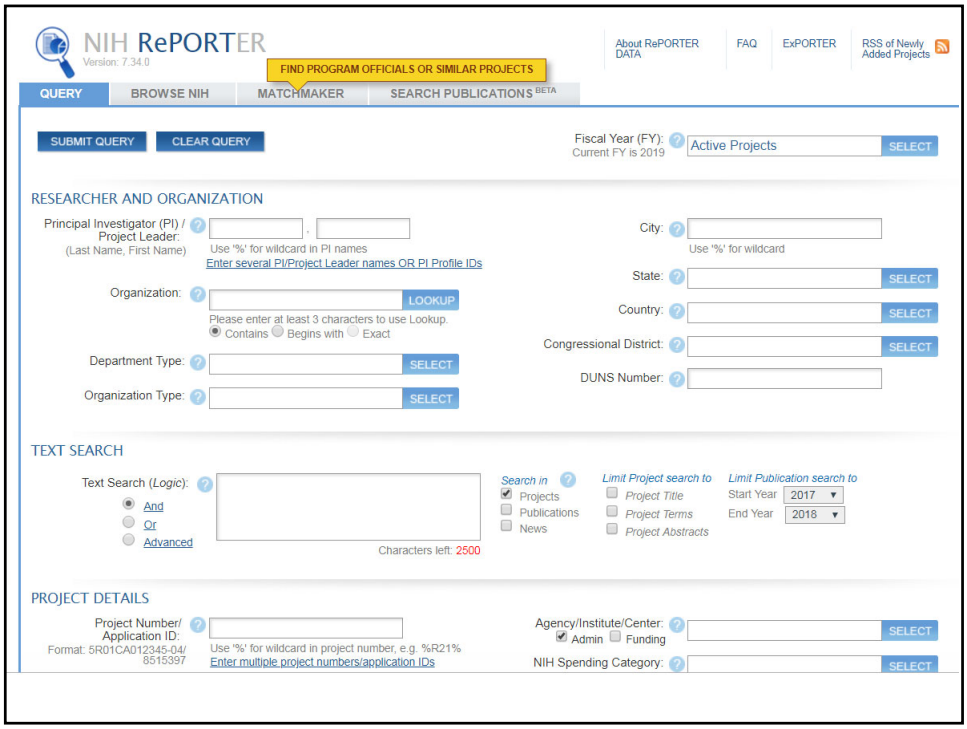
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CLEAR QUERY
Fiscal Year (FY):
Current FY is 2019
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SELECT
RESEARCHER AND ORGANIZATION
Principal Investigator (PI) / Project Leader:
(Last Name, First Name)
Use '%' for wildcard in PI names
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Organization:
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Please enter at least 3 characters to use Lookup.
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Department Type:
Organization Type:
City:
Use '%' for wildcard
State:
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Text Search (Logic):
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Projects
Publications
News
Limit Project search to
Project Title
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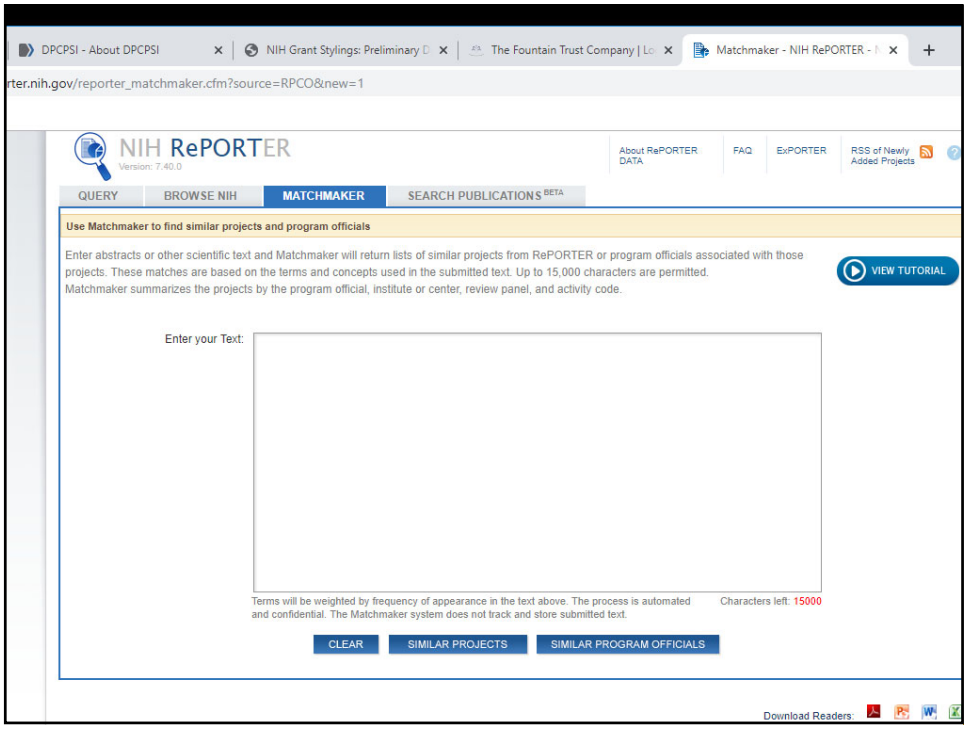
Project Abstracts
Limit Publication search to
Start Year 2017
End Year 2018
PROJECT DETAILS
Project Number/ Application ID:
Format: 5R01CA012345-04/ 8515397
Use '%' for wildcard in project number, e.g. %R21%
Enter multiple project numbers/application IDs
Agency/Institute/Center:
Admin Funding
NIH Spending Category: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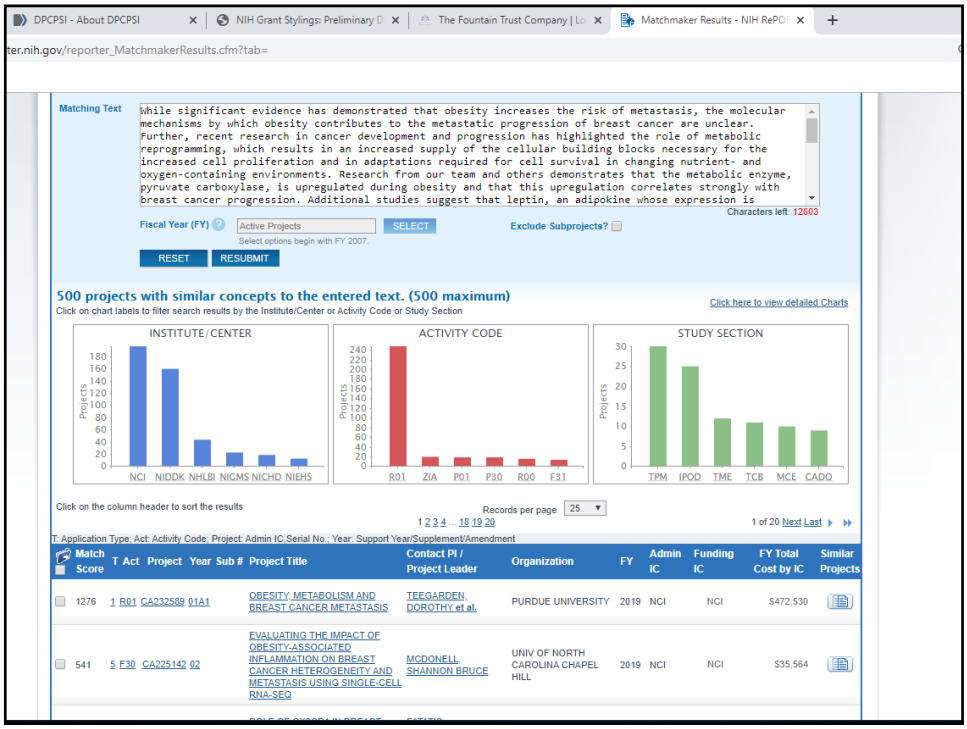
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Matching Text
while significant evidence has demonstrated that obesity increases the risk of metastasis, the molecular mechanisms by which obesity contributes to the metastatic progression of breast cancer are unclear. Further, recent research in cancer 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
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Fiscal Year (FY)
Active Projects
SELECT
Exclude Subprojects?
Select options begin with FY 2007.
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RESUBMIT
500 projects with similar concepts to the entered text. (500 maximum)
Click on chart labels to filter search results by the Institute/Center or Activity Code or Study Section
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ACTIVITY CODE
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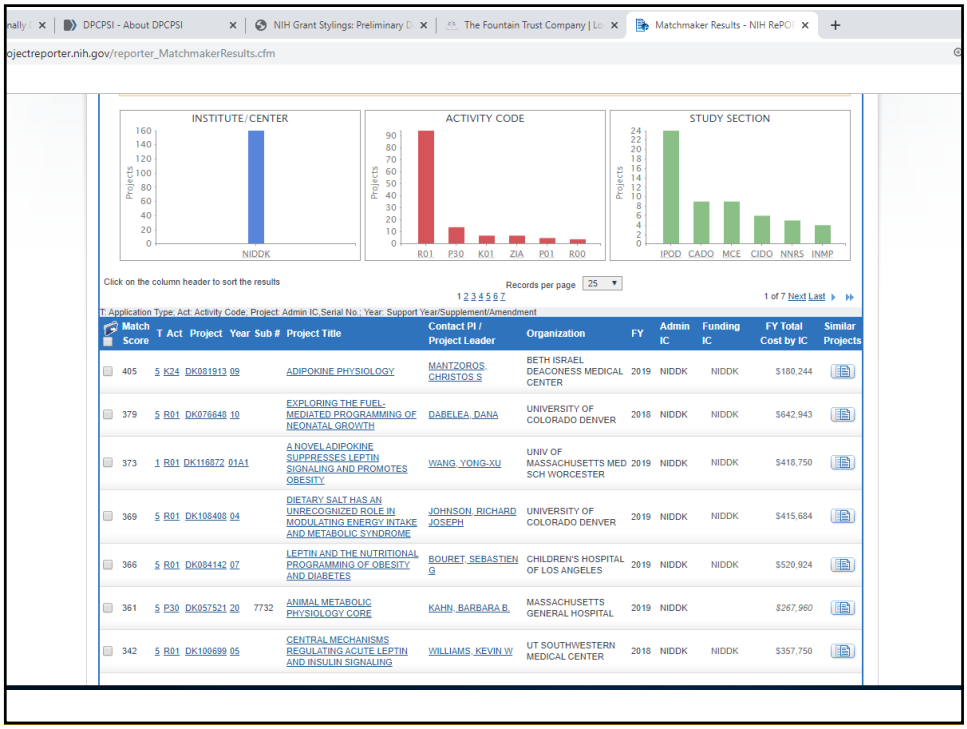
Project
Year
Sub #
Project Title
Contact PI / Project Leader
Organization
FY
Admin IC
Funding IC
FY Total Cost by IC
Similar Projects
1276 1 R01 CA232589 01A1 OBESITY, METABOLISM AND BREAST CANCER METASTASIS TEEGARDEN, DOROTHY et al. PURDUE UNIVERSITY 2019 NCI NCI $472,530
541 5 F30 CA225142 02 EVALUATING THE IMPACT OF OBESITY-ASSOCIATED INFLAMMATION ON BREAST CANCER HETEROGENEITY AND METASTASIS USING SINGLE-CELL RNA-SEQ MCDONELL, SHANNON BRUCE UNIV OF NORTH CAROLINA CHAPEL HILL 2019 NCI NCI $35,564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Projects
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Match Score
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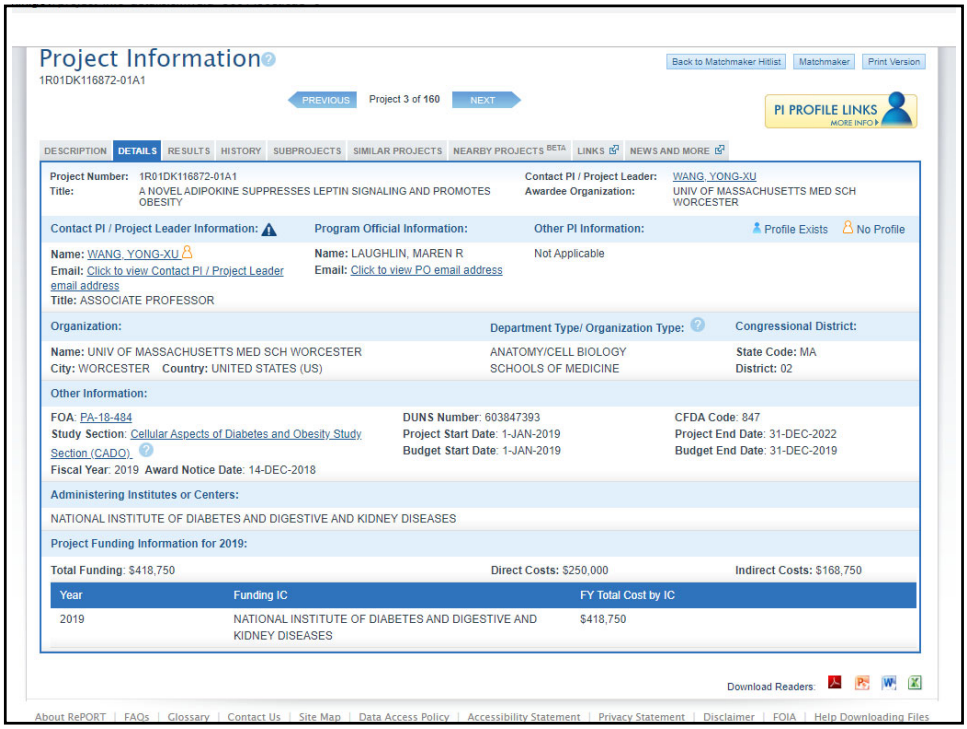
Year
Sub #
Project Title
Contact PI / Project Leader
Organization
FY
Admin IC
Funding IC
FY Total Cost by IC
Similar Projects
405 5 K24 DK081913 09 ADIPOKINE PHYSIOLOGY MANTZOROS, CHRISTOS S BETH ISRAEL DEACONESS MEDICAL CENTER 2019 NIDDK NIDDK $180,244
379 5 R01 DK076648 10 EXPLORING THE FUEL-MEDIATED PROGRAMMING OF NEONATAL GROWTH DABELEA, DANA UNIVERSITY OF COLORADO DENVER 2018 NIDDK NIDDK $642,943
373 1 R01 DK116872 01A1 A NOVEL ADIPOKINE SUPPRESSES LEPTIN SIGNALING AND PROMOTES OBESITY WANG, YONG-XU UNIV OF MASSACHUSETTS MED SCH WORCESTER 2019 NIDDK NIDDK $418,750
369 5 R01 DK108408 04 DIETARY SALT HAS AN UNRECOGNIZED ROLE IN MODULATING ENERGY INTAKE AND METABOLIC SYNDROME JOHNSON, RICHARD JOSEPH UNIVERSITY OF COLORADO DENVER 2019 NIDDK NIDDK $415,684
366 5 R01 DK084142 07 LEPTIN AND THE NUTRITIONAL PROGRAMMING OF OBESITY AND DIABETES BOURET, SEBASTIEN G CHILDREN'S HOSPITAL OF LOS ANGELES 2019 NIDDK NIDDK $520,924
361 5 P30 DK057521 20 7732 ANIMAL METABOLIC PHYSIOLOGY CORE KAHN, BARBARA B. MASSACHUSETTS GENERAL HOSPITAL 2019 NIDDK $267,960
342 5 R01 DK100699 05 CENTRAL MECHANISMS REGULATING ACUTE LEPTIN AND INSULIN SIGNALING WILLIAMS, KEVIN W UT SOUTHWESTERN MEDICAL CENTER 2018 NIDDK NIDDK $357,750



Project Information
1R01DK116872-01A1

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PREVIOUS Project 3 of 160 NEXT

PI PROFILE LINKS MORE INFO

DESCRIPTION | DETAILS | RESULTS | HISTORY | SUBPROJECTS | SIMILAR PROJECTS | NEARBY PROJECTS BETA | LINKS | NEWS AND MORE

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:
Name: WANG, YONG-XU
Email: Click to view Contact PI / Project Leader email address
Title: ASSOCIATE PROFESSOR

Program Official Information:
Name: LAUGHLIN, MAREN R
Email: Click to view PO email address

Other PI Information: Not Applicable

Profile Exists | No Profile

Organization:
Name: UNIV OF MASSACHUSETTS MED SCH WORCESTER
City: WORCESTER **Country:** UNITED STATES (US)

Department Type/ Organization Type:
ANATOMY/CELL BIOLOGY
SCHOOLS OF MEDICINE

Congressional District:
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

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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**

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NIH 102 follow-up:

- **What should I do to help my proposal be reviewed well?**
- **Hit significance very, very hard. Use 20-25% of your space to address why this work must be done**
- **Judicious use of figures and white space**
- **Grammar and consistency of outline**

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- **Know the mission and priorities of the IC(s) and the President**
- **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**

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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

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What has changed at the NIH in the last 18 months?

Review criteria (and, thus, how to write for the review)

How the reviews are done

What they are and are not looking to fund

How awards are made and disbursed (e.g. multi-year funding, reduced success rates [NCI at 4%, NIAID at 10%,16%, NINDS 8%,16%])

Budget? Reorganization?

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What are the new NIH review criteria?

Five regulatory criteria reorganized into three factors

For due dates before Jan 25, 2025

(all considered in overall impact score)

- **Significance** - scored
- **Investigator(s)** - scored
- **Innovation** - scored
- **Approach** - scored
- **Environment** - scored

For due dates on/after Jan 25, 2025

- **Factor 1 : Importance of the Research**
  - Significance, Innovation
  - Scored 1 - 9
- **Factor 2 : Rigor and Feasibility**
  - Approach (also includes Inclusion and Clinical Trial (CT) Study Timeline)
  - Scored 1 - 9
- **Factor 3 : Expertise and Resources**
  - Investigators, Environment
  - Evaluated as appropriate or gaps identified; gaps require explanation
  - Considered in overall impact; no individual score

Factor 1:
"How will this move the field forward?", and "Should this be done?"

Factor 2:
"Can this work be done well?"

Factor 3:
Unacceptable or acceptable

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Considering the new NIH review criteria:

Factor 1:
Do not use the old headers <u>Significance</u> and <u>Innovation</u>, and add a lot more narrative concerning the importance of the work.
What are the short-and long-term impacts?
Refer to the rigor of the hypothesis and background work more.
The score on this section sets the standard for the overall impact score.

Factor 2:
"Can this work be done well?"
Factor 2 score cannot be better than the score for factor 1, i.e. factor 2 cannot help your score, but it can hurt it.

Factor 3:
Unacceptable or acceptable
Do not address the strength of the team *per se*. Let the biosketches state your case

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Considering the new NIH review criteria:

Efficiency reviews

Study section scores and reviews are being utilized as guidelines for the next round of "efficiency reviews". While these reviews have always been done, they were carried out by the IC staff to ensure programmatic priorities, budgetary issues, and potential conflicts were dealth with.

The new type of efficiency reviews are being carried out by appointees to ensure that the awarded proposals meet the priorities set out by the administration.

Faculty are being advised to write the public-facing sections of the proposal to a 9th grader. This is primarily the abstract and the public health relevance statement. However, when possible, simplify the language and terms used in the proposal itself.

Justify models! In fact, justify everything that might be misinterpreted or misunderstood.

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- NIH will only accept six new, renewal, resubmission, or revision applications from an individual Principal Investigator/Program Director or Multiple Principal Investigator for all council rounds in a calendar year.
- NIH is establishing a new award structure that will prohibit foreign subawards from being nested under a parent grant.
- Plans for Enhancing Diverse Perspectives (PEDP)
  - PEDP requirements have been removed from funding opportunities.
  - PEDP plans included in applications under review will not be evaluated or considered in funding decisions.
- NIH will not consider applications that are either substantially developed by AI, or contain sections substantially developed by AI, to be original ideas of applicants.

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- **Both the House and Senate Appropriations Committees have approved their versions of the FY 2026 Appropriations Act for the Departments of Labor, Health and Human Services, Education, and Related Agencies. As part of these bills, both House and Senate appropriators rejected proposed cuts to the National Institutes of Health (NIH) proposed in the President's budget request, as well as the proposed reorganization of the agency. The Senate Appropriations Committee approved a $400 million increase for NIH above the FY 2025 funding level, while the House Appropriations Committee approved and NIH increase of $99 million over current levels.**
- **The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative receives $195 million, split evenly between the National Institute of Mental Health (NIMH) and the National Institute of Neurological Disorders and Stroke (NINDS)).**

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NIH 102 follow-up:

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

SUMMARY STATEMENT

PROGRAM CONTACT: [redacted] (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
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		
TOTAL		

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.

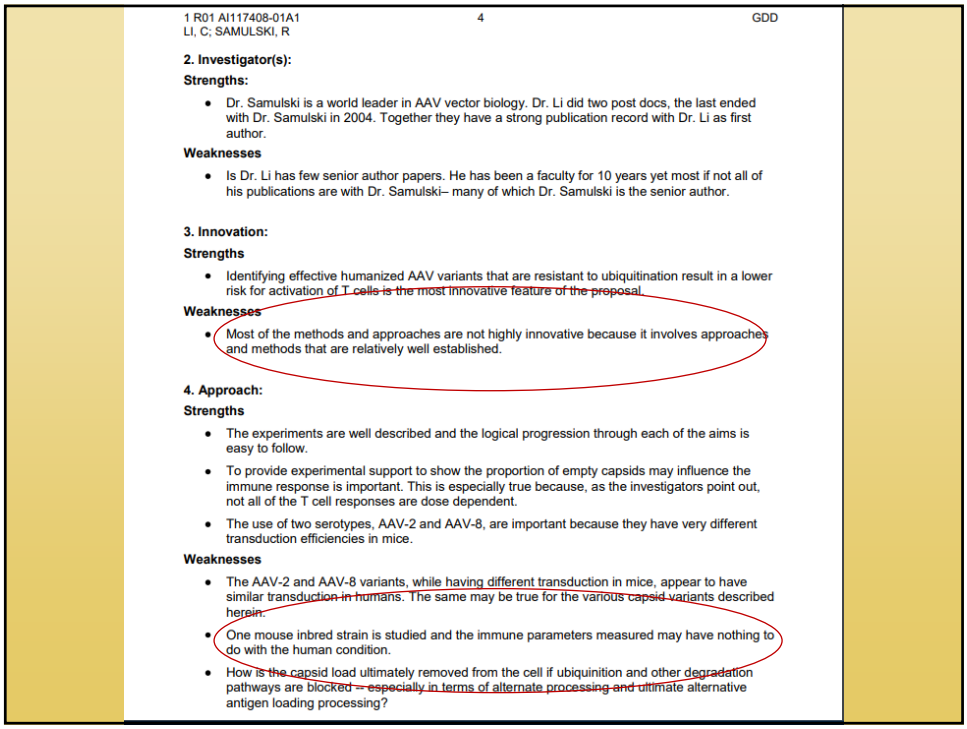
1. Significance:

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.



1 R01 AI117408-01A1 4 GDD
LI, C; SAMULSKI, R

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 ubiquinition and other degradation pathways are blocked – especially in terms of alternate processing and ultimate alternative antigen loading processing?