Welcome
We will begin at 12:00 PM ET

SOT Research Funding Insights Session

You have two choices for audio

via audio broadcast (Default)

The Audio Broadcast will connect automatically and the Audio Broadcast panel will appear. Listen through your computer speakers or headset.

Please note that this webinar will be recorded.

via telephone/or computer (if needed)

Select the phone icon below the participants list. Connect using computer audio or dial-in using the specified phone number, event number, and your attendee ID. Phone lines will be muted.

Send questions to “All Panelists” the Q&A panel.
Welcome

SOT Research Funding Insights Session
Understanding the NIH Grant
Peer Review Process
May 13, 2021

Laura Thomas, Ph.D.
Scientific Review Officer
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
laura.thomas@nih.gov
The Path of a Successful Application

1st Level of Review

Center for Scientific Review
Assigns to NIH Institute and Peer Review Group

Study Section
Reviews for Scientific Merit

Institute
Evaluates for Relevance to Research Priorities

2nd Level of Review

Advisory Council or Board
Recommends Action

Institute Director
Takes Final Action
Applications are assigned to:

• **Institutes or Centers:**
  – Based on overall mission and guidelines of the Institute or Center.
  – Can be dual assignments.

• **CSR or a study section at an Institute/Center**
  – Special emphasis panels (SEPs) are review groups formed on an ad hoc basis for apps requiring special expertise or certain types of grants (fellowships, training grants, small businesses, etc.).

[https://public.csr.nih.gov/ForApplicants](https://public.csr.nih.gov/ForApplicants)
Review Meetings

• Each standing study section has ~12-22 regular members, plus temporary reviewers from the scientific community.

• SEPs can be smaller or larger.

• Number of applications reviewed depends on number received and if all applications are being discussed.

Meeting formats:
1) In person
2) Telephone
3) Online asynchronous
4) Zoom

YouTube: “NIH Peer Review Revealed” for a mock study section
Typical Study Section
Initial Scoring
Review

C

SRO

Bla bla bla bla bla
bla bla bla bla bla
bla bla bla bla bla

Bla bla bla bla

Bla bla bla bla
bla bla bla bla

1

2

3

PO  PO  GMO
Discussion

C

1

2

3

Bla bla bla bla

Bla bla bla bla

Bla bla bla

Bla bla bla

PO  PO  GMO
Range: 3 to 5
Average: 3.6
Priority Score: 36
Percentile: 18

Final Scoring

Percentile Score
1 10
1 14
1 16
2 17
3 18
6 20
7 21
10 23
13 26
14 27
15 29
17 30
17 31
17 32
17 33
17 35
19 37
19 37
21 39
21 40
23 43
24 44
26 45
Summary Statement

SRO Summary: Write write write write write write write write write write write write write write

Priority Score: 36
Percentile: 18

Rev 1: Write write write write write write write write write write write write write write

Rev 2: Write write write write write write write write write write write write write write

Rev 3: Write write write write write write write write write write write write write write
Next Review

Conflict
Final Score

- The Final Score is based on the criterion scores

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Rev 1</th>
<th>Rev 2</th>
<th>Rev 3</th>
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</thead>
<tbody>
<tr>
<td>Fellowship Applicant</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Sponsors, Collaborators, and Consultants</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Research Training Plan</td>
<td>5</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Training Potential</td>
<td>4</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Inst'l Environment &amp; Commitment to Training</td>
<td>3</td>
<td>3</td>
<td>2</td>
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</tbody>
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Average: 5, 5, 4

Overall Average: 3.3, so a Priority Score of 33
Criterion Score Impact on Final Score

NIH Criterion Scores
Summary Statement

- Scores for each review criterion (scale of 1-9)
- Critiques from assigned reviewers
- Administrative notes (if any)

If application is discussed you will also have:
- Overall impact/priority score and (sometimes) percentile ranking
- Summary of review meeting discussion (written by Scientific Review Officer)
- Budget recommendations

<table>
<thead>
<tr>
<th>Overall Impact or Criterion Strength</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
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<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
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<td>2</td>
<td>Outstanding</td>
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<td>3</td>
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<td>Medium</td>
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<td>6</td>
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<td>Low</td>
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<td>8</td>
<td>Marginal</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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</table>
Program Contact:
Timothy Gonde-Lewis

Program Contact:

Application Number: 1R01AI117408-01A1

Principal Investigators (Listed Alphabetically):
LI, CHENGWEN PHD (Contact)
SAMULSKI, RICHARD J PHD

Applicant Organization: UNIV OF NORTH CAROLINA CHAPEL HILL

Review Group: GDD
Gene and Drug Delivery Systems Study Section

Meeting Date: 10/21/2016
Council: JAN 2016
Requested Start: 04/01/2016

RFA/PA: PA13-302
PCC: I2F

Dual IC(s): HL, DK

Project Title: Enhanced HIV Transduction with Capsid Immune Evasion
SRG Action: Impact Score: 20 Percentile: 2

Visit http://grants.nih.gov/grants/next_steps.htm

Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

<table>
<thead>
<tr>
<th>Project Year</th>
<th>Direct Costs Requested</th>
<th>Estimated Total Cost</th>
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<tbody>
<tr>
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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.
Resume and Summary of Discussion

RESUME AND SUMMARY OF DISCUSSION: The applicants propose to identify methods to prevent immune system clearance of hepatocytes transduced with adeno-associated virus (AAV) vectors by examining the role of empty capsids in the immune response, modifying AAV capsid antigen presentation and identifying new AAV vectors capable of avoiding the capsid-specific cytotoxic T lymphocyte (CTL) response through a directed evolution approach. The research was thought to be highly significant because of the importance of overcoming the immune response to AAV gene therapy for successful treatment of diseases such as hemophilia. The innovative concepts of exploring the CTL response and the role of empty capsids in the AAV immune response, thorough experimental plan and outstanding investigative team that includes a world leader in AAV gene therapy are among the other strengths of the application discussed by the panel. Questions were raised about the suitability of mouse models for identifying immune responses that will be relevant to humans. Reviewers disagreed about the necessity for testing multiple capsid mutants. Overall, reviewers agreed that the strengths outweigh the weaknesses and rated the application likely to have high impact on the field of AAV gene therapy.

DESCRIPTION: Adeno-associated virus (AAV) vector has been successfully applied in phase I clinical trials in hemophilia B patients with liver targeting. However, these studies have suggested that AAV capsid specific cytotoxic T lymphocytes (CTL) have the potential to eliminate AAV transduced hepatocytes. Thus, new AAV vectors are needed for successful gene therapy.
CRITIQUE 3:

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

Overall Impact: This is a revised multiple Principal Investigator application with due modifications submitted by Dr. Chengwen Li. Here the investigators have proposed to tackle the issue of antigen cross-presentation which is a major limiting factor for successful gene therapy for liver diseases using AAV. The investigators have proposed to develop AAV mutants that will avoid capsid ubiquitination and proteasomal degradation thereby decreasing AAV capsid antigen presentation and possibly minimizing CTL-mediated elimination, thereby leading to enhanced hepatocyte transduction. The mechanism of capsid antigen presentation from empty virions and full AAV particles will be elucidated using TAP-/- and Cat S-/- mice. Further, the investigators will explore directed evolution and rational design strategy to isolate AAV vectors with preferential hepatotropism and their ability to evade capsid specific CTL response in humanized mice. If successful, it will enable the development of potentially safer AAV vectors for hepatic gene therapy.

1. Significance:

Strengths

- Gene therapy using current AAV vectors suggest that capsid-specific CTLs eliminate AAV transduced hepatocytes thereby leading to suboptimal results. Therefore, the proposed strategy to develop new AAV capsids that bypass the host immune response is exciting.

Weaknesses

- Although TAP-/- and Cat S-/- are very useful to determine molecular mechanisms involved in
How is your Application Reviewed?

Check the Funding Opportunity Announcement (FOA)!!

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following: Reviewers should evaluate the candidate's potential for obtaining a tenure-track or equivalent faculty position and developing an independent research program that will make important contributions to the field. Reviewers should consider in their evaluation the likely value of the proposed K99 phase research and career development in facilitating transition to research independence, and the feasibility of the proposed research project as a vehicle for developing a successful, independent research program after transition to the R00 award phase.

Overall Impact

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Candidate

- Based on the candidate's prior research and training experience, track record, referee's evaluations, and the quality and originality of prior research and the current application, what is the candidate's potential to become a highly successful, independent investigator who will contribute significantly to his/her chosen field of biomedical, behavioral, or clinical related research?
- Considering the years of postdoctoral research experience to date, what is the candidate's record of research productivity, including the quality of peer-reviewed scientific publications?
- What is the quality of the candidate's pre- and postdoctoral research training, with respect to development of appropriate scientific and technical expertise?
- Given the candidate's prior training, proposed career development plan, and the referees' evaluations, is it reasonable to expect that the candidate will be able to achieve an independent, tenure-track or equivalent faculty position within the time period requested for the K99 phase of this award?
Fellowship Training: Main Review Criteria

- Overall Impact:
  Assessment of the likelihood that the fellowship training will enhance the candidate's potential for, and commitment to, an independent, productive scientific research career in a health-related field, in consideration of the **5 Scored Review Criteria** and **Additional Review Criteria**, if relevant.
**Career Development (K awards): Main Review Criteria**

- **Overall Impact:**
  Assessment of the likelihood that the **proposed career development and research plan** will enhance the candidate's potential for, and commitment to, an independent, productive scientific research career in a health-related field, in consideration of the **5 Scored Review Criteria** and **Additional Review Criteria**, if relevant.


- Training in responsible Conduct of Research
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Bio or Chem Resources
R-Type Grant Applications: Main Review Criteria

• Overall Impact:
  – Assessment of the likelihood for the scientific project to exert a sustained, powerful influence on the research field, in consideration of the 5 Scored Review Criteria and Additional Review Criteria, if relevant.
What Makes a Strong Candidate?

- Publication record: not just # but relevance
- Excellent training
- Research and career plans build on training
- Uniquely positioned for proposed research
- Strong potential to succeed in an independent research career

What Makes a Weak Candidate?

- Limited pubs as first author
- Pubs are unrelated to stated area of interest or research proposal
- Limited research presentations (suggests weak communication skills)
- Limited demonstration of potential for independent research
- Little evidence of leadership skills
- Already achieved research independence- no need for further mentored training
What Makes a **Strong** Career Development Plan?

- Logical, systematic, and appropriate for career stage
- Candidate will gain needed expertise
- Specific courses and experiences are outlined which complement the research plan – be explicit!
- Will enhance communication skills and professional development
- Includes grant writing and laboratory management skills

What Makes a **Weak** Career Development Plan?

- Research too close to mentor’s, not clear how will develop independent career
- Not clear how the career development plan differs from postdoctoral experience
- Mentor’s input into plan not apparent
- No training in grant writing or laboratory management
What Makes a Strong Mentor?

• Outstanding scientist
• Excellent plan to facilitate transition
• Successfully mentored other trainees
• Consultants/collaborators are in appropriate areas

What Makes a Weak Mentor?

• Evident lack of input into application
• May be overcommitted (lack of time commitment to trainee)
• Lack of definitive mentoring plan
• Lack of accomplishments by former trainees
• Lack of appropriate consultants/collaborators
What Makes a **Strong Environment?**

- Appropriate laboratory space/equipment (research env)
- Institutional commitment to candidate
- Appropriate letters of support

What Makes a **Weak Environment?**

- Lack of facilities/resources (research env)
- Lack of institutional commitment
- Vague, “canned” letters of support
- Lack of letters of support from needed collaborators
Ask the right person for help:

• **BEFORE** you submit
  – Program Officer
  – Scientific Review Officer (both noted on RFA)

• **AFTER you submit** (but before review)
  – Scientific Review Officer

• **AFTER review**
  – Assigned Program Officer
Check the status of your app in eRA Commons
NIH has a ton of good information online...

https://grants.nih.gov/grants/about_grants.htm

https://www.niaid.nih.gov/grants-contracts/apply-grant

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

Feel free to reach out to me!
Laura.Thomas@nih.gov
Living the *Academic* Dream: One scientist's perspective

Aishwarya Prakash, Ph.D
Associate Professor
University of South Alabama
Department of Biochemistry and Molecular Biology
Outline

- My Education/Scientific Pathway
- The *Academic* Dream
- Navigating the Grant Process as an Early-Stage Investigator
- What happens next?
- Living the Dream
My Education/Scientific Pathway
The *Academic Dream*

Finding an Independent Faculty Position

- Personnel
- High-quality Publications
- Extramural Funds

Teaching

- Start-up Funds
- D'Arcy et al., 2019, Human Mutation
Navigating the Grant Process as an Early-Stage Investigator

Know:

• your requirements for Promotion and Tenure
  • Faculty affairs handbook/ bylaws etc.

• your Office of Sponsored Projects contact person
  • How far in advance does your proposal have to be internally routed?

• how to identify funding opportunities best suited to YOU and YOUR research
  • Contact NIH program officials to determine grant fit and suitability
  • Budgeting people vs. research materials

• how to distinguish your science from collaborative science
Identifying the funding that's right for ME!

- What do I want to do?
- Why do I want to do it?
- Who cares about it/its outcomes?

**Federal**
- NIH, DoD, DoE, NSF, etc.

**Non-Profit**
- American Cancer Society, Mary Kay Foundation, etc.

**Industry**
- Pfizer, Genentech, etc.

**Foreign**
Grantsmanship as a novice: My experience

• Make an outline
• The Aims page can change until the hour before submission (this is OK!)
• Get other folks involved early on (collaborators, letters of support, mentors/ colleagues to critique)
• Preliminary data (set goals and plans for the lab early on, so that everyone is on the same page)
• Write edit write (repeat)
Navigating the Grant Process as an Early-Stage Investigator: Dealing with Rejection

Every grant writer experiences rejection: You are not alone!

“A good idea is no guarantee of grant success.”

“Work towards a portfolio of activities.”

Illustration of boxer being punched in the stomach.

“It is the exception to get funded, not the rule.”

“Give yourself time.”

Share your setback – Misery loves company, right?

Nature: Career Feature. What to do when your grant is rejected? Feb 2020
Navigating the Grant Process as an Early-Stage Investigator: Dealing with Acceptance

Congratulations! Your proposal was funded! Now for the easy part…

“Express Gratitude.”

“Read the funding award guidelines and requirements.”

“Manage/ budget your funds.”

Do good science and publish your results and get ready for the next grant application!

“Give yourself time. It is the exception to get funded, not the rule.”

http://whyopenresearch.org/funding
What happens next?

Secure an Independent Faculty Position
Prepare for Transition
Year 0

Purchase Supplies/ Equipment
Identify Lab Personnel
Train Personnel
Acquire Data for Publications/Grant Applications
Year 1

Publish/Publish/Publish Secure First R01/ Equivalent Mid-Tenure Evaluation Attend Conferences Teaching/ Service
Years 2/3

Tenure/ Promotion Publish/Publish/Publish Teaching/Service Conferences/Talks
Years 4/5

Established Laboratory Grants/ Funding Publish/Publish/Publish Teaching/ Service
Years 6-10

Promotion Grants Publish/Publish/Publish
> Year 10
Living the Dream: What does this look like for me?

DREAM. DO. DOCUMENT.
Prakash Lab: Research and Funding

Reactive Oxygen Species

Replication Errors

ROS

X-rays

Ionizing Radiation

Anti-tumor Drugs

UV Light

Mismatch Repair (MMR)

Excision Repair (BER, SSBR)

Recombinational Repair (HR, NHEJ)

Nucleotide Excision Repair (NER)

Adapted from Tubbs, Cell 2017; https://diethylstilbestrol.co.uk/dna-repair-system/
Collaborations and their importance

PRAKASH LAB FOCUS: DNA Repair

Reactive Oxygen Species

- Replication Errors
- Mismatch Repair (MMR)
- Excision Repair (BER, SSBR)
- Recombinational Repair (HR, NHEJ)
- Nucleotide Excision Repair (NER)
- X-rays
- Ionizing Radiation
- Anti-tumor Drugs
- UV Light

Jessa Blount
Circulogene theranostics
Lynch Syndrome

Dr. Joann Sweasy
U. of Arizona
DNA Repair & Lupus

Dr. Gary A. Piazza and Alex Coley
U. of South Alabama/Auburn University
Pan Ras Inhibitors

Dr. Robert W. Sobol Jr.
U. of South Alabama
BER/MMR

Drs. Richard Honkanen and Mark Swingle
U. of South Alabama
Inhibition of PP5
Acknowledgements

**Prakash Laboratory (Current and Past)**
Nidhi Sharma, Ph.D.
Brandon M. D’Arcy, Ph.D.
Jennifer Arrington
Marlo Thompson
Vandana Sood, Ph.D.
Alex Coley
Dava Mackensie Terry
Caleb Lange (past Technician)
Justin Weisman (past Undergrad)
Monica Pasala (past Undergrad)

**Collaborators:**
- Jessa Blount, MS, CGC (Circulogene)
- Joann Sweasy, Ph.D. (U. of Arizona)
- Srinivas Chakravarthy, Ph.D. (APS)
- Robert W. Sobol, Ph.D. (USA)
- Sachin Pai, M.D. (USA)
- Richard Honkanen, Ph.D. (USA)
- Gary Piazza, Ph.D. (Auburn U.)
- Glen Borchert, Ph.D. (USA)

**Current & Past Funding:**
- NIEHS: R00-ES024417; ONES R01-ES030084
- NIEHS: R35 Subcontract R35-ES031708 to Dr. Joann Sweasy
- Mitchell Cancer Institute, Start up Funds & post-doc fellowship to Brandon D’Arcy
- Center for Clinical and Translational Science, UAB
Making Grant Writing a Hobby

Lauren Aleksunes, PharmD, PhD
Rutgers University
Start Early
Diversify Your Research Areas
Diversifying Research Areas Opens Funding Opportunities

NIDDK
My K99/R00

NIEHS
My 1st R01 (And Others)

NIGMS
My Current R01
Where Do I Start?

Podcast
Pitfall to Avoid: Overly Ambitious
Hone Your Sales Skills
Your New Hobby:

Specific Aims Pages

Gap/Critical Need

Objective

Central Hypothesis

Specific Aims

Expected Outcomes
The University of Utah Grant Writing Coaching Groups Study

Are you an early stage researcher ready to write a new or revised NIH-style proposal and interested in receiving coaching support while you write? If so, we invite you to apply for participation in the University of Utah Grant Writing Coaching Research Study, funded by the NIH Common Fund (grant U01 GM132366; administered by the NIGMS). This study will compare variations of an established grant writing group coaching process to identify features that influence its effectiveness.

https://nrmnet.net/university-of-utah-nrmn-u01/
NIH Center for Scientific Review

Jumpstart Your Career

Join the NIH Early Career Reviewer Program

www.csr.nih.gov/ECR
Who Reads My Grants?

“The Expert”

“The Generalist”

“The Perfectionist”
Any Questions?
Questions...

If you have a question or comment, please use the “Q&A” function on the right side of your screen.
SOT Full and Associate members were sent an email on May 5 with a link to the survey; please email SOT Headquarters to request that the link be resent to you if needed. The survey will be open until May 31, 2021.

This spring, you will receive the link to the 10 min survey! Your input is valuable!

The published results are beneficial to you!
- Identifies pay standards and inequities amongst toxicologists
- Tool for negotiating salary, benefits and promotions
- Insight for attracting best talent and support for diversity and inclusion efforts
- Assists with career planning - higher education, certification, changing employers, sectors or disciplines
- Informs SOT and other societies of underemployment and helps with the design of education and career development programs
Thank you for participating!

- Webinar recording will be available on the SOT website.

- Additional resources mentioned in the webinar chat:
  - https://www.youtube.com/channel/UC1ZUJIWDf-3ItBo8301YF-A
  - https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/ECR