ZoomGov SEPA Grant Workshop
Monday, June 1, 2020
2:00 pm - 3:30 pm Eastern Daylight Time

NIGMS is inviting you to a scheduled ZoomGov workshop for (SEPA) PAR-209-153

National Institute of General Medical Sciences (NIGMS)
Division for Research Capacity Building
National Institutes of Health (NIH)
Webinar Presenters

**Scientific/FOA Content**
Tony Beck, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Email: beckl@mail.nih.gov

**Human Subjects**
Zuzana Justinova, MD, Ph.D.
National Institute of General Medical Sciences (NIGMS)
Email: zuzana.justinova@nih.gov

**Peer Review**
Jonathan Arias, Ph.D.
Center for Scientific Review (CSR)
Email: ariasj@csr.nih.gov

**Financial/Grants Management**
Christy Leake
National Institute of General Medical Sciences (NIGMS)
Email: christy.leake@nih.gov
NIH Science Education Partnership Award (SEPA) (R25 - Clinical Trial Not Allowed)

R25 Education Projects

Reissue of PAR-17-339


July 26, 2019- Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128


PAR-20-153
Funding:

R25 NIH Research Science Education funding mechanism
5-Year, $1.35M award
Budget FY20 = $20.1M

KEY DATES
Letter of Intent Due Date       June 14, 2020
Application Due Date             July 14, 2020, 5:00 PM local time
Scientific Merit Review          October/November 2020
Advisory Council Review          January 2021
Earliest Start Date              March/April 2021
## FOA Section VII. Agency Contacts

<table>
<thead>
<tr>
<th>Contact Type</th>
<th>Contact Name</th>
<th>Affiliation</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scientific/Research Contact (PO)</strong></td>
<td>Tony Beck, Ph.D.</td>
<td>SEPA, NIGMS</td>
<td><a href="mailto:beckl@mail.nih.gov">beckl@mail.nih.gov</a></td>
</tr>
<tr>
<td><strong>Peer Review Contact (SRO)</strong></td>
<td>Jonathan Arias, Ph.D.</td>
<td>CSR, NIGMS</td>
<td><a href="mailto:ariasj@csr.nih.gov">ariasj@csr.nih.gov</a></td>
</tr>
<tr>
<td><strong>Financial/Grants Management Contact (GMS)</strong></td>
<td>Christy Leake</td>
<td>NIGMS</td>
<td><a href="mailto:christy.leake@nih.gov">christy.leake@nih.gov</a></td>
</tr>
</tbody>
</table>
FY20 SEPA REVIEW & AWARD CYCLE

Timeline for Planning a Grant

- Prepare: July 2020
- Internal Deadline: Nov 2020
- Due: Mar – Apr 2021
- Review
- Council
- Funding
- End-of-Year Funding
- Awards
- Receipt Date
- Scores
- Summary Statement
FY20 SEPA REVIEW & AWARD CYCLE
staff contacts

Timeline for Planning a Grant

- July 2020
- Nov 2020
- Mar – Apr 2021

- PO
- SRO
- GMS

- RECEIPT DATE
- REVIEW
- SCORES
- AWARDS
- SUMMARY STATEMENT
FY20 SEPA REVIEW & AWARD CYCLE

staff contacts

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RECEIPT DATE
REVIEW
SCORES
SUMMARY STATEMENT

AWARDS

PO
SRO
GMS
FY20 SEPA REVIEW & AWARD CYCLE

Staff contacts

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FY20 SEPA REVIEW & AWARD CYCLE
staff contacts

Timeline for Planning a Grant

July 2020
PO
SRO
GMS

Nov 2020
RECEIPT DATE

Mar – Apr 2021
REVIEW
SCORES
SUMMARY STATEMENT

AWARDS
Our goal - a diverse pipeline
**Purpose**

- Increase the numbers of urban, rural and minority students considering research and medical careers
- Public health literacy

---

Our goal - a diverse pipeline

Supported by the National Institutes of Health
Our goal - a diverse pipeline

Partnerships

- Scientists and clinicians partnering with educators, community organizations and science centers
Goals:
- Career opportunities for minority and underserved students to increase workforce diversity
- Teacher professional development
- Increased public health literacy

Our goal - a diverse pipeline
Our goal - a diverse pipeline

Target Audiences
- Pre-K to grade 12
- General public
Our goal - a diverse pipeline

Topics
- Any area of NIH funded basic or medical research
SEPA EVOLUTION – FOA-Driven New Areas of Emphasis

- Clinical Trials, Stem Cells
- RCT, Case Comp., Logic Model (Encouraged)
- RCT, Case Comp., Logic Model (Required)
- Citizen Science
- Maker Movement, Biotinkering

Academic and Clinical Partnerships

SEPA EVOLUTION – FOA-Driven New Areas of Emphasis

- Clinical Trials, Stem Cells
- RCT, Case Comp., Logic Model (Encouraged)
- RCT, Case Comp., Logic Model (Required)
- Citizen Science
- Maker Movement, Biotinkering
- Broader impact statement
- Data science & informatics
- Imbedded math & reading
- Culture of lab safety
- Replicate successful SEPAs

Academic and Clinical Partnerships

Clinical Trials, Stem Cells

NCRR

RCT, Case Comp., Logic Model (Encouraged)

K

Pre-K

Citizen Science

NIH OD

NIH OD

NIGMS

The Human Microbiome

ZOO in YOU
El Microbioma Humano

https://omsi.edu/exhibitions/zoo-in-you/
Biohealth Learning Lab and Makerspace for the Community

- Activate and test a museum a bio-makerspace
- Develop and evaluate a cohort of novel hands-on experiences
- Create resources for replication
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https://nihsepa.org/
Filter by state:

Choose a State

Please make a selection

PA
<table>
<thead>
<tr>
<th>Project Title</th>
<th>Institution</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planarians and the pharmacology of addiction: an in vitro model for K-12 education</td>
<td>Temple University – Lewis Katz School of Medicine, Philadelphia PA</td>
<td>01/18/2014</td>
<td>03/30/2015</td>
</tr>
<tr>
<td>A Partnership in Neuroscience Education</td>
<td>Temple University, Pittsburgh PA</td>
<td>01/01/2014</td>
<td>03/28/2014</td>
</tr>
<tr>
<td>Resources for Education and Action for Community Health in Ambler (REACH Ambler)</td>
<td>University of Pennsylvania – School of Medicine, Philadelphia PA</td>
<td>06/27/2012</td>
<td>07/19/2017</td>
</tr>
<tr>
<td>Investing in the Future: Collaborative Research Experiences for Students and Teachers</td>
<td>Pennsylvania State University, Hershey Med Ctr, Hershey PA</td>
<td>08/01/2006</td>
<td>05/31/2012</td>
</tr>
<tr>
<td>If a Starfish Can Grow a New Arm, Why Can’t?</td>
<td>Pittsburgh Tissue Engineering Initiative, Pittsburgh PA</td>
<td>03/20/2007</td>
<td>02/28/2012</td>
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<td>Regenerative Medicine Partnership in Education (Phase III)</td>
<td>Temple University, Pittsburgh PA</td>
<td>03/01/2008</td>
<td>03/15/2010</td>
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<tr>
<td>Partnership in Biomedical Discovery</td>
<td>University of Pittsburgh, Pittsburgh PA</td>
<td>03/01/2008</td>
<td>03/01/2011</td>
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<tr>
<td>Heart of the Matter</td>
<td>Franklin Institute, Philadelphia PA</td>
<td>03/05/2003</td>
<td>03/05/2006</td>
</tr>
<tr>
<td>Tissue Engineering Show and Educational Partnership</td>
<td>Temple University, Pittsburgh PA</td>
<td>08/01/2009</td>
<td>08/31/2009</td>
</tr>
<tr>
<td>Science Teachers Workshops for Computer Training</td>
<td>Carnegie Mellon University, Pittsburgh PA</td>
<td>09/01/1991</td>
<td>03/01/1995</td>
</tr>
<tr>
<td>Universe Within</td>
<td>GED Communications Inc, Pittsburgh PA</td>
<td>08/01/1991</td>
<td>09/29/1991</td>
</tr>
<tr>
<td>Science Teachers Workshops for Computer Training</td>
<td>Carnegie Mellon University, Pittsburgh PA</td>
<td>09/01/1991</td>
<td>03/28/1995</td>
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</tbody>
</table>
Planarians and the pharmacology of addiction: an in vivo model for K-12 education
Temple University – Lewis Katz School of Medicine, Philadelphia PA
1R25DA033270-01A1 : 07/15/2014 - 06/30/2018

A Partnership in Neuroscience Education
Duquesne University, Pittsburgh PA
R25OD016516 : 04/15/2014 - 02/28/2019

Resources for Education and Action for Community Health in Ambler (REACH Ambler)
University of Pennsylvania – School of Medicine, Philadelphia PA
R25OD010521-01 : 08/27/2012 - 07/31/2017
High-caliber, rigorously-tested STEM teaching tools for the 21st century

Scientastic! Are You Sleeping? is an Emmy® Award-winning show, which blends live-action with 2-D and 3-D animations that incorporates a fictional plot with interviews from actual doctors and scientists, to view at

http://thepartnershiptineducation.com
Scientastic! Are You Sleeping? is an Emmy® Award-winning show, which blends live-action with 2-D and 3-D animations that incorporates a fictional plot with interviews from actual doctors and scientists, to view at http://thepartnershipineducation.com.
A Partnership in Neuroscience Education

Scientastic! Are You Sleeping? [Image]

Winner of two Emmy® Awards!

Project Information
- Project ID: R25OD016516
- Project Type: formal
- Project Status: active
- Funding Years: 04/15/2014 - 02/28/2019
- State: PA

Institution:
Duquesne University
Department:
Department of Biological Sciences
Address:
Duquesne University Administration Bldg. 600 Forbes Avenue Room 301A
Pittsburgh, PA 15282

Project Contact(s):
Pollock, John, PhD
Role: PI / Project Leader
Phone: 412-855-4043
Email: pollock@duq.edu

Project Website(s)
- http://thepartnershipineducation.com

Project Description

High-caliber, rigorously-tested STEM teaching tools for the 21st century

Scientastic! Are You Sleeping? is an Emmy® Award-winning show, which blends live-action with 2-D and 3-D animations that incorporates a fictional plot with interviews from actual doctors and scientists, to view at [Website Link].
PREPARATION

START

1

2

3

4

5

https://www.eliteresearch.com/how-do-you-develop-a-logic-model
1. Study SEPA FOA
2. Visit SEPA website, [https://nihsepa.org/](https://nihsepa.org/)
   - Search by
     - Topic
     - Target Audience
     - Applicant Organization
   - SEPA Projects by Funding Year
   - Annual SEPA PI Conference Reports
• Assemble team

• Identify partners

• Draft research plan

• Email to schedule a call
Electronic Application Process

1. Prepare to Apply & Register
   - Register with Grants.gov & eRA Commons

2. Find Opportunity
   - Submit in response to Funding Opportunity Announcement (FOA)

3. Prepare Application
   - Follow Application Guide & Instructions

4. Submit, Track & View
   - Submit via your organizational representative
   - Use eRA Commons to view & track

http://slideplayer.com/slide/5288203/
PREPARATION – PART 3

https://era.nih.gov/commons/faq_commons.cfm
PROGRAM

• Human Subjects
• Inclusion

Zuzana Justinova, MD, PhD
What’s New with Human Subjects?

- Revised Common Rule: Changes include IRB Review, consent in the Common Rule, and exemption categories.
- Expanded exemption categories that cover the work proposed in most SEPA applications.
- Changes to human subjects research-related NIH policies to align with Common Rule changes and the 21st Century Cures Act.
- New Human Subjects and Clinical Trials Information forms – Affects all types of human subjects research.
- Resources to help you navigate the changes: [https://grants.nih.gov/policy/humansubjects/research.htm](https://grants.nih.gov/policy/humansubjects/research.htm)
I think I have a project with human subjects. What next?

- The exemptions listed are likely to cover most SEPA projects that do involve human subjects research.

- If your proposal seems to include work beyond Exemptions 1-8, contact the SEPA Program Director to discuss the work you want to propose and its fit with SEPA’s goals.

- Note: Expedited IRB review does not mean exempt human subjects research.

Remember:
Randomized Controlled Trial (RCT) or a Well-Matched Comparison study evaluation design to evaluate project effectiveness ≠ Clinical Research

https://grants.nih.gov/sites/default/files/exemption_infographic_v7_508c-4-4-19.pdf
Keep in Mind: Definition of Research

• A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

• Program evaluations that
  • do not involve experimental or non-standard interventions,
  • provide information for and about the setting in which the program is conducted,
  • are considered to be a requirement or standard operating procedure of the program,
  • and are not subject to peer review
  ➢ are not considered research.

• Publishing the results of a program evaluation does not necessarily mean that the program evaluation must be treated as human subjects research.
New G.500 - PHS Human Subjects and Clinical Trials Information

- Video walkthrough of the forms:  
  https://www.youtube.com/watch?v=FNgOHqmk0rY&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=2&t=0s

- Detailed instructions to fill them out:  

- Clearly describe the activities in the IRB protocol that will be used to evaluate the program effectiveness.
  - Ex.: “Health-related biomedical or behavioral outcomes will not be evaluated and the proposed human subjects research does not meet the NIH Definition of Clinical Research.”
What about Behavioral Interventions in Educational Settings?

**NOT CLINICAL TRIALS**
- Pay attention to semantics
- Clearly describe outcome measures
- State health-related biomedical or behavioral outcomes will NOT be evaluated

**FAQ C.3: What are some examples of outcomes that are not "health related biomedical or behavioral"?**
While the vast majority of NIH-funded studies are health related, a few are not. For example, a study that evaluates if enrollment in a summer internship program alters the student’s opinions on their educational pathway would not be assessing a health-related biomedical or behavioral outcome.
Helpful Hints

• Check with your IRB and institutional business officials (HRPP) prior to submission (early and often).

• Consider the Revised Common Rule changes as you develop your proposal.

• Separate program evaluation from other types of human subjects research.

• Program evaluations are NOT subject to Inclusion Monitoring.

• Program evaluations that use RCT methodology are NOT clinical trials.

• Provide extra detail on wearable devices and what will be done with the information.
  • Educational purposes only
  • Data collection, storage and access
  • Informed consent procedure if applicable
  • IRB evaluation and whether the IRB considers the research human subjects
Resources for Navigating Human Subjects Questions

https://grants.nih.gov/policy/humansubjects/training-and-resources.htm
• Review-related issues

Jonathan Arias, Ph.D.
REVIEW CONSIDERATIONS

NIH REVIEW CRITERIA:
Significance
Investigator(s)
Innovation
Approach (Evaluation Plan, Dissemination Plan, Website)
Environment

ADDITIONAL REVIEW CRITERIA:
Recruitment Plan to Enhance Diversity
Training in the Responsible Conduct of Research
Resource Sharing Plans
Protections for Human Subjects
Inclusion of Women, Minorities, and Children
Vertebrate Animals
Biohazards
Select Agents
*Budget*
REVIEW CONSIDERATIONS

SEPA-SPECIFIC REQUIRED DOCUMENTS:
Application will be withdrawn prior to peer review if any of these SEPA-specific sections of the application are missing:

* Diversity Recruitment Plan
* Plan for Instruction in the Responsible Conduct of Research
* Evaluation Plan
* Dissemination Plan

APPENDIX: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide
Institutional Environment and Commitment

Letters of Support

A letter of institutional commitment must be attached as part of Letters of Support

(see: "Institutional Environment and Commitment.")
Letters of commitment from partners and/or collaborators must be attached as part of Letters of Support.
GRANTS MANAGEMENT BASICS

Christy Leake
Grants Management Basics

• Annual Award Budget: $250,000 direct costs
• Award Project Period: Up to 5 years
• Indirect Costs are reimbursed at 8% of MTDC
• Only one SEPA application is allowed per institution
• Organizations may be a subcontract on another SEPA award as long as the subcontract does not exceed 20% of the direct costs requested.
Participant costs are allowable for those individuals who are involved in the proposed research education activity.
Grants Management Basics

Questionable Costs:

• Honorarium – not allowable when it is used to confer distinction on a speaker

• General Supplies – only costs directly related to the grant and/or project are allowable as direct costs

• Meals/Food – only allowable as part of meeting necessary for disseminating information

All costs must be allowable, reasonable, allocable, necessary and be accorded consistent treatment.
Grants Management Basics

Unallowable Costs:

• **Stipends** are not allowable on R25 awards. Teachers and students participating in a SEPA project can be compensated for their participation in the project.

• **Gifts** are unallowable on all NIH awards. Incentive payments to volunteers or participants in a grant-supported project are allowable.

• **Entertainment** is not allowable on NIH awards.

• **Promotional Items** are not allowable on NIH awards.
Grants Management Basics

• Competing applications with a detailed budget can continue to request cost-of-living/inflationary increases in accordance with institutional policy.
• Under the current budget climate, it is likely that requests associated solely with inflationary increases will be eliminated from the awarded budget for competing awards.
• Requests associated with special needs (e.g., equipment, added personnel or increased effort) will continue to be considered.
Grants Management Basics

Best Practices:

• Ensure costs are reasonable, allocable, necessary and consistently treated

• Provide adequate budget justifications to explain the relevance of costs to the proposed SEPA project

• Research proposed costs in advance – check with your Office of Sponsored Programs, or equivalent office, as many institutions have cost policies in place as guides
PROGRAM
Final Thoughts
NIH Scoring System

Scored Review Criteria

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

- Current state of the field
- Hypothesis driven innovation
- Move the field forward

Investigators

- Prior work
  - Publications
  - Evaluation data
- Key personnel listed
Approach

• 3 Specific Aims
  • SA1, SA2, SA3; SA1.1, SA.1.2
• Potential problems & solutions
• Evaluator input – early and sustained
• Teacher input – early and sustained
• Logic Model
• Validated evaluation instruments
• Control group(s)
• NGSS alignment
• Time & Events
• Tables, figures, charts
• Images
• Literature documentation
“what differentiates this STEM resource from others out there?"
Significance:

- **Strengths**
  - A well-organized proposal
  - Scientific premise is sound.
  - Proposed pedagogical plan for student learning is well supported by research
  - Past team and key personnel successes

- **Weaknesses**
  - No discussion of the existing STEM resources
  - The applicants claim that the product will positively impact teachers’ effectiveness and content knowledge but does not offer evidence
  - No link to NGSS, the relevant state science standards, or the national health education standards.
  - Gender differences do not appear to be considered.
Innovation:

- **Strengths**
  - The game as presented *draws on previous successes of the team members.*
  - Using *real world examples and scientific data* to engage students in STEM learning.
  - **Including students and teachers** – the end users – in the development of the STEM resource.
  - While specific elements of application are not innovative, the entire package is an innovative way to teach.

- **Weaknesses**
  - It is not clear *what differentiates this STEM resource from others* or how it will contribute uniquely to the teacher/student audiences.
  - It seems the **teacher is not part of the process** during project development.
  - The proposed product may not provide sufficient *flexibility for use* by many teachers and/or district curricula.
Approach:

- **Strengths**
  - The application is **clearly written**.
  - The **specific aims are clearly articulated**
  - **NGSS** science standards will be incorporated.
  - **Teacher feedback** is planned.
  - Comparisons between groups will include the **biological (sex and age)** and **social (poverty and learning skills)**.

- **Weaknesses**
  - The approach seems **overly ambitious**
  - Educational **goals are not articulated in a measurable way**
  - **Assessment tools are not validated** and will not provide information for design and implementation
  - **No control** is mentioned against which to evaluate the intervention.
  - The **user** group that is informing the development of the STEM resource **lacks diversity**
Approach:

- **Strengths**
  - The application is **clearly written**.
  - The **specific aims are clearly articulated**
    - NGSS science standards will be incorporated.
    - Teacher feedback is planned.
    - Comparisons between groups will include the biological (sex and age) and social (poverty and learning skills).

- **Weaknesses**
  - The approach seems **overly ambitious**
  - Educational **goals are not articulated in a measurable way**
  - Assessment plan is a marketing and usability study. It will not provide information for design and implementation
  - **No control** is mentioned against which to evaluate the game.
  - The end user group that is informing the development of the product lacks diversity
Use plain, simple language, short words and brief sentences. Don't let fluff and flowers and verbosity creep in.

Mark Twain
“This application was a pleasure to read”
QUESTIONS?