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

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

Human Subjects
Rashada Alexander, Ph.D. (SEPA-Human Subjects SME)
National Institute of General Medical Sciences (NIGMS)
Email: rashada.alexander@nih.gov

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

Financial/Grants Management
Brian Iglesias
National Institute of General Medical Sciences (NIGMS)
Email: iglesiab@mail.nih.gov
SEPA Funding Opportunity Announcement (FOA)

### Part 1. Overview Information

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
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<tbody>
<tr>
<td>Components of Participating Organizations</td>
<td>National Institute of General Medical Sciences (NIGMS)</td>
</tr>
<tr>
<td>Funding Opportunity Title</td>
<td>NIH Science Education Partnership Award (SEPA)(R25)</td>
</tr>
<tr>
<td>Funding Opportunity Announcement (FOA) Number</td>
<td>PAR-17-339</td>
</tr>
</tbody>
</table>
Section VII. Agency Contacts

Scientific/Research Contact
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National Institute of General Medical Sciences (NIGMS)
Email: beckl@mail.nih.gov

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Email: ariasj@csr.nih.gov

Financial/Grants Management Contact
Brian Iglesias
National Institute of General Medical Sciences (NIGMS)
Email: iglesiab@mail.nih.gov
Funding:

- **R25 NIH Research Science Education funding mechanism**
- **5-Year, $1.35M award**
- **Budget FY18 = $18.5M**

**Letter of Intent Due Date**: June 9, 2019
**Application Due Date**: July 9, 2019, 5:00 PM local time
**Scientific Merit Review**: September/October 2019
**Advisory Council Review**: January 2020
**Earliest Start Date**: March/April 2020
FY19 SEPA Review & Award Cycle

staff contacts

Timeline for Planning a Grant

- July 2019
- Nov 2019
- Mar – Apr 2020

- PO
- SRO
- GMS

- RECEIPT DATE
- REVIEW
- SCORES

- AWARDS
- SUMMARY STATEMENT
FY19 SEPA Review & Award Cycle

staff contacts (PO & GMS)

Timeline for Planning a Grant

- July 2019
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PO
SRO
GMS

RECEIPT
DATE

REVIEW

SCORES

AWARDS

SUMMARY
STATEMENT
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
Partnerships

• Scientists and clinicians partnering with educators, community organizations and science centers

Our goal - a diverse pipeline
Goals
- Career opportunities for minority and underserved students to increase workforce diversity
- Teacher professional development
Target Audiences

• Pre-K to grade 12
• General public

Our goal - a diverse pipeline

Supported by the National Institutes of Health
Topics
• Any area of NIH funded basic or medical research

Our goal - a diverse pipeline

Supported by the National Institutes of Health
SEPA Project Diversity

- Systems: Aging, Hearing, Brain, Lung, Bone
- Microbiology, Virology & Disease Vectors
- Nutrition, Obesity, Diabetes & Cardiovascular
- Community Understanding about Clinical Trials
- Molecular Biology
- Citizen Science
- Early Stem
- Basic & Clinical Research Methods
- Infectious Disease, Immunology & Epidemiology
- Veterinary Medicine
- Interactive Digital Media
- Molecular Biology
- Public Health, Lifestyle & Health
- Mentoring, Workforce Development & Teacher Professional Development
- Human Genetics & Genomics
- Systems: Aging, Hearing, Brain, Lung, Bone
- Microbiology, Virology & Disease Vectors
- Nutrition, Obesity, Diabetes & Cardiovascular
- Community Understanding about Clinical Trials
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- Veterinary Medicine
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- Molecular Biology
- Public Health, Lifestyle & Health
- Mentoring, Workforce Development & Teacher Professional Development
- Human Genetics & Genomics
PREPARATION

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
SEPA Overview and Grant Application Webinar
Wednesday, June 5, 2019
2:00 pm Eastern Daylight Time (GMT-04:00)

SEPA Overview and Grant Application Process Webinar

https://nihsepa.org/
https://nihsepa.org/
SEPA Overview and Grant Application Webinar
Wednesday, June 5, 2019
2:00 pm Eastern Daylight Time (GMT-04:00)

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| **Partnerships for Prevention: A plan for managing student stress, anxiety, and pain through interactive media**  
Duquesne University, Pittsburgh, PA  
R25GM132910-01: 06/01/2019 - 07/31/2024 |
| **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  
R25OD010516: 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  
R25OD0210521-01: 08/27/2012 - 07/31/2017 |
| **Investing in the Future: Collaborative Research Experiences for Students and Teachers**  
Pennsylvania State University Hershey Med Ctr, Hershey, PA  
R25RR023280-01A2: 09/01/2008 - 09/30/2013 |
| **If a Starfish Can Grow a New Arm, Why Can't I?**  
Pittsburgh Tissue Engineering Initiative, Pittsburgh, PA  
R25RR023286: 03/26/2007 - 02/28/2012 |
| **Regenerative Medicine Partnership in Education — Phase III**  
Duquesne University, Pittsburgh, PA  
R25RR020403: 04/01/2006 - 03/31/2010 |
| **Partnership in Biomedical Discovery**  
University of Pittsburgh, Pittsburgh, PA  
R25RR020463: 04/01/2006 - 03/31/2011 |
| **Heart of the Matter**  
Franklin Institute, Philadelphia, PA  
Partnerships for Prevention: A plan for managing student stress, anxiety, and pain through interactive media
Duquesne University, Pittsburgh PA
R25GM132910-01 : 08/01/2019 - 07/31/2024

Planarians and the Pharmacology of Addiction: An In Vivo Model for K-12 Education
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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
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
A Partnership in Neuroscience Education

Scientastic! Are You Sleeping? Winner of two Emmy® Awards!

Scientastic: Are You Sleeping? | Preview

![Scientastic Logo](http://www.scientasticshow.com)

**Project Website(s)**

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---

**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
**Scientastic! Are You Sleeping?**

Winner of two *Emmy*® Awards!

[Image of the Scientastic show logo]

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Department: Department of Biological Sciences
Address: Duquesne University Administration Bldg. 600 Forbes Avenue Room 301A Pittsburgh, PA 15282
PREPARATION – PART 2

- Assemble team
- Identify partners
- Draft research plan
- Email to schedule a call
PREPARATION – PART 3

Electronic Application Process

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

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

Prepare Application
- Follow Application Guide & Instructions

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

Rashada Alexander, Ph.D
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)
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 PHS Human Subjects and Clinical Trials Information Form

- Video walkthrough of new forms: https://youtu.be/nz9NWFhYOG8
- Detailed instructions to fill them out: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf
- 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

Policy & Compliance
- NIH Grants Policy
- Notice of Policy Changes
- Compliance & Oversight
- Select Policy Topics
  - Anti-Sexual Harassment
  - Animal Welfare
  - Conflict of Interest
- Financial Conflict of Interest

Human Subjects Research
- Definition of Human Subjects Research
- Pre and Post Award Process
- Single IRB Policy
- Policies & Regulations
  - Training & Resources
  - Intellectual Property Policy
  - Lobbying Guidance for Grantee Activities
  - NIH Funding Strategies
- Peer Review Policies and Practices
- Public Access
- Research Integrity

Grant & Funding
- Entire Site
- Search this Site

Policy & Compliance - Human Subjects

Education Requirement

Protection of Human Subjects Education

On this page:
- **Education Requirement**, including information about fulfilling the required education in the protection of human research participants.
- **Training**, including required training, information for completing applications, training for using the Human Subjects System (HSS), and Single IRB training.
- **Resources**, including the course content from the retired PHRP course, the Human Subjects Research and Exempt Human Subjects Research infographics, funding opportunity announcements, bioethics information, links to OHRP, and more.

Education Requirement

Protection of Human Subjects Education

Investigators and all key personnel who will be involved in the design or conduct of NIH-funded human subjects research must fulfill the protection of human subjects education requirement. For additional information, please see the Human Subjects Research FAQs. Additional information about the requirement for education on the protection of human subjects policy can be found here.

Training

Assistance Preparing the PHS Human Subjects and Clinical Trials Information Form

Find useful resources for filling out the PHS Human Subjects and Clinical Trials Information form, study records application submission presentations, and annotated form sets.

Human Subjects System (HSS) Overview Video Tutorials and Resources

The HSS system is a shared system that enables grant recipients to electronically report and update their data on human subjects research and clinical trials to NIH; and for NIH agency staff to monitor and manage the study progress.

NIH Single IRB Webinar - October 2017

To prepare investigators, signing officials, research organizations or institutions, and institutional review board (IRB) staff involved in the design, conduct, or review of research involving domestic multi-site non-exempt human subjects studies to understand their roles and responsibilities with the NIH Single IRB policy.

https://grants.nih.gov/policy/humansubjects/training-and-resources.htm
REVIEW

• 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
Letters of Support

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

(see: "Institutional Environment and Commitment."
Letters of Partner Commitment

Letters of commitment from partners and/or collaborators must be attached as part of Letters of Support.
GRANTS MANAGEMENT BASICS

Brian Iglesias
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.
Grants Management Basics

**Personnel Costs**
Individuals designing, directing, and implementing the research education program may request salary and fringe benefits appropriate for the person months devoted to the program. Salaries requested may not exceed the levels commensurate with the institution's policy for similar positions and may not exceed the congressionally mandated cap. (If mentoring interactions and other activities with participants are considered a regular part of an individual's academic duties, then any costs associated with the mentoring and other interactions with participants are not allowable costs from grant funds).

**Participant Costs**
Not Applicable

**Other Program-Related Expenses**
Consultant costs, equipment, supplies, travel for key persons, and other program-related expenses may be included in the proposed budget. These expenses must be justified as specifically required by the proposed program and must not duplicate items generally available at the applicant institution.

There is an Annual SEPA PD/PI Conference, usually in the Washington, DC area. It is required that the PD/PI(s) attend this meeting. PD/PI(s) are encouraged to bring key personnel, e.g., the project evaluator to the annual conference. Funds to support travel to the annual conference must be requested in the budget. If not used, these funds may not be rebudgeted.

A minimum of ten percent (10%) of the direct costs must be devoted to project evaluation.

Enter costs that previously fit into section “E. Participant/Trainee Other Support Costs” into section “F. Other Direct Costs” in the SF424 R&R application.
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.
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
NIH Scoring System

Scored Review Criteria
• Significance
• Investigator(s)
• Innovation
• Approach
• Environment
Approach

• 3 Specific Aims
  • SA1, SA2, SA3; SA1.1, SA.1.2
• Potential problems & solutions
• Evaluator input
• Teacher input
• Logic Model
• Validated evaluation instruments
• Control group(s)
• 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?