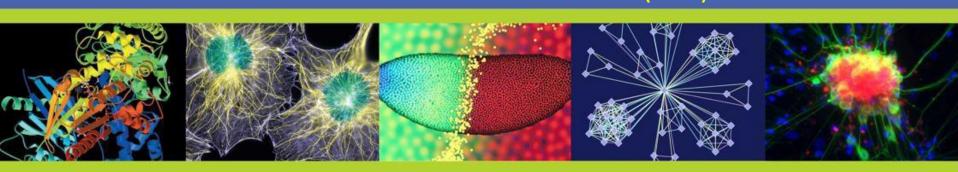


National Institute of General Medical Sciences (NIGMS)

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: <u>ariasj@csr.nih.gov</u>

Financial/Grants Management

Brian Iglesias

National Institute of General Medical Sciences (NIGMS)

Email: iglesiab@mail.nih.gov

SEPA Funding Opportunity Announcement (FOA)

Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute of General Medical Sciences (NIGMS (http://www.nigms.nih.gov))

Funding Opportunity Title

NIH Science Education Partnership Award (SEPA)(R25)

Funding Opportunity Announcement (FOA) Number

PAR-17-339



Section VII. Agency Contacts

Scientific/Research Contact (PO)

Tony Beck, Ph.D. (SEPA)

National Institute of General Medical Sciences (NIGMS)

Email: beckl@mail.nih.gov

Peer Review Contact (SRO)

Jonathan Arias, Ph.D.

Center for Scientific Review (CSR)

Email: ariasj@csr.nih.gov

Financial/Grants Management Contact (GMS)

Christy Leake, christy.leake@nih.gov

Brian Iglesias, <u>iglesiab@mail.nih.gov</u>

National Institute of General Medical Sciences

(NIGMS)

Funding:

- R25 NIH Research Science Education funding mechanism
- 5-Year, \$1.35M award
- Budget FY19 = \$20.1M

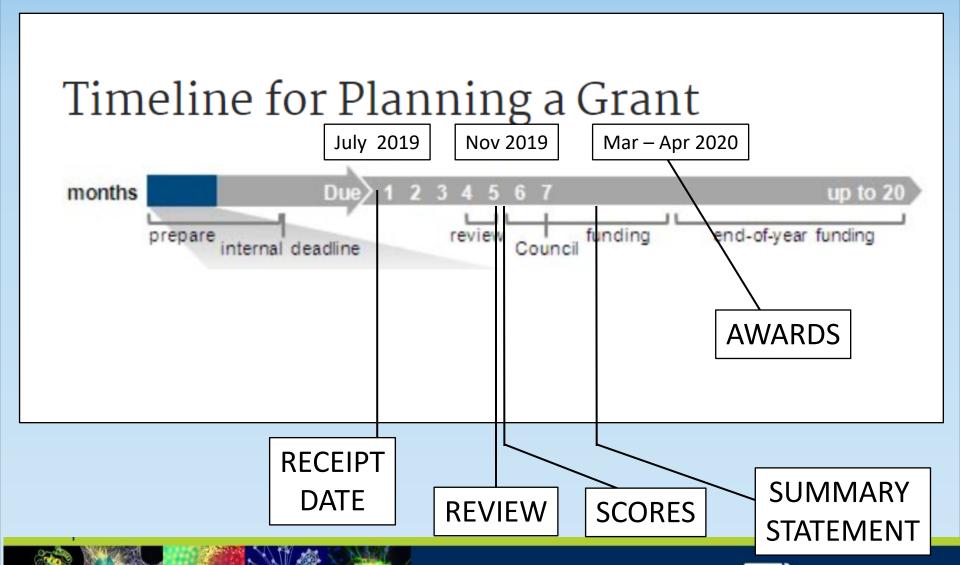
Letter of Intent Due Date June 9, 2019

Application Due Date July 9, 2019, 5:00 PM local time

Scientific Merit Review September/October 2019

Advisory Council Review January 2020

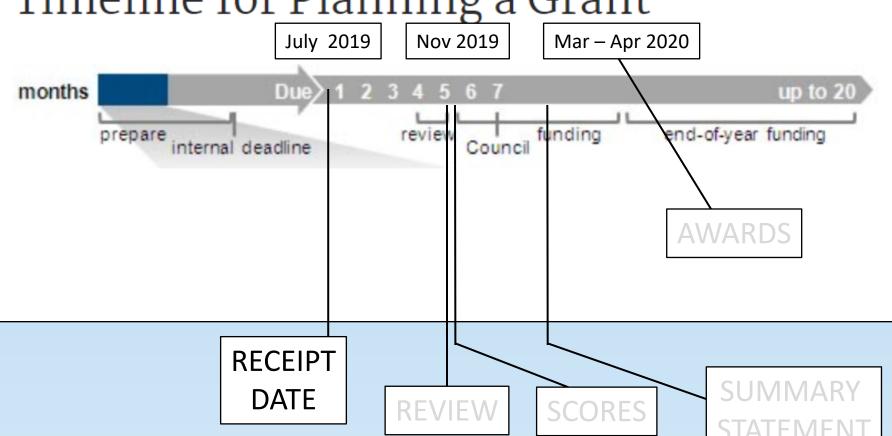
Earliest Start Date March/April 2020





staff contacts

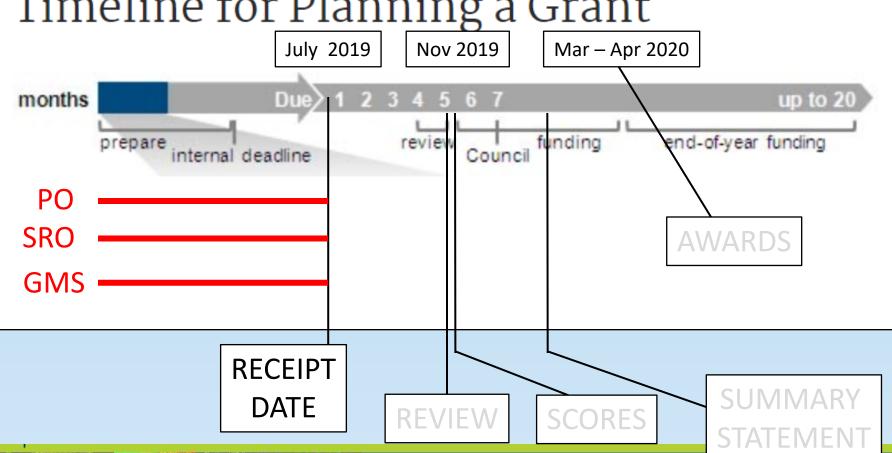






staff contacts

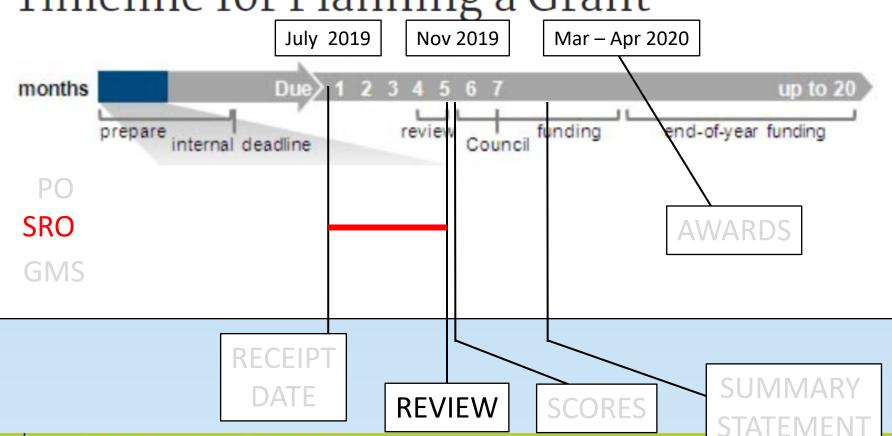






staff contacts

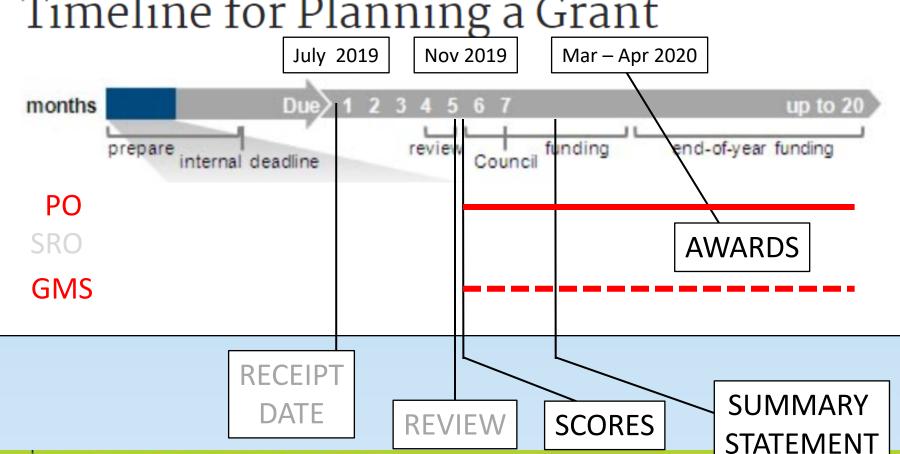






FY19 SEPA REVIEW & AWARD CYCLE staff contacts

Timeline for Planning a Grant







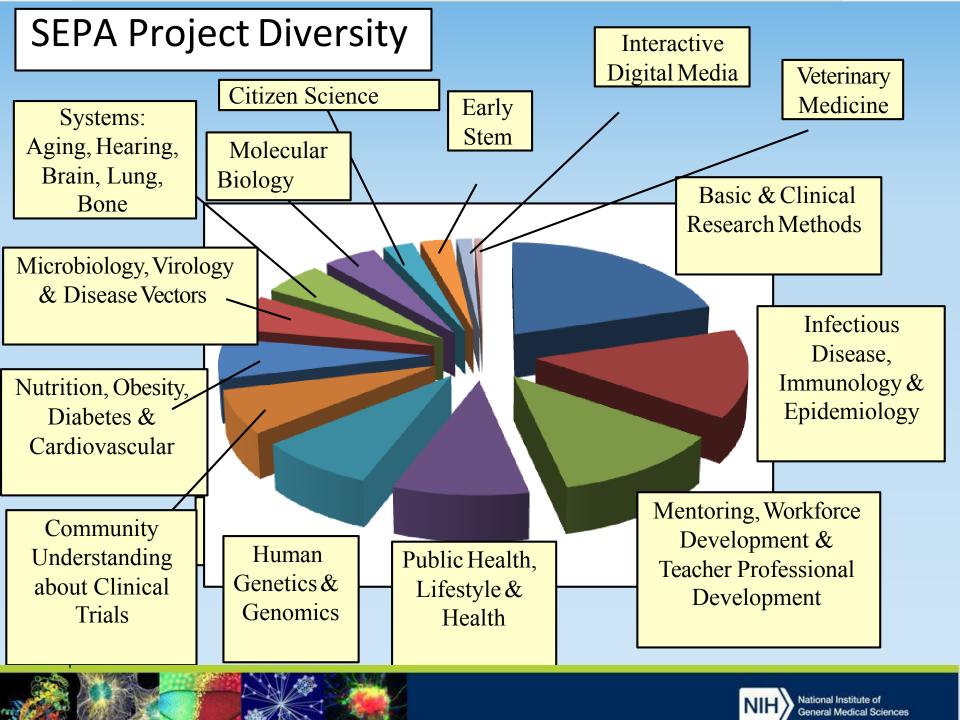












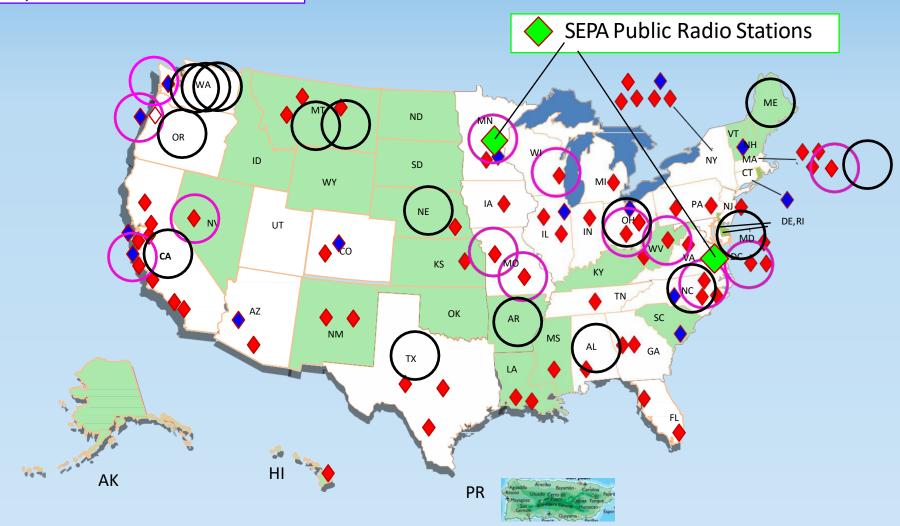


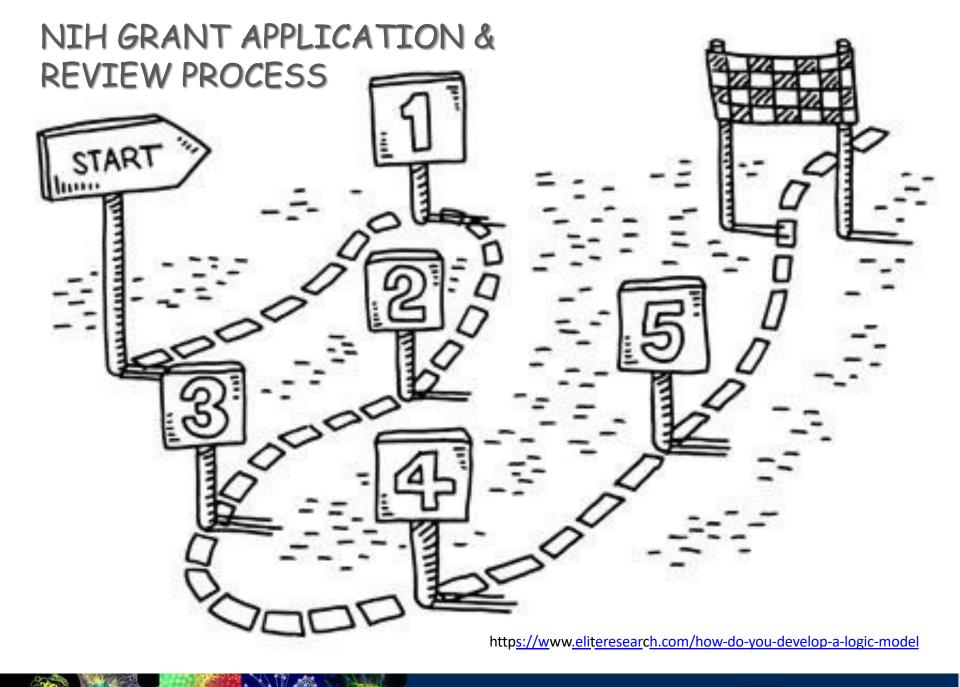
FY17 AWARDS



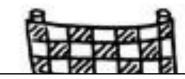


Museum Exhibits





PREPARATION – PART 1



Electronic Application Process

Prepare to Apply & Register

Find Opportunity

Prepare Application Submit, Track & View

- Register with Grants.gov & eRA Commons
- Submit in response to Funding Opportunity Announcement (FOA)
- Follow
 Application
 Guide &
 Instructions
- Submit via your organizational representative
- Use eRA
 Commons to
 view & track

http://slideplayer.com/slide/5288203/



PREPARATION - PART 1



electronic Research Administration (eRA)



A program of the National Institutes of Health

Other Web Resources

eRA Commons Registration & Accounts

eRA Training

Modules, User Guides & Documentation

Related NIH Guide Notices

PubRoster (Rosters of NIH Scientific Review Groups)

Grants & Funding Info

NIH (OER)

AHRQ

eRA Commons Frequently Asked Questions

I. General Questions

II. eRA Commons Registration

III. Accounts Log In and Password

IV. Roles in eRA Commons

V. Creating Accounts; Delegating and Revoking Authority; Affiliating

VI. Personal Profile

VII. Research Performance Progress Report (RPPR)

VIII. Financial Status Report

IX. Grants Closeout

X. Just in Time

XI. No Cost Extension

XII. Reference Letters

XIII. Internet Assisted Review

XIV. Summary Statement

XV. My NCBI

XVI. xTrain

XVII. LikeThis

XVIII. Administrative Supplements (Type 3s)

XIX. Change of Institution/Relinquishing Statement (Type 7s)

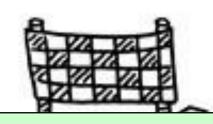
XX. Extramural Trainee Reporting And Career Tracking (xTRACT)

XXI. PI Verification of Preferred eRA Commons Account



PREPARATION – PART 2





- 1. Study SEPA FOA
- 2. Visit SEPA website, https://nihsepa.org/
 - Search by
 - Topic
 - Target Audience
 - Applicant Organization
 - SEPA Projects by Funding Year
 - Annual SEPA PI Conference Reports





Evaluation

Annual Meeting



SEPA Overview and Grant Application Process Webinar

News **▼**

Community **▼**



https://nihsepa.org/

SEPA Projects ▼

Publications





Evaluation

Annual Meeting



News **▼**

Community **▼**

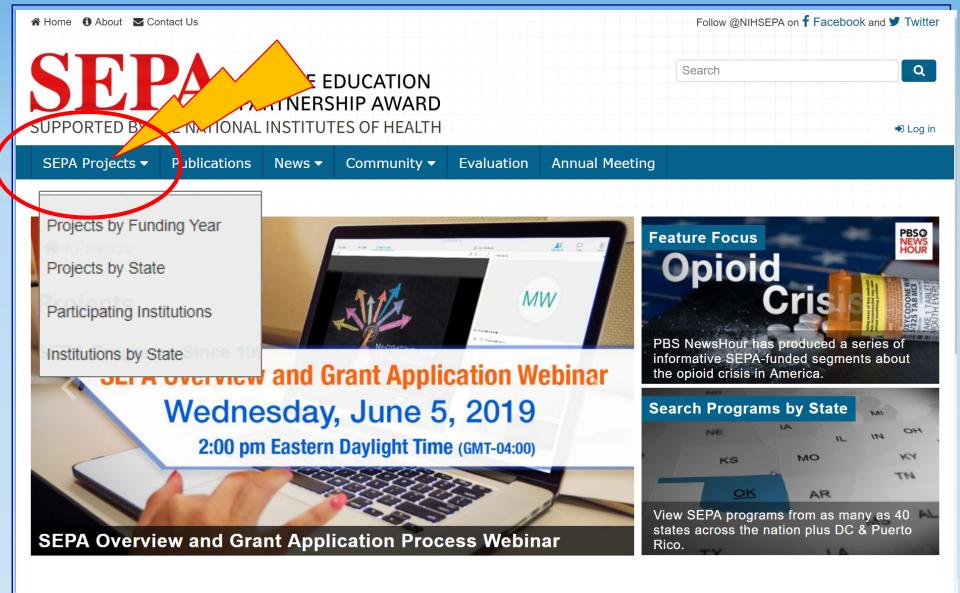


https://nihsepa.org/

SEPA Projects ▼

Publications

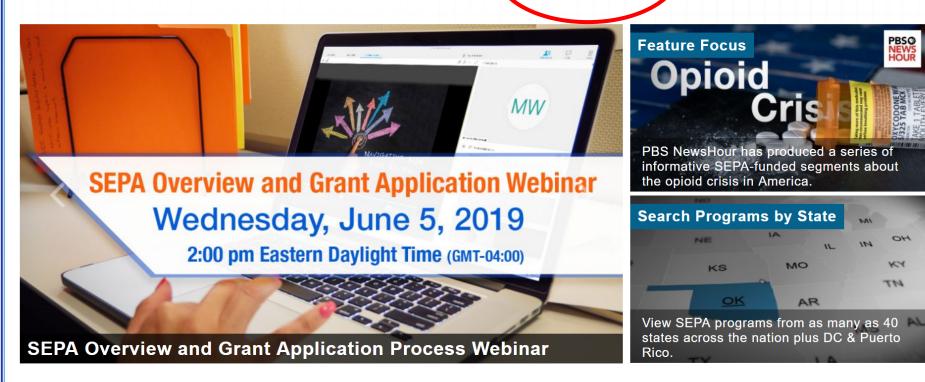




https://nihsepa.org/







https://nihsepa.org/



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Evaluation

Annual Meeting







View SEPA programs from as many as 40 states across the nation plus DC & Puerto Rico.

https://nihsepa.org/

www.nihsepa.org

Search

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SEPA Projects

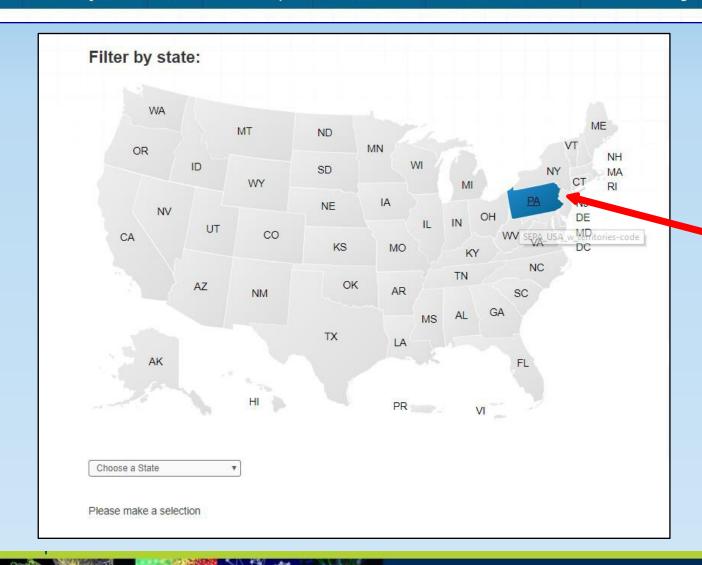
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www.nihsepa.org

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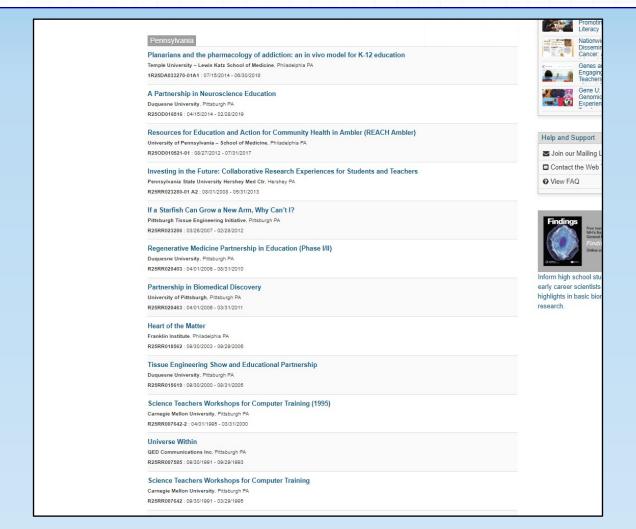
News

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Evaluation Resources

Annual Meeting



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Search

Log in

SEPA Projects

News

Community

Publications

Evaluation Resources

Annual Meeting

Pennsylvania

Pennsylvania

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

R250D016516: 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

R250D010521-01: 08/27/2012 - 07/31/2017

A Partnership in Neuroscience Education

Scientastic! Are You Sleeping?

Winner of two Emmy® Awards!



Project Website(s)

http://thepartnershipineducation.com

Project Description

Abstract

Dissemination

Evaluation(s)

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

Project Information

Project ID: R250D016516

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

Haburah D

Pittsburgh, PA 15282

Project Contact(s):

Pollock, John, PhD

Role: PI / Project Leader Phone: 412-855-4043 Email: pollock@duq.edu

Explore SEPA



DNA is Elementary: Promoting Genetics Literacy



Nationwide Dissemination of Inside Cancer: A SEPA-Funded



Genes and Microbes: Engaging Students and Teachers in NGSS-



Gene U: Inquiry-based Genomics Learning Experiences for

Help and Support

A Partnership in Neuroscience Education



Project Website(s)

http://thepartnershipineducation.com

Project Description

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Pittsburgh, PA 15282

Project Contact(s):

Pollock, John, PhD

Role: PI / Project Leader Phone: 412-855-4043 Email: pollock@duq.edu

Help and Support

A Partnership in Neuroscience Education

Scientastic: Are You Sleeping? | Preview | Scientastic: Are You S

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Pittsburgh, PA 15282

Project Contact(s):

Pollock, John, PhD

Role: PI / Project Leader Phone: 412-855-4043 Email: pollock@duq.edu

Help and Support

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

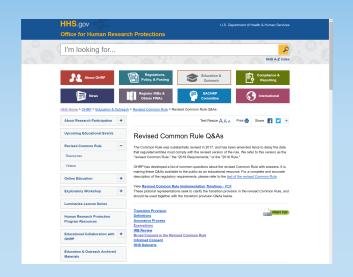
PROGRAM

- Human Subjects
- Inclusion

Rashada Alexander, Ph.D

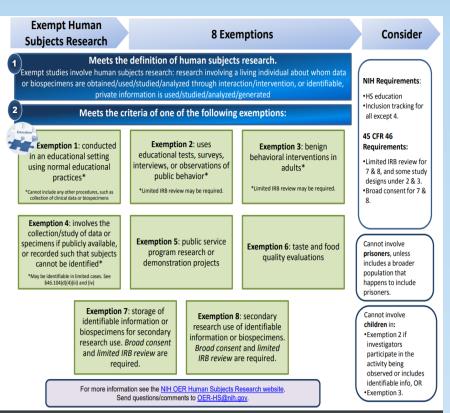


What's New with Human Subjects?



- 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.
- Information to understand the changes:
 https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#collapse-qa-e6
- | County & Compilance | Process | P
- 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/resear-ch.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

Keep in Mind: Definition of Research

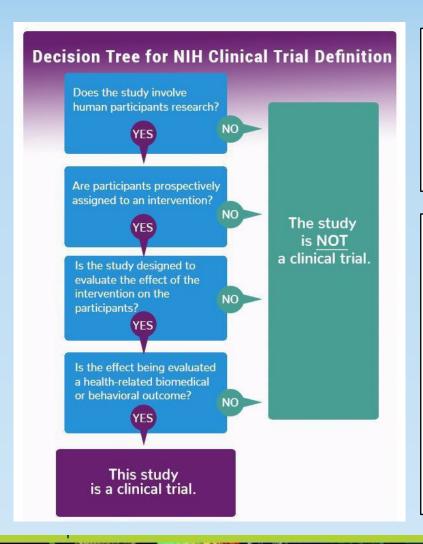
- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- Program evaluations that do not involve experimental or nonstandard interventions, provide information for and about the setting in which the program is 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://www.youtube.com/watch?v=nz
 9NWFhYOG8&list=PLOEUwSnjvqBJeHcb
 4yai7 fDnFZFPEmQK&index=1
- 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."

| View Burden State | | | OMB Number: 0925-0001 Expiration Date: 03/31/2000 |
|--|---|-------------------------|--|
| | in subjects section of the Research & Related Ot less from the Research & Related Other Project Is | - | form prior to completing this form. played here for your reference. Any changes to these |
| fields must be made on the | Research & Related Other Project Information f | form and may impact the | e data items you are required to complete on this form. |
| | Are Human Subjects Involved? | Yes | No No |
| | is the Project Exempt from Federal regular Exemption number: | | 3 7 4 7 5 7 6 7 7 8 |
| | | | |
| If No to Human Subjec | ats | | |
| Does the proposed | research involve human specimens and/or data? | ? Yes | □No |
| l'Yes, provide an o | explanation of why the application does not involve | ve human subjects rese | ard. |
| | | | Delete Attachment View Attachment |
| Skip the rest of the | PHS Human Subjects and Clinical Trials Informa | | |
| If Yes to Human Subje | ects | | |
| Other Requested Inford Study Record(s) | Click here to estract the Human records using unique filenames. | | Dalete Attachment Mew Attachment ord Attachment |
| 1) Please attach Huma Add New Study | in Subject Study 1 | | Add Attachment Delete Attachment Mew Attachment |
| | es) | | |
| Delayed Onset Study(i | | Anticipated | Justification |
| Delayed Onset Study() | Study Title | Clinical Trial? | Justification |
| Delayed Onset Study(i) | Study Title | | Add Allachment Celete Allachment Wew Atlachment |
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| Delayed Onset Study(i) X Add New Delayed C | | | |
| K | | | |

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

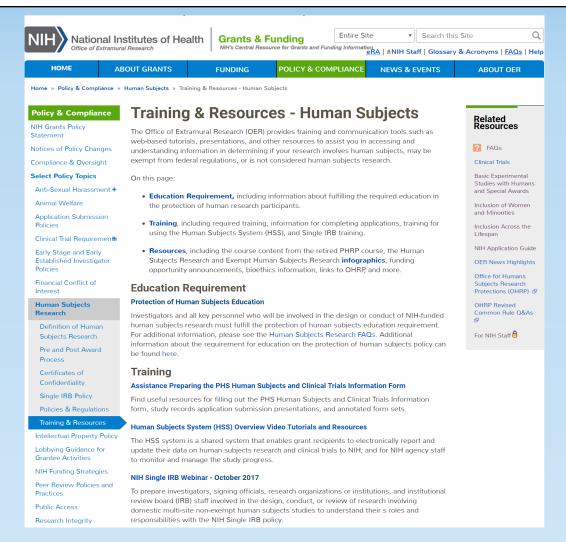
FAQ C.3: What are some examples of outcomes that are not "health related biomedical or behavioral"?

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

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 Partner Commitment

Letters of commitment from partners and/or collaborators must be attached as part of Letters of Support

GRANTS MANAGEMENT BASICS

Brian Iglesias



- 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.



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.

Aminimum 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.



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.



Unallowable Costs:

- <u>Stipends</u> 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.

- 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.
- http://grants.nih.gov/grants/financial/fiscal policy faq .htm



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

- APPROACH
 - 3 Specific Aims: SA1, SA2, SA3; SA1.1, SA.1.2
 - Evaluator input
 - Teacher input
 - Logic Model
 - Validated evaluation instruments
 - Control group(s)
 - Potential problems & solutions
 - Literature documentation
- Visual
 - Time & Events
 - Tables, figures, charts
 - Images
- Letters of support



"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?

