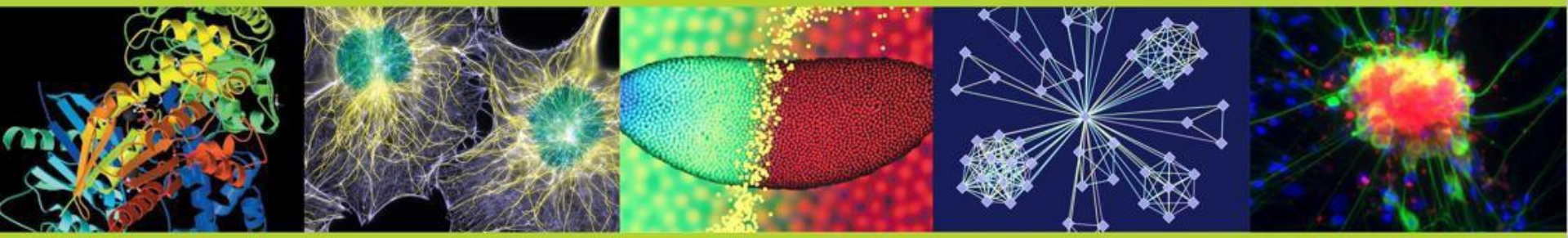
National Institute of General Medical Sciences (NIGMS)
Division for Research Capacity Building
National Institutes of Health (NIH)



NIH National Institute of General Medical Sciences

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)

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of General Medical Sciences (NIGMS)
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
Tony Beck, Ph.D. (SEPA)
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Peer Review Contact
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Center for Scientific Review (CSR)
Email: ariasj@csr.nih.gov

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

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD
Supported by the National Institutes of Health

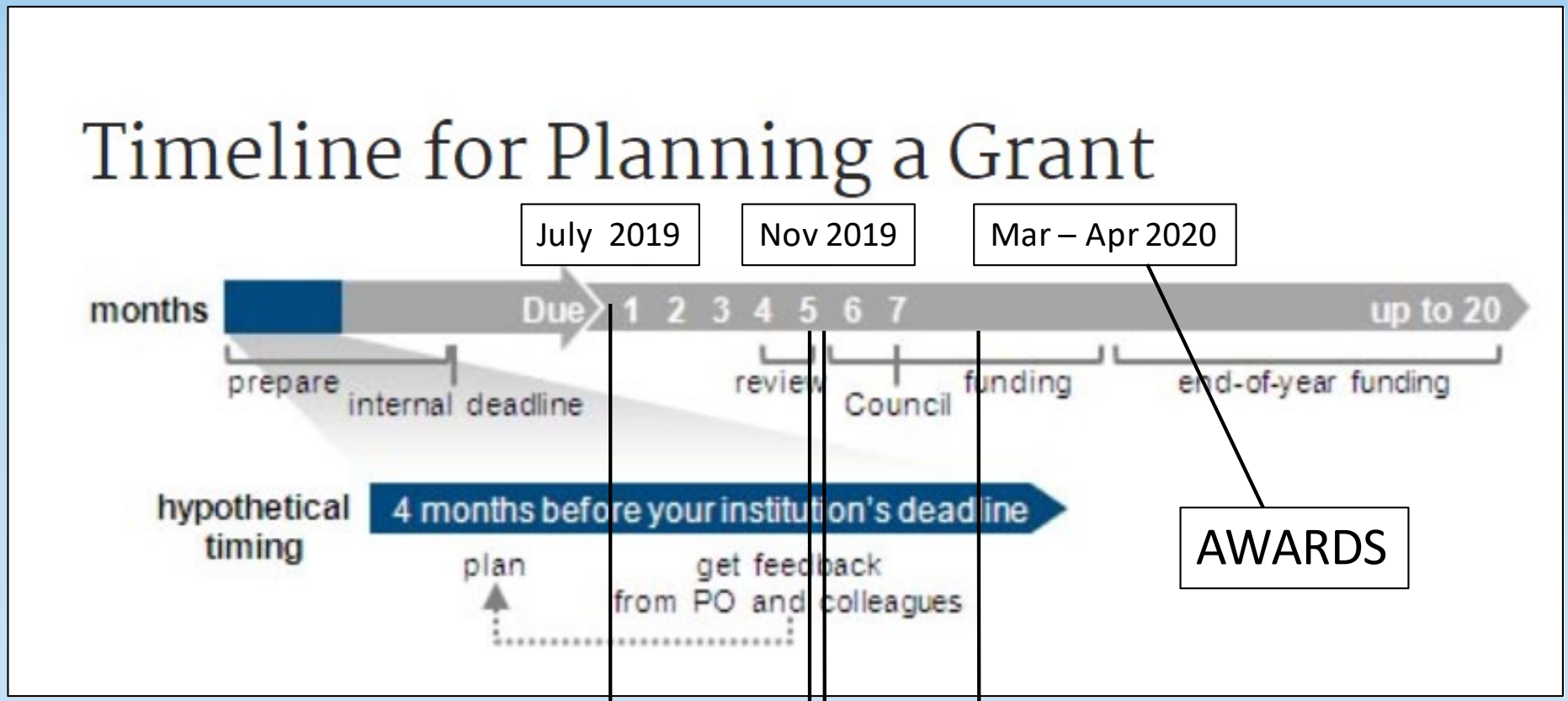
Celebrating 25 years

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



July 2019

Nov 2019

Mar – Apr 2020

AWARDS

RECEIPT DATE

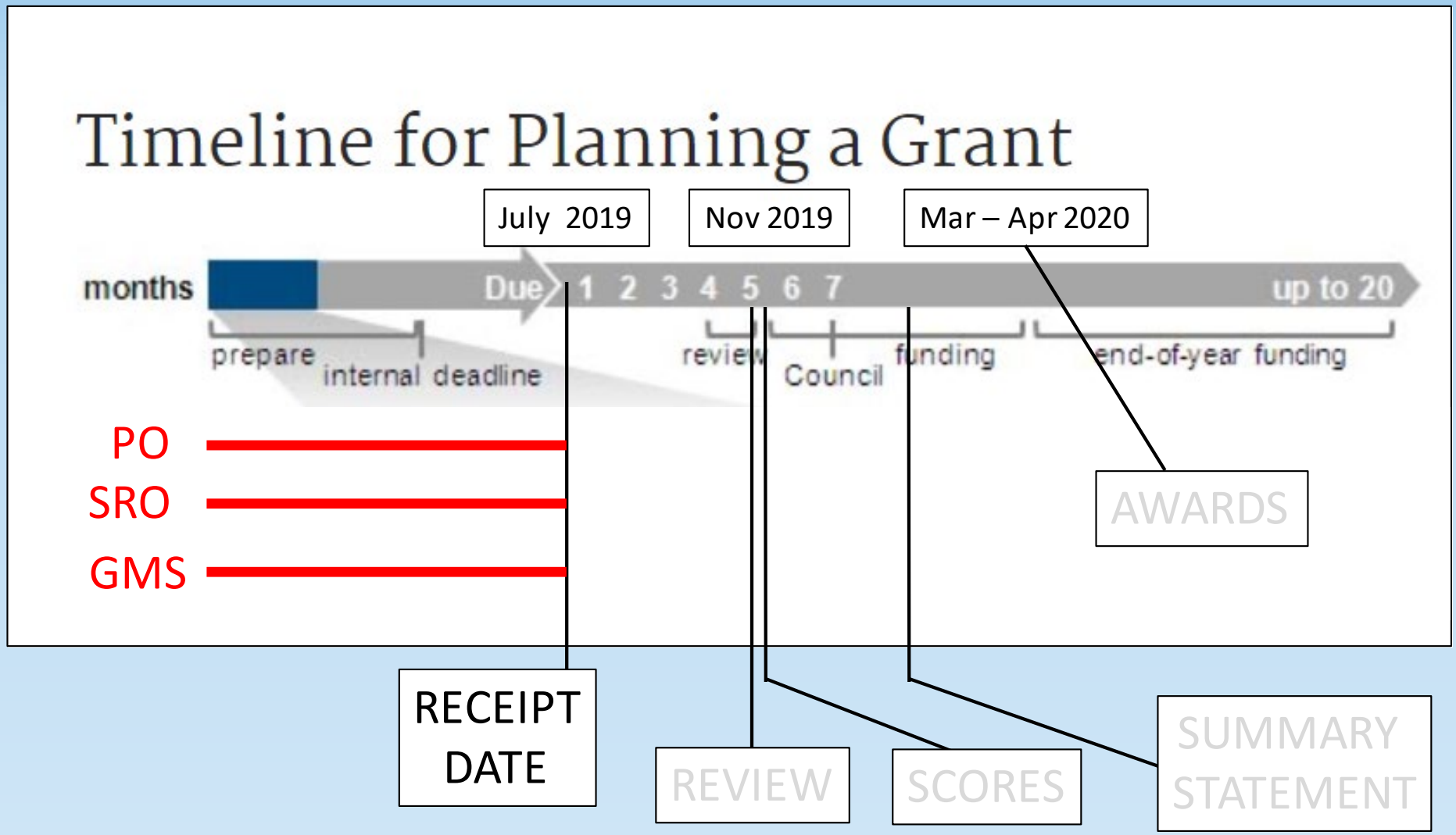
REVIEW

SCORES

SUMMARY STATEMENT

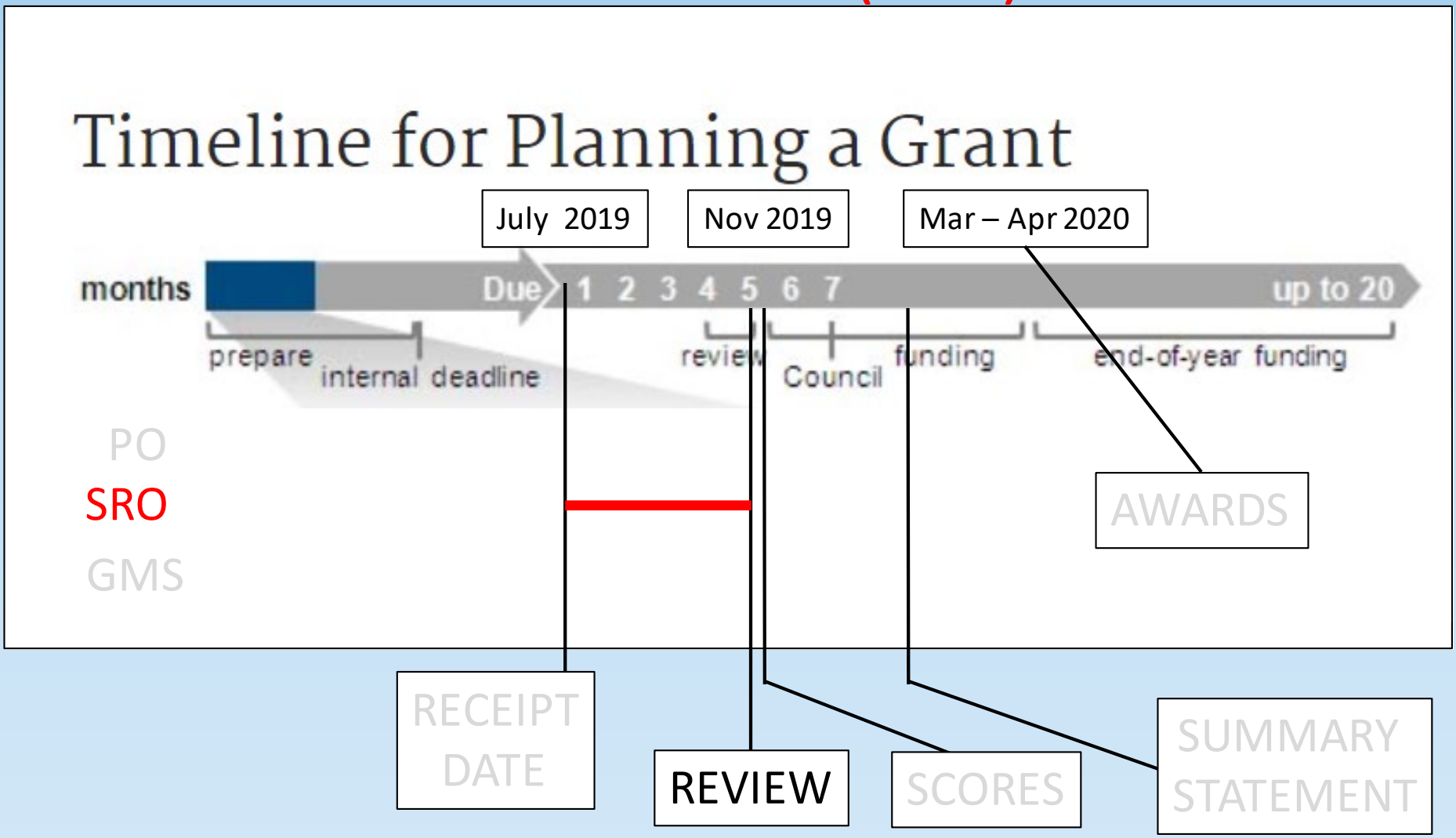
FY19 SEPA Review & Award Cycle

staff contacts



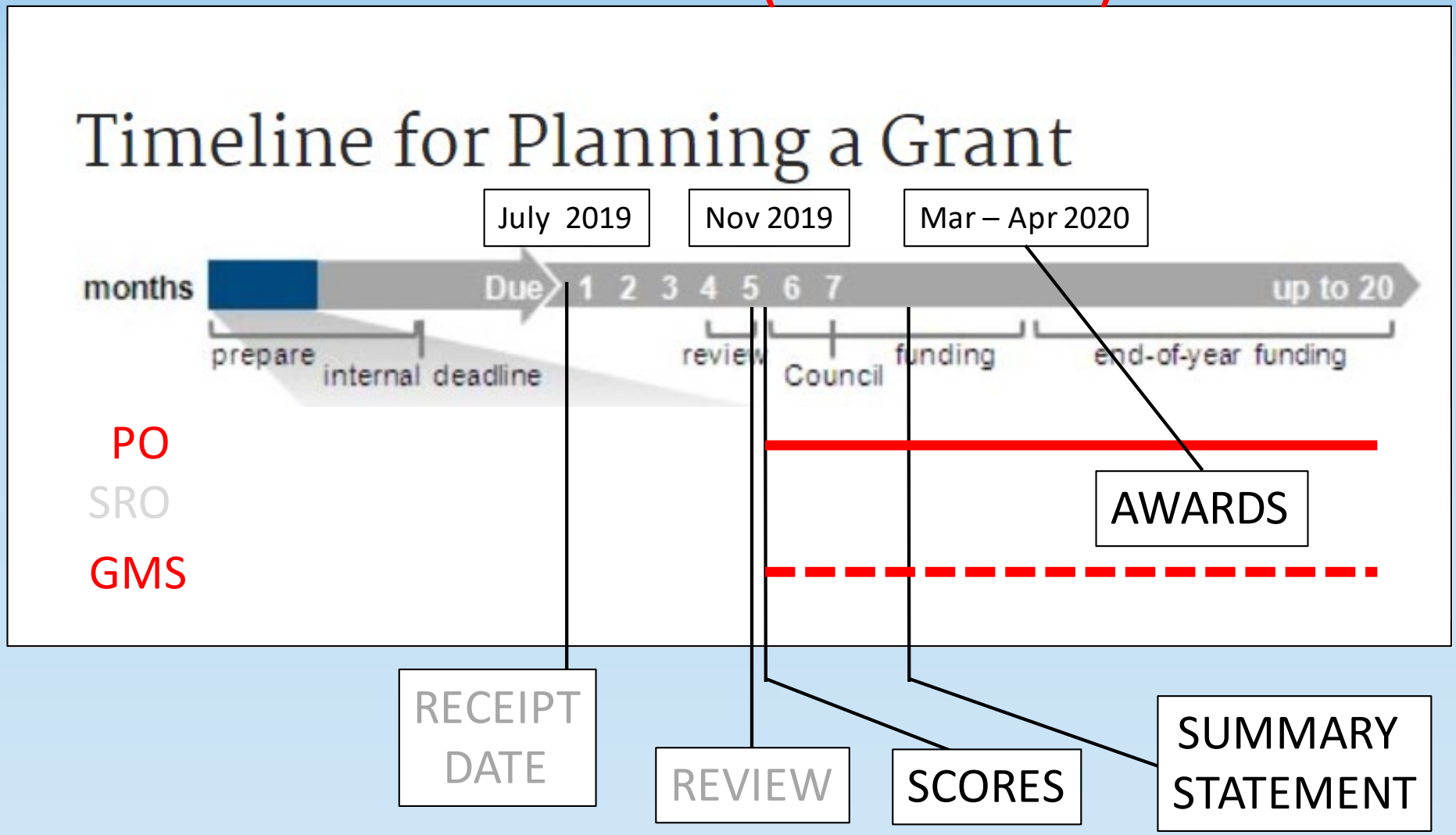
FY19 SEPA Review & Award Cycle

staff contacts (SRO)



FY19 SEPA Review & Award Cycle

staff contacts (PO & GMS)



SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

Supported by the National Institutes of Health

Our goal - a diverse pipeline

Purpose

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

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

Supported by the National Institutes of Health

Our goal - a diverse pipeline

Partnerships

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

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

Supported by the National Institutes of Health

Our goal - a diverse pipeline

Goals

- Career opportunities for minority and underserved students to increase workforce diversity
- Teacher professional development

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

Supported by the National Institutes of Health

Our goal - a diverse pipeline

Target Audiences

- Pre-K to grade 12
- General public

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

Supported by the National Institutes of Health

Our goal - a diverse pipeline

Topics

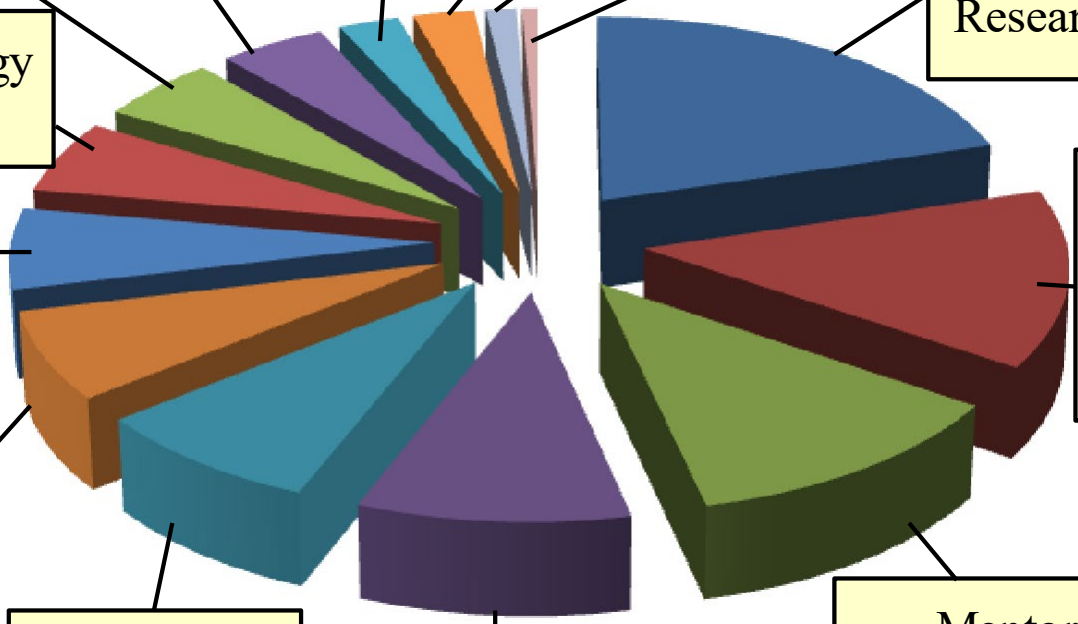
- Any area of NIH funded basic or medical research

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

Supported by the National Institutes of Health

Our goal - a diverse pipeline

SEPA Project Diversity



Interactive Digital Media

Veterinary Medicine

Citizen Science

Early Stem

Molecular Biology

Systems: Aging, Hearing, Brain, Lung, Bone

Basic & Clinical Research Methods

Microbiology, Virology & Disease Vectors

Infectious Disease, Immunology & Epidemiology

Nutrition, Obesity, Diabetes & Cardiovascular

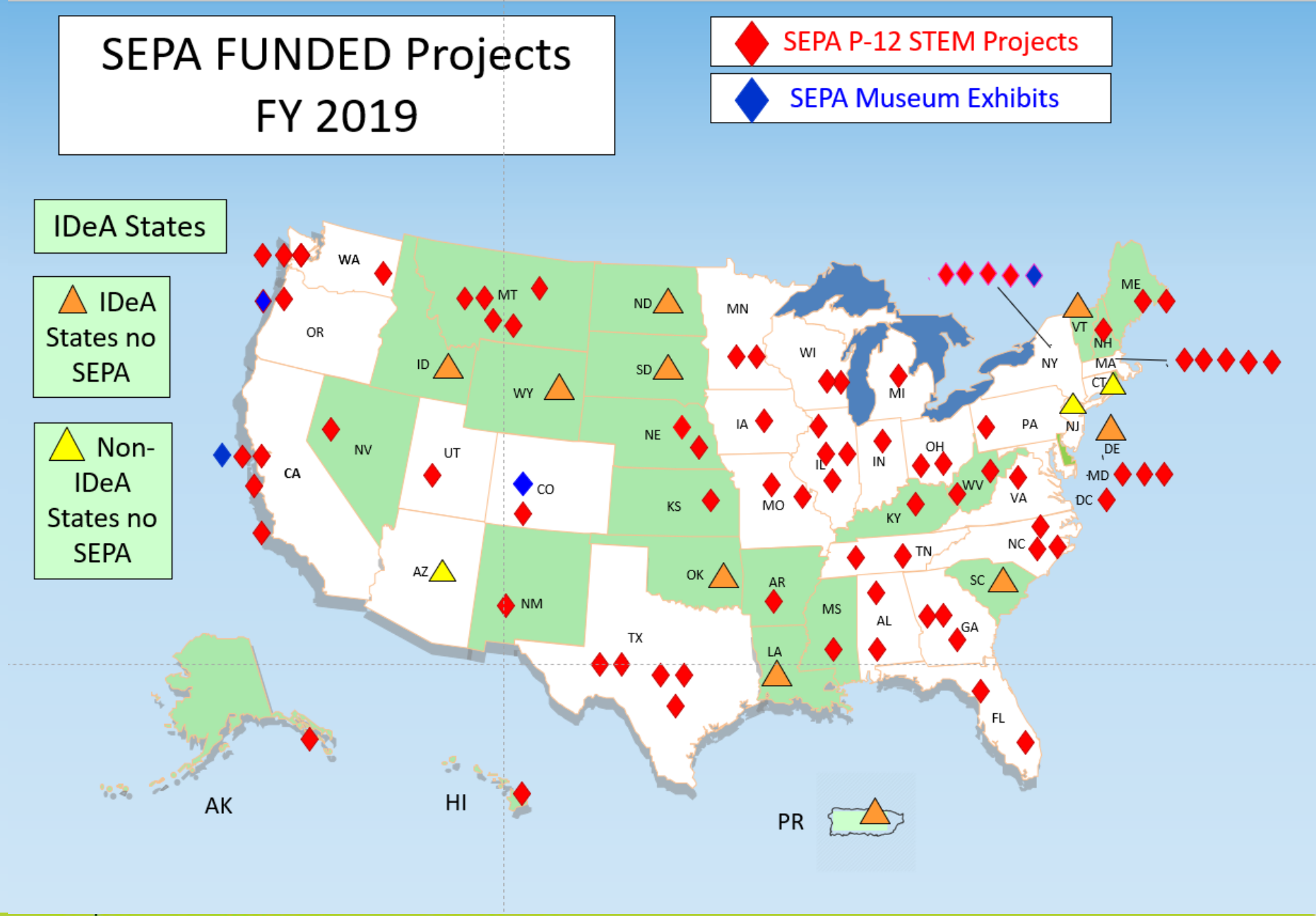
Community Understanding about Clinical Trials

Human Genetics & Genomics

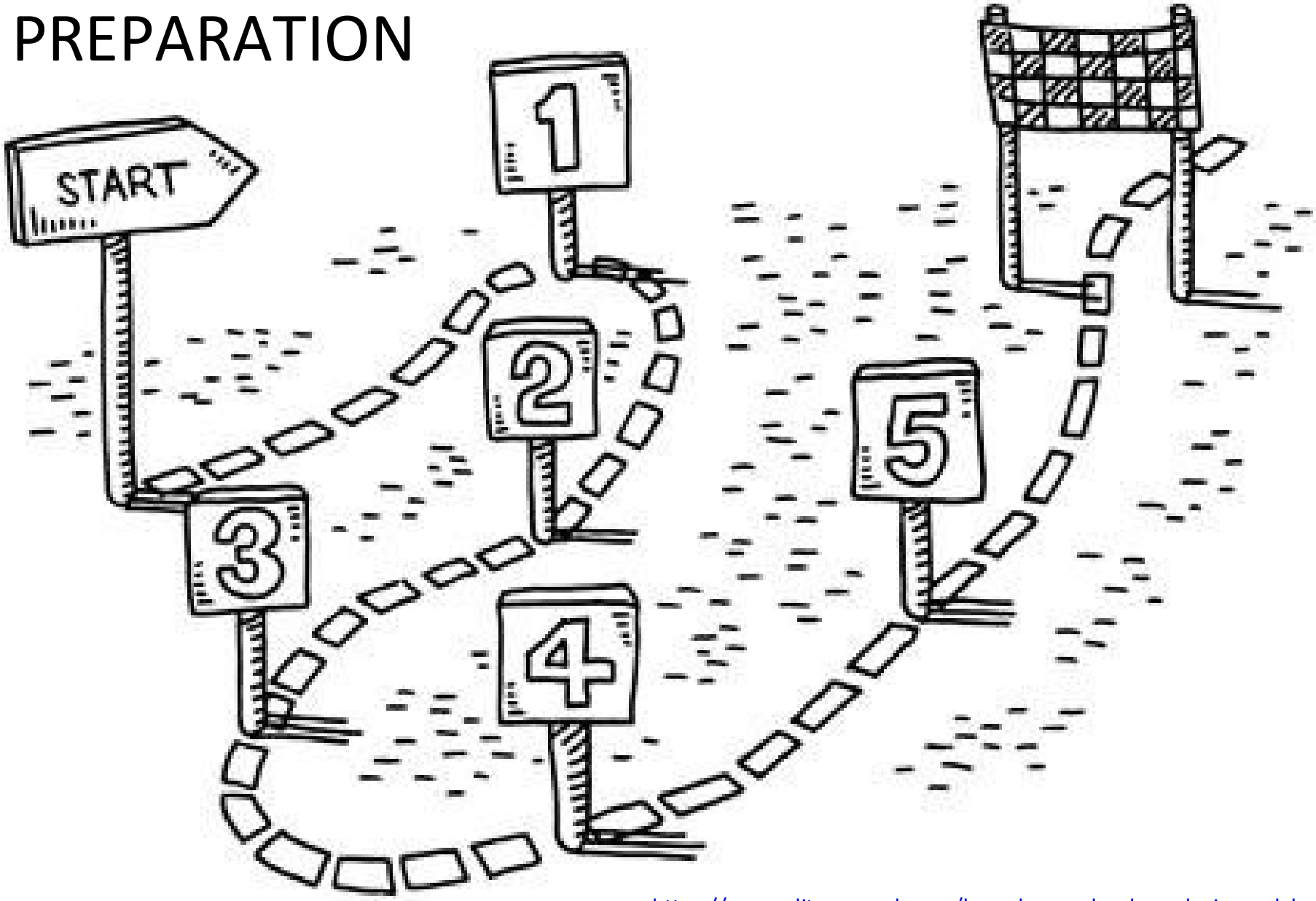
Public Health, Lifestyle & Health

Mentoring, Workforce Development & Teacher Professional Development

SEPA FUNDED Projects FY 2019

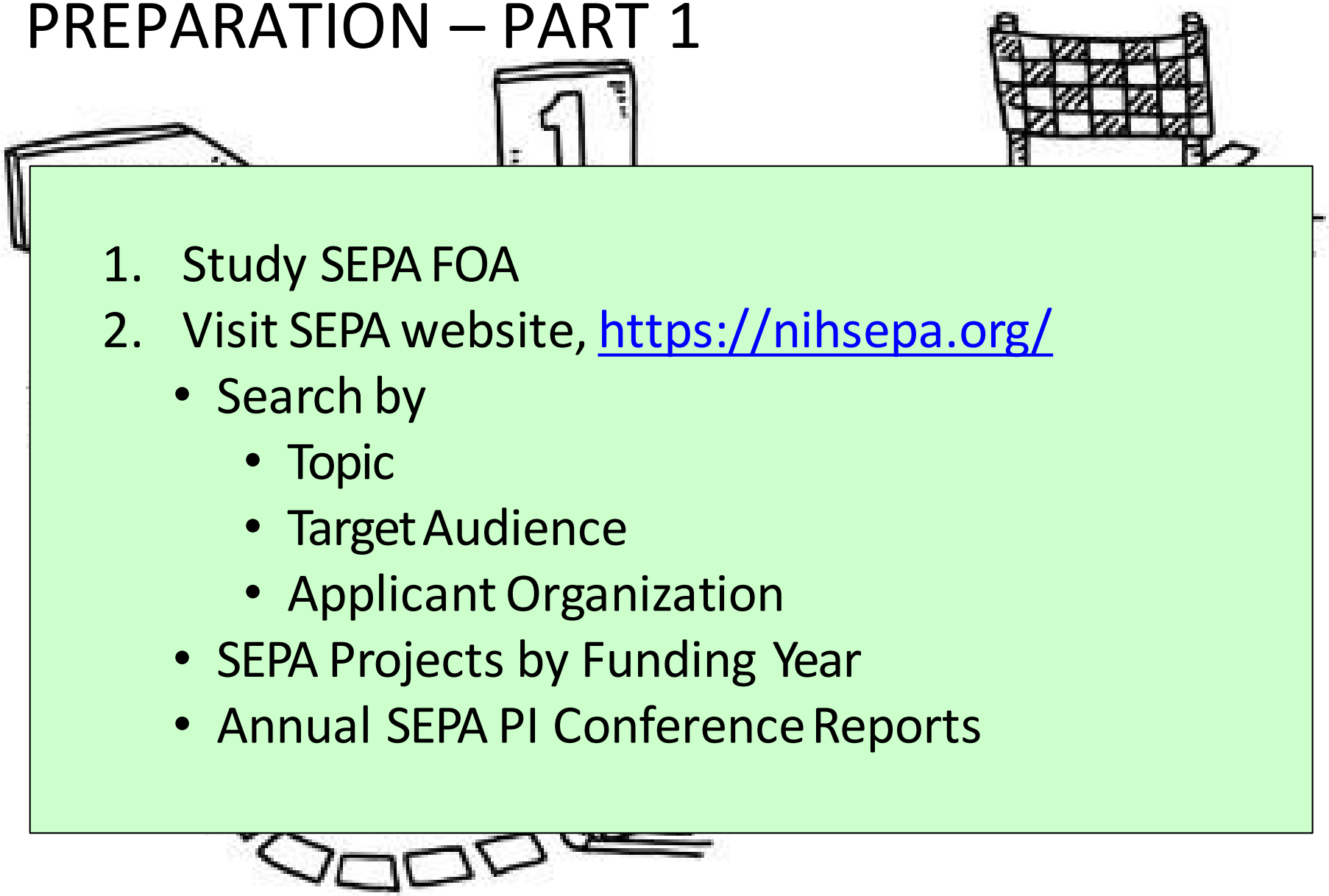


PREPARATION



https://www.eliteresearch.com/how-do-you-develop-a-logic-model

PREPARATION – PART 1

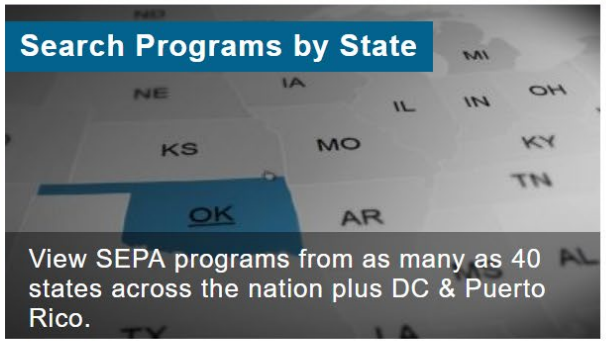


1. Study SEPA FOA
2. Visit SEPA website, https://nihsepa.org/
   - Search by
     - Topic
     - Target Audience
     - Applicant Organization
   - SEPA Projects by Funding Year
   - Annual SEPA PI Conference Reports

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD

SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH

https://nihsepa.org/



https://nihsepa.org/

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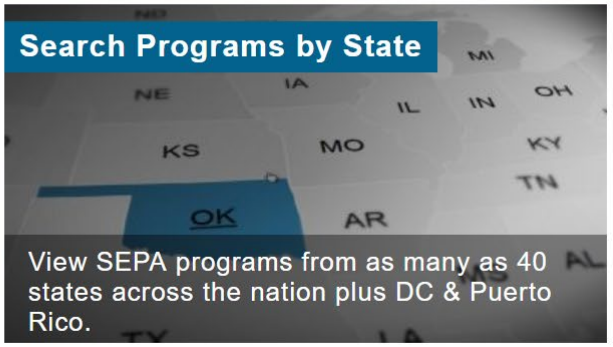
SEPA Projects | Publications | News | Community | Evaluation | Annual Meeting

- Projects by Funding Year
- Projects by State
- Participating Institutions
- Institutions by State



https://nihsepa.org/

NIH National Institute of General Medical Sciences

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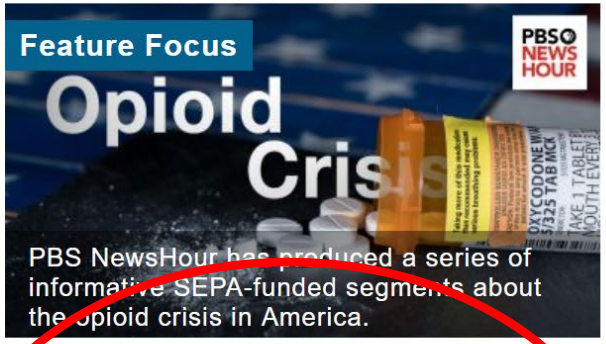

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NIH National Institute of General Medical Sciences

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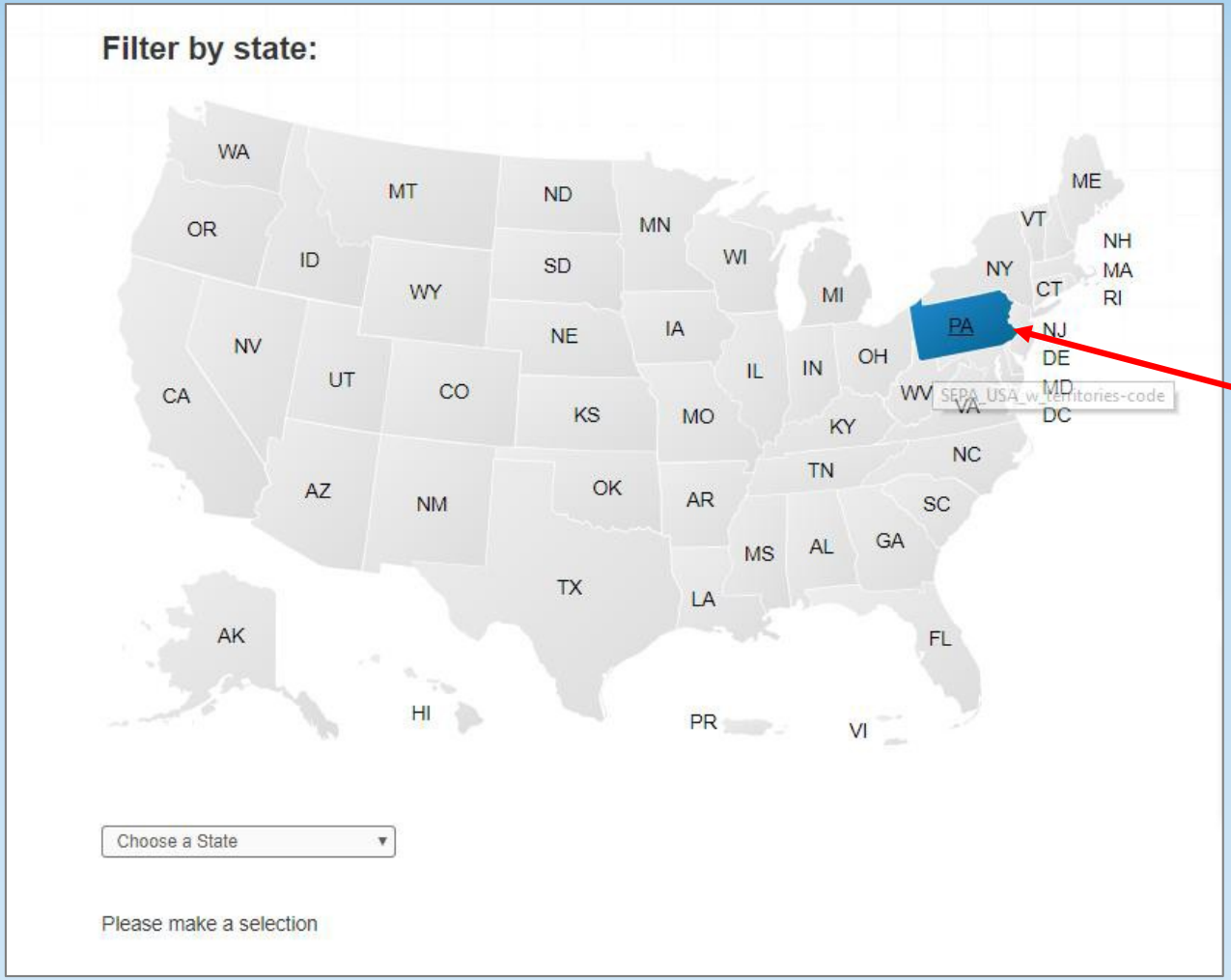

PA

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SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH

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Pennsylvania

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
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

Investing in the Future: Collaborative Research Experiences for Students and Teachers
Pennsylvania State University Hershey Med Ctr, Hershey PA
R25RR023280-01 A2 : 08/01/2008 - 05/31/2013

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 I/II
Duquesne University, Pittsburgh PA
R25RR020403 : 04/01/2006 - 08/31/2010

Partnership in Biomedical Discovery
University of Pittsburgh, Pittsburgh PA
R25RR020463 : 04/01/2006 - 03/31/2011

Heart of the Matter
Franklin Institute, Philadelphia PA
R25RR018562 : 09/30/2003 - 09/29/2006

NIH National Institute of General Medical Sciences

SEPA SCIENCE EDUCATION PARTNERSHIP AWARD
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Pennsylvania

Pennsylvania

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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NIH National Institute of General Medical Sciences

A Partnership in Neuroscience Education

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: **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

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

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Pollock, John, PhD
Role: PI / Project Leader
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Help and Support

A Partnership in Neuroscience Education

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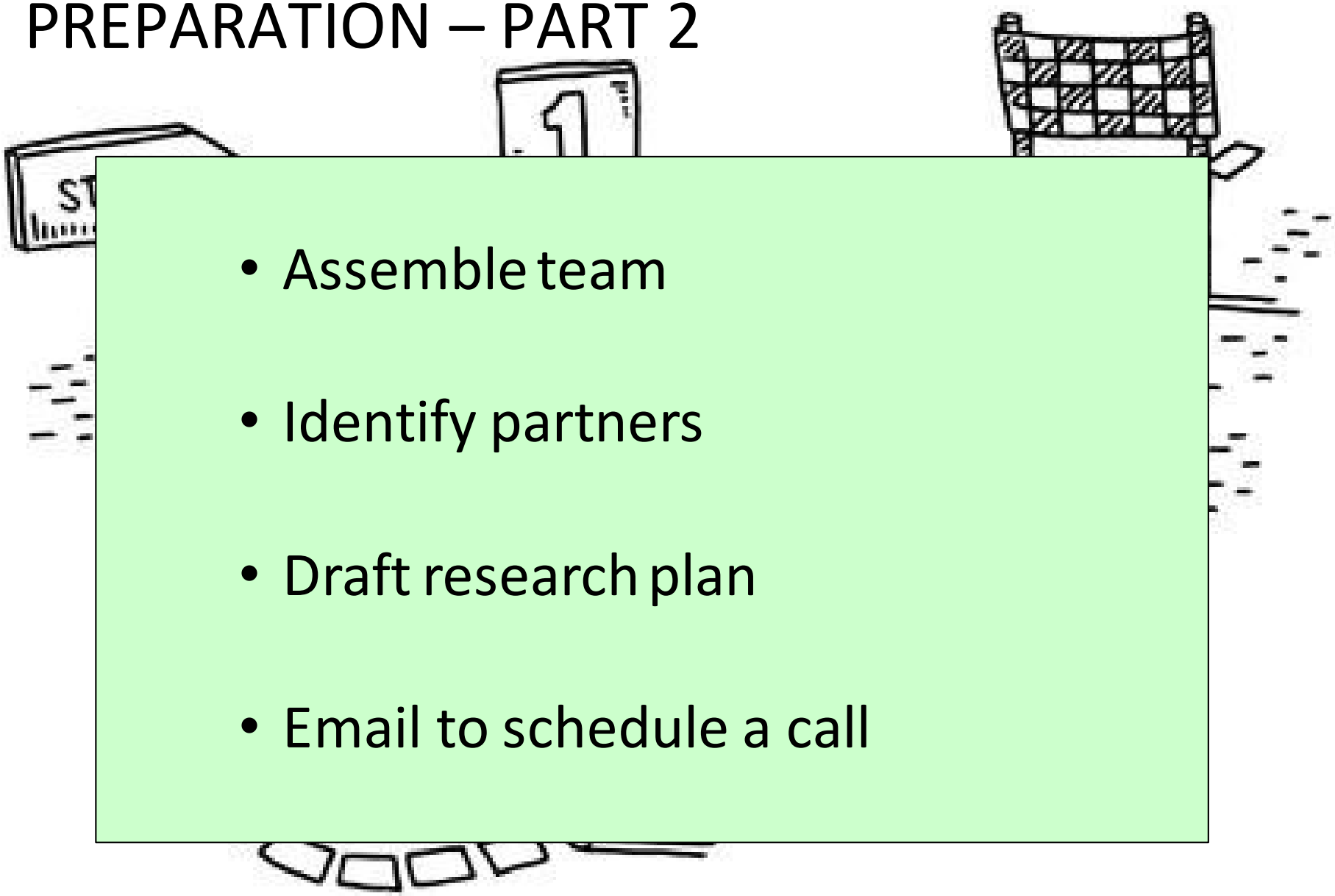
Pittsburgh, PA 15282

Project Contact(s):

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

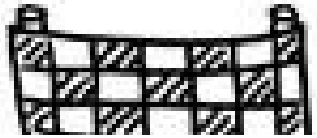
Help and Support

PREPARATION – PART 2



- Assemble team
- Identify partners
- Draft research plan
- Email to schedule a call

PREPARATION – PART 3

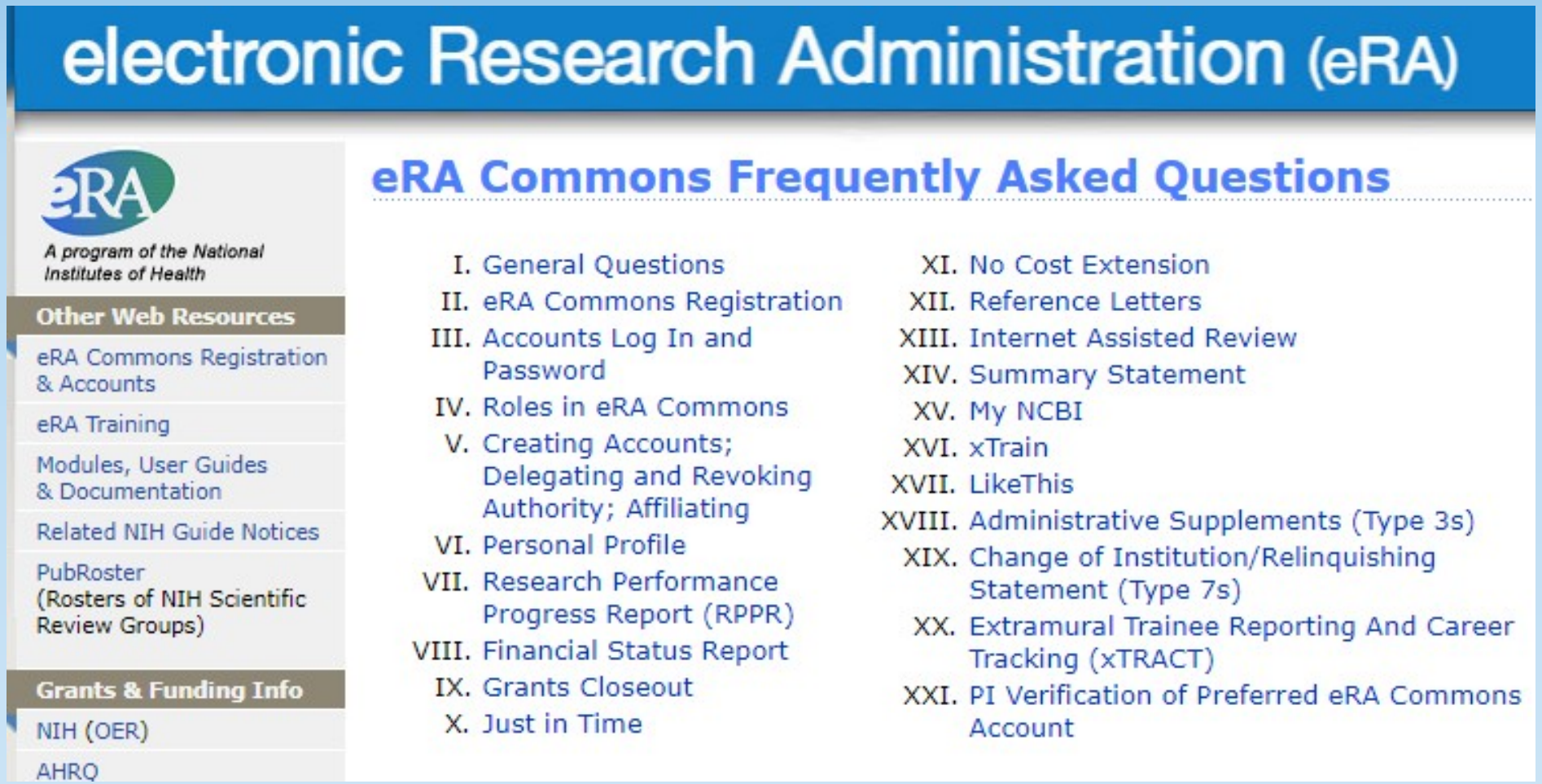


Electronic Application Process

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 3



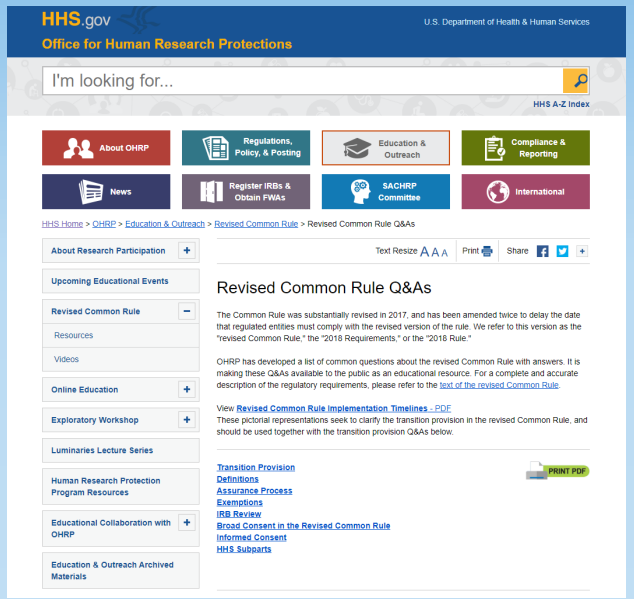
https://era.nih.gov/commons/faq_commons.cfm

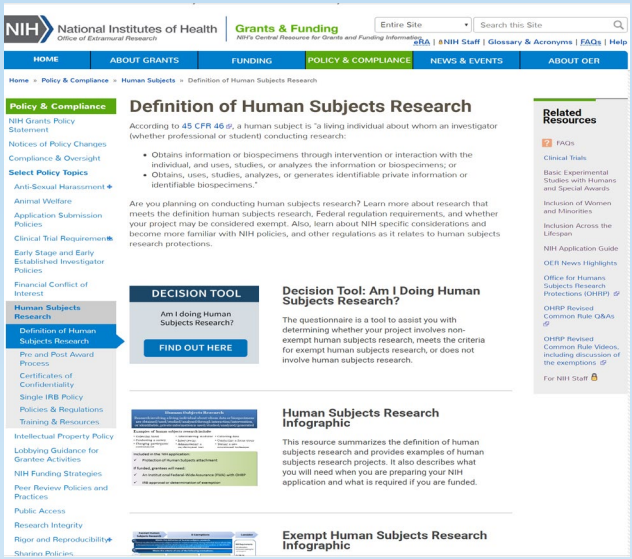
PROGRAM

- Human Subjects
- Inclusion

Rashada Alexander, Ph.D

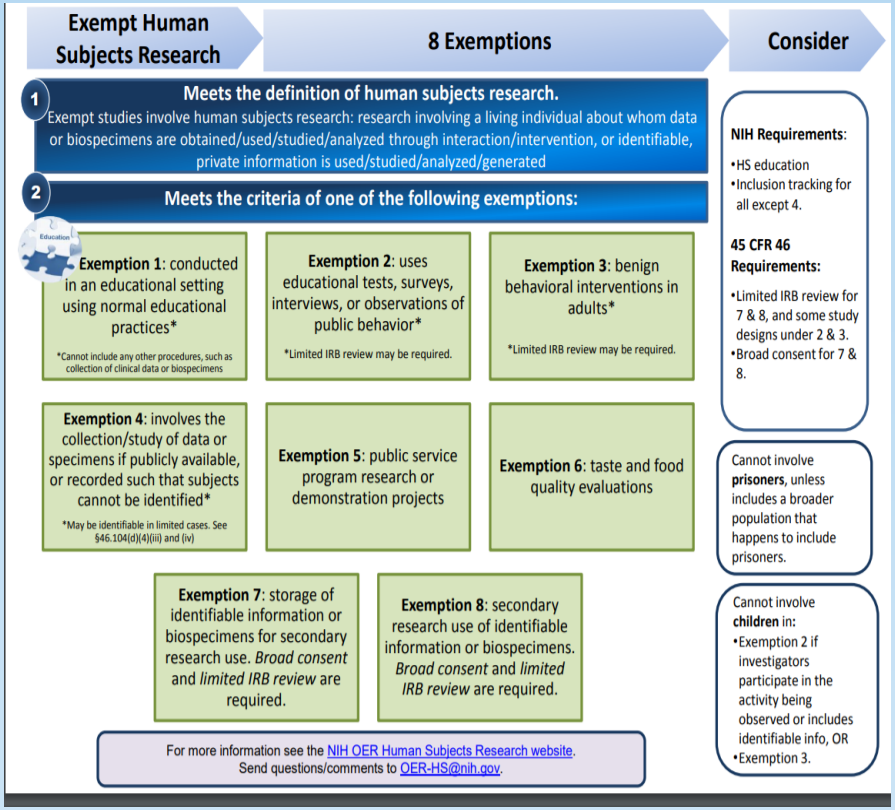
What's New with Human Subjects?





- 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.**
- 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
- 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

I think I have a project with human subjects. What next?



https://grants.nih.gov/sites/default/files/exemption_infographic_v7_508c-4-4-19.pdf

- 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

≠

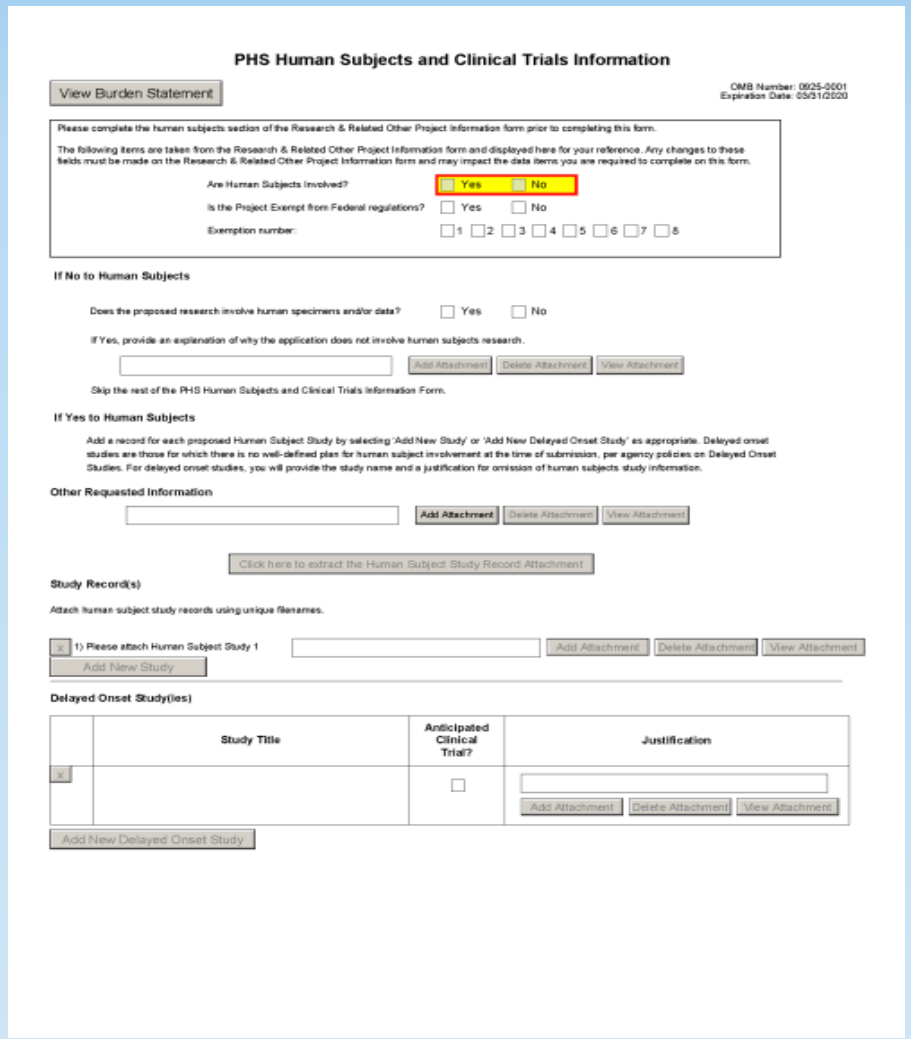
Clinical Research

Keep in Mind: Definition of Research

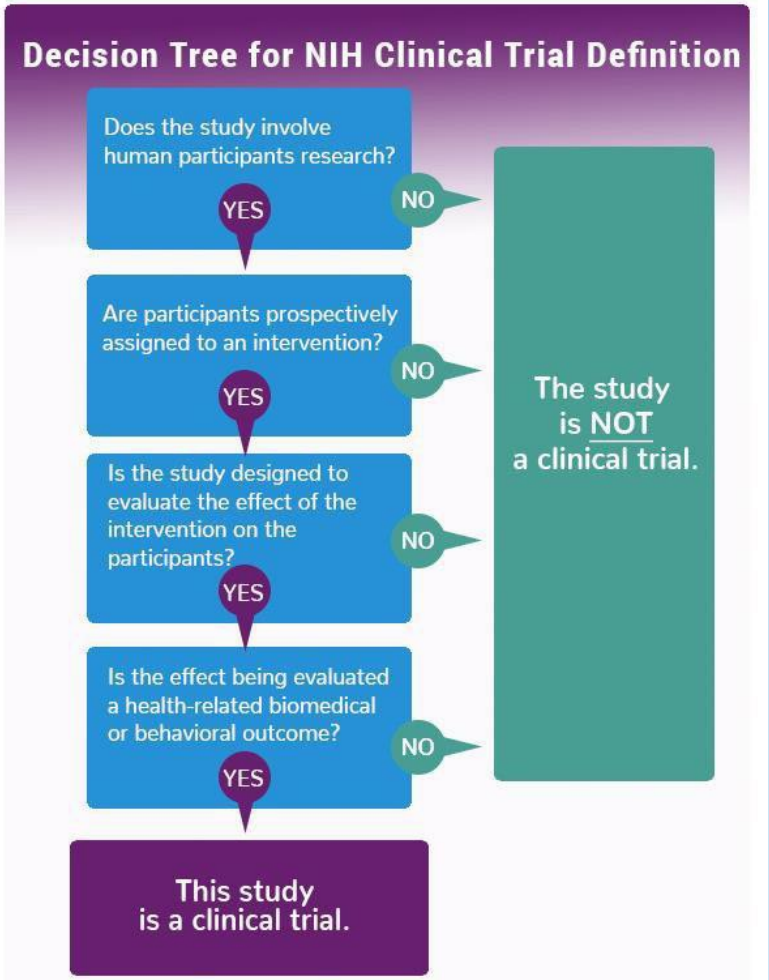
- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge.**
- Program evaluations that do not involve experimental or non-standard interventions, provide information for and about the setting in which the program 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

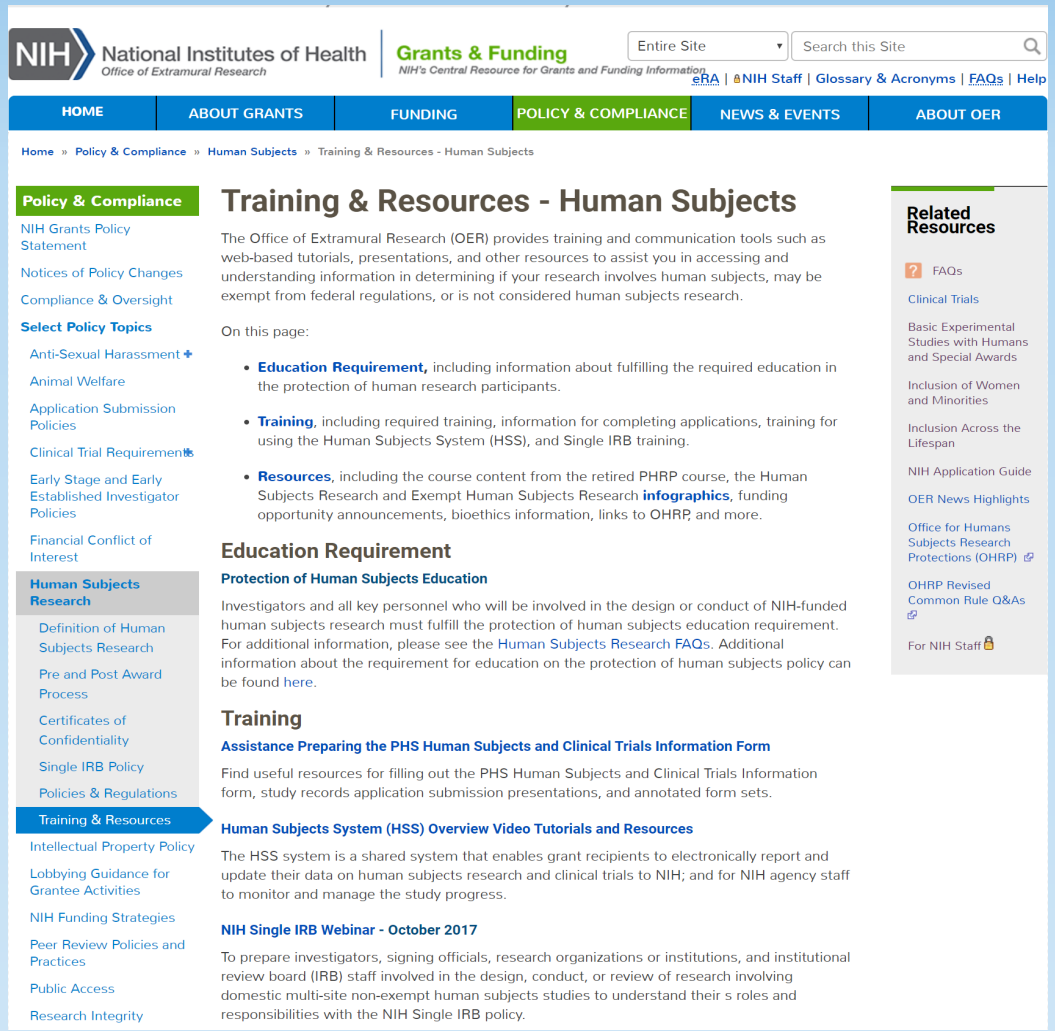
FAQ C.3: **What are some examples of outcomes that are not "health related biomedical or behavioral"?**

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



NIH National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

Entire Site | Search this Site

eRA | NIH Staff | Glossary & Acronyms | FAQs | Help

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER

Home » Policy & Compliance » Human Subjects » Training & Resources - Human Subjects

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight

Select Policy Topics

- Anti-Sexual Harassment
- Animal Welfare
- Application Submission Policies
- Clinical Trial Requirements
- Early Stage and Early Established Investigator Policies
- Financial Conflict of Interest
- **Human Subjects Research**
  - Definition of Human Subjects Research
  - Pre and Post Award Process
  - Certificates of Confidentiality
  - 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

Training & Resources - Human Subjects

The Office of Extramural Research (OER) provides training and communication tools such as web-based tutorials, presentations, and other resources to assist you in accessing and understanding information in determining if your research involves human subjects, may be exempt from federal regulations, or is not considered human subjects research.

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 s roles and responsibilities with the NIH Single IRB policy.

Related Resources

- FAQs
- Clinical Trials
- Basic Experimental Studies with Humans and Special Awards
- Inclusion of Women and Minorities
- Inclusion Across the Lifespan
- NIH Application Guide
- OER News Highlights
- Office for Humans Subjects Research Protections (OHRP)
- OHRP Revised Common Rule Q&As
- For NIH Staff

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

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.
- http://grants.nih.gov/grants/financial/fiscal_policy_faq.htm

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

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?