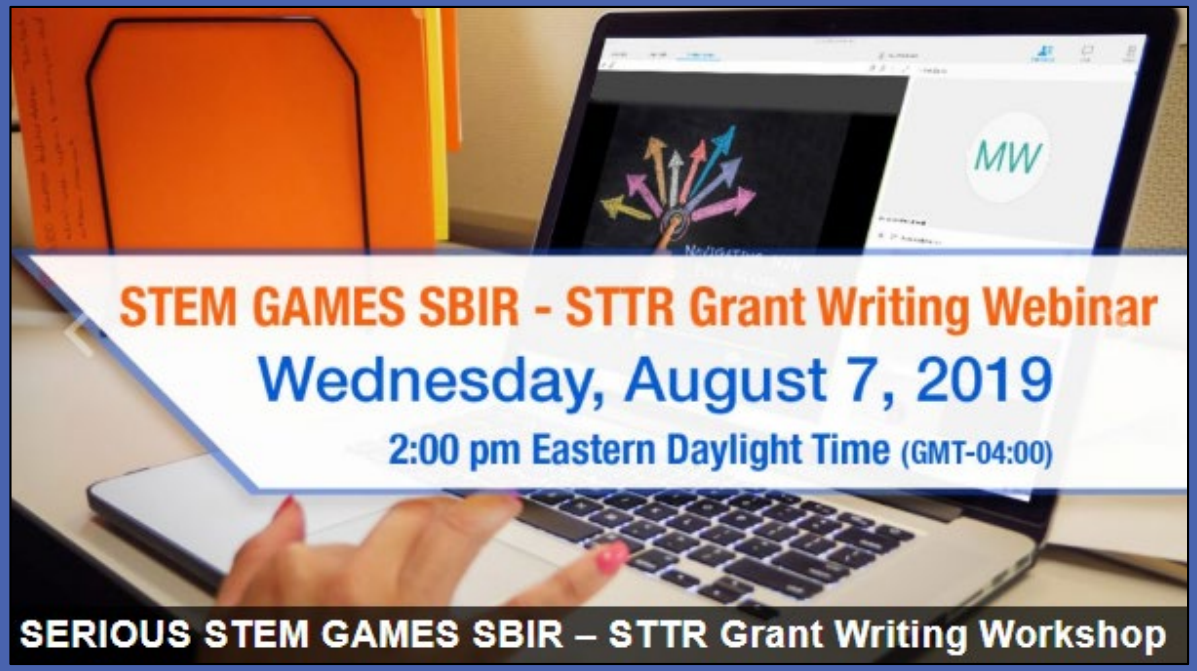
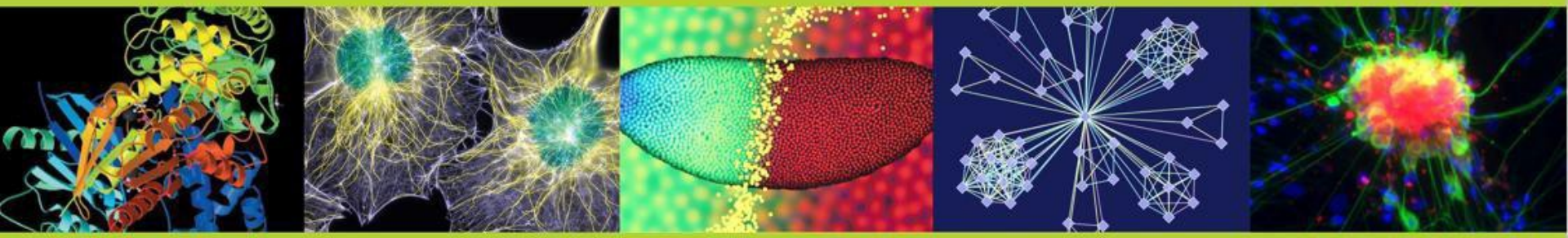


National Institute of General Medical Sciences (NIGMS)
Division for Research Capacity Building
National Institutes of Health (NIH)



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.
National Institute of General Medical Sciences (NIGMS)
Email: rashada.alexander@nih.gov

Peer Review

Marie-Jose Belanger, Ph.D.
Center for Scientific Review (CSR)
Email: belanger@csr.nih.gov

Financial/Grants Management

Brian Iglesias
National Institute of General Medical Sciences (NIGMS)
Email: iglesiab@mail.nih.gov

NIH National Institutes of Health

SBIR/STTR

SMALL BUSINESS INNOVATION RESEARCH
SMALL BUSINESS TECHNOLOGY TRANSFER

SBIR Purpose and Goals

- Stimulate technological innovation
- Use small business to meet Federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from Federal R&D

Small Business Innovation Development Act of 1982

P.L. 112-81 Re-Authorizes program through FY2017

SBIR Purpose and Goals

- Stimulate and foster scientific and technological innovation through cooperative research and development carried out **between** small business concerns and research institutions
- Foster technology transfer between small business concerns and research institutions

Small Business Innovation Development Act of 1982

P.L. 112-81 Re-Authorizes program through FY2017

SBIR and STTR Critical Differences

• Research Partner

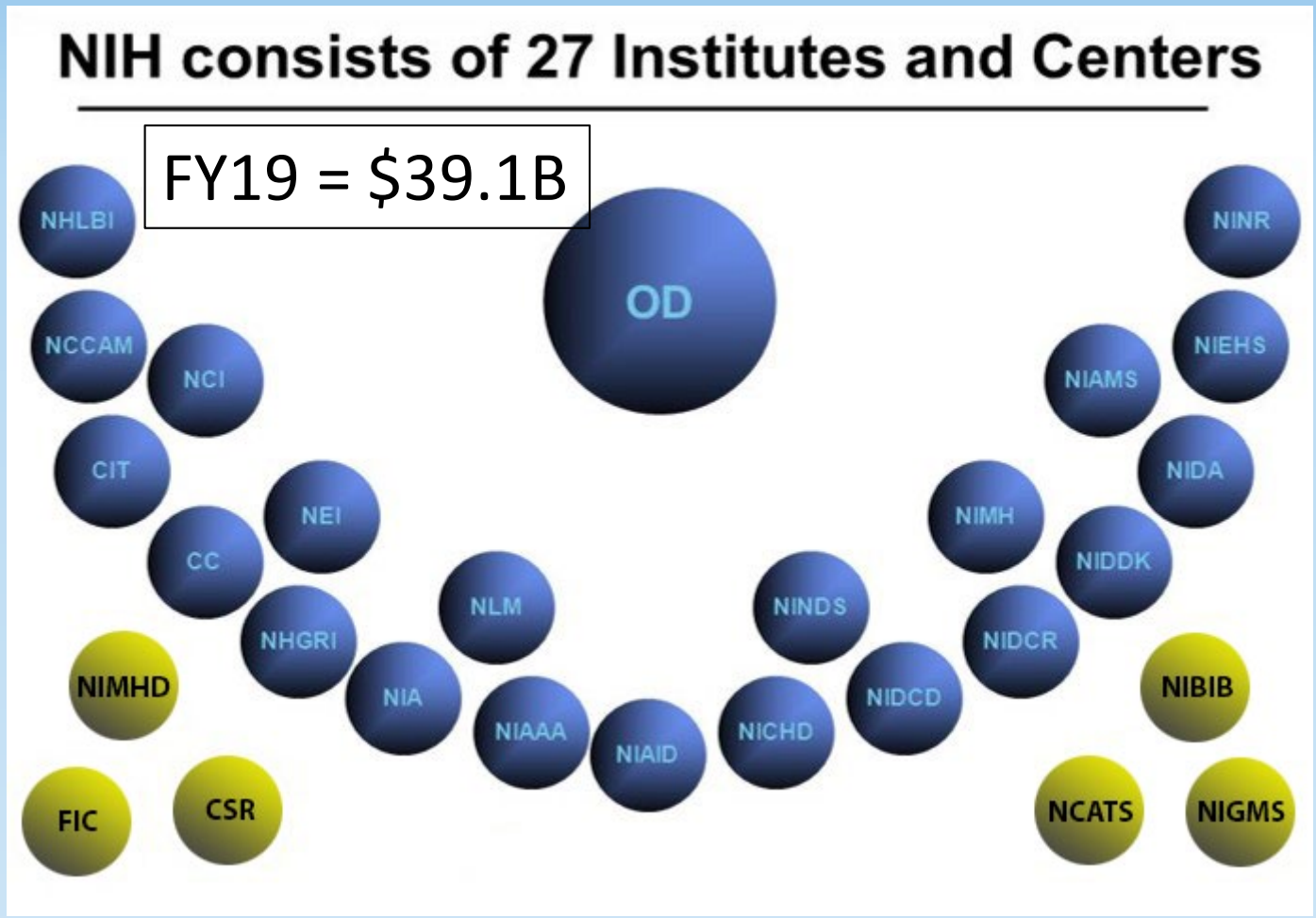
- SBIR: Permits partnering *33% Phase I and 50% Phase II*
- STTR: Requires partnering with research institution. *Small business (40%) and U.S. research institution (30%)*

• Principal Investigator

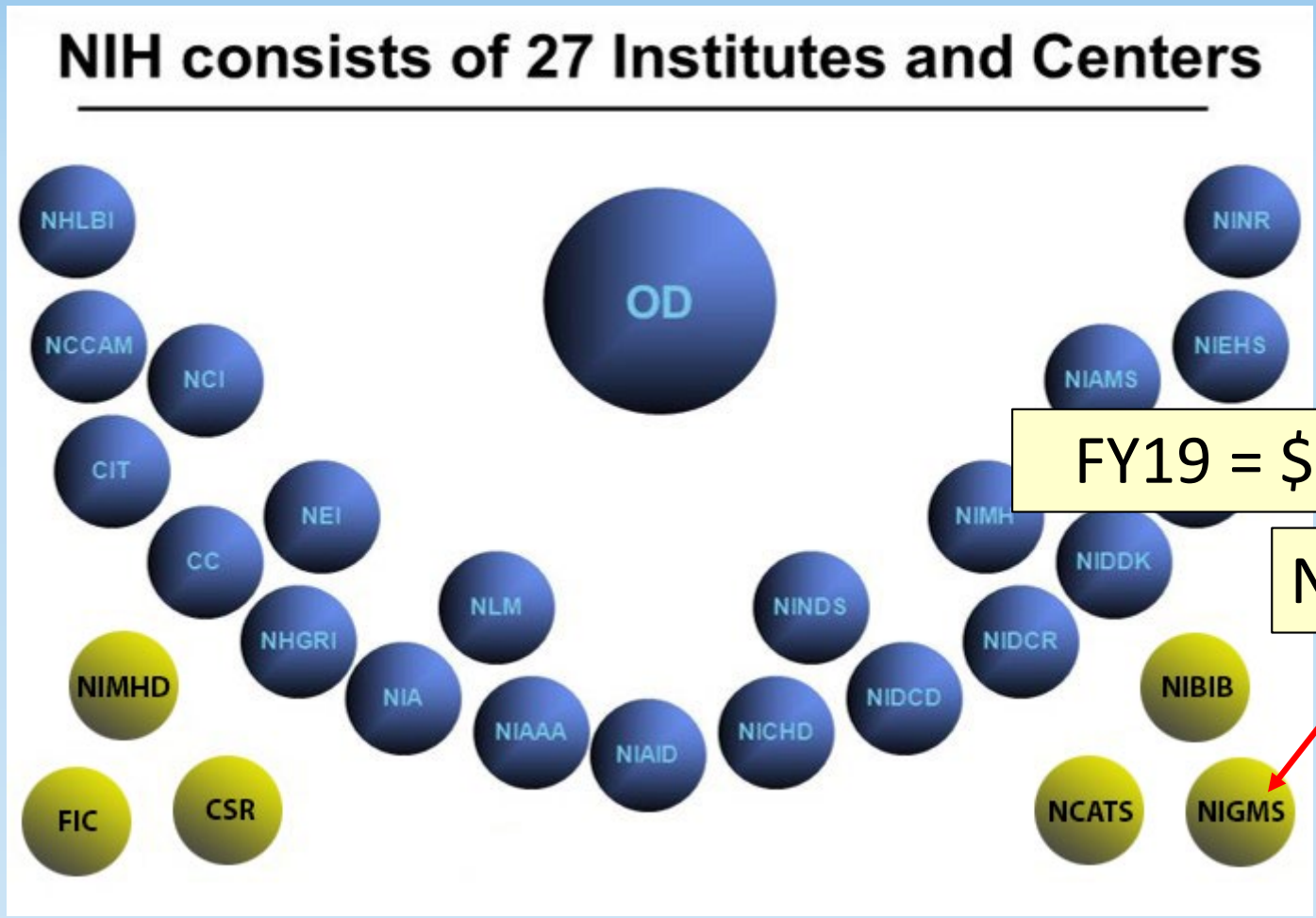
- SBIR: Primary (>50%) employment must be with small business concern
- STTR: PI may be employed by either research institution or small business concern

Award is always made to Small Business Concern

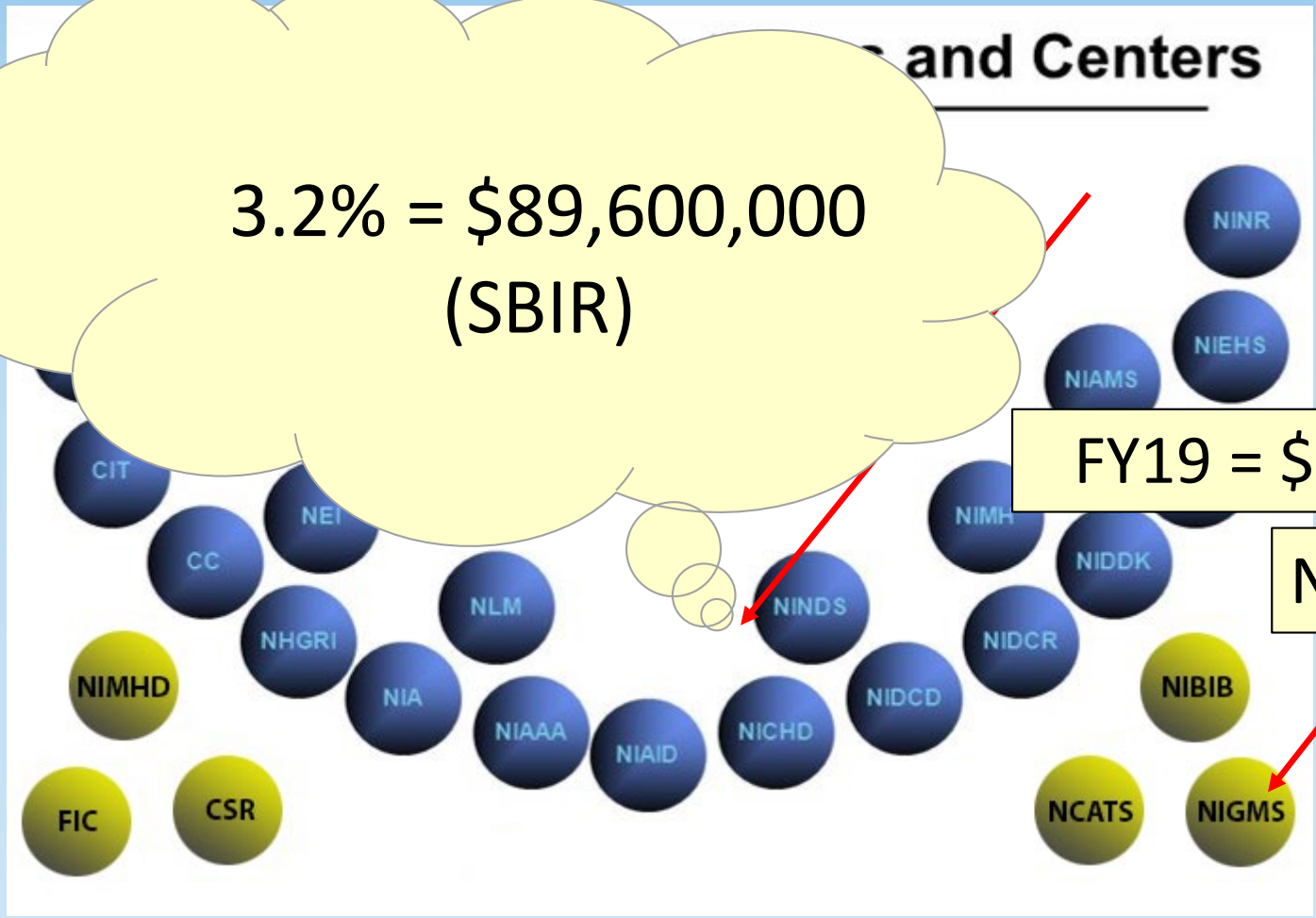
National Institutes of Health (NIH)



National Institute of General Medical Sciences



National Institute of General Medical Sciences



NIGMS SBIR/STTR

STEM Interactive Digital Media (IDM)

Funding Opportunity Announcements (FOAs)

PHS 2018-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])

https://grants.nih.gov/grants/guide/pa-files/PA-18-574.html

Omnibus

Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR) (R43/R44), PAR-18-402

https://grants.nih.gov/grants/guide/pa-files/PAR-18-402.html

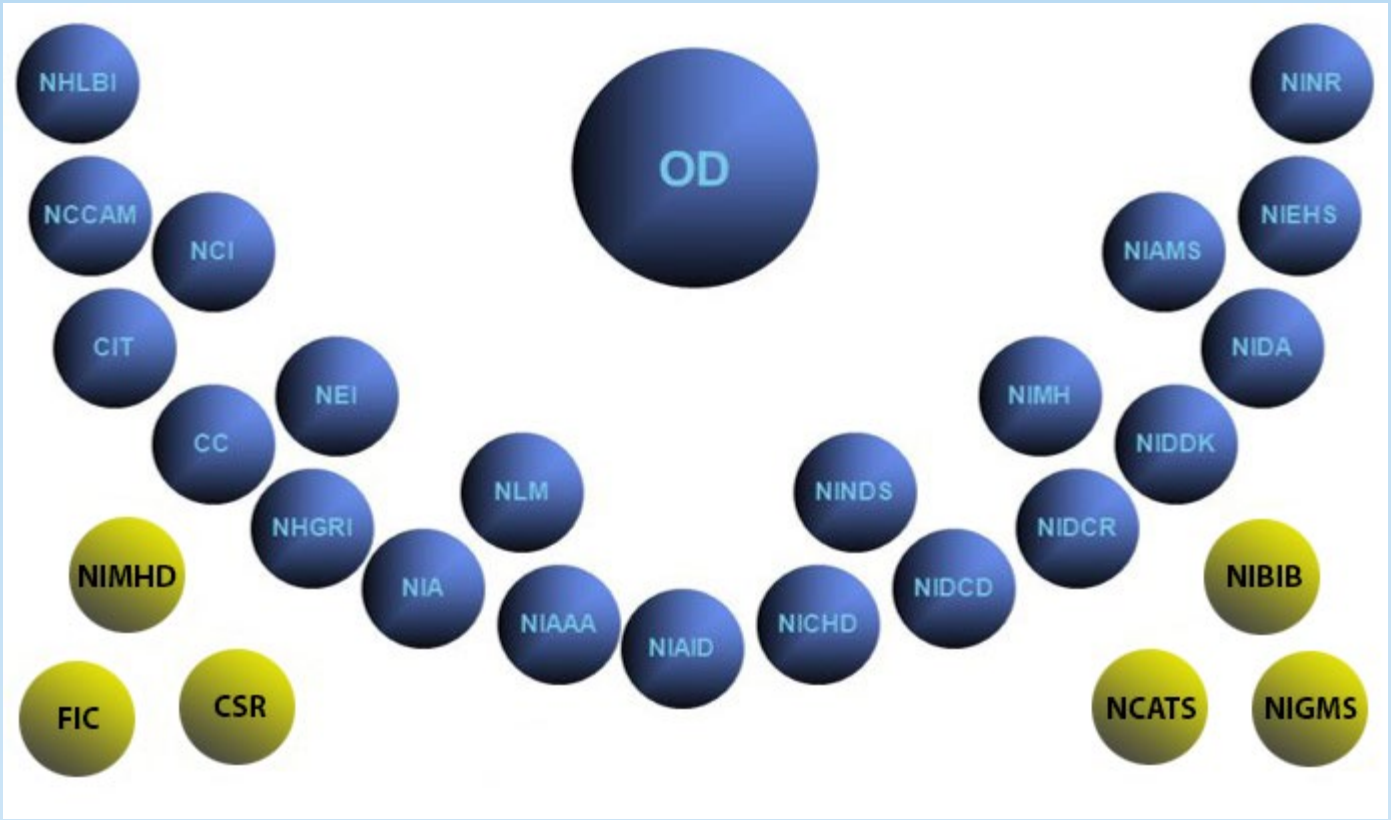
STEM IDM

Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR) (R43/R44), PAR-18-403

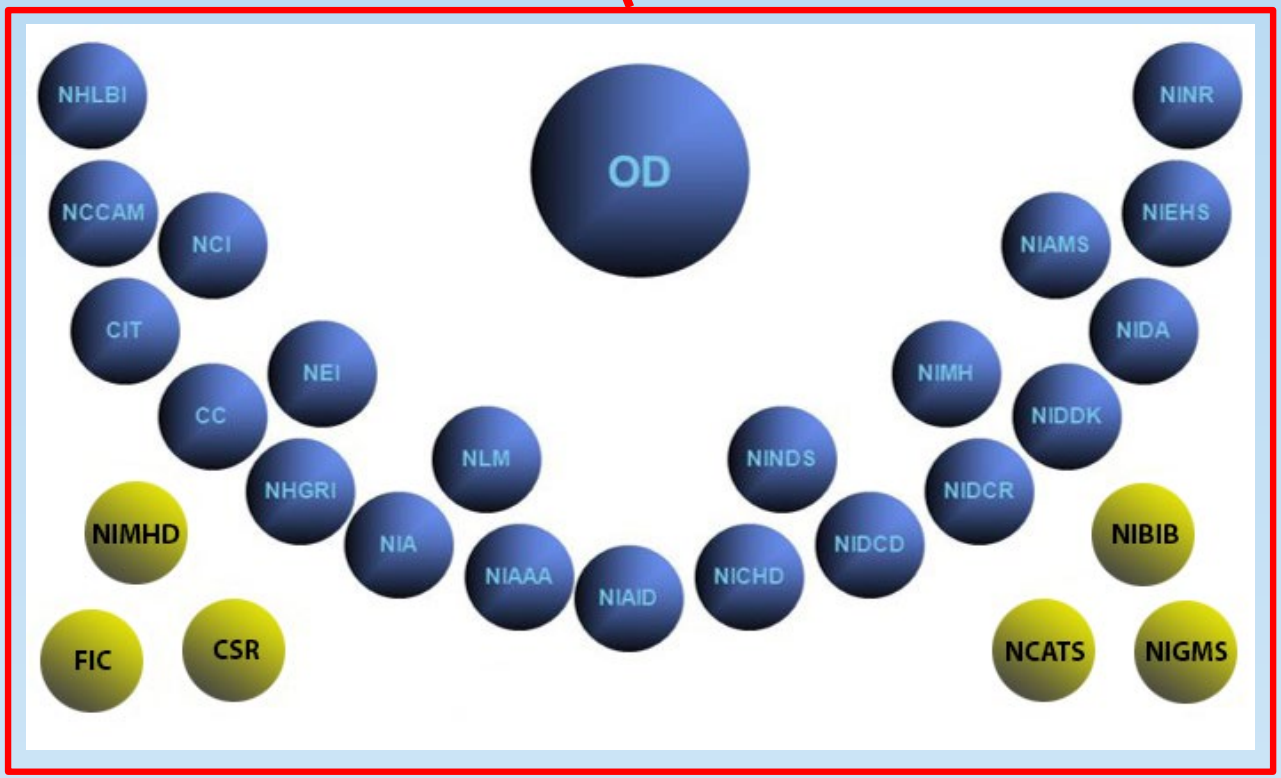
https://grants.nih.gov/grants/guide/pa-files/PAR-18-402.html

Next receipt date: September 5, 2019

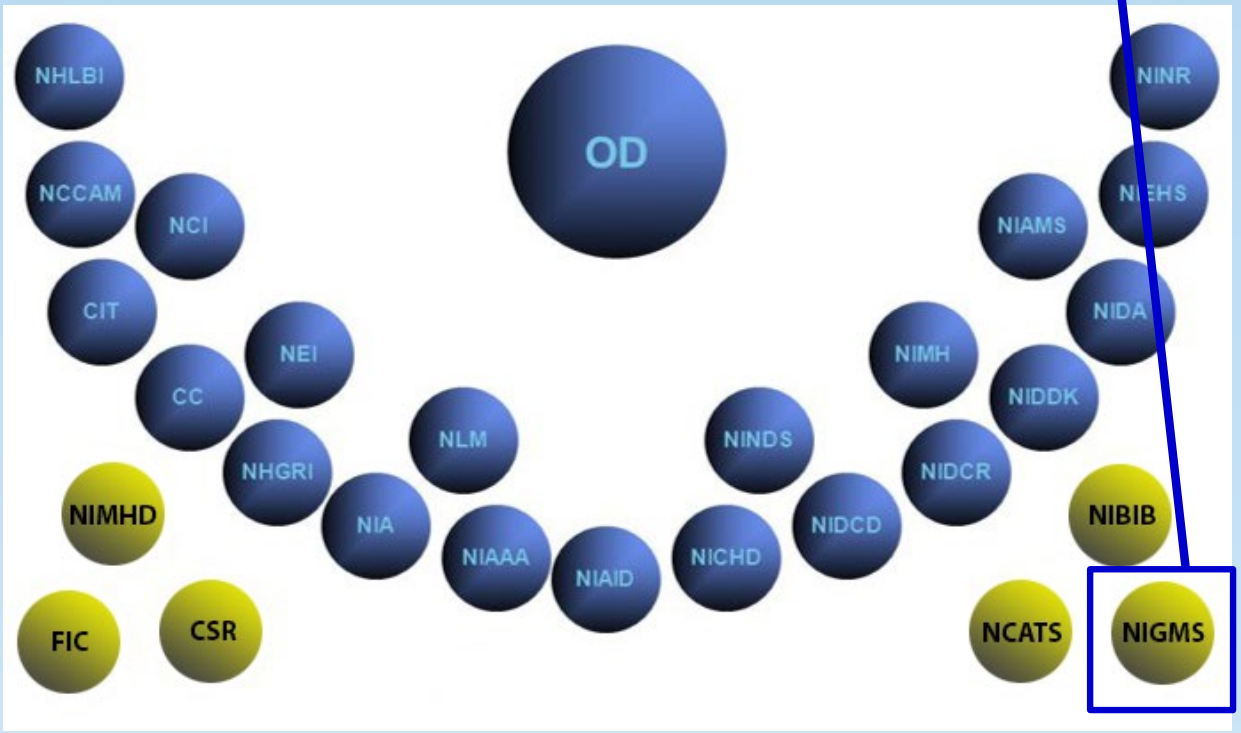
Omnibus vs. STEM IDM



Omnibus vs. STEM IDM

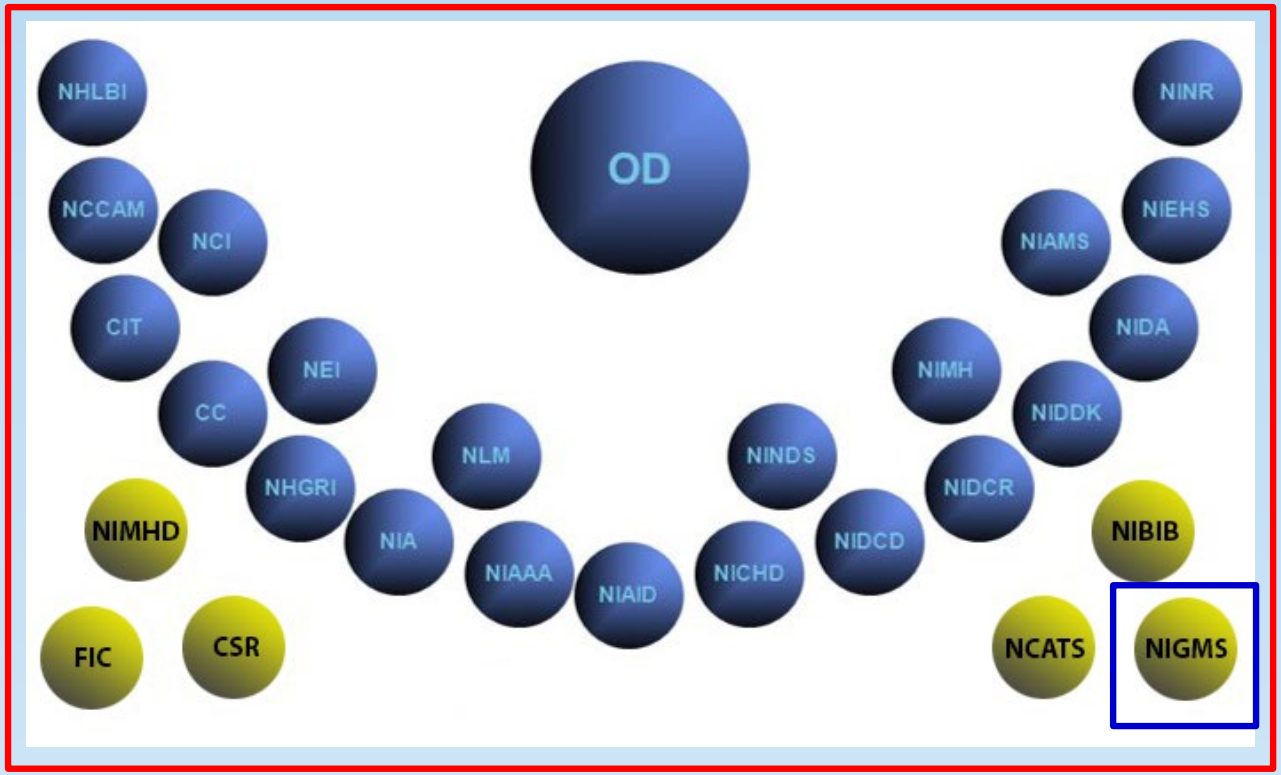


Omnibus vs. STEM IDM



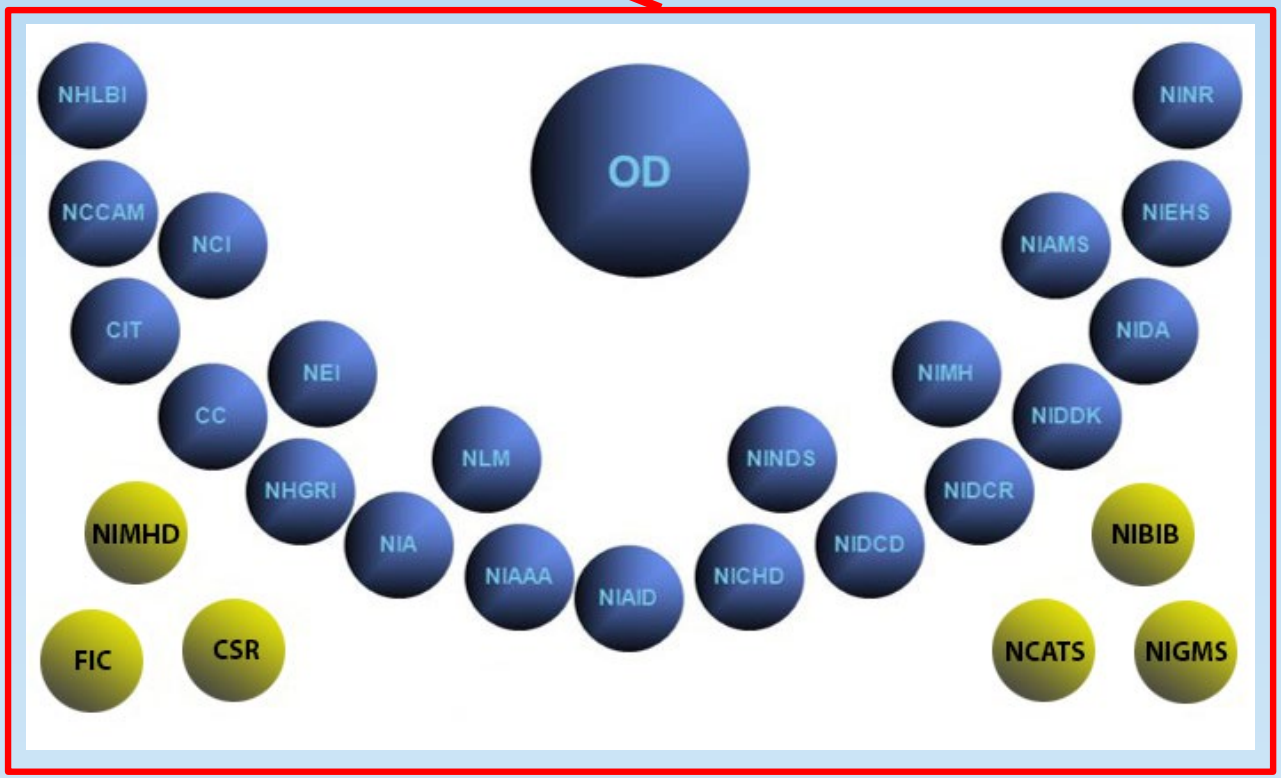
Omnibus vs. STEM IDM

- SAME TOPICS
- SAME DOLLAR AMT
- SAME REVIEW CRITERIA



Omnibus

3X/year

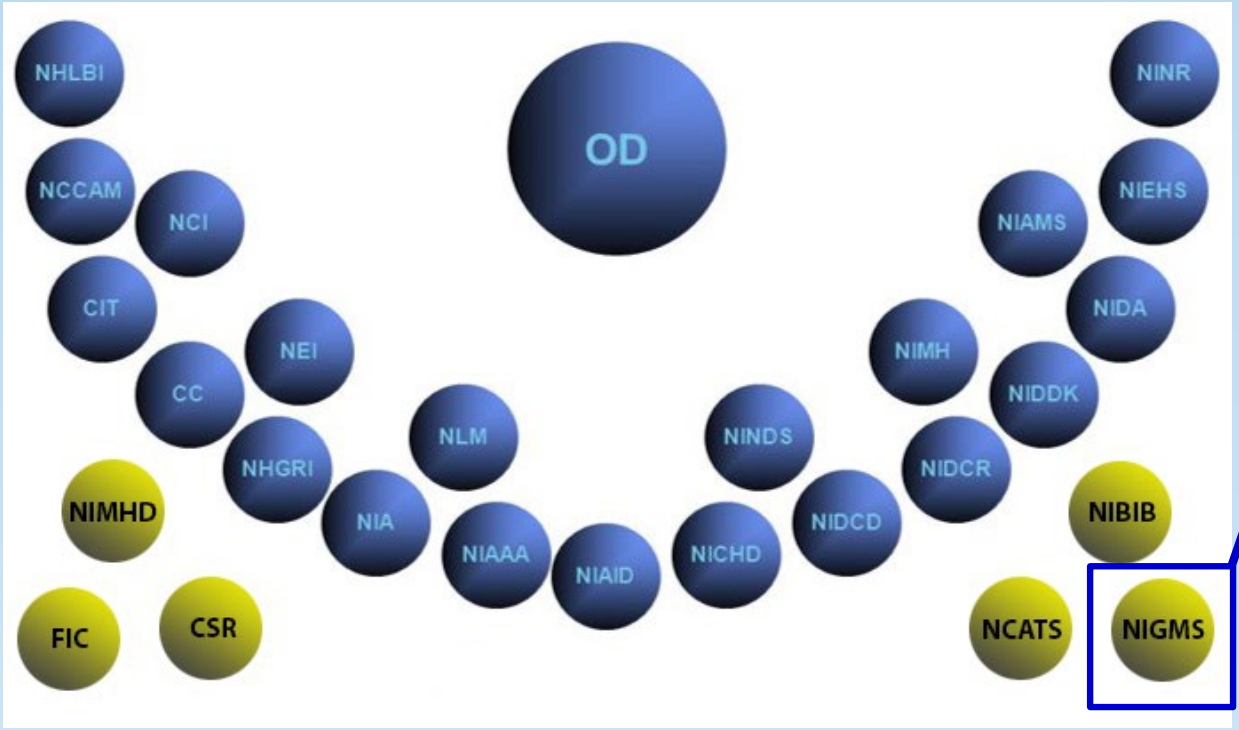


Jan 5
Apr 5
Sept 5

STEM IDM

1X/year

Sept 5



Interactive Digital Media STEM Topic Areas

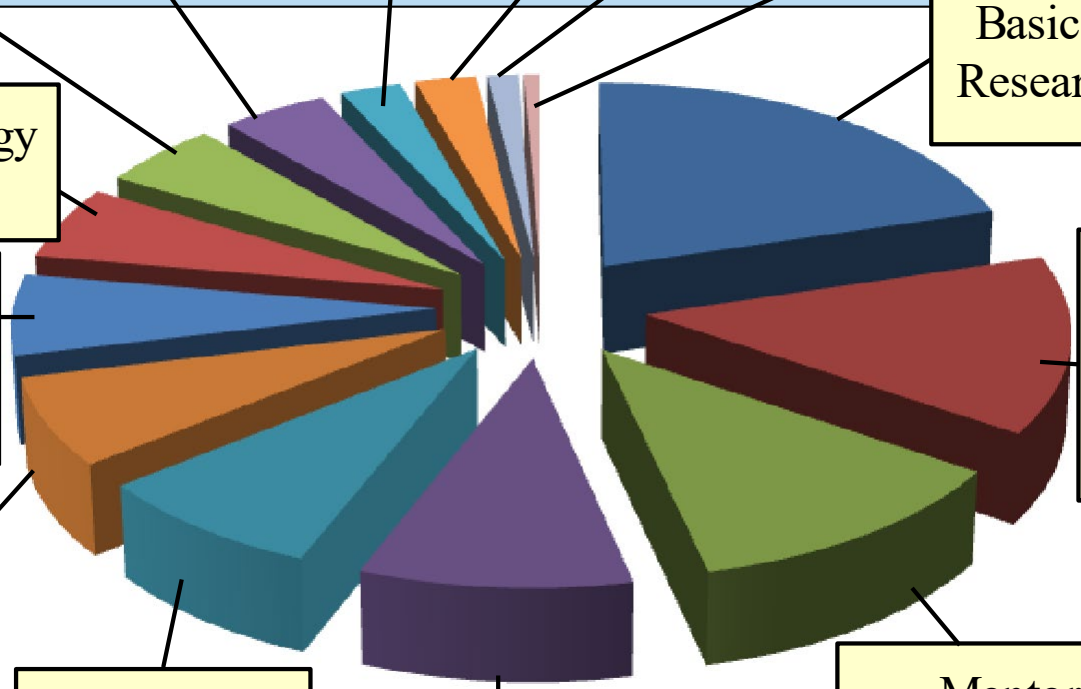
- Web-based, stand-alone computational tools, instructional software or other interactive media for dissemination of science education

- Pre-K To Grade 12 curriculum and other educational materials, Interactive teaching aids, models for classroom instruction, and teacher education resources

- Health promotion, disease prevention/intervention and public health literacy materials such as informational videos and/or print materials and programs which re culturally appropriate for populations and special communities.

STEM IDM

TOPIC AREAS



Interactive Digital Media

Citizen Science

Early Stem

Veterinary Medicine

Systems: Aging, Hearing, Brain, Lung, Bone

Molecular Biology

Basic & Clinical Research Methods

Microbiology, Virology & Disease Vectors

Nutrition, Obesity, Diabetes & Cardiovascular

Infectious Disease, Immunology & Epidemiology

Community Understanding about Clinical Trials

Human Genetics & Genomics

Public Health, Lifestyle & Health

Mentoring, Workforce Development & Teacher Professional Development

NIGMS STEM IDM STTR & SBIR Awards

- Classroom-based games to improve mathematical reasoning for K-5 students
- Science of baseball to teach mathematics and statistics
- Virtual Reality platform to teach difficult concepts in organic chemistry
- Digital psychoeducation for adolescents and young adults with substance use disorders.


NAVIGATING NIH
PEER REVIEW

Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR) (R43/R44), PAR-18-402
https://grants.nih.gov/grants/guide/pa-files/PAR-18-402.html

Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR) (R43/R44), PAR-18-403
https://grants.nih.gov/grants/guide/pa-files/PAR-18-402.html

Next receipt date: September 5, 2019

STEM IDM

NIH National Institute of General Medical Sciences

Section VII. Agency Contacts

Scientific/Research Contact **PO**

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

Peer Review Contact **SRO**

Marie-Jose Belanger, Ph.D
Center for Scientific Review (CSR)
belanger@csr.nih.gov

Financial/Grants Management Contact **GMS**

Brian Iglesias, iglesiab@mail.nih.gov
National Institute of General Medical Sciences (NIGMS)

STEM IDM SBIR - STTR

2019 Timeline: PAR-18-402, -403

Receipt Date

Sept 5 ‘19

Scientific Review

Nov ‘19

Council Review

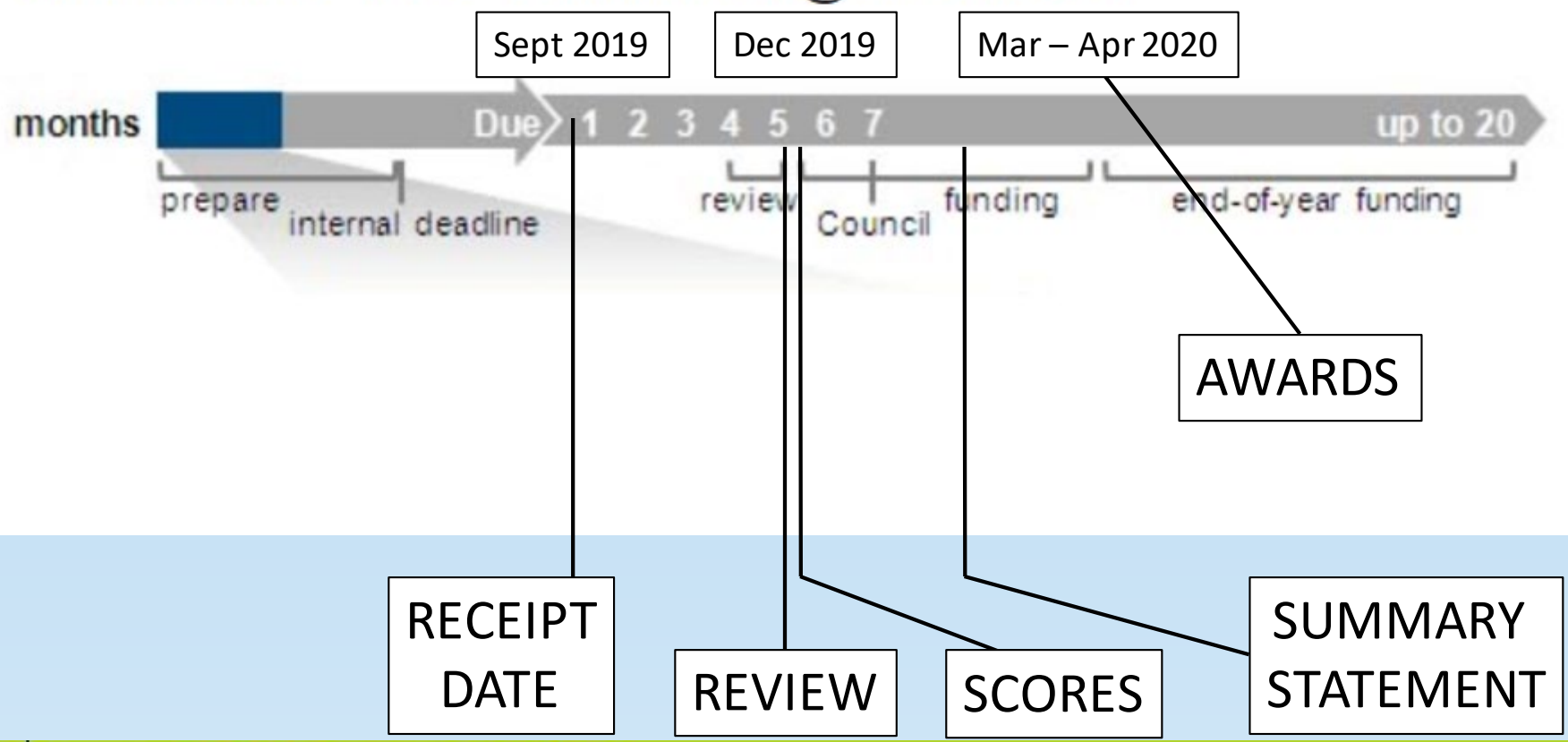
Jan ‘20

Award Date

Mar ‘20

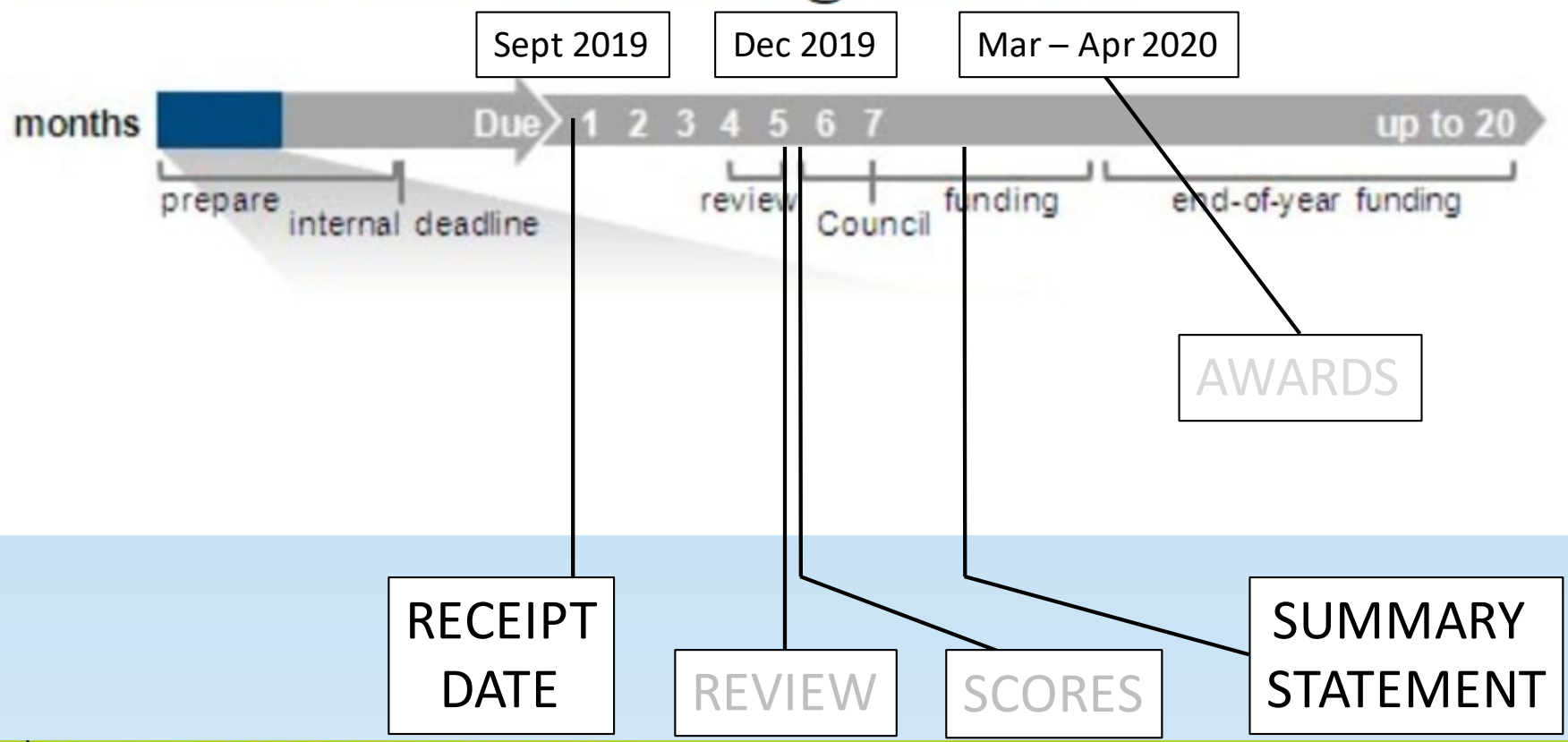
STEM IDM

FY19 REVIEW & AWARD CYCLE



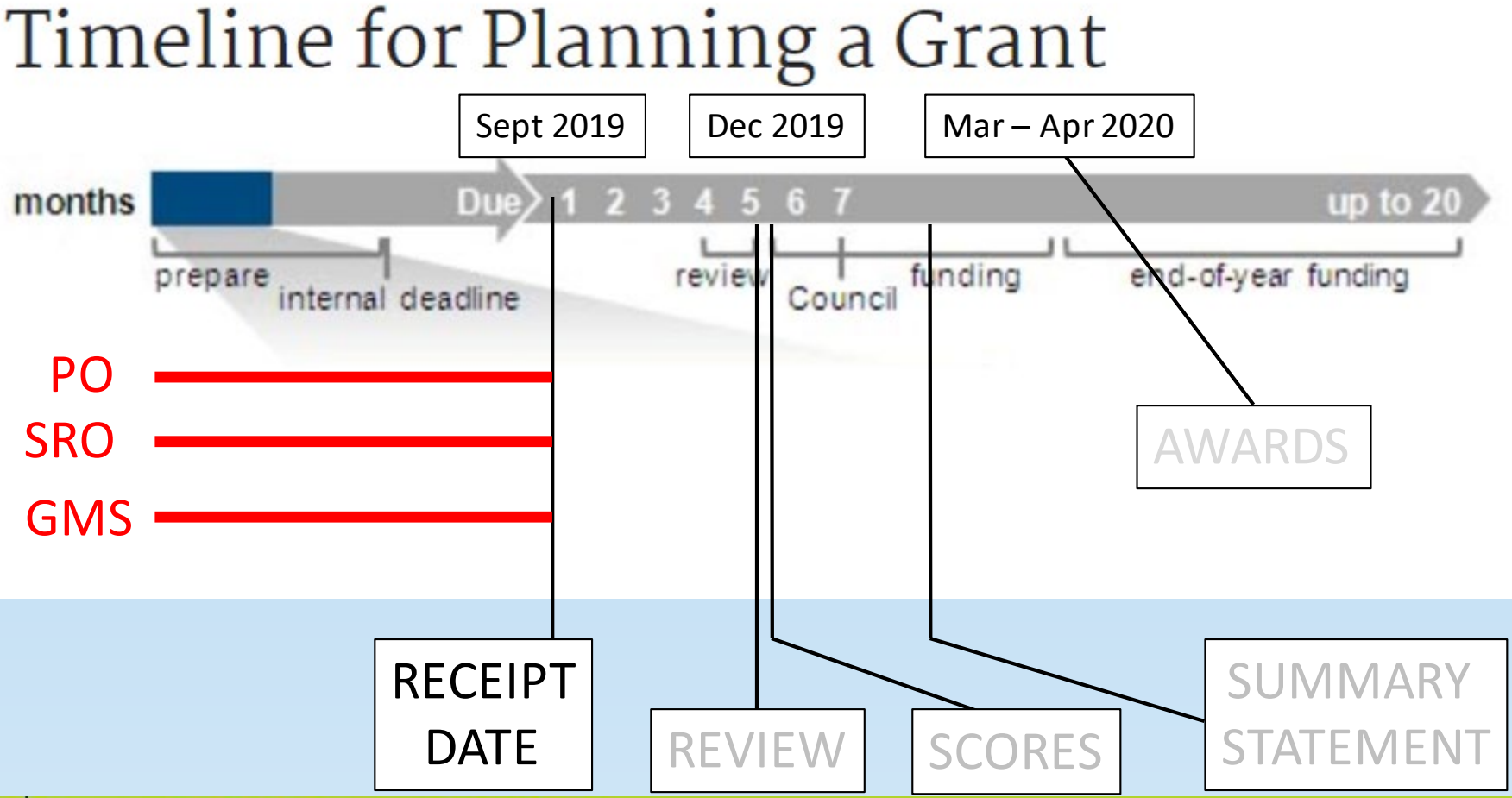
FY19 REVIEW & AWARD CYCLE

staff contacts



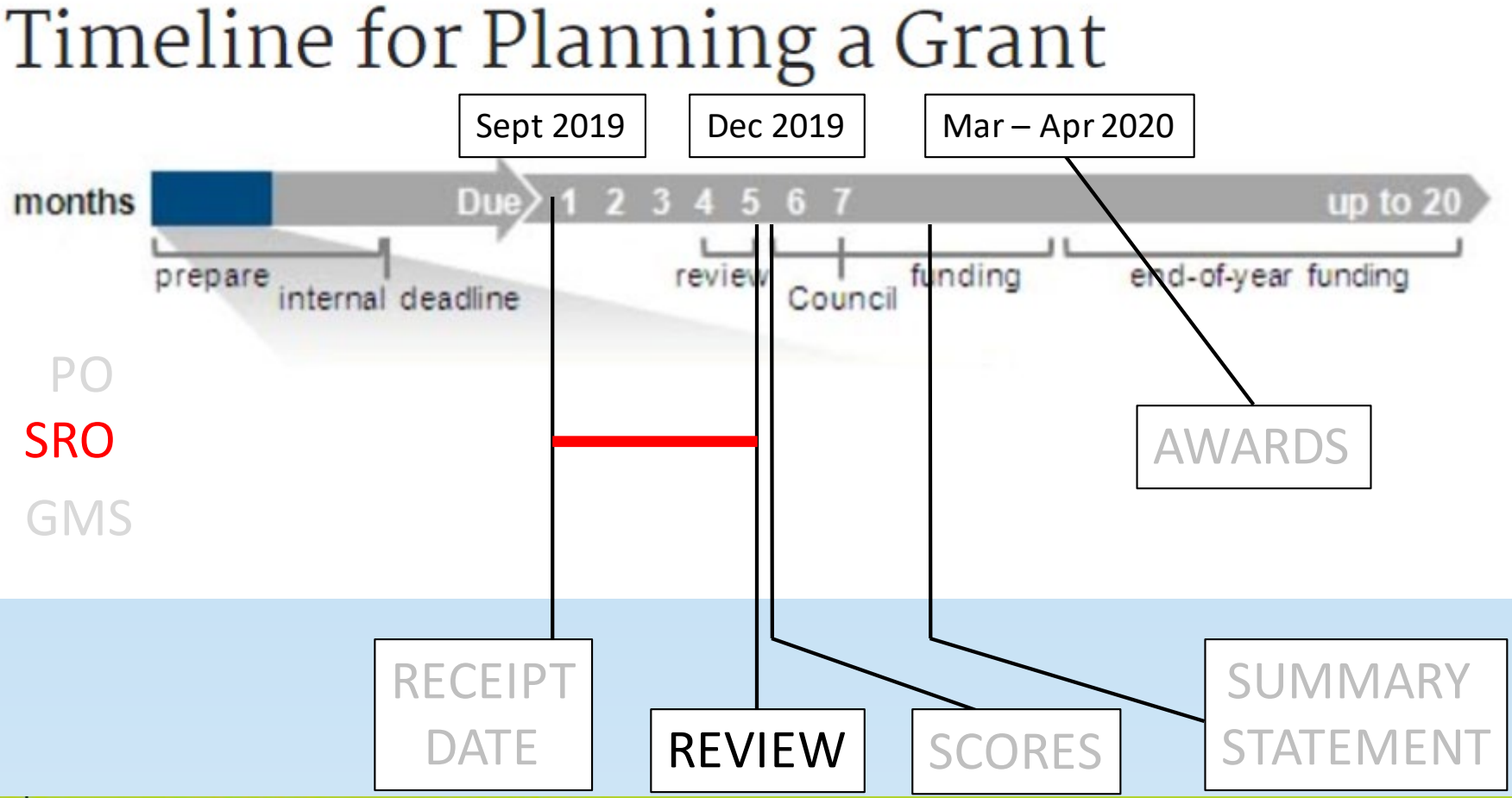
FY19 REVIEW & AWARD CYCLE

staff contacts



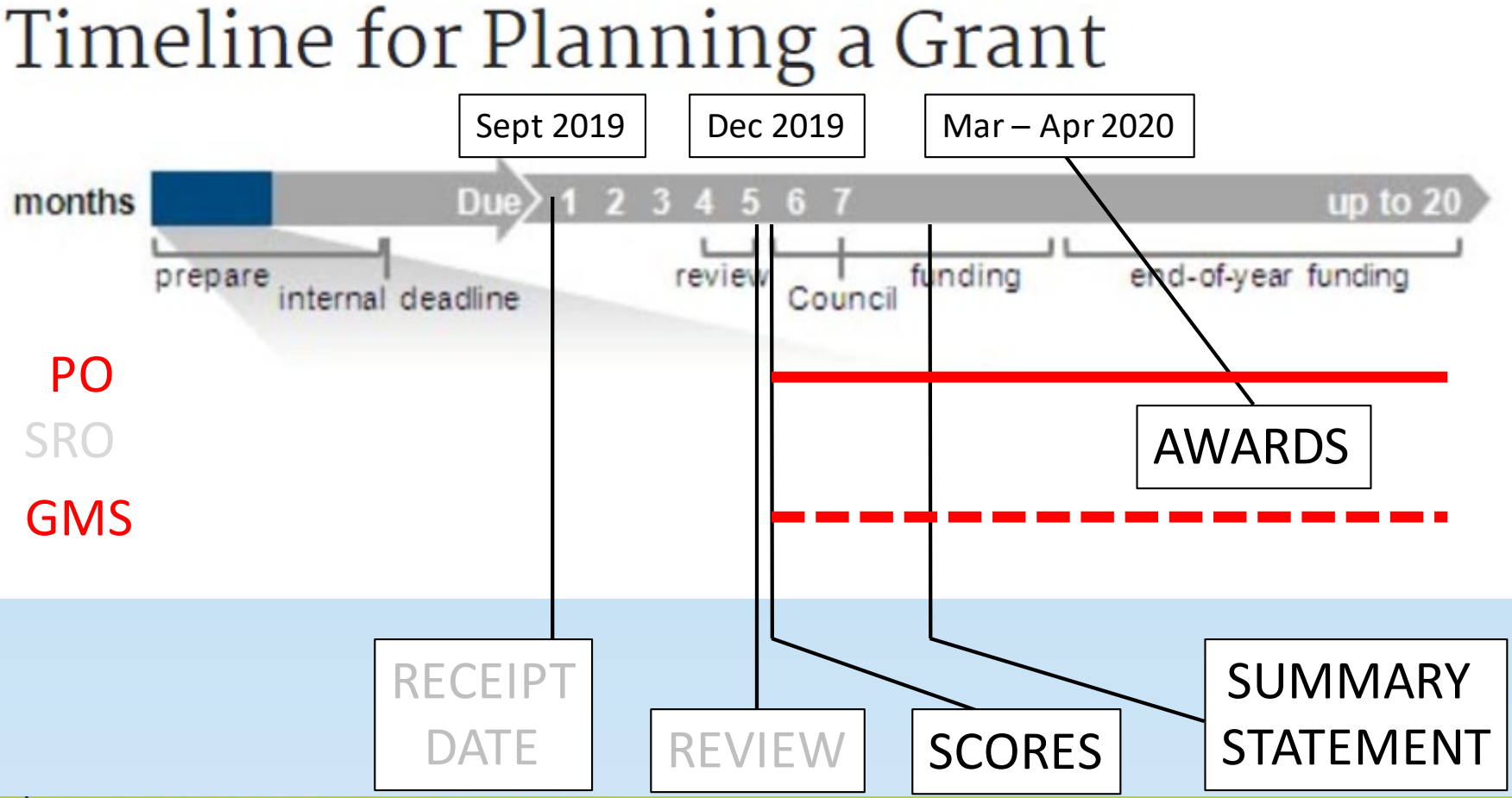
FY19 REVIEW & AWARD CYCLE

staff contacts

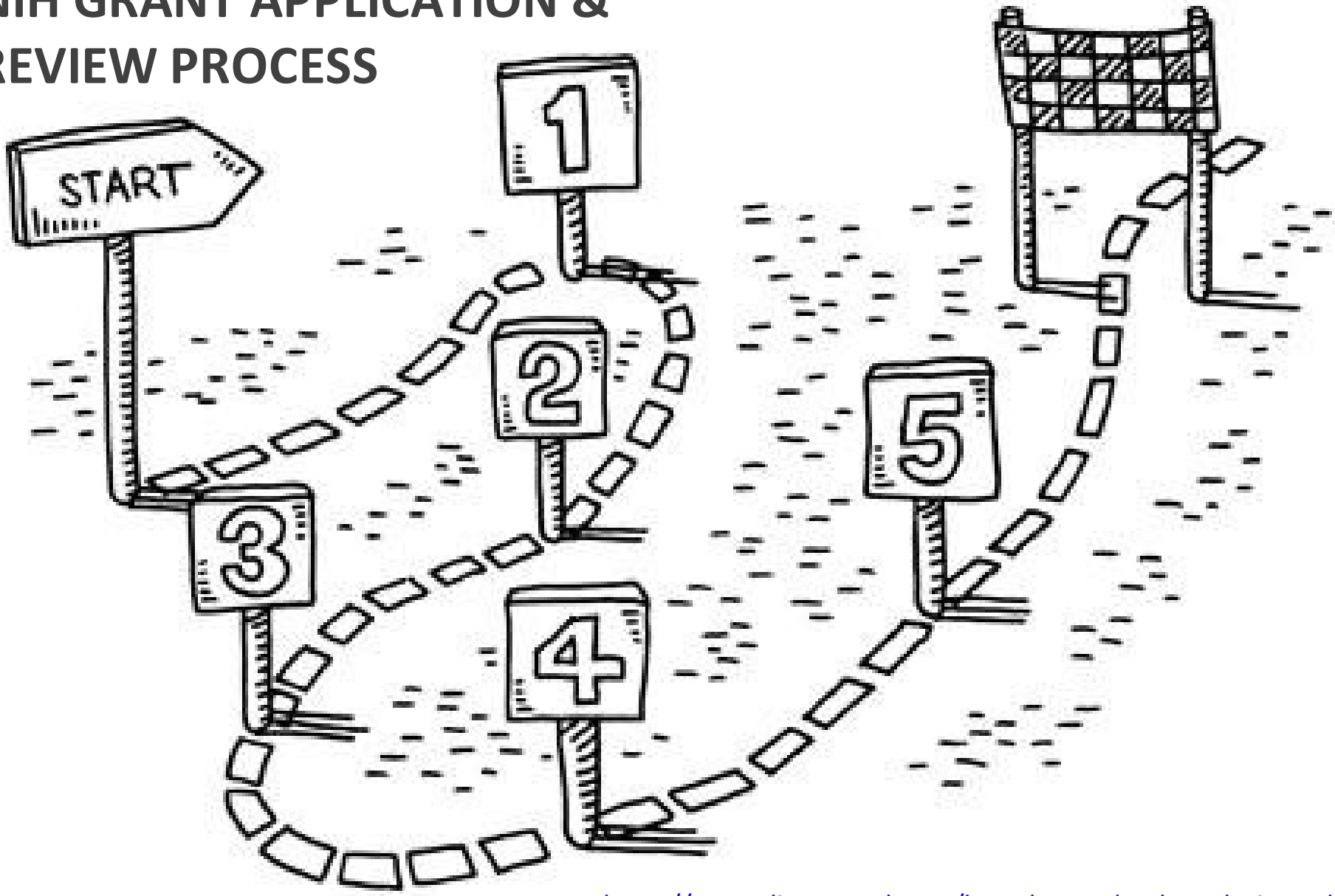


FY19 REVIEW & AWARD CYCLE

staff contacts



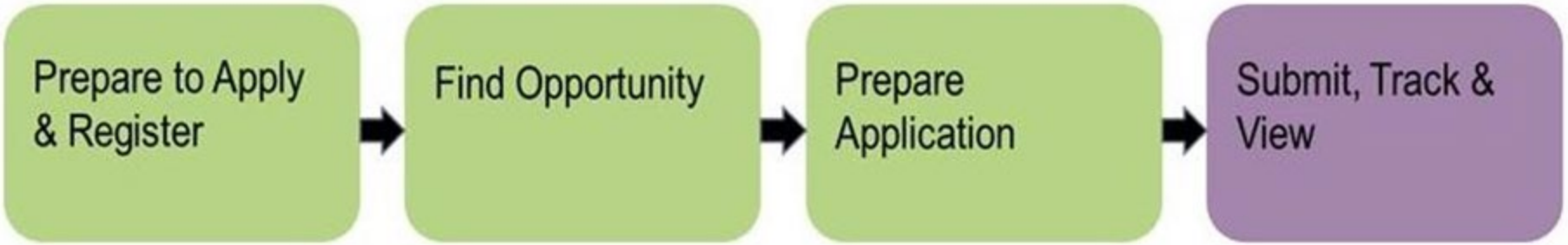
NIH GRANT APPLICATION & REVIEW PROCESS



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

PREPARATION – PART 1

Electronic Application Process



- **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

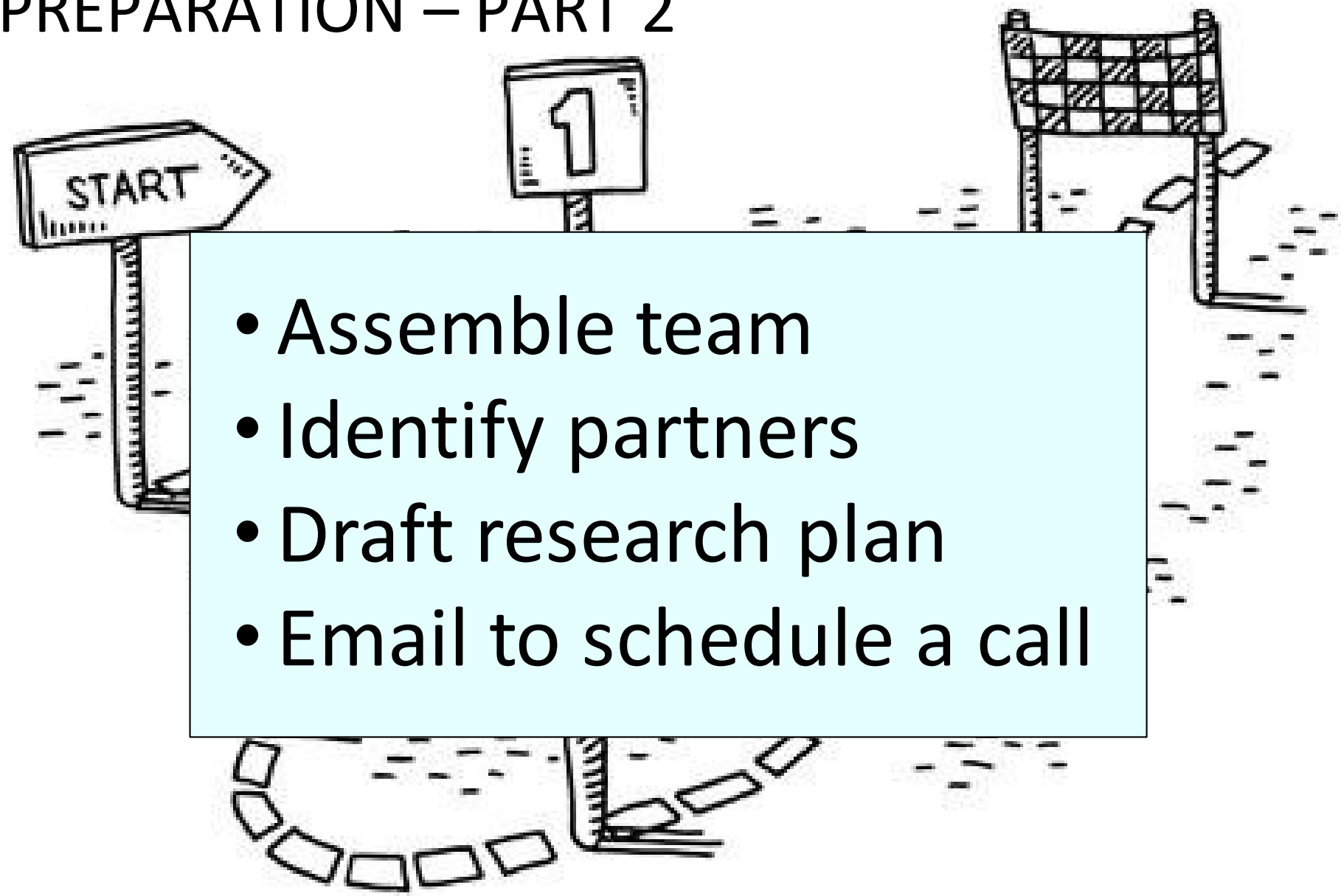
- NIH (OER)
- AHRQ

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

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

PREPARATION – PART 2



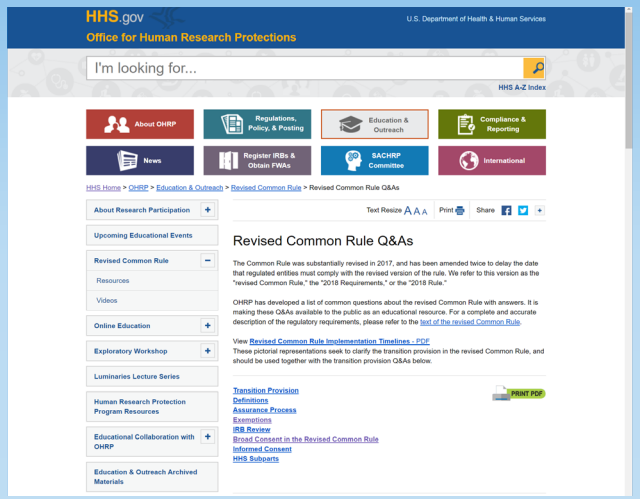
- Assemble team
- Identify partners
- Draft research plan
- Email to schedule a call

PROGRAM

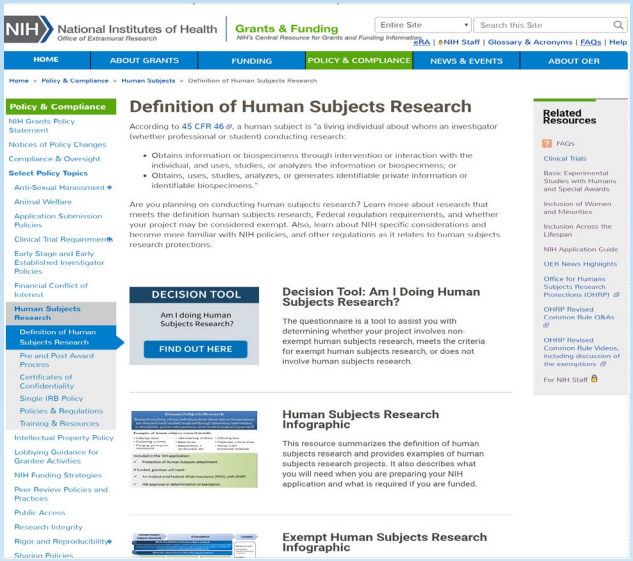
- **Human Subjects**
- **Inclusion**

Rashada Alexander, Ph.D

What's New with Human Subjects?

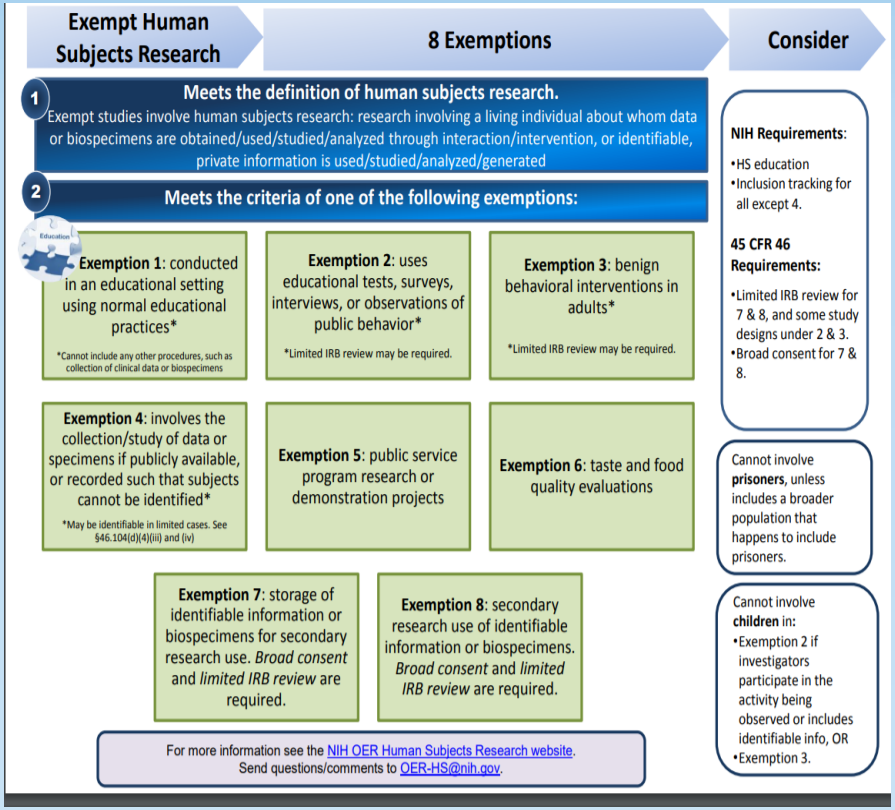


- Revised Common Rule: Changes include IRB Review, consent in the Common Rule, and exemption categories.
- **Expanded exemption categories that cover the work proposed in most SEPA applications.**
- Information to understand the changes: https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#collapse-qa-e6



- 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?



- The exemptions listed are likely to cover most SEPA projects that do involve human subjects research.
- **Exemptions 1 and 2 = most likely**
- **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.**

Remember:

Randomized Controlled Trial (RCT) or a Well-Matched Comparison study evaluation design to evaluate project effectiveness

≠

Clinical Research

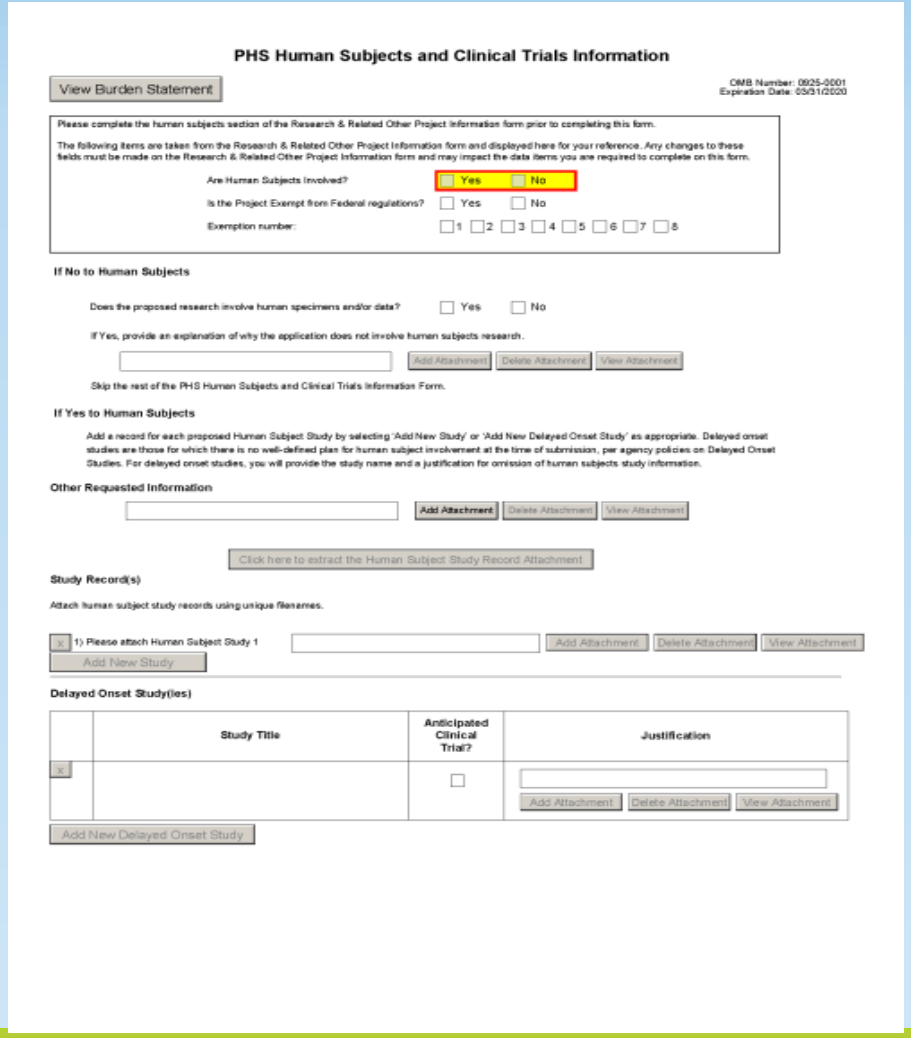
https://grants.nih.gov/sites/default/files/exemption_infographic_v7_508c-4-4-19.pdf

Keep in Mind: Definition of Research

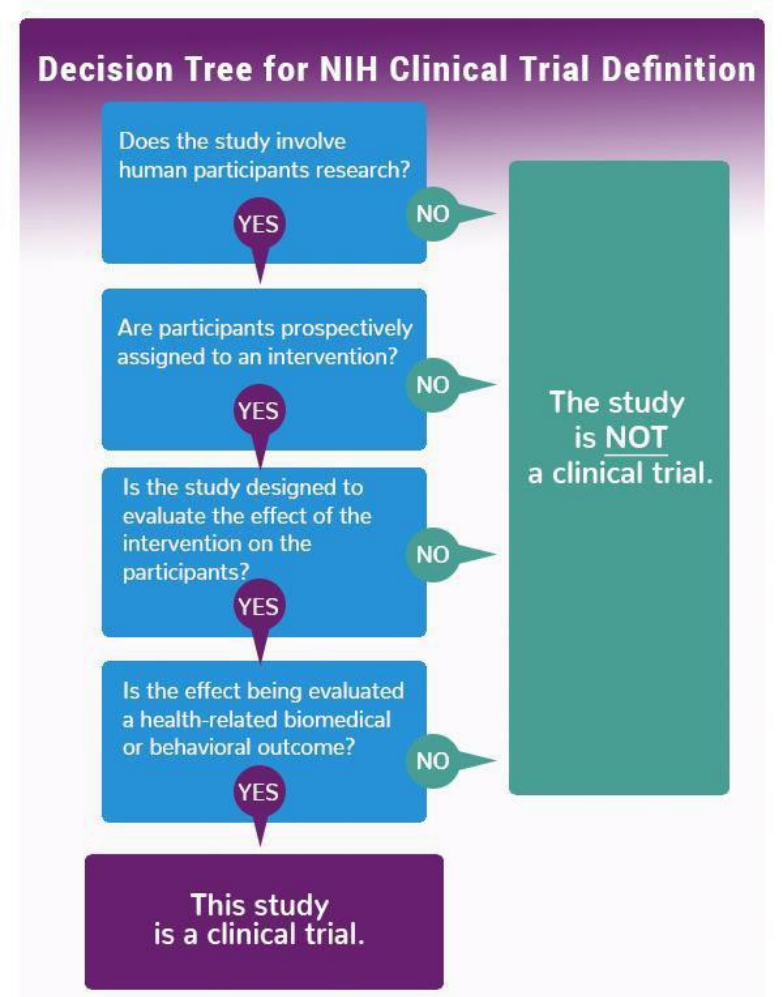
- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge.**
- Program evaluations that do not involve experimental or non-standard interventions, provide information for and about the setting in which the program 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://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_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.
  - Facilitates pre-award processing for applications selected for funding.
  - 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
- **Misclassifying activity as clinical trials activity in applications can result in an application being withdrawn, and not being reviewed.**

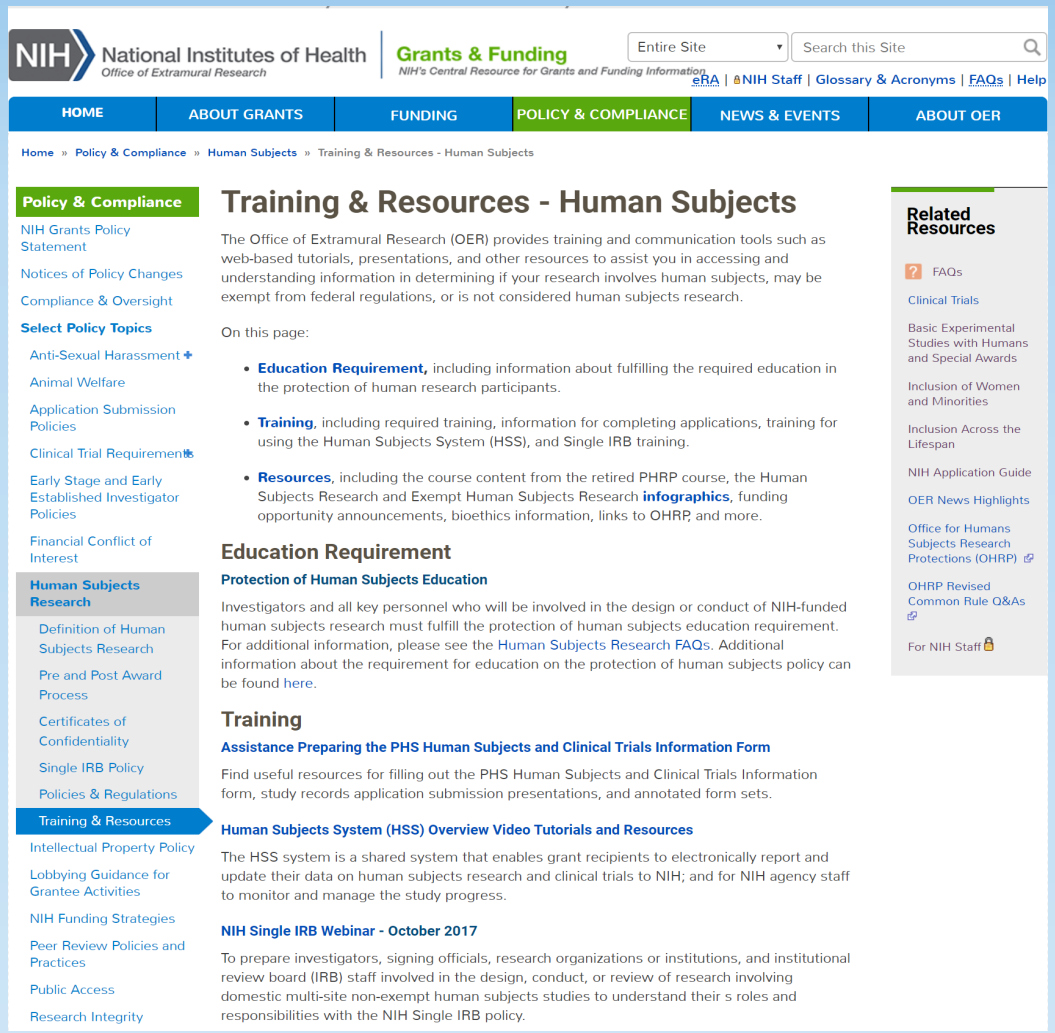
FAQ C.3: **What are some examples of outcomes that are not "health related biomedical or behavioral"?**

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

PEER REVIEW

Contact: Marie-Jose Belanger, Ph.D.
Scientific Review Officer
NIH/Center for Scientific Review
301-435-1267, belanger@csr.nih.gov

ROLE OF THE SCIENTIFIC REVIEW OFFICER

Designated Federal Official with overall responsibility for the review process and authority over the meeting

- Selects reviewers and study chairs
- Manages conflicts-of-interest
- Independently assigns at least 3 reviewers to applications
- Trains reviewers in review policy and process
- Oversees the review meeting process to ensure fairness and appropriate application of NIH policies
- Independently prepares summary statements including the resume (summary of the discussion)

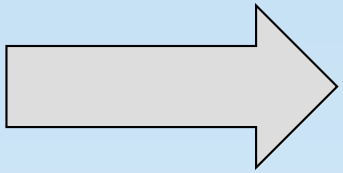
SELECTING REVIEWERS FOR SBIR/STTR STUDY SECTIONS

- Demonstrated scientific expertise/research support
- Mature judgment
- Breadth of perspective
- Impartiality
- Commercialization and Technology Transfer expertise
- Representation from both academia and industry. At least one member must be from small business, 25-50% small business or other industry members is encouraged.

PAR-18-402 - Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (SBIR) (R43/R44 Clinical Trial Not Allowed)

PAR-18-403 - Interactive Digital Media STEM Resources for Pre-College and Informal Science Education Audiences (STTR) (R41/R42 Clinical Trial Not Allowed)

Highlights of Section V: Application Review Information



REVIEW CRITERIA

5 Core Review Criteria

Each scored from 1-9

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

Overall Impact

Scored from 1-9

Assessment of the likelihood that the IDM STEM application will exert a powerful, hands-on, inquiry-based and learning-by-doing experience.

Also,

- Human subjects/inclusion
- Adequacy of phase2/fast track/direct to phase2

1. SIGNIFICANCE

- ***Assuming that all the aims are successful, does the project address an important problem? Will it advance scientific knowledge?***
- **Does it have <u>commercial potential</u> to lead to a viable STEM product? (In the case of Phase II and Fast-Track, does the Commercialization Plan demonstrate a high probability of commercialization?)**
- **Does it combine STEM content acquisition with understanding in an entertaining learning environment?**
- **Is the evaluation plan provides new metrics for tracking increased learning and problem-solving skills?**
- **Will the proposed IDM STEM project add to our knowledge of cognitive learning and will it move the STEM education field forward?**

2. INVESTIGATOR(S)

- Have the PD(s)/PI(s) provided evidence, e.g., publications and evaluation reports that demonstrate the ability of the project team to develop effective P-12 STEM and/or IDM STEM educational resources?
- Is the project team multidisciplinary with expertise in instructional and subject matter, IDM design and evaluation tools?
- Is there a plan for effective teamwork and collaboration among the key personnel?

3. INNOVATION

- *Does the application employ novel theoretical concepts, approaches, methodologies. Is the product needed by the marketplace?*

- **Does it discuss and utilize current knowledge on classroom and games-based learning theory on student teamwork, enhanced reading skills, problem solving, interest in research careers and health-related lifestyle changes?**

- **Are the IDM technology and operating platform sufficiently current and cutting edge to ensure user interest?**

INNOVATION (examples of critique comments)

- Strengths
  - The game as presented draws on previous successes of the team members.
  - Project will create multiple outcomes, not a linear experience.
  - 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 game
  - Innovative use of content, delivery method and learning strategies.
  - While specific elements of application are not completely innovative, the entire package of materials is an innovative way to teach
- Weaknesses
  - It is not clear what differentiates this simulation game from others or how it will contribute uniquely to the market/student audiences
  - It seems the teacher is not part of the process during game play
  - The proposed product may not provide sufficient flexibility for use by many teachers and/or district curricula

4. APPROACH

- *Does the application have clear milestones, rigor, possible pitfall identified and alternative approaches considered? Are both sexes considered?*
- Does it include input from Teachers, students and the community? Will the proposed project address diversity of student ethnicity and backgrounds?
- Are pedagogical issues integral components of the plan?
  - e.g., collaboration and teamwork, content progression that is grade-level appropriate, timely student feedback and opportunities for the student to create or modify gaming content,
- Does it challenge the players to innovate and think critically? Is the project likely to increase the diversity of students considering careers in basic, behavioral or clinical research?
- Are evaluation metrics and/or beta testing plans:
  1) appropriate to the proposed project and
  2) clearly described?
- Where appropriate, did the project include plans to obtain feedback from participants to help identify weaknesses and to provide suggestions for program improvements?
- Is there a plan to determine effectiveness through formative evaluation and/or beta testing with students, Teachers and other target groups?

APPROACH (examples of critique comments)

- Strengths
  - The specific aims are clearly articulated
  - Application will use a team-based, collaborative learning approach that research has shown to be successful
  - 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

5. ENVIRONMENT

Assess the appropriateness of the resources, facilities and equipment for the needs of the proposed project.

COMMERCIALIZATION PLAN

ADDRESSED in SIGNIFICANCE, and adequacy of phase 2/fast-track/direct to phase 2)

- To what extent was the applicant able to obtain letters of interest, additional funding commitments, and/or resources from the private sector or non-SBIR/STTR funding source, as well as IP protection, identification of market and competition, production, marketing, and distribution that would enhance the likelihood for commercialization? …
- How is the company organized and are the leaders the right people to commercialize the Interactive digital STEM media?

ADEQUACY OF FAST TRACK

- Does the application have two distinct Phases?
- Does the Phase 1 portion of the application specify clear, appropriate and measurable goals (milestones) that have to be achieved before initiating Phase 2?

ADEQUACY OF PHASE 2 OR DIRECT TO PHASE 2

- Does the application report successful completion of Phase 1 milestones?
- Does the application specify clear, appropriate and measurable goals (milestones) that have to be achieved during Phase 2?

9-POINT SCORING SCALE

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgement) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

e.g. Applications are addressing a problem of high importance/ interest in the field. May have some or no weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no weaknesses.

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

NIH PEER-REVIEW REVEALED (VIDEO)

https://youtu.be/fBDxI6l4dOA

SUMMARY STATEMENT TO APPLICANTS

- SRO will convert discussion and critiques into summary statements
- Summary statements for ALL applications will include critiques and criterion scores provided by the three assigned reviewers.
- The final Impact score: the average of the final Overall Impact scores from all eligible reviewers, averaged to one decimal place and multiplied by 10.
- All summary statements will be released within 30 days of the review meeting.

GRANTS MANAGEMENT BASICS

Brian Iglesias

Grants Management Basics

- Annual Award Budget: $150,000 DC Phase I / $1M Phase II.
  - May exceed by up to 50%
- Award Project Period: 6 Months Phase I / 2 Years Phase II
- Indirect Costs are reimbursed at 40% of MTDC without a negotiated rate
- Only one SEPA application is allowed per institution

Grant 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 R43/R44 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

REVIEW CRITERIA

5 Core Review Criteria

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

"what differentiates this STEM resource from others out there?"

REVIEW CRITERIA

5 Core Review Criteria

- **Significance** — Current body of knowledge
- Investigator(s)
- **Innovation** — What's out there?
- Approach
- Environment — Competitive edge?

REVIEW CRITERIA

5 Core Review Criteria

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

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

- Specific Aims
  - SA-1,
  - SA-2,
  - SA-3
    - SA-3.1
      - SA-3.1.a

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

- Evaluator input
- Teacher input

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

- Potential problems & solutions
- Literature documentation

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

- Validated evaluation instruments
- Control group(s)

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

- Visual
  - Time & Events, Gantt
  - Tables, figures, charts
  - Images

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**.
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  - The approach seems **overly ambitious**
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  - **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?