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

Scientific/Research
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Financial/Grants Management
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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
• 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
• 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)

NIH consists of 27 Institutes and Centers

FY19 = $39.1B
National Institute of General Medical Sciences

NIH consists of 27 Institutes and Centers

FY19 = $2.8B

NIGMS
3.2\% = \$89,600,000 (SBIR)
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])

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

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

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
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 are culturally appropriate for populations and special communities.
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

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

Next receipt date: September 5, 2019
Section VII. Agency Contacts

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Financial/Grants Management Contact  **GMS**
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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

Timeline for Planning a Grant

- Sept 2019: Receipt Date
- Dec 2019: Review
- Mar – Apr 2020: Scores
- AWARDS
- SUMMARY STATEMENT
FY19 REVIEW & AWARD CYCLE

staff contacts

Timeline for Planning a Grant

- Sept 2019
- Dec 2019
- Mar – Apr 2020

RECEIPT DATE

REVIEW

SCORES

SUMMARY STATEMENT

AWARDS
FY19 REVIEW & AWARD CYCLE

staff contacts

Timeline for Planning a Grant

- Sept 2019
- Dec 2019
- Mar – Apr 2020

PO
SRO
GMS

RECEIPT DATE
REVIEW
SCORES
AWARDS
SUMMARY STATEMENT
FY19 REVIEW & AWARD CYCLE

staff contacts
FY19 REVIEW & AWARD CYCLE

staff contacts

Timeline for Planning a Grant

- Sept 2019
- Dec 2019
- Mar – Apr 2020

PO
SRO
GMS

RECEIPT
DATE

REVIEW

SCORES

SUMMARY
STATEMENT

AWARDS

National Institute of General Medical Sciences
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/
### Preparations – Part 1

**Electronic Research Administration (eRA)**

#### eRA Commons Frequently Asked Questions

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<th>XI. No Cost Extension</th>
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<td>XXI. PI Verification of Preferred eRA Commons Account</td>
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[https://era.nih.gov/commons/faq_commons.cfm](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.
- Changes to human subjects research-related NIH policies to align with Common Rule changes and the 21st Century Cures Act.
- New Human Subjects and Clinical Trials Information forms – Affects all types of human subjects research.
- Resources to help you navigate the changes: [https://grants.nih.gov/policy/humansubjects/research.htm](https://grants.nih.gov/policy/humansubjects/research.htm)
I think I have a project with human subjects. What next?

- The exemptions listed are likely to cover most SEPA projects that do involve human subjects research.
- 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=nz9NWFWhYOG8&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 "healthrelated 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

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 OHRR 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
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**

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

Each scored from 1-9

**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 commercial potential 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?
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

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

### 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

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
</tbody>
</table>

- **High Impact**
  - Applications are addressing a problem of **high** importance/interest in the field.
  - May have some or no weaknesses.

- **Medium Impact**
  - Applications may be addressing a problem of **high** importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

- **Low Impact**
  - 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.

- **Applications may be addressing a problem of moderate/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
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.

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
- Investigator(s)
- Innovation
- Approach
- Environment

Current body of knowledge
What’s out there?
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.
  - 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?