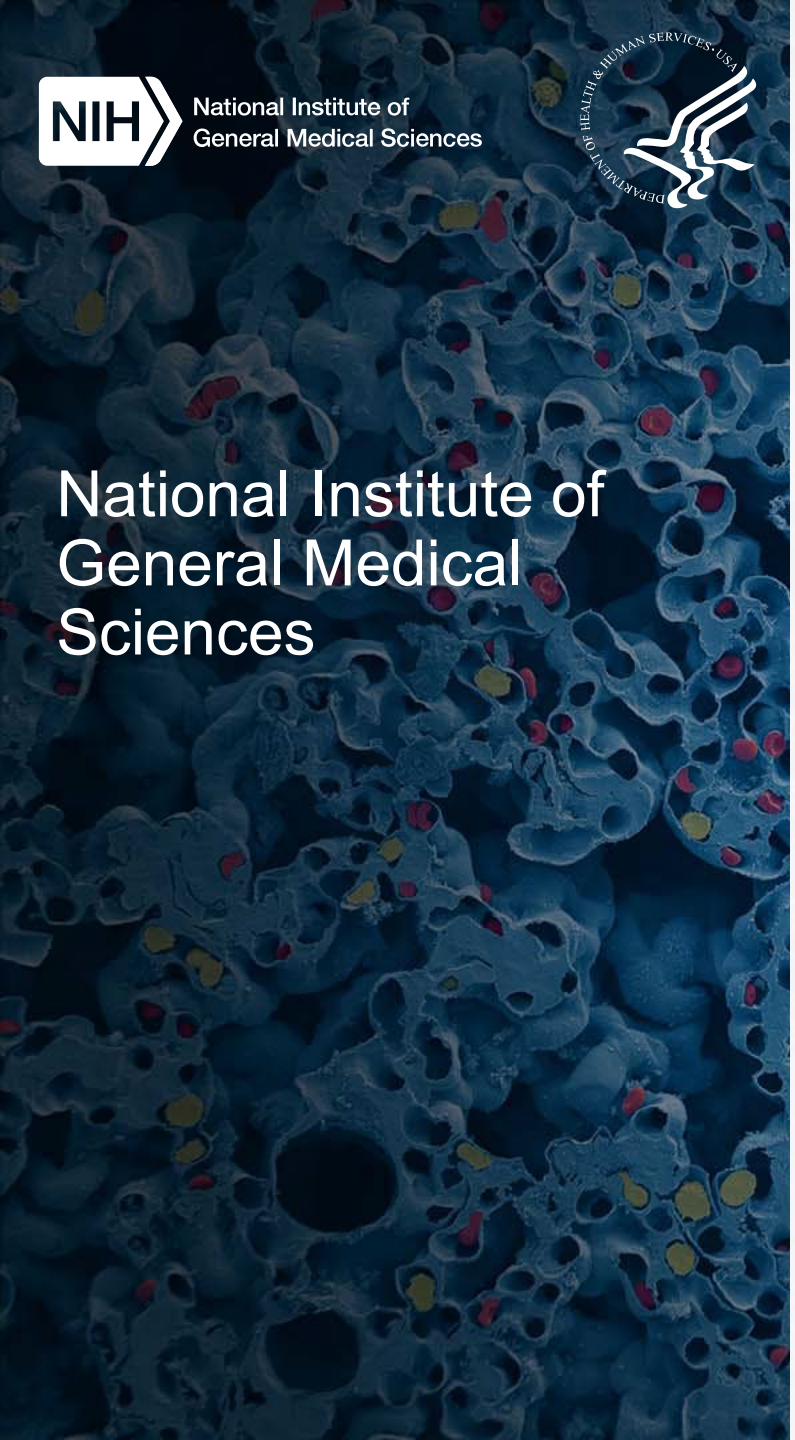
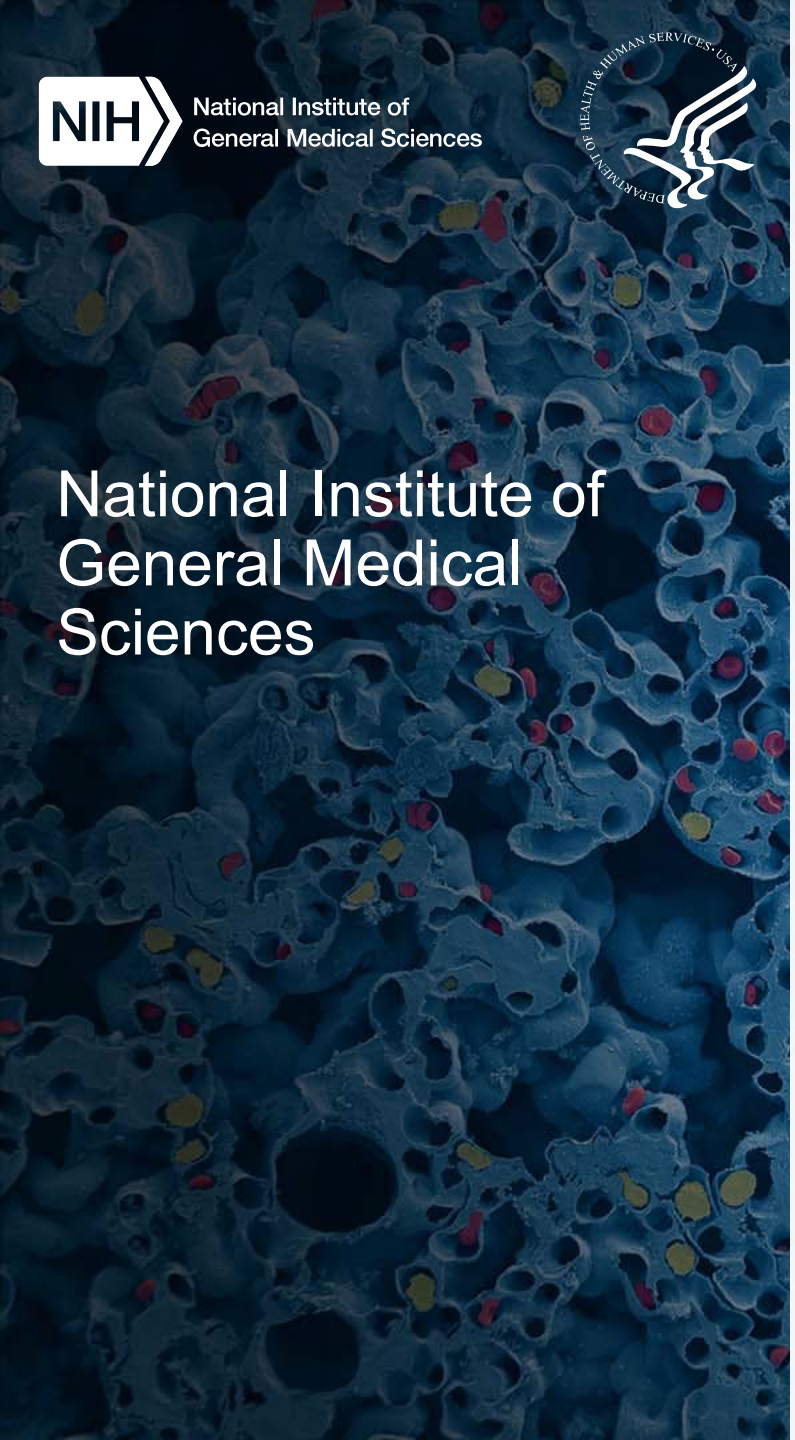


Pre-Submission Webinar for Interactive Digital Media (IDM) Biomedical Science Resources, SBIR/STTR

Tuesday August 6, 2024



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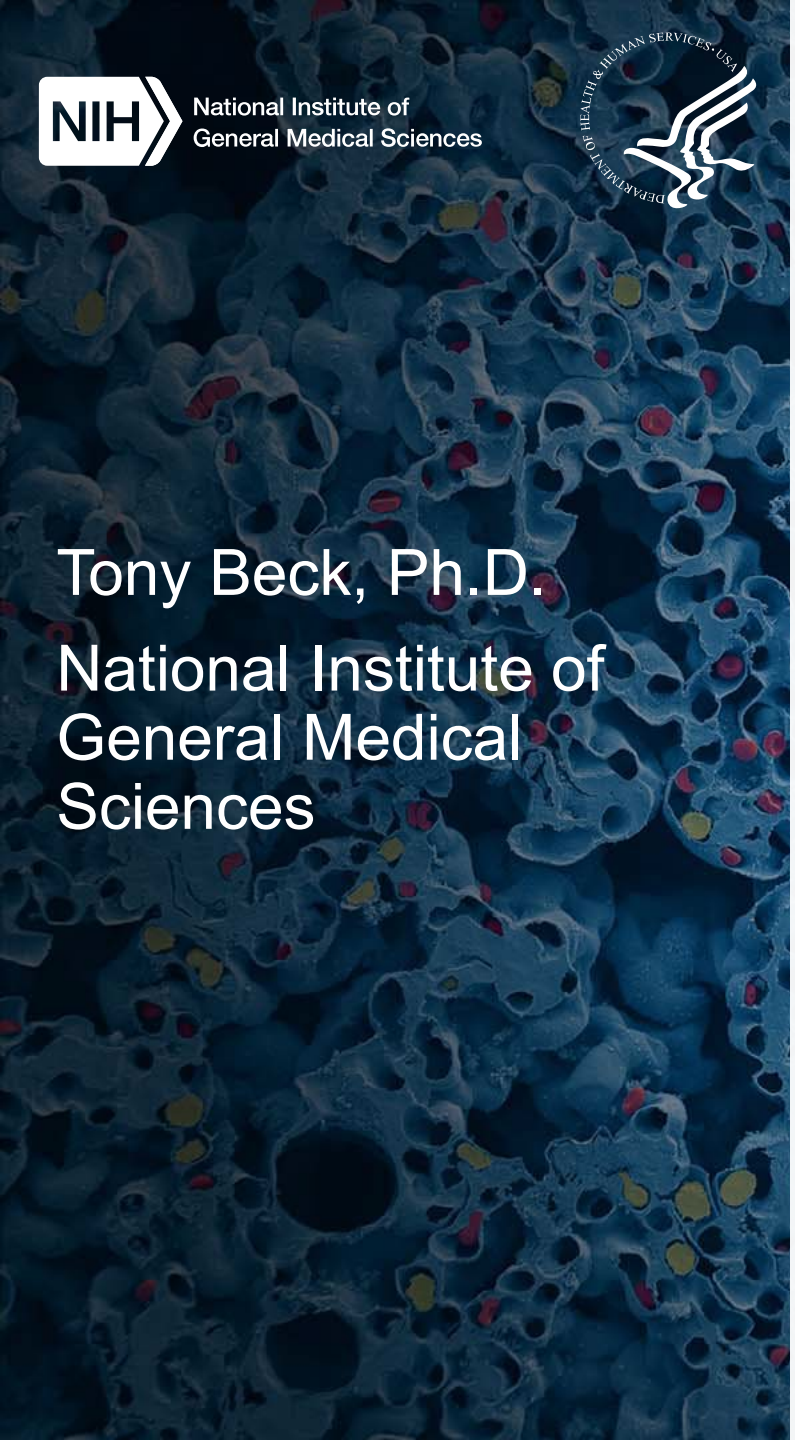


National Institute of General Medical Sciences

Tony Beck, Ph.D.

National Institute of General Medical Sciences

Agenda

- Overview of the IDM SBIR/STTR Program
- Grant Review Process
- Human Subjects
- Budget Basics
- Q&A

Federal SBIR & STTR Goals – Part 1

- Meet federal research and development needs
- Increase private-sector commercialization of innovation derived from federal research and development funding
- Stimulate technological innovation
- Foster and encourage participation in innovation and entrepreneurship by women and socially/economically disadvantaged individuals
- Foster technology transfer through cooperative R&D between small businesses and research institutions (STTR)

Federal SBIR & STTR Goals – Part 2

SBIR/STTR provides competitively awarded grants to small business concerns (SBCs) with technically sound and commercially promising but unproved ideas

“Too Risky for Venture Capital” - Angel investors find SBIR/STTR awards to be an effective funding mechanism to bring a SBC forward in its product development to the point where risk is sufficiently diminished to justify their investment

Federal SBIR & STTR Programs – Part 1

Small Business Innovation Research (SBIR)

- 3.2% of the extramural research budget for agencies with a budget greater than $100 M per year
- ~$3.2 billion minimum spend each year

Small Business Technology Transfer (STTR)

- 0.45% of the extramural research budget for agencies with a budget greater than $1B per year
- ~$450 million minimum spend each year

Over 5,000 new awards every year

Federal SBIR & STTR Programs – Part 2

What does an SBIR/STTR firm look like?

- Company must be for profit, U.S. owned/operated, and under 500 people
- Work must be done in the U.S.
- Focus is on performing R&D – Not purchasing equipment, commercializing a technology that has already been developed, or one that has very low risk and only needs capital

Federal SBIR & STTR Programs – Part 3

Primary SBIR/STTR Application Options

Phase I

- Concept Development
- 6 months – 1 year, up to $306,872 in total costs
- “Proof of Principle” 6-page research plan

Phase II

- Prototype Development 24 months
- Up to $2,045,816 in total costs
- 12-page research plan, 12-page commercialization plan

NIH has received a waiver from SBA, as authorized by statute, to exceed these total award amount hard caps for specific topics.

Federal SBIR & STTR Programs – Part 4

Additional SBIR/STTR Application Options

Fast Track

- Phase I & Phase II combined application
- Submitted and reviewed together
- Fast-Track applications receive a single rating

Direct to Phase II

- Nearly identical to a regular Phase II
- Applicants:
  - Phase I-equivalent work has been conducted
  - Describe their Phase I-like work, similar to a Phase I progress report

Federal SBIR & STTR Programs – Part 5

Differences Between SBIR and STTR

Partnering Requirement
- SBIR Permits partnering
- STTR Requires a non-profit research institution partner

Principal Investigator
- SBIR Primary employment (>50%) must be with the small business
- STTR PI may be employed by either the research institution partner or small business

3rd Party Allowances
- SBIR May subcontract up to 33% (Phase I), 50% (Phase II)
- STTR Minimum: 40% Small Business and 30% Research Institution Partner

The small business is ALWAYS the applicant and awardee

PowerPoint Presentation (sbir.gov)

Interactive Digital Media (IDM) Purposes – Part 1

- Widely used in science, technology, engineering, and mathematics (STEM) education to enrich student's learning experience both inside and outside of classroom settings
- Disseminate knowledge of biomedical science
- Enhance students' interest in learning more about biomedical science and related research
- Develop and strengthen students' problem-solving skills

Interactive Digital Media (IDM) Biomedical Science Resources for Pre-College Students and Teachers (SBIR) (R43/R44), PAR-23-213

Interactive Digital Media (IDM) Purposes – Part 2

- MedTech and health service sector training

- Pre-kindergarten to grade 12 STEM products should be:
  - Age, grade and culturally appropriate for its target audience
  - Use on IDM platforms that are accessible to the target learner level

- IDM that develops students' quantitative and computational skills is particularly encouraged

Interactive Digital Media (IDM) Biomedical Science Resources for Pre-College Students and Teachers (SBIR) (R43/R44), PAR-23-213

Interactive Digital Media (IDM) Purposes – Part 3

- Features that allow real-time student assessment are strongly encouraged
- Inside or outside of classroom use
- Students individually or in a group setting, with or without teacher or adult participation or supervision

Interactive Digital Media (IDM) Biomedical Science Resources for Pre-College Students and Teachers - STTR

Interactive Digital Media (IDM) STTR

- PHS 2024-2 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications (Parent STTR [R41/R42] Clinical Trial Not Allowed), https://grants.nih.gov/grants/guide/pa-files/PA-24-247.html
    - Same topics
    - Same budget and project duration guidelines
    - Same application and review criteria

National Institute of General Medical Sciences

Marie-Jose Belanger, Ph.D.

Scientific Review Officer
Center for Scientific Review (CSR)

PEER REVIEW

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.

New NIH STEM Games SBIR/STTR Program

- PAR-23-213 - Interactive Digital Media (IDM) Biomedical Science Resources for Pre-College Students and Teachers (SBIR) (R43/R44 Clinical Trial Not Allowed)

Highlights of Section V: Application Review Information - NEXT

Review Criteria

5 Core Review Criteria
(between 1 and 9)

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

Overall Impact
(between 1 and 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

Significance

- Does the project address an important problem or a critical barrier to progress in the field?
- Does the proposed project have **commercial potential** to lead to a marketable STEM product? (In the case of Phase II and Fast-Track, does the Commercialization Plan demonstrate a high probability of commercialization?)
- **How well does the project plan demonstrate the potential to enhance the user's knowledge of biomedical science, interest in learning, and skills in solving problems?**

COMMERCIALIZATION PLAN (Significance)

Needed for a Phase II Fast-Track

- 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 sources that would enhance the likelihood for commercialization?

- Does it provide sufficient and compelling information about the management, the plans for product development, a demonstrated need for the STEM game, an adequate evaluation of the market and competitors, and address the contribution this project will make towards supporting the organization's long-term goals?

INVESTIGATOR(S)

- Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project?
- If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training?
- If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

INNOVATION

- Does the application employ novel theoretical concepts, approaches, methodologies. Is the product needed by the marketplace?
- Does the application challenge and seek to shift IDM or STEM education research paradigms by utilizing novel concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of IDM research or novel in a broad sense?
- **Are there new technologies or education methodologies used in the product design that will enhance the effectiveness of the product? Does the project plan demonstrate potential to break new ground in applying IDM for pre-college education?**

APPROACH

- Does the application have **clear milestones**, rigor, possible pitfall identified and alternative approaches considered? If human subjects, are both sexes considered? Does the inclusion/exclusion of groups justified?
- Does the proposed product development plan include sufficient early input from teachers and students?
- Is there a sufficient plan to collect and incorporate user feedback?
- Is the product interactive?
- Is the product built on a technology platform accessible to the targeted user group?
- Is the product grade and culturally appropriate? Are the evaluation instruments and metrics appropriate to assess project effectiveness?

ENVIRONMENT

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangement?

Adequacy of Fast-Track/Phase 2

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?

PHASE 2 or DIRECT TO PHASE 2

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

Overall Impact Scoring

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

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

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.

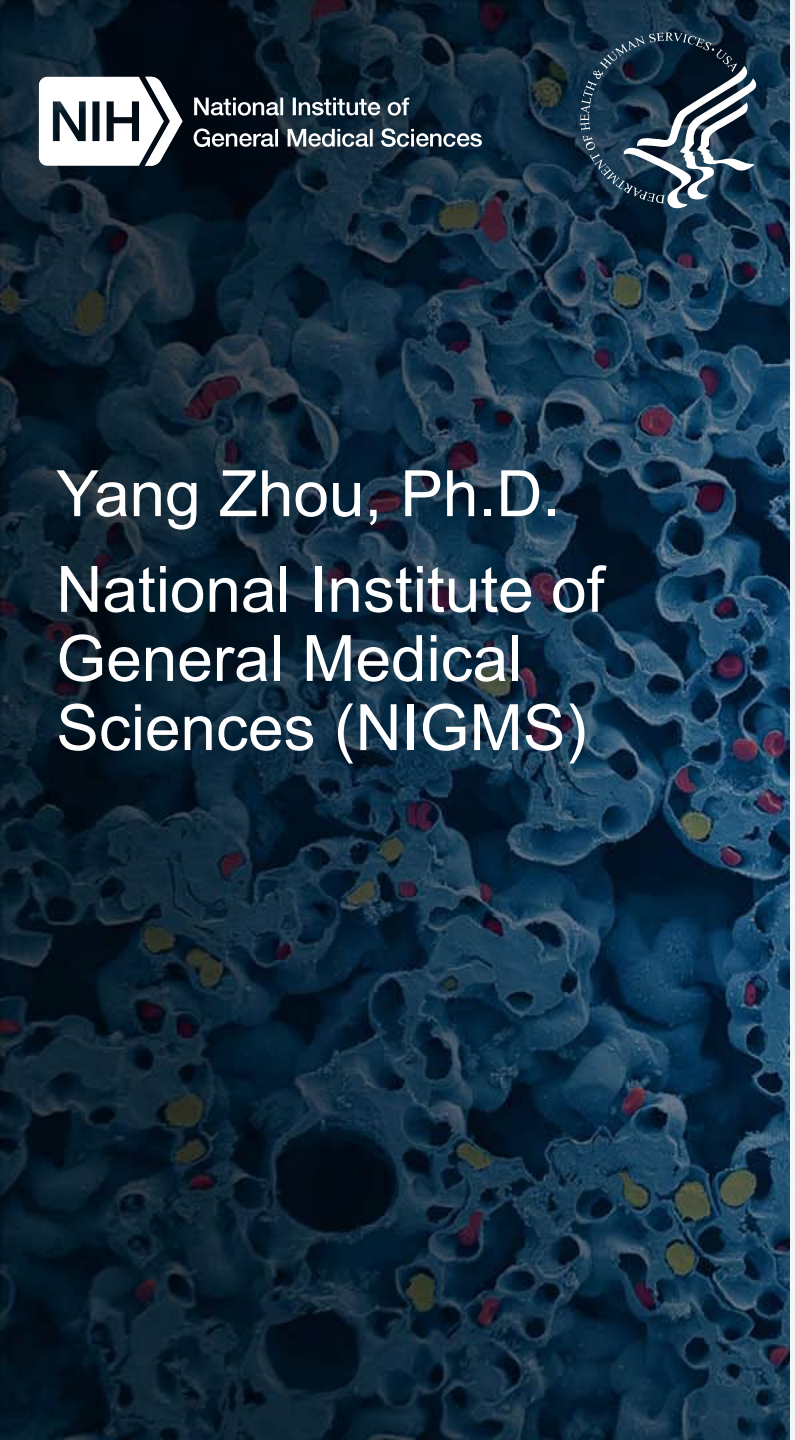
e.g. Applications may be addressing a problem of low or no importance in the field, with some or no weaknesses.

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

SUMMARY STATEMENT TO APPLICANTS

- The applications discussed at the meeting will get a final score: the average of the final Overall Impact scores from all eligible reviewers, averaged to one decimal place and multiplied by 10.
- At least 50% of the applications are discussed at the meeting, triaged by the preliminary overall score of the assigned reviewers.
- SRO will convert discussion and critiques into summary statements
- Summary statements for ALL applications (discussed and non-discussed) will include critiques and criterion scores provided by the three assigned reviewers.
- All summary statements will be released within 30 days of the review meeting.

Center for :Scientific Review: Information for Applicants



Yang Zhou, Ph.D.

National Institute of General Medical Sciences (NIGMS)

Human Subjects

Human Subjects Research

Research involving a living individual about whom:

- Data are obtained/used/studied/analyzed through interaction/intervention
- Interaction with subjects for the collection of biospecimens or data (including health or clinical data, surveys, focus groups or observation of behavior)
- Examples:
  - Testing a new educational technique
  - Conducting a focus group
  - Conducting a survey
  - Interviewing

Human Subjects Exemptions

- Human subjects research classified as “Exempt” means that the research qualifies as no risk or minimal risk to subjects and is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects, but is still considered research requiring an IRB review for an exemption determination.

- Exemption E1 (X1): conducted in an educational setting using normal educational practices
  - Effectiveness of a classroom-based STEM games device
  - Effectiveness of activities to increase awareness of oral health delivered at a community science museum

- Exemption E2 (X2): uses educational tests, surveys, interviews, or observations of public behavior*
  - Focus group of adult community members to discuss access to dental care
  - Questionnaire about outdoor exercise, including collection of participants’ age and zip code

- Check with your institutional review board (IRB) and Human Research Protection Program (HRPP) Resources prior to submission

Alania Foster

National Institute of General Medical Sciences (NIGMS)

Grants Management Basics

Grants Management Basics - General Guidance Part 1

Application Budget:

- Total costs normally may not exceed $306,872 - Phase I; $2,045,816 for Phase II. Unless the proposal falls under one of the approved waiver topics. NIGMS waiver topic caps - $350,000 – Phase I; $2,500,000 – Phase II

Application Indirect Costs:

- In the absence of a currently effective negotiated indirect costs rate, applicants may request a rate up to 40% of the total direct costs (no exclusions).

Proposed Project Period:

- Phase I – 6 to 12 months
- Phase II – up to 24 months

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 organization's policy for similar positions and may not exceed the congressionally mandated salary cap.

Grants Management Basics - Participant Costs

- Participants are those individuals who are involved in the proposed research education activity.
- Participants may be paid if specifically required for the proposed research education program and sufficiently justified.
- Participant costs must be itemized in the proposed budget.

Grants Management Basics - Meals

- Allowable for subjects and patients under study, or where specifically approved as part of the project activity
- Meal charges cannot be duplicated in the participants' per diem or subsistence allowances
- When certain meals are an integral and necessary part of a meeting or conference i.e., a working meal where business is transacted, grant funds may be used
- Recurring business meetings, such as staff meetings, cannot use grant funds for meals
- Please see section 7.9.1 of the NIH Grants Policy Statement

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 project
- Research proposed costs in advance and make sure the costs align with applicant organizational practices and are allowable under NIH policy

Grants Management Basics - 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 and must not duplicate items generally available at the applicant organization.
- Funds to support travel to the annual SEPA PI conference should be requested in the budget.

Grants Management Basics – Allowable and Unallowable Costs

Allowable Costs:

- Teachers and students participating in an IDM STEM SBIR project can be compensated for their participation in the project
- Incentive payments to volunteers or participants in a grant-supported project are allowable

Unallowable Costs:

- Stipends are not allowable on small business awards.
- Entertainment is not allowable on NIH awards
- Gifts are unallowable on all NIH awards.
- Promotional Items are not allowable on NIH awards

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

All costs must be allowable, reasonable, allocable, necessary and be accorded consistent treatment.

Grants Management Basics – Additional Policies

Foreign Disclosure and Risk Management:

- In the SBIR and STTR Extension Act of 2022, Congress required Federal agencies to establish a due diligence program to assess security risks posed by applicants.

Technical and Business Assistance (TABA) Funding:

- These funds are intended to help SBIR/STTR recipients:
  - make better technical decisions concerning such projects;
  - solve technical problems which arise during the conduct of such projects;
  - minimize technical risks associated with such projects; and
  - develop and commercialize new commercial products and processes resulting from such projects, including intellectual property protections.


ANY
QUESTIONS?