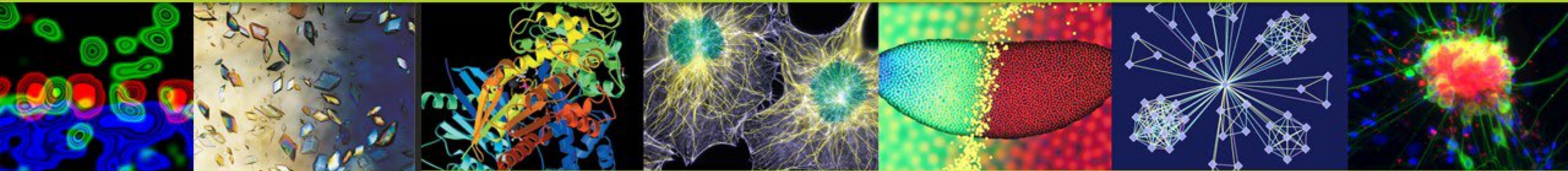National Institute of
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Pre-application Webinar

IDeA Regional Entrepreneurship Development (I-RED) Program (RFA-GM-22-001)

November 1, 2021
3:00 – 4:30 PM

Agenda

Welcome Remarks	• Dorit Zuk, Ph.D., Deputy Director, NIGMS
Program Description	• Behrous Davani, Ph.D., Program Director, Division for Research Capacity Building (DRCB), Networks and Development Programs Branch (NDP) • Christy Leake, NIGMS Grants Management Lead
Q&A via Chat Window	• Ming Lei, Ph.D., Director, DRCB • Krishan Arora, Ph.D., Branch Chief, NDP, DRCB • Behrous Davani • Christy Leake

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Disclaimer

- The webinar and accompanying slides serve as an overview of the funding opportunity RFA-GM-22-001. They are not meant to be comprehensive in coverage of all required components of an application.

Applicants are responsible for following the instructions in the FOA and any related Notices included in the FOA.

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IDeA Program, States and Regions

- Increase research capacity and **enhance** geographical distribution of NIH research funds

- Current eligibility: 23 States and Puerto Rico

- Disproportionately fewer SBIR/STTR applications and awards

https://www.nigms.nih.gov/Research/DRCB/IDeA/Pages/default.aspx
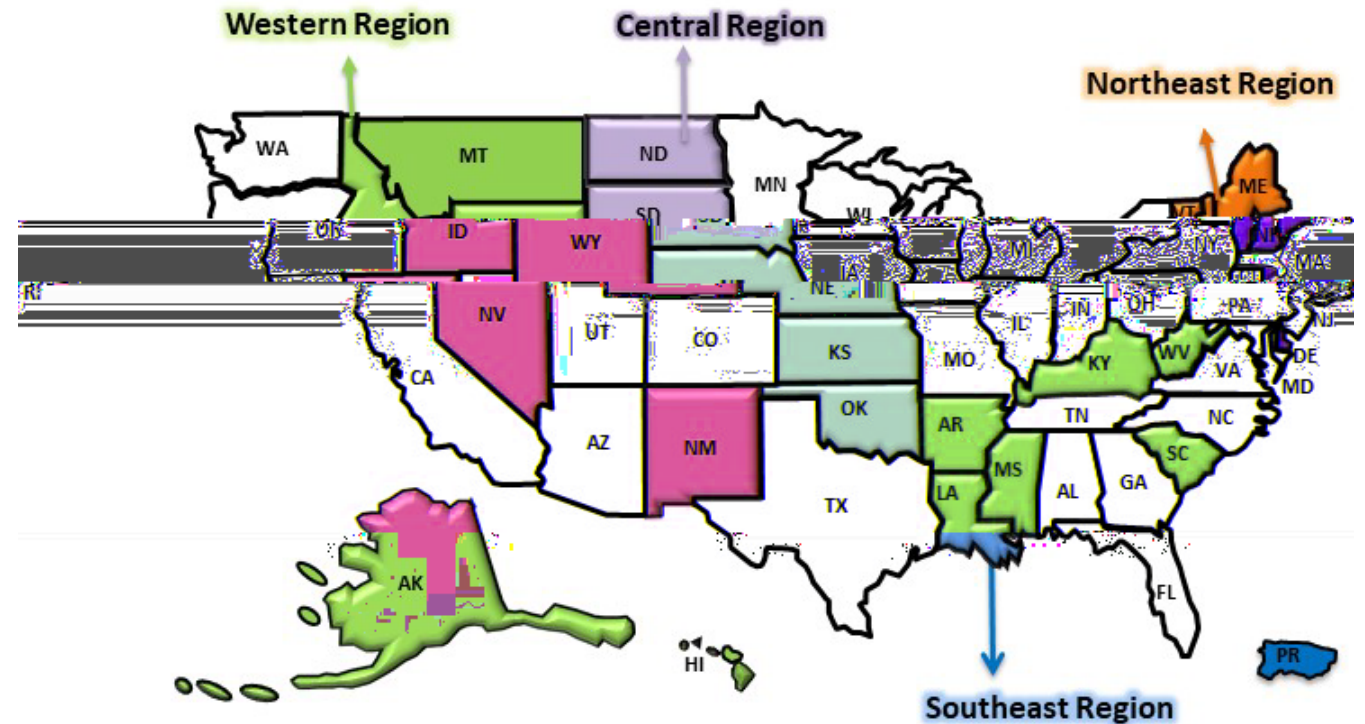
# Four Regional Technology Transfer Accelerator HUBs Funded in 2018*

- Conducted gap analyses at academic partner institutions in each of the IDeA regions

- Developed and delivered entrepreneurship training and education materials based on the gap analyses for faculty, postdoctoral fellows, graduate and undergraduate students

- Supported the establishment of technology transfer offices in many academic institutions and developed Technology (Tech) Transfer Networks

- Supported Pilot Projects

* Active Awards: https://www.nigms.nih.gov/Research/DRCB/Pages/DRCB-IDeA-Interactive-Portfolio-Dashboard.aspx?awardsby=program

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I-RED Program: Purpose

- Support eligible [small business concerns](#) (SBC) to develop educational products to promote biomedical entrepreneurship:

  - *Didactic or interactive forms of courses (in-person, virtual or recorded), manuals, casebooks, databases, and/or algorithms*

- Enhance entrepreneurial knowledge and skills:

  - *Patent filing, business plan development, capital raising, bookkeeping, financial management, business operation, and marketing*

- Develop and strengthen Technology Transfer Programs

- Stimulate technological innovation and translate technologies, materials, and/or services from academic research into commercial products

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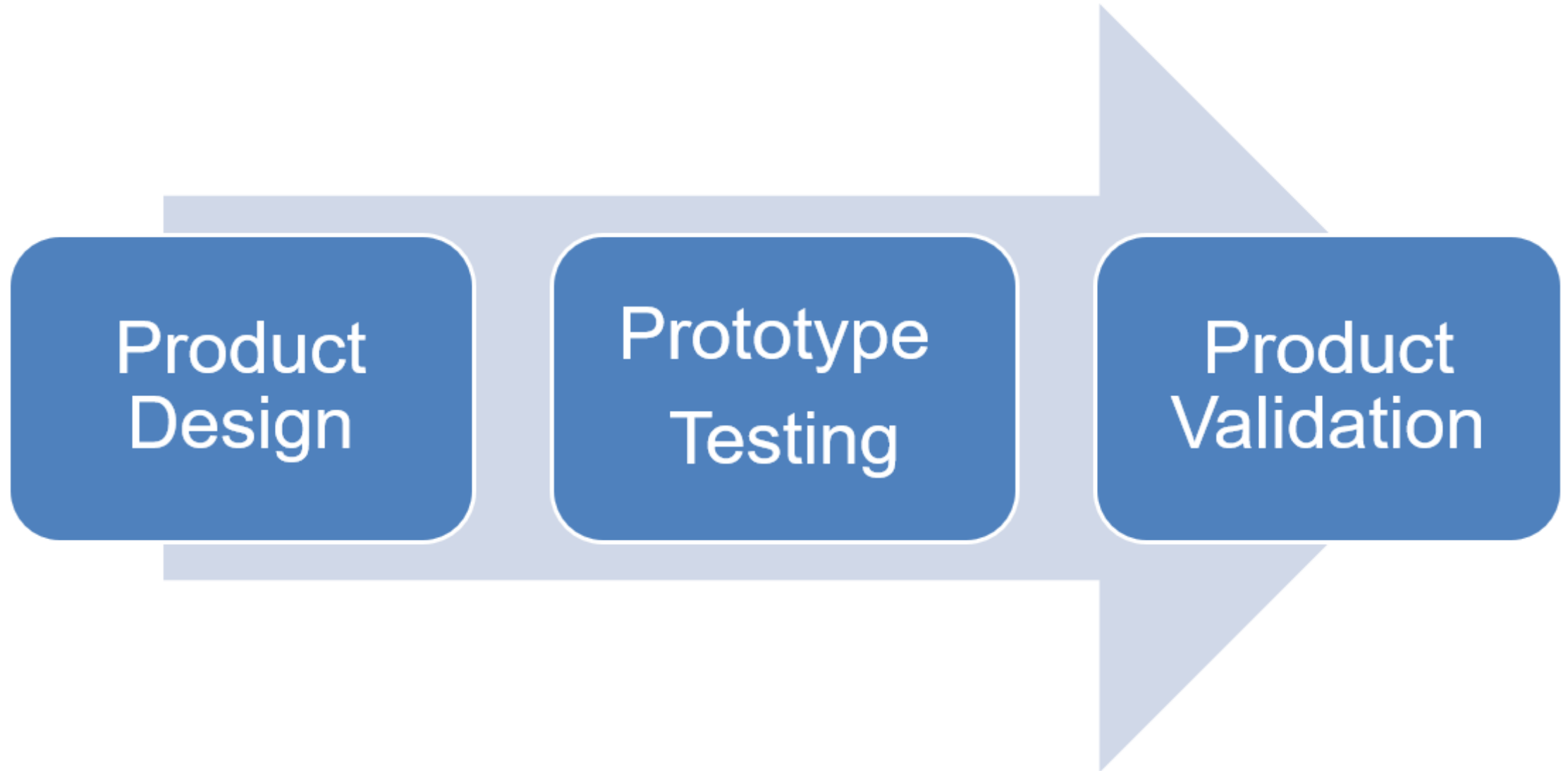
Product Design

- Must be novel products that meet the needs of the IDeA region it serves

- Using the gap analysis to identify the needs

- Assemble a team(s) that is capable of developing designs based on appropriate methodologies, building prototypes, and testing/assessing/adjusting process to refine the prototypes

- Must have commercialization potential

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Prototype Testing through Conducting Training

- Must be tested at academic institutions in the IDeA region the program serves

- Assemble a testing team(s) to conduct entrepreneurship training for students and faculty

- Develop methods and metrics to assess the effectiveness of the prototypes

- Leverage the institutions in the Tech Transfer Network for the testing efforts

Product Validation through Supporting a Pilot Project Program

- Products must be validated through support of Pilot Project Program that develops the process and criteria to identify a cohort of investigators from institutions in the Tech Transfer Network

- Assemble a validation team(s) to provide entrepreneurship training of a cohort of academic investigators

- Develop methods, metrics, and milestones to assess the entrepreneurship growth of these investigators and the performance of their pilot projects

- The scientific merit and commercial potential of the selected pilot project(s) must be reviewed by the EAC and approved by the SC before submitting to NIGMS staff for final approval

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Governance and Operation

Administrative Committee (AC)

- Administers the award in accordance with NIH policies and under the guidance of the SC
- The contact PI serves as the Chairperson of the AC

Steering Committee (SC)

- Provides scientific and administrative oversight of the program.
- Composition: contact PI, a corporate officer of the SBC, a member of the institutional leadership from the academic partner, a representative from each state in the IDeA region, and the NIH Project Coordinator
- The contact PI serves as the Chairperson of the SC

External Advisory Committee (EAC)

- Provides consultation and advice to the SC
- Members are selected by the PI(s in consultation with the SC
- EAC members *NOT* to be named in the application

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Applicant SBC, Academic Partner, & PD/PI(s)

- SBC must be from one of the four IDeA regions, and partner with one academic institution in the same IDeA region

- The academic partner must be an institution with robust biomedical research programs and an established technology transfer office

- The PD(s)/PI(s) must have expertise in technology transfer and commercialization and experience in developing and marketing entrepreneurship educational products

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I-RED Program: Mechanism and Project Period

- STTR Cooperative Agreement (UT2) – (Fast-Track)

- Phase I (one year)

- Phase II (two years)

- The Fast-Track mechanism requires that milestones of Phase I must be completed before Phase II funding released

Milestones

Phase I   **Phase II**

Phase I:
- Establishing functional SC, AC, and EAC
- Completing research and needs analyses to set product development goals
- Completing product design, and developing prototypes, and developing/adapting effective strategies and plans for product testing
- Developing Pilot Project funding opportunity and establishing the process

Phase II:
- Continuing the process of product development
- Funding pilot projects
- Testing training products designed to build the skills needed to develop successful SBIR/STTR applications
- Implementing an evaluation plan to monitor the success of the I-RED program
- Developing commercialization plans

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Required Components of I-RED Application

1) Specific Aims *(1 page)*

2) Research Strategy *(12 pages)*

- Overview
- Program organization, operation, governance, and key personnel
- Product Development
  A. Design
  B. Testing
  C. Validation
    ✓ Pilot Project Program
  D. Program Evaluation
    ✓ Evaluation metrics tied to the goals of the program

3) Commercialization Plan *(12 pages)*

- The planned path, efforts, timeline, and milestones toward reaching the commercialization goals

4) Letters of Support

- Evidence of strong and specific institutional commitment from partner institution
- No letter of support is required from other academic institutions in the region at the time of application submission
- Support from other local or regional sources

5) Resource Sharing Plan

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I-RED Program: Key Dates

- **Letter of Intent Due Date**   **December 5, 2021 (encouraged)**

- **Application Due Date**   **January 5, 2022**

- **Scientific Merit Review**   **March 2022**

- **Advisory Council Review**   **May 2022**

- **Earliest Start Date**   **July 2022**

  - Link to FOA: https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-22-001.html

Grants Management: Christy Leake
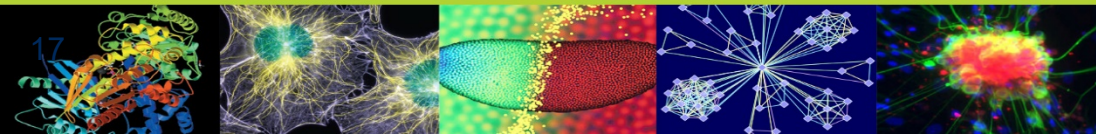
Eligibility

Applicant organizations must complete and maintain the following registrations as described in the SF424 (R&R) application guide:

- Dun and Bradstreet Universal Numbering System (DUNS)

- System for Award Management (SAM) – formerly CCR

- SBA Company Registry

- eRA Commons

- Grants.gov

**All PD(s)/PI(s) must have an eRA Commons account

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Eligibility

- Only United States small business concerns (SBCs) *from IDeA states* **are eligible** to submit applications for this opportunity.

- To receive an SBIR or STTR award, the awardee must qualify as a Small Business Concern (SBC) as defined by SBA regulations at 13 C.F.R. §§ 701-705. The eligibility requirements for the SBIR/STTR programs are unique and do not correspond to those of other small business programs.

- The eligibility criteria is outlined in Section III. Eligibility Information of this FOA.

- Small business concerns that are more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these are NOT eligible to apply to the NIH STTR program.

- The PD(s)/PI(s) may be employed with the SBC or the single, "partnering" non-profit research institution as long as s/he has a formal appointment with or commitment to the applicant SBC.

- Multiple PD/PI arrangement is allowed

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Contractual/Consortium Arrangements

- In Phase I and Phase II, at least 40% of the research or analytical effort must be performed by the small business concern and at least 30% of the research or analytical effort must be performed by the single, "partnering" research institution.

- The remaining 30% may be attributed to either the SBC/primary research institution or additional third party organizations.

- Contractual arrangements or a Memorandum of Understanding (MOU) must be established between the SBC and the participating institutions as a part of Phase I scope.

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Budget

- Budgets up to $252,000 total costs per year for Phase I awards may be requested.

- Budgets up to $1.5 million total costs per year for Phase II awards may be requested.

- Phase I applicants who do not have a negotiated F&A rate with a Federal agency should propose an estimated rate not to exceed 40 percent of the total direct costs.

- A reasonable fee, not to exceed 7 percent of total costs (direct and indirect) for each Phase of the project, is available to SBCs receiving awards under the SBIR/STTR program.

- Only one award per IDeA region

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Additional Budget Considerations

- The budget may include salary support for key person(s) including PD(s)/PI(s), R&D team, Commercialization team members, other persons essential for administering the award.

- Support for consultants not employed by the SBC or academic partner is allowed.

- Up to 40% of the Phase II budget may be requested to support the Pilot Project Program.

- Other allowable costs include, but are not limited to:

  - Product development, including product design, testing, and validation

  - Program evaluation

  - Operations of the SC, AC, and EAC

  - Travel to institutions in the regional Tech Transfer Network

- Travel of PD(s)/PI(s) (and other I-RED staff as appropriate) to attend I-RED program meetings organized by NIGMS, and other meetings directly related to entrepreneurship training

**Adequate budget justifications must be provided in the application to explain the relevance of the request's costs to the proposed activities.

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Questionable Budget Costs

- **Honorarium** – unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium; a payment for services rendered is allowable

- **Stipends** – only allowable on training grants; unallowable on other NIH grants; "Compensation of Students" is allowable

- **General Supplies** – only costs directly related to the grant and/or project are allowable as direct costs

- **Meals/Food** – allowable in cases when they are an integral and necessary part of a meeting; must be consistently treated and reasonable

- **Scholarships** – not allowable on NIH grants

Agency Contacts

- **Scientific/Research Contact**

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- **Peer Review Contact**

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- **Financial/Grants Management Contact**

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