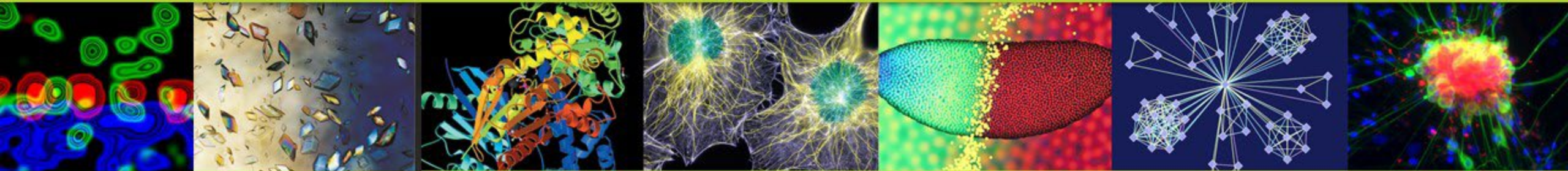


# Pre-application Webinar

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

November 1, 2021  
3:00 – 4:30 PM



# Agenda

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<b>Welcome Remarks</b>	<ul style="list-style-type: none"><li>• Dorit Zuk, Ph.D., Deputy Director, NIGMS</li></ul>
<b>Program Description</b>	<ul style="list-style-type: none"><li>• Behrouz Davani, Ph.D., Program Director, Division for Research Capacity Building (DRCB), Networks and Development Programs Branch (NDP)</li><li>• Christy Leake, NIGMS Grants Management Lead</li></ul>
<b>Q&amp;A via Chat Window</b>	<ul style="list-style-type: none"><li>• Ming Lei, Ph.D., Director, DRCB</li><li>• Krishan Arora, Ph.D., Branch Chief, NDP, DRCB</li><li>• Behrouz Davani</li><li>• Christy Leake</li></ul>

# Disclaimer

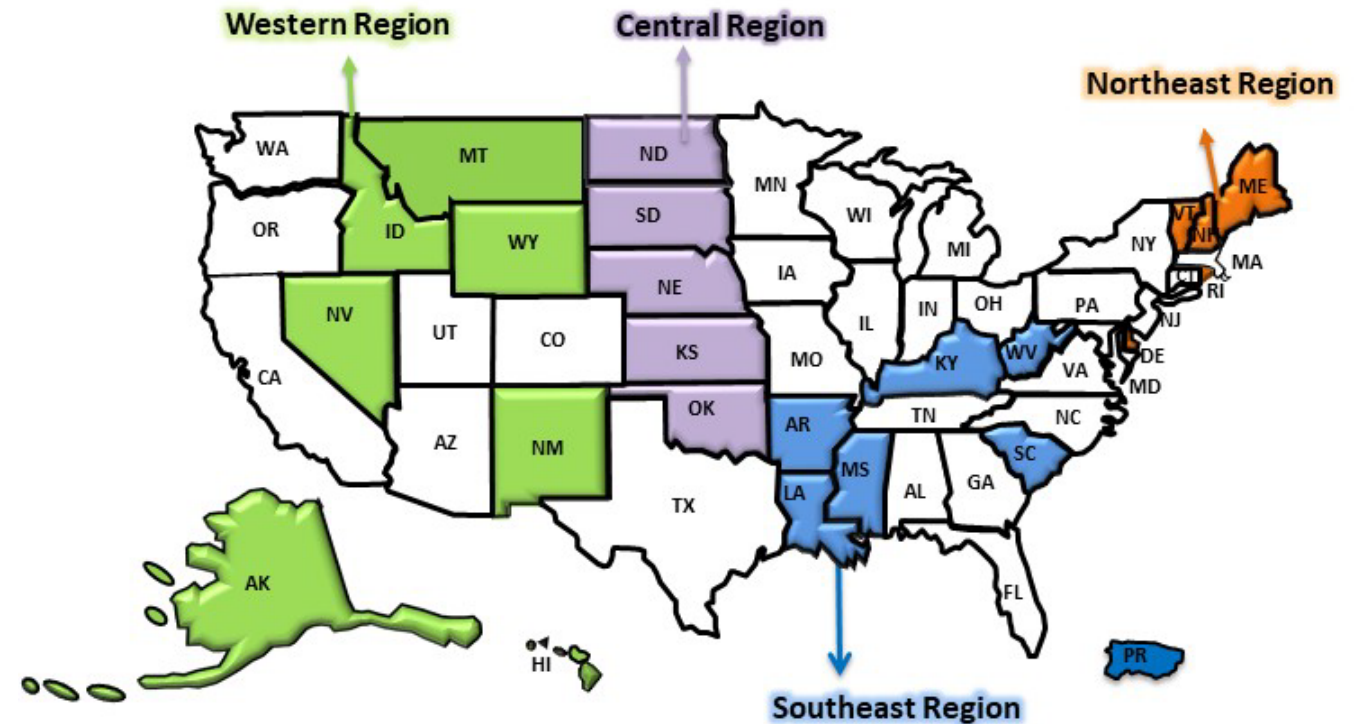
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- The webinar and accompanying slides serve as an overview of the funding opportunity RFA-GM-22-001. They are not meant to be comprehensive in coverage of all required components of an application.

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

# 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): <https://www.nigms.nih.gov/Research/DRCB/Pages/DRCB-IDeA-Interactive-Portfolio-Dashboard.aspx?awardsby=program>

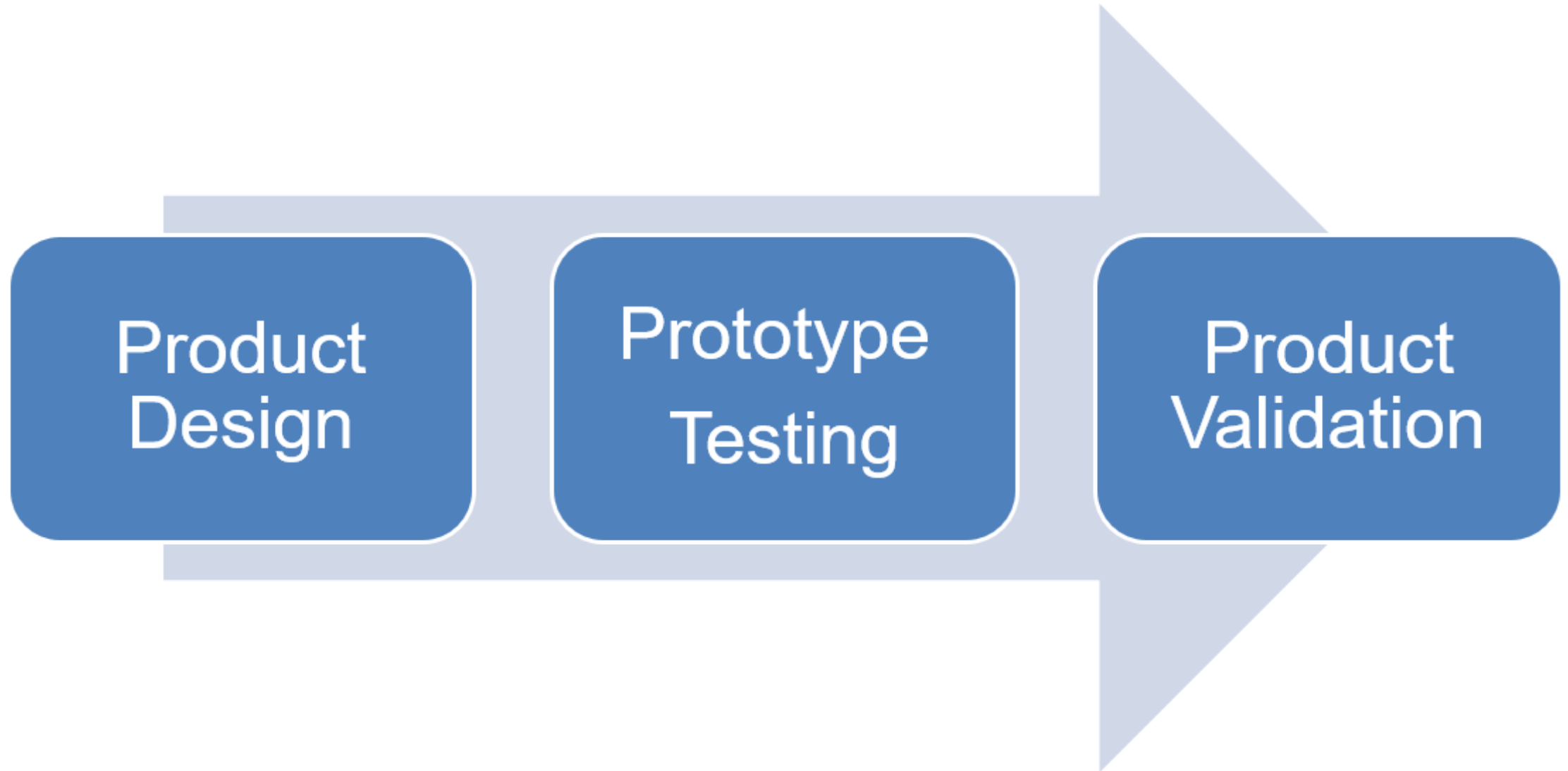
# I-RED Program: Purpose

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- 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

# Product Development and R&D Process

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# Product Design

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- 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



# Prototype Testing through Conducting Training

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- 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

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- 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

# 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

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

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- 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

# I-RED Program: Mechanism and Project Period

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- 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

- 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

# 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

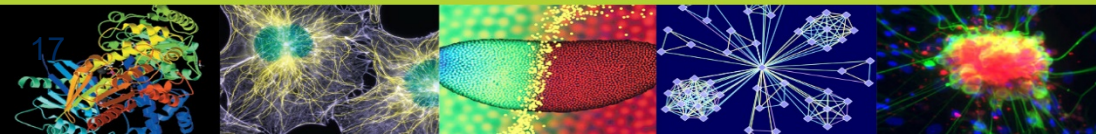
# I-RED Program: Key Dates

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- **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

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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

# Eligibility

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- 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

# Contractual/Consortium Arrangements

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- 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.

# Budget

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- 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

# 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.**

# Questionable Budget Costs

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- **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

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- **Scientific/Research Contact**

Behrous Davani Ph.D.

National Institute of General Medical Sciences

(NIGMS) [behrous.davani@nih.gov](mailto:behrous.davani@nih.gov)

- **Peer Review Contact**

Mark Caprara, Ph.D.

Center for Scientific Review (CSR)

[capraramg@mail.nih.gov](mailto:capraramg@mail.nih.gov)

- **Financial/Grants Management Contact**

Christy Leake

National Institute of General Medical Sciences

(NIGMS) [Christy.leake@nih.gov](mailto:Christy.leake@nih.gov)



# Thank you!

Please enter your questions into the chat box.

