National Institute of General Medical Sciences

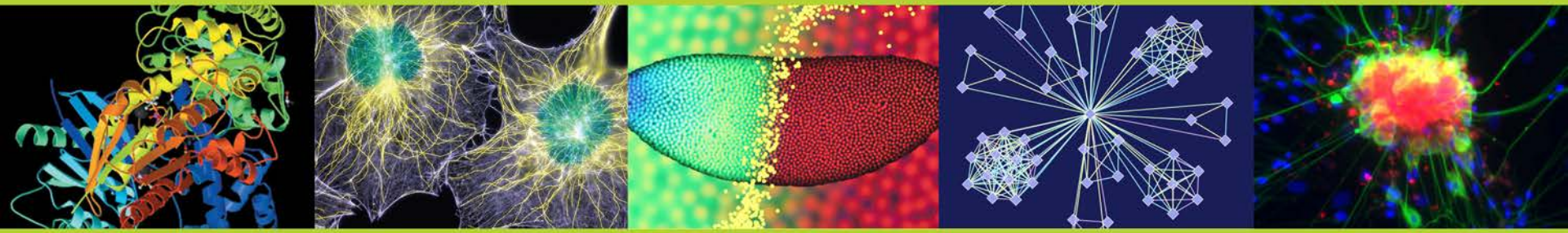
Webinar November 15, 2017: 3:00 – 4:30 p.m. ET

Regional Technology Transfer Accelerator Hubs for IDeA States (STTR) (UT2 – Clinical Trial Not Allowed)

RFA-GM-18-001

https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-18-001.html

National Institute of General Medical Sciences (NIGMS)
Center for Scientific Review (CSR)
National Institutes of Health (NIH)



Webinar Presenters

Scientific/Research

- Krishan K. Arora, Ph.D.
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- Joseph Gindhart, Ph.D.
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Peer Review

- Allen Richon, Ph.D.
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Financial/Grants Management

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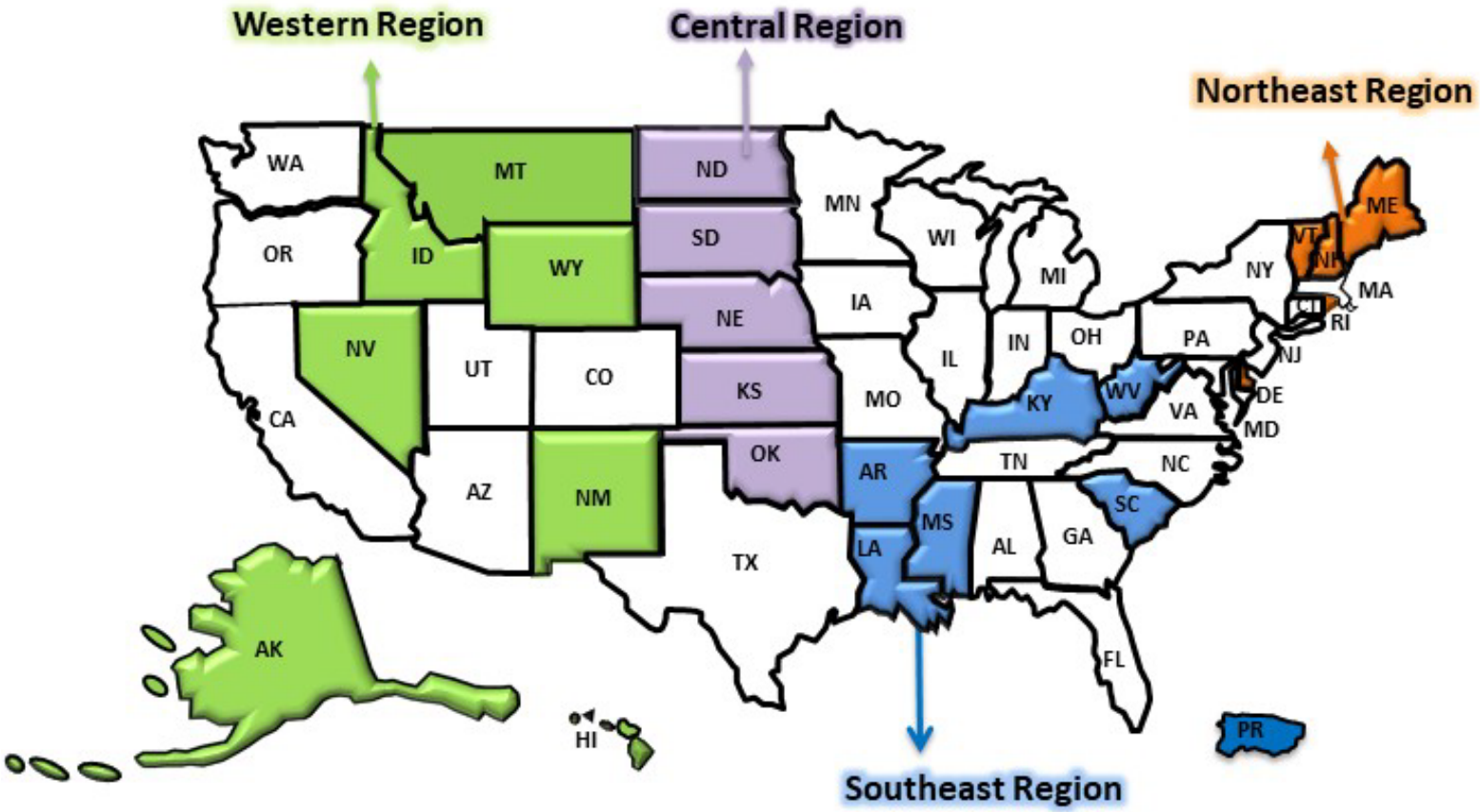
Program: Krishan Arora and Joe Gindhart

Regional Tech Transfer Accelerator Hubs for IDeA States

- **Intent**
  - One shared regional technology transfer accelerator hub in each of the four IDeA regions
  - Regional consortia to provide infrastructure and build an entrepreneurial culture at the IDeA institutions

The Four IDeA Regions



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Regional Tech Transfer Accelerator Hubs for IDeA States

- **Purpose**
  - Develop, implement, and test a comprehensive program for promoting:
    - Entrepreneurship
    - Technology transfer
    - Intellectual property
    - Management
    - Small business finance
    - Other business skills
  - Generate educational and training tools – i.e., curricula, texts, webinars and modules

Regional Tech Transfer Accelerator Hubs for IDeA States

- **Target applicants**
  - Small business concerns (SBCs) from any state in the U.S. with the requirement to partner with academic institutions in the IDeA states to create a regional network

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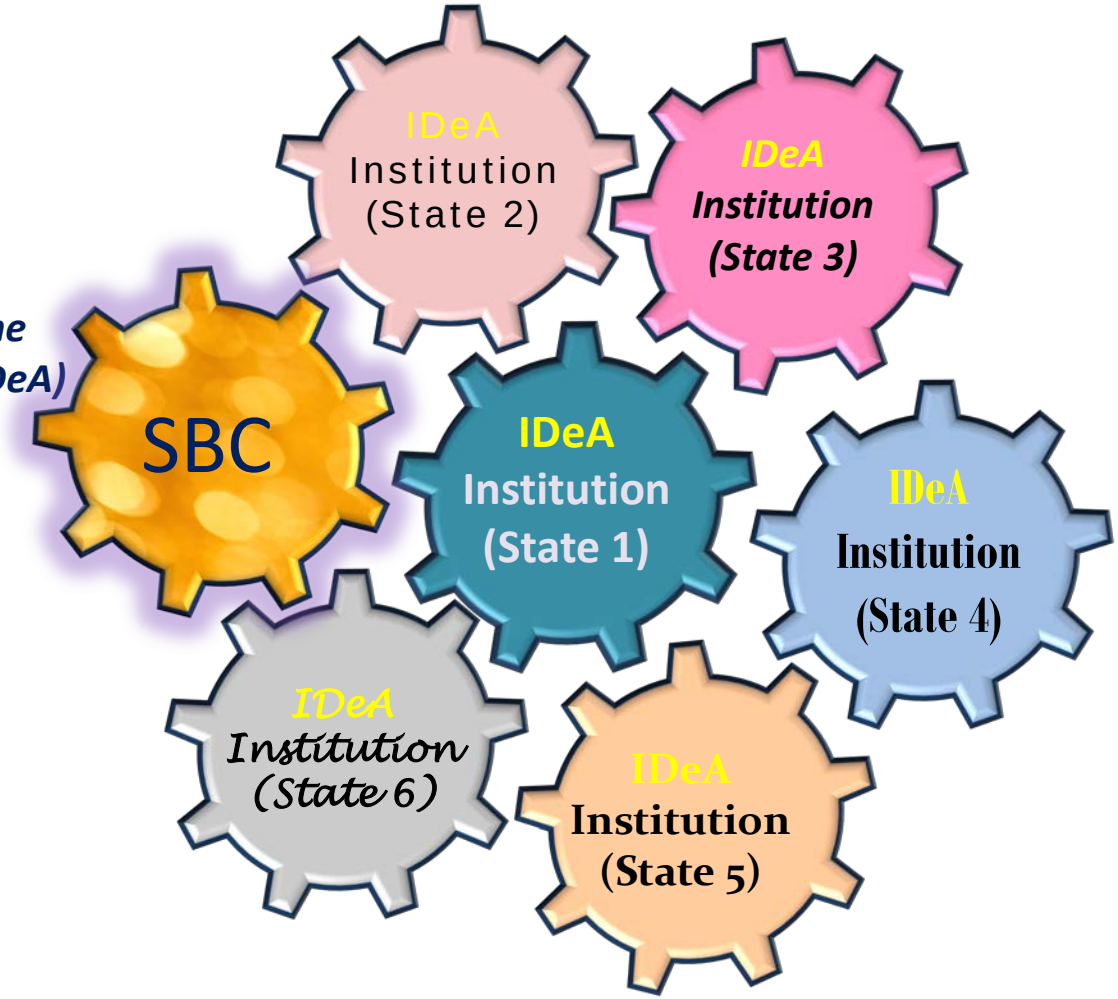
STTR Regional Accelerator Hub: Collaboration Between *Small Business Concern (SBC)* & *Academic Institutions* in IDeA States

From <u>any state</u> in the U.S. (IDeA or non-IDeA)



Regional Tech Transfer Accelerator Hubs for IDeA States

- **Mechanism:**
  - STTR Cooperative Agreement (UT2) – (Fast-Track)
  - Phase I (one year)
  - Phase II (two years)

- **Funding:**
  - Phase I: up to $500K total costs per year
  - Phase II: up to $1.5 million total costs per year

Regional Tech Transfer Accelerator Hubs for IDeA States

FOA: *https://grants.nih.gov/grants/guide/rfa-files/RFA-GM-18-001.html*

Letter of Intent Due Date	December 5, 2017
*Application Due Date	January 5, 2018
Scientific Merit Review	March 2018
Advisory Council Review	May 2018
Earliest Start Date	September 2018

Letter of Intent

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

Characteristics of Regional Accelerator Hubs

- **Each Hub:**
  - Governed by leadership experienced in translating biomedical advances to marketplace;
  - Develop collaborations and partnerships effectively with other entities to meet the goals of this FOA;
  - Provide and strengthen infrastructure for an Office of Tech Transfer and Commercialization at the partner institutions;
  - Provide entrepreneurial educational opportunities for innovators to create cultural and systemic changes;
  - Provide entrepreneurial faculty, investigators, post-docs and students with skills development, hands-on entrepreneurial experience, educational and networking activities;
  - Develop linkages with state, local and other available resources;
  - Develop courses at graduate and undergraduate levels to enhance their awareness and skills for careers in industry;
  - Develop and implement a plan for transitioning to a self-sustaining structure.

Characteristics of Regional Accelerator Hubs

- **Leveraging with existing NIGMS and NIH funded programs and other Federal, state, local and non-Federal resources:**
  - IDeA programs: COBRE, INBRE and IDeA-CTR
  - REACH and NCAI centers
  - CTSAs
  - Cancer centers

  State and Local:
  - Small Business Development Centers
  - Economic Development Administration Offices and

  - Others as appropriate

Regional Accelerator Hubs for IDeA States

❖ Institutional Commitment and Regional Support:

Need to demonstrate evidence of strong and specific institutional commitment by Hub's academic partners; may include:

- adequate laboratory space,
- seed money for pilot projects at their institutions,
- providing entrepreneurial faculty release time and recognition in terms of rewards/incentives/tenure and promotion,
- creation of undergraduate and graduate courses in biomedical technology research, development, and entrepreneurship
- Local or regional sources such as state governments or business development organizations

Regional Tech Transfer Accelerator Hubs for IDeA States

- **Hub Leadership must:**
  - have necessary operational, business and scientific expertise with a documented track record of success

Hubs Structure

- **Each Hub must have:**
  - A governance team consisting of Program Director/Principal Investigator and the institutional leadership from the IDeA partner institutions

  - Each Hub must have the following committees:
    - Administrative Committee
    - Internal Advisory Committee
    - External Advisory Committee
    - Program Steering Committee

Hub Activities

- A program fostering entrepreneurship in biomedical research should encompass:
  - Development of educational and training materials such as curricula, courses, webinars, texts and workshops
  - Skills development
  - Mentoring and coaching
  - Internships in small biomedical businesses and other related activities
  - Consulting and advising
  - Preparing an SBIR/STTR application
  - Creating an entrepreneurial culture
  - Establishing and/or improving the operations of technology transfer and commercialization offices and
  - Others as appropriate

Evaluation Plan and Milestones for the Hub

- The Administrative Committee is responsible to oversee and monitor progress

- Criteria for evaluation and success may include:
  - Number of participating faculty
  - Development of curricular and skills development materials and effective strategies
  - Number of patents
  - Number of licensing agreements
  - Increase in technology transfer from IDeA institutions into the private sector for commercialization
  - Number of startups focused on biotechnology
  - New applications for SBIR/STTR – submitted and awarded
  - In the long-term, marketing of products, diagnostics , tools and technology to improve human health and an increase in regional biotech-related jobs and economic activity in IDeA states

STTR Regional Hubs (UT2 – Fast Track)

- **Specific Aims (1 page)**
- **Research Strategy should include following subsections: (12 pages)**
  - Leadership and Governance
  - Collaborations and Partnerships
  - Skills Development, Education, Mentoring, Consulting and Advising
  - Plans for self-sustaining operations
  - Program Evaluation
  - (Optional) Pilot Projects
- **Commercialization Plan (12 pages)**

Regional Accelerator Hubs for IDeA States

- **Institutional Commitment**
- **Pilot projects***
  - An optional element of the Hub
  - To demonstrate the feasibility and proof-of-concept studies for an innovative product, biomarker, diagnostic or technology through the commercialization pipeline
  - Pilot projects are not to be proposed in the application
  - After the award is made, these projects can be solicited from faculty at participating institutions and selected by the EAC

*, federal funding under this FOA may not be used to support this activity.

Letters of Support

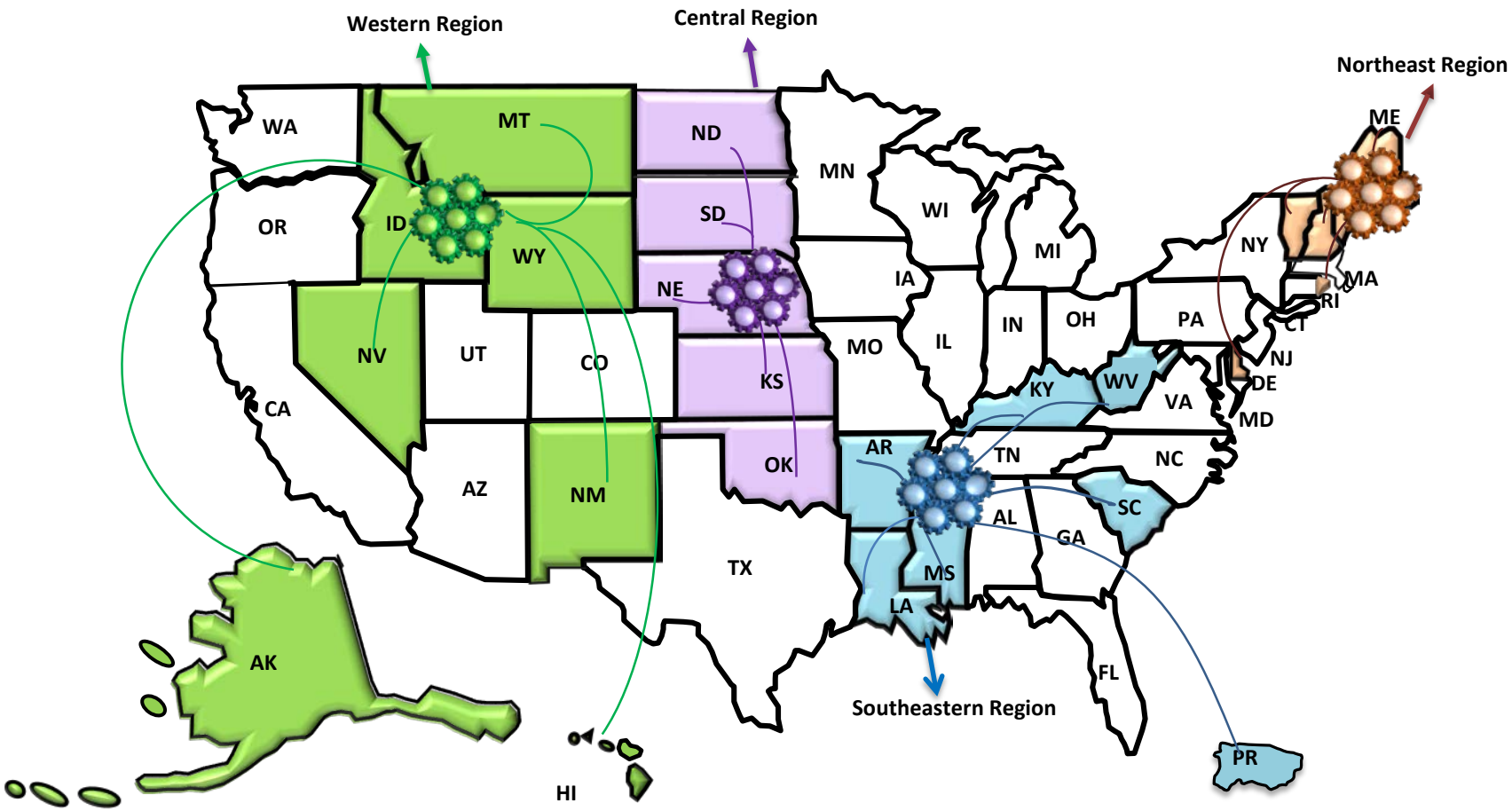
- Applicants should include letters of support from *academic partners, consultants, contractors, and collaborators* as appropriate.
- It is recognized that the availability of resources is variable among IDeA institutions. Consequently, the level of institutional commitment will differ among applicant institutions. At a minimum, the application should include communication from a senior institutional official from each of the partner institutions (e.g., President or Dean) outlining the resources and facilities that will be committed by the institution to support and sustain the regional Hub throughout the period of funding and beyond.
- As appropriate, letters of support from the Program Directors/Principal Investigators of other awardees of NIH and other Federal and non-Federal entities (*e.g., COBREs, INBREs, IDeA-CTRs, REACH and CTSAs)* may be included to indicate their role in assisting the regional tech transfer accelerator Hub. Letters of support indicating prior/current relationships with applicant SBCs (if any) may be included.
- Letters indicating support or resources available from *state or local government agencies or other groups (e.g., business development organizations)* may also be included.

UT2 Phase I/II Transition

- An administrative review by NIGMS Program Staff

- Specific milestones/criteria for entering from *Phase I to Phase II* must include:
  - Functional Administrative Committee, Internal Advisory Committee, Program Steering Committee and External Advisory Committee that have established the Hub structure, governance and leadership plan
  - Contractual arrangements/memoranda of understanding (MOU) between the SBC and academic partners in the IDeA region established and in place
  - Assessment of the infrastructure needs at the academic partners and formulation of an implementation plan
  - Assessment of the innovators' skillset and learning needs, the local ecosystem's resources for relevant content, and plan for developing additional content for education and workshops
  - Develop a prototype for training and educational courses for faculty, post-doctoral fellows, graduate students and undergraduate students
  - Establish a system for webinar delivery, organizing webinars, and visiting academic institutions for outreach

Regional Technology Transfer Accelerator Hubs for IDeA States



Review: Allen Richon

U.S. Department of Health & Human Services

NIH Center for Scientific Review

Review of STTR Application in Response to RFA-GM-18-001

Allen Richon, Ph.D.
Scientific Review Officer
Coordinator for Review of Small Business Applications
Center for Scientific Review, NIH

Role of the Scientific Review Officer

Designated Federal Official with overall responsibility for the review process

- Legal responsibility for study section and management of review.
- Performs administrative review of applications to ensure completeness and accuracy
- Selects reviewers based on broad input
- Manages study section meetings
- Prepares summary statements

Role of Study Section Chair

- Partners with their Scientific Review Officer to conduct the meeting
- Guides and summarizes study section discussion
- Ensures all study section member opinions are given careful consideration
- Manages scientific discussions at the meeting, e.g., timeliness and thoroughness

Extramural Support Assistant

- Assists Scientific Review Officer with administrative and technical review of applications
- Makes preparation for study section meetings and project site visits
- Shares administrative responsibilities at meetings
- Prepares preliminary summary statements for Scientific Review Officers

Selecting Reviewers for SBIR/STTR Study Sections

- Demonstrated scientific expertise/research support
- Mature judgment
- Breadth of perspective
- Impartiality
- 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.
- Representation of women and minority scientists
- Geographic distribution
- Commercialization and Technology Transfer expertise

Before the Study Section Meeting

- Each application is assigned to 3 or more reviewers 5-6 weeks in advance
- Reviewers assess each application by providing:
  - A preliminary Overall Impact score
  - Criterion Scores for each of the 5 Core Review Criteria
  - A written critique

Review Criteria

5 Core Review Criteria

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

Each scored from 1-9

Overall Impact

Assessment of the likelihood that the Hub described will exert a sustained, powerful influence on how well the Hub's expertise, capabilities, partnerships, and resources will enable it to significantly impact the pace and probability of success for discoveries and innovations being developed into commercial products at academic partner institutions in the regional network.

Scored from 1-9

Additional Criteria that Contribute to Overall Impact Scores

These will be considered as <u>score-driving</u> criteria
(but are not scored individually).

- Hub Impact and Organization
- Education and Skills Development
- Technology Transfer Capacity Development
- Project Management, Mentoring, Consulting and Advising

Additional Criteria that Contribute to Overall Impact Scores

Fast Track criteria to be considered as <u>score-driving</u>
(but are not scored individually).

- Does the application have two distinct Phases?
- Does the Phase I portion of the application specify clear, appropriate and measurable goals (milestones) that have to be achieved before initiating Phase II?
- Do these milestones meet the requirements for the UT2 Phase I/Phase II transition?

Additional Criteria that Contribute to Overall Impact Scores

Commercialization criteria to be considered as <u>score-driving</u>
(but are not scored individually).

- 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?
- To what extent does the application provide a reasonable plan for transitioning to a self-sustaining structure, both at the IDeA institutions and the SBC?

Additional Criteria Contribute to Overall Impact Scores (Likely Not Applicable)

- Protections for human subjects
- Inclusions of women, minorities, and children
- Appropriate use of vertebrate animals
- Management of biohazards

Other Considerations that Do Not Affect Overall Impact Scores

- Resource Sharing Plans:
  - Data
  - Model Organisms
  - Genomic Data (Human and nonhuman)
  - Foreign Organizations
- Select Agents
- Authentication of Key Biological and/or Chemical Resources
- Budget

9-Point Scoring Scale

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Medium Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor

At the Review Meeting

- Chair asks primary reviewers to state their preliminary overall impact scores.
- Reviewer 1 introduces the application to the panel.
- Reviewers 2 and 3 offer complementary insights.
- Discussion is open to the entire panel.
- After discussion, Chair asks primary reviewers to state their final overall impact score.
- Entire panel enters their scores for the application.

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 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 must be released within 30 days from the meeting, starting from the best-scored application.

Financial/Grants Management: Christy Leake

Required Registrations

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

- 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.
- 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

- 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

- Budgets up to $500,000 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. NIH will not negotiate F&A rates for Phase I awards.
- 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. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work.

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Additional Budget Considerations

- Each PD/PI must commit a minimum of 10% effort to the project.
- Funds should be requested for the Hub PD(s)/PI(s) (and other Hub staff as appropriate) to attend the annual in-person Program Steering Committee meeting in Bethesda, Maryland.
- Funds should also be requested for the operations of the External Advisory Committee.
- Other allowable costs as described in the FOA.

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

Questionable 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 IDeA grants; “Compensation of Students” is allowable
- **Housing** – not allowable on NIH grants – should be paid as travel costs
- **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

Program Slides

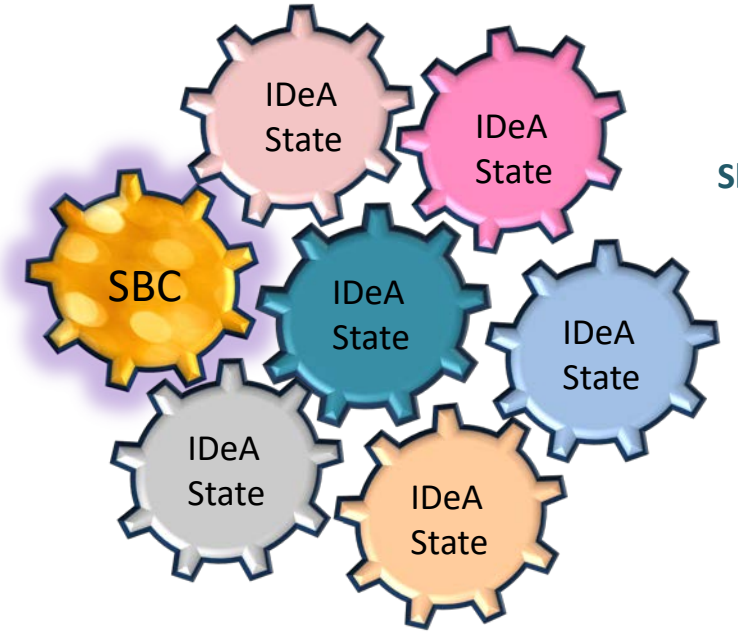
Final Reminders

- **Read and follow** all instructions in the Funding Opportunity Announcement.
- A small business concern (SBC) could be located anywhere in the U.S. from an IDeA or non-IDeA state.
- SBC must partner with academic institutions in IDeA states to create a regional tech transfer accelerator hub.
- You may include consultants/experts/advisors/coach/mentors from IDeA or non-IDeA states, as you deem appropriate.
- An application must include milestones that will be achieved for Phase I to Phase II transition.
- Potential members of an external advisory committee (EAC) should not be named and should not be contacted prior to the review of an application.

Fostering Biomedical Entrepreneurship in IDeA States

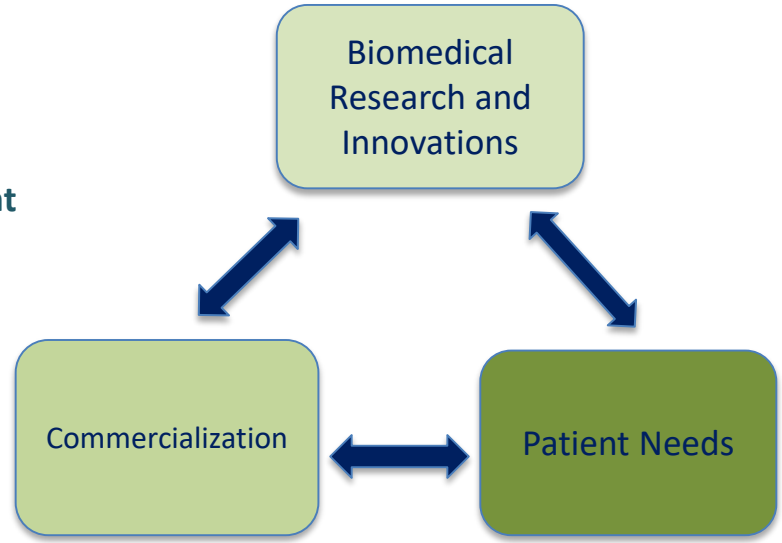
Regional Technology Transfer Accelerator Hub

Entrepreneurship Ecosystem



Skills Development
Mentoring
Education
Training

& Outreach



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