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NCATS

COLLABORATE. INNOVATE. ACCELERATE.

Peer Review for Small Business Funding: An Overview of the Process

February 24, 2022

Featured Speakers

Allen Richon, Ph.D.

Scientific Review Officer and
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MODERATOR

Agenda

Welcome, Introductions and Overview

NCATS SBIR & STTR Programs

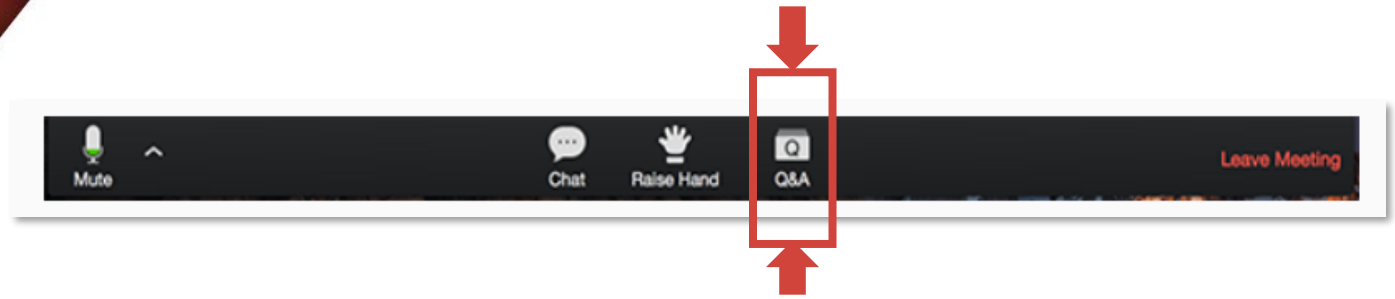
- Program Overview
- Opportunities and Resources

Peer Review Process

- Selection of Reviewers
- SBIR/STTR Applications Review Process

Moderated Q&A

- Please use the chat or Q&A function to submit questions at any time during the presentation



Meena U. Rajagopal, Ph.D.
Program Officer
Office of Strategic Alliances
National Center for Advancing Translational Sciences
National Institutes of Health

What Does the National Center for Advancing Translational Sciences (NCATS) Do?

1 of 27

Institutes and Centers at the National Institutes of Health (NIH).

Conducts and supports research on the science and operation of translation to allow more treatments to get to more patients more quickly.

Focuses on what is common across diseases and the translational process.

NCATS

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

TRANSLATIONAL SCIENCES

SBIR and STTR:
One of the Largest Sources of Early-Stage Financing

41.68 Billion

2021 NIH budget for basic & applied biomedical science

1.0356 Billion

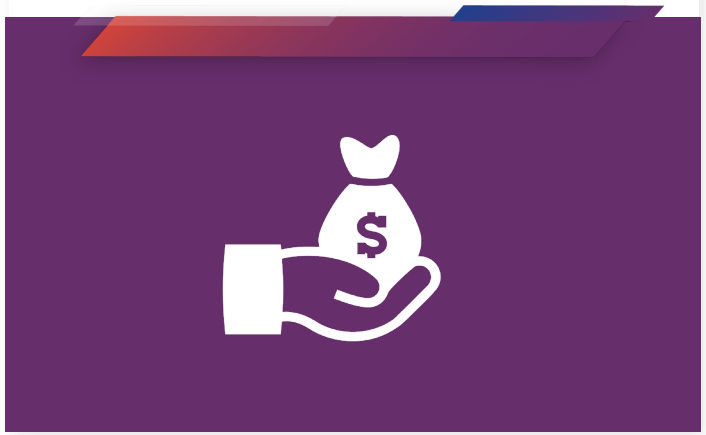
2021 NIH funds for small businesses (SBIR & STTR)

3.65% Set-aside for SBIR/STTR support

The Benefits

NCATS SMALL BUSINESS PROGRAMS (SBIR/STTR)

Stable and predictable. Not a loan. Funds don't have to be repaid.



Non-dilutive. IP rights are retained by the small business.

Technical assistance to advance and commercialize technologies for public good.

Projects undergo NIH's rigorous scientific peer review process, which awardees leverage to attract other funding and collaborations.

SBIR and STTR Critical Differences

	SBIR	STTR
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner (e.g., university)
Work Requirement	Guidelines: May outsource 33% (Phase I) 50% (Phase II)	Minimum Work Requirements: 40% small business 30% research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business

Award is always made to the small business

Translational Science and Research Areas of Interest

SBIR and STTR programs support NCATS' **mission to transform the translational science process** so that **new treatments and cures** for disease can be **delivered to patients more efficiently.**

TOPICS OF INTEREST

1. Preclinical Drug Discovery & Development
2. Biomedical, Clinical & Health Research Informatics
3. Clinical, Dissemination & Implementation Research

2022-2023 DEADLINES:

April 5
September 5
January 5

Funding Overview

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are some of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow U.S.-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

Omnibus Solicitation	• Investigator-initiated grant funding • Standard Deadlines: April 5, September 5, January 5
Grant Solicitations in Targeted Areas	• Grant to advance a particular technology/research area • Due dates may vary
Contract Solicitation	• Contract opportunity to advance areas of high research interest • Typically due in October or November

NIH SBIR/STTR Is a Three-Phase Program

Phase I Feasibility Study

Budget Guide: $275,766K for SBIR and STTR *($325K Waiver)*
Project Period: 6 months (SBIR); 1 year (STTR)

Phase II Full Research/R&D

$1,838,436 for SBIR and STTR, over two years *($2M)*

Fast Track combines Phase I and Phase 2
Direct to Phase 2 – allows to skip Phase 1

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/to FDA
Funding Varies (~$1M per year) for up to 3 years

Phase III Commercialization

NIH, generally, not the "customer"
Consider partnering and exit strategy

Application Process Timeline

Due Dates	Scientific Review	Council Review	Award Date (earliest)
SEPTEMBER 5	OCTOBER/NOVEMBER	JANUARY/FEBRUARY	MARCH/APRIL
JANUARY 5	FEBRUARY/MARCH	MAY/JUNE	JULY
APRIL 5	JUNE/JULY	AUGUST	SEPTEMBER OR DECEMBER

Targeted Funding Opportunities for 2022

- **NHLBI SBIR Phase IIB Small Market Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (R44 Clinical Trial Optional)**
  - **SBIR:** RFA-HL-23-008
  - Next Deadline: Feb. 28, 2022
- **Notice of Special Interest (NOSI): Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health**
  - NOT-EB-21-001
  - Next Deadline: April 5, 2022
- **Technology for Improving Minority Health and Eliminating Health Disparities**
  - **SBIR:** RFA-MD-22-003 (R41/R42 - Clinical Trial Optional)
  - Next Deadline: April 5, 2022
- **Innovations for Healthy Living – Improving Minority Health and Eliminating Health Disparities**
  - **SBIR:** RFA-MD-22-004 (R43/R44 - Clinical Trial Optional)
  - Posted: Jan. 5, 2022
  - Next Deadline: April 5, 2022
- **Development of Highly Innovative Tools and Technology for Analysis of Single Cells**
  - **SBIR:** PA-20-047 (R43/R44 Clinical Trial Not Allowed)
  - **STTR:** PA-20-025 (R41/R42 Clinical Trial Not Allowed)

Allen Richon, Ph.D.
Scientific Review Officer
SBIR/STTR Review Coordinator
Center for Scientific Review
National Institutes of Health

Peer Review and Funding of NIH Grant Applications

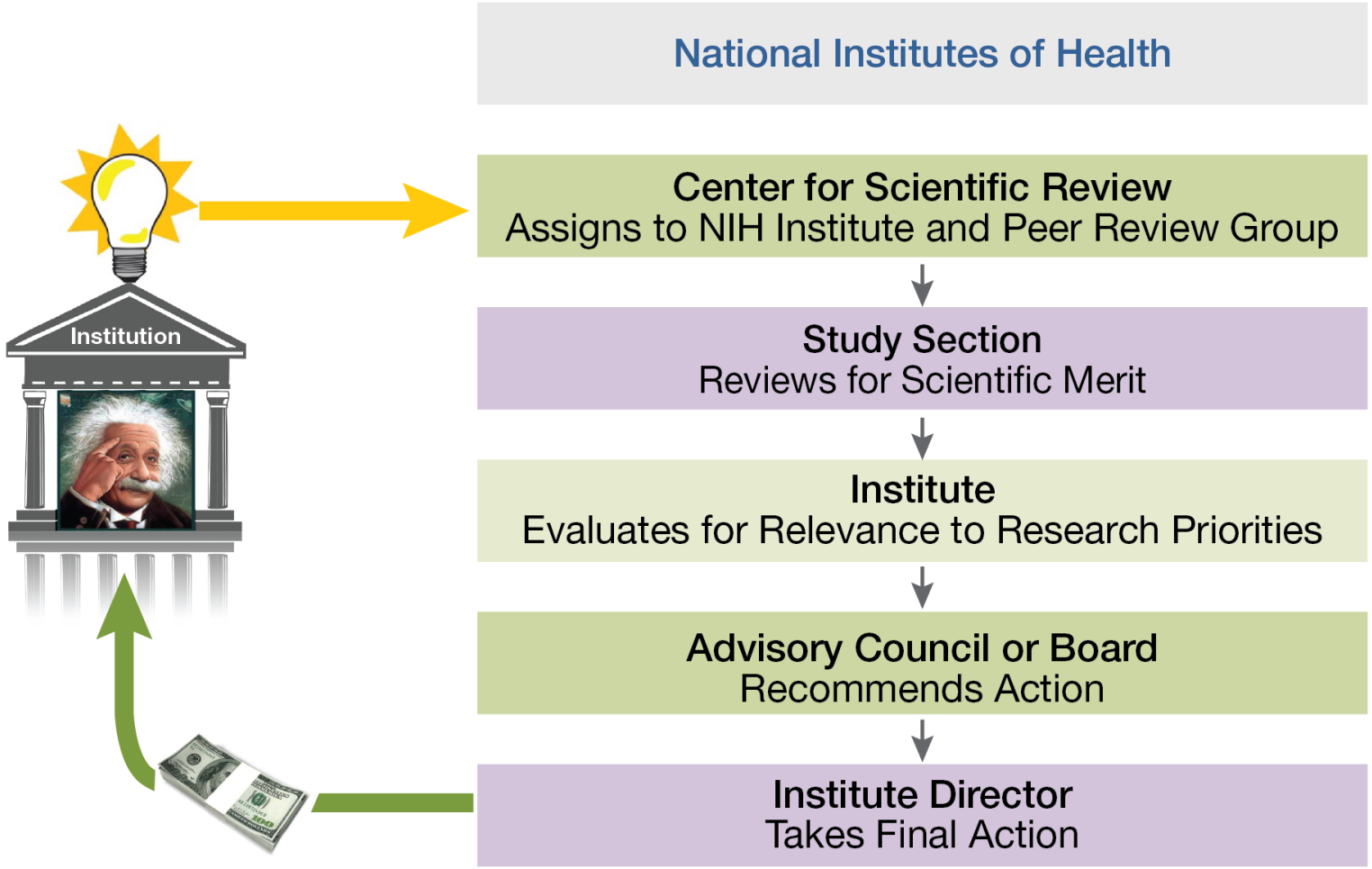
Mission

Our mission is to ensure that grant applications receive fair, independent, expert, and timely scientific reviews – free from inappropriate influences- so the NIH can fund the most promising research.

Focus of SBIR/STTR Review

Impact: Will the project have a sustained, powerful influence on the research field(s) or *marketplace* involved?

Peer Review and Funding of NIH Grant Applications



SBIR/STTR Peer Review

- NIH receives ~85,000 applications/year
- CSR organizes 18,000 scientists who participate in 1,300 review meetings
- ~7,500 SBIR/STTR applications are reviewed in ~40 study sections
  - Applicants can locate the one that best fits their application by using the CSR Assisted Referral Tool: https://art.csr.nih.gov, then use the Assignment Request Form to suggest a specific Study Section when they apply

Submission Process

- Applicant submits their application to Grants.gov or through ASSIST
- Once complete, the application is processed into eRA Commons where PIs have 2 days to check for errors
- Application is sent to the Division of Receipt and Referral (DRR) where it is assigned to an Institute(s) and an Integrated Review Group (IRG)
- DRR prescreens applications for compliance
- IRG Chief assigns applications to study sections
- Scientific Review Officers screen for fit and notify applicants

Peer Review System – The Referral Officer

- An SRO who receives significant training in the art of referral
- Works with the Institutes and Centers to make the connection between the application's goals and NIH's goals
- Has an in-depth knowledge of the scope of each CSR Study Section
- Prescreens applications for compliance
- Investigator has input – the Assignment Request Form (ARF)

Peer Review System – The Scientific Review Officer (SRO)

- Applications are reviewed under law defined by the Federal Advisory Committee Act (FACA) of 1972
- Designated Federal Official with overall responsibility for the review process
  - Doctoral level scientist with expertise related to the science reviewed in their Study Section
  - Legal responsibility for Study Section and the management of review
  - Reviews applications assigned to the Study Section (fit, scope, compliance, etc.)
  - Recruits the review panel based on the content of the applications
  - Ensures the review process for every application is consistent and follows applicable regulations, rules and best practices
  - Point of contact from initial assignment to release of summary statements

How Are Reviewers Selected for SBIR/STTR Study Sections?

- All SBIR/STTR reviews are conducted by Special Emphasis Panels (SEPs)
- Expertise is recruited as needed to review the science proposed in the applications, so the reviewers selected will not necessarily be the same from round to round. We seek reviewers with
  - Demonstrated scientific, technical and market expertise combined with impartiality
  - Research support – preferably small business
  - Doctoral degree or terminal degree equivalent; mature judgment; breadth of perspective

How Are Reviewers Selected for SBIR/STTR Study Sections?

- We build review panels with
  - Reviewers from academia, industry, small business, tech transfer and VC/investment firms
  - ≥25% small business or other industry members (encouraged)
  - Representation of women and minority scientists
  - Geographic distribution
  - Fresh perspectives (avoid excessive service on a panel)

Where Do We Find Reviewers?

- Successful applicants (NIH databases)
- Dimensions™ searches of patent documents
- LinkedIn keyword searches
- Google keyword searches (use the site:*.com qualifier)
- Regional incubator hubs (e.g., qb3 in Palo Alto)
- Nonprofits like the International Business Innovation Association (InBIA)
- Academic technology transfer offices
- Professional societies (e.g., the Association of University Technology Managers - AUTM)
- Volunteers from industry

Assigning Applications

- SRO makes review assignments by matching expertise on the panel to the content of the applications
- Five to six weeks before the meeting, each application is assigned to at least 3 reviewers
- Reviewers are trained on the goals of the SBIR/STTR program and on what to evaluate in applications

Conflicts of Interest (COI) – Applicant Identified

- Applicants can use the Assignment Request Form to request exclusion of companies or individuals from reviewing their application
- Rosters are published 30 days prior to the meeting – investigators can contact the SRO if they are concerned about panel members

Conflicts of Interest (COI) – SRO Identified

- Reviewers who have a major role in the application – Out of Meeting
- Letters of Support – generic versus specific
- Employed by the same organization (3-year limit)
- Co-authors on publications (3-year limit)/Past collaborations (QVR report for all key personnel in application)
- Members of any NIH Advisory Council (undue influence)
- An applicant responding to an RFA as a key personnel may not serve - even on a different Study Section
- Applications from frequent panel members (i.e., served 4 times within the last 6 rounds)

Conflicts of Interest (COI) – Reviewer Identified

- Employees of companies in direct competition with the applicant's company
- Financial interest in the company or in competing companies (including $5K in stock holdings) or consulting agreements of $10K or more
- Financial benefits – institutional, family member, close friend
- Academic scientists that hold patents for competing technologies
- Reviewer's company has IP overlap with application
- Patents or publications with any of the applicants

Managing Conflicts of Interest (COI)

- Personal
  - Family member/close friend
- Professional
  - Collaborator
  - Employees of companies in direct competition (or collaboration) with applicant's company
- Financial
  - Financial interest in company or competing companies
  - Academic scientists that hold patents for competing technologies
- Institutional
- Longstanding scientific disagreement
- Personal bias
- Appearance of conflict

Confidentiality

- Reviewers are required to complete ethics training every year
- Reviewers sign a confidentiality agreement prior to reading any application
- Review materials and proceedings of review meetings represent confidential information for reviewers and NIH staff – it cannot be shared with anyone
- At the end of each meeting, reviewers must destroy or return all review-related material
- All peer review meetings are closed to the public
- Reviewers may not discuss review proceedings with anyone except the SRO and questions concerning review proceedings are referred only to the SRO
- Applicants are not allowed to communicate directly with any members of the study section about an application

Consequences for Breaching Confidentiality and COI Laws

- Reviewers serve as ad hoc advisors to the Federal government
- Rules and regulations are codified in the Federal Advisory Committee Act
- Reviewers legally certify lack of COI at three stages of the review process
- Reviewers can be removed from study sections and barred from future service
- Reviewers and applicants can be barred from receiving Federal funding
- Cases can be (and have been) referred to the Office of the Inspector General for prosecution

What Reviewers Look for in SBIR/STTR Applications

- Why is there a need for the envisioned product
- How will the product be first in class or a significant improvement over what is on the market
- How will successful development of the product change concepts, methods, treatments, services or interventions that drive the field
- How does the project demonstrate the commercial potential to become a marketable product

Common Problems Identified in SBIR/STTR Applications

- No Significance: describes a problem of minor interest or makes an unconvincing case for commercial potential or societal impact
- Inadequate consideration/assessment of scientific literature
- Lack of knowledge of relevant published work and/or technologies and the market
- Absence of an acceptable scientific rationale or questionable reasoning in the experimental approach
- Insufficient experimental/developmental detail or failure to consider potential pitfalls and alternatives
- Expertise in the essential methodology is not described
- Experimental plan lacks rigor and/or weak milestones
- Unrealistic amount of work detailed

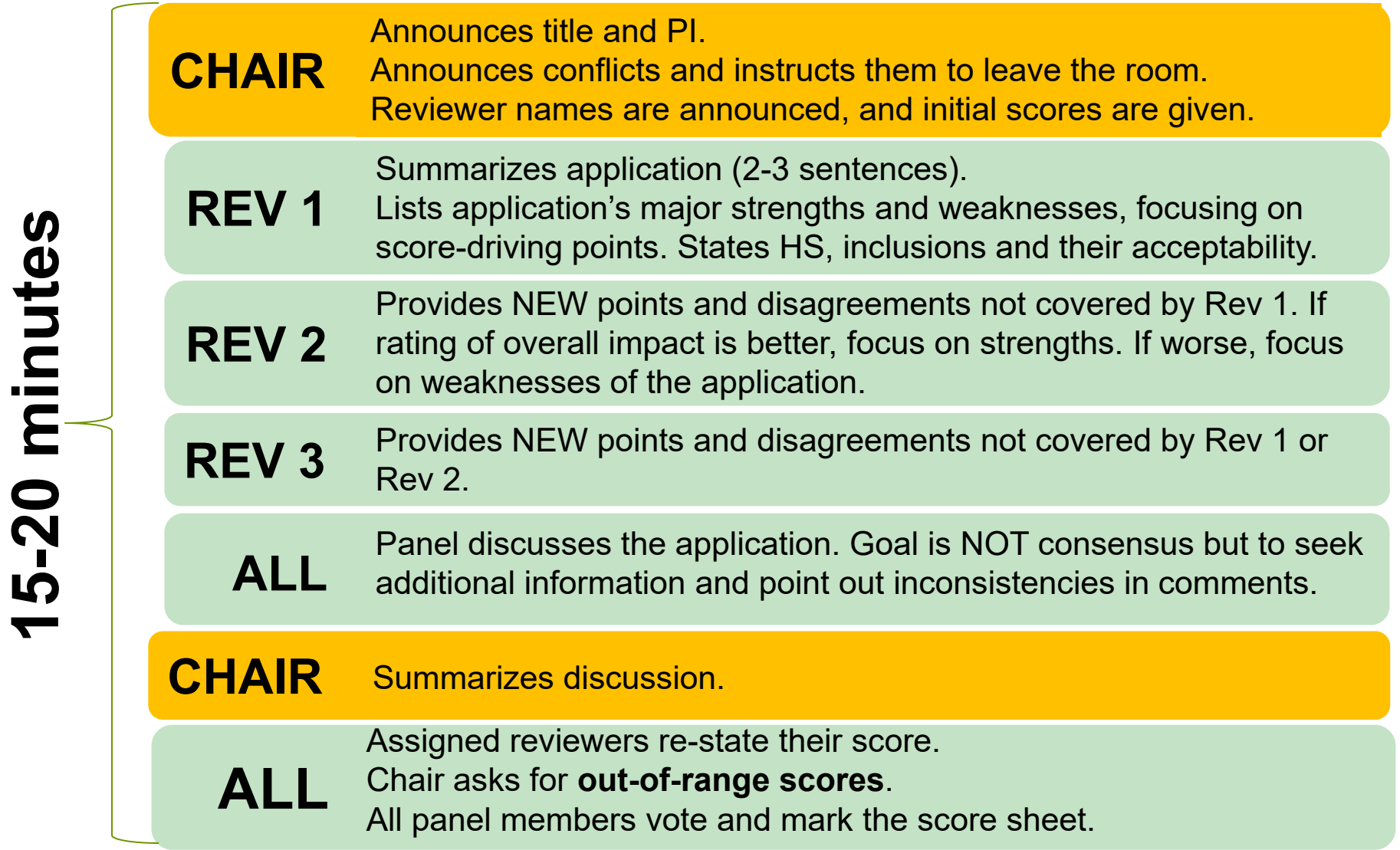
Peer Review System
Template-Guided Review Process

- Microsoft Word templates are linked on IAR for every application
- 1-9 scoring scale (1 = exceptional, 9 = poor)
- Each application has five individual criterion scores: Significance, Investigator(s), Innovation, Approach, and Environment plus comments on Additional Review Criteria
- Small Business review is focused on the product, not just the science
- Each application will be given a Preliminary Overall Impact score by three assigned reviewers
- Top scoring applications (50%) will be discussed at the meeting

Managing the Review Meeting: Setting the Stage

- Preliminary Overall Impact scores and critiques are uploaded by the assigned reviewers
- SRO checks for missing information, errors and mismatched comments/scores
- Applications are divided into two clusters: Phase I (Cluster A) and Phase II/Fast Track/Direct to Phase II (Cluster B)
- SRO rank orders applications – top scoring 50% within each cluster are discussed at the meeting
- Within clusters, score order is randomized for discussion

Managing the Review Meeting: At the Meeting



Peer Review and Funding of NIH Grant Applications

National Institutes of Health

Center for Scientific Review
Assigns to NIH Institute and Peer Review Group

Study Section
Reviews for Scientific Merit

Institute
Evaluates for Relevance to Research Priorities

Advisory Council or Board
Recommends Action

Institute Director
Takes Final Action

Peer Review Summary

- Applications are screened by several groups to ensure best fit
- Policies, procedures and Federal laws define the process
- Reviewers are carefully selected, vetted and trained
- Conflicts are checked at several points during the review process
- Review is conducted only within the study section, and the process is uniformly applied with several levels of checks and balances

Questions?

ncats.nih.gov/smallbusiness | NCATS-SBIRSTTR@mail.nih.gov

Connect with NCATS

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Twitter: twitter.com/ncats_nih_gov

YouTube: youtube.com/user/ncatsmedia

E-Newsletter: ncats.nih.gov/enews

Listserv: bit.ly/1sdOI5w

Research Priorities

Preclinical Drug Discovery and Development
Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact, such as those that are: implicated for disease, have genetic variations that have been identified in functional regions of receptor targets and/or have high potential for biased signaling that would promote the beneficial effects of receptor signaling and reduce the unwanted effects
Tools and technologies to enable high-throughput screening of compound activity on currently “non-druggable” targets
Assays for high-throughput screening of rare diseases-related targets
Co-crystallization high-throughput screening techniques
Fluorescence probes to replace antibodies for determination of cellular protein translocation
Phenotypic assay development, including stem cell technology platforms for human “disease-in-a-dish” applications and the evaluation of toxicity
Interventions that target molecular pathways or mechanisms common to multiple diseases
Platforms for non-antibody biologics, cell-based therapies and gene therapy discovery
Small molecule and biologics analytical characterization
Accelerated bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics and/or diagnostics

Research Priorities

Preclinical Drug Discovery and Development
Development of novel technologies for enzyme replacement therapies (e.g., new cell culture/expression system) to solve a major bottleneck in rare diseases research
Innovative methods to determine alternative uses for existing therapeutic interventions for high priority areas, such as rare diseases and pain
Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic or other intervention optimization
Technologies to deliver nucleic acid therapeutics to tissues other than the liver
Methodologies and technologies to increase efficiencies of manufacturing therapeutics
Development of novel high-throughput technologies that focus on making translational research more efficient
GMP production of exosome/extracellular vesicles
Generation of producer lines for large-scale production of exosomes/extracellular vesicles
Extracellular RNA-based biomarkers and therapeutics of human diseases
Approaches to targeting the human microbiome for therapeutic or diagnostic purposes

Research Priorities

Preclinical Drug Discovery and Development
Scale up, manufacturing and characterization of IPS cells
3D printing technologies
Technologies to substantially improve the efficiency and reduce the cost of clinical-grade gene therapy vector manufacturing
Development of in vitro human tissue models (organs, 3D printing)
Technologies to allow therapeutic proteins other than lysosomal enzymes to be secreted and taken up by other cells via cross-correction
Novel strategies to prevent deleterious immune responses to gene therapy, genome editing and/or enzyme replacement therapy
Establishing more robust phenotypic screens that may help prioritize candidate compounds for further testing
Innovative technology for non-small molecule delivery
High-throughput epigenetics screening/characterization tools and technologies
Microphysiological systems (MPS)/Tissue Chips, including MPS/Tissue Chips that incorporate known functional variants, e.g., ACMG 59 or CPIC A alleles, for study comparison using the same derived genetic background across a set of tissue chips with the functional variant

Research Priorities

Biomedical, Clinical & Health Research Informatics
Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays and/or technologies with evidence about their use in research studies
Cloud-based tools and methods for meaningful sharing, re-use and integration of research data
Novel platforms, technologies and tools for: (1) enabling clinical and translational research, particularly those with mechanisms for inclusion of patient-reported data and (2) integration of patient data collected from multiple devices and multiple/diverse clinical studies
Development of personalized phenotypic profiling (as well as personalized intervention) based on patient-centered integration of data from multiple data sources, including social media
Development of predictive models for translational science
Digital applications and tools (including telemedicine platforms) that facilitate/enhance translational research and medicine in rural populations
Generic disease registry template platforms that can be reused for multiple diseases
Mobile device validation tools to ensure data from different brands or versions have compatible results
Tools to assess algorithms developed with artificial intelligence and/or machine learning
Tools that allow for persistent identifier and attribution for data contributors that give credit to the data producers while ensuring that shared data has not been altered
Patient mobile tool platforms that facilitate tool developers to build “apps” that integrate into their medical records
Tools and environments that enable an easy interrogation of publicly available data

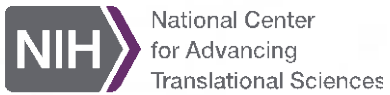
Research Priorities

Clinical, Dissemination and Implementation Research
Tools and technologies that increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation and/or regulatory processes
Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking
Tools, technologies and other strategies to evaluate and improve the process of informed consent
Educational tools for clinical and translational science
Computational or web-based health research methods, including: • Platforms for generally applicable and scalable multi-disease registries and natural history studies • Clinical trial designs and analyses (e.g., for pragmatic clinical trials)
Approaches, tools, platforms and environments to integrate data in novel ways for development of new biomarkers that can be tested in translational research paradigms for which there are barriers or bottlenecks
Strategies to enhance the quality of and accelerate the conduct of dissemination and implementation research
Tools and technologies that increase the efficiency of human subjects research, that facilitate the rapid diagnosis and/or clinical trial recruitment and subject tracking, institutional review board evaluation and/or regulatory processes

Research Priorities

Clinical, Dissemination and Implementation Research
Increased efficiency of clinical research conduct, including but not limited to regulatory decision support, patient eligibility analysis and recruitment and retention tracking
Sustainable solutions for effective tools and environments in translational research
Development and validation of patient reported outcomes, clinician-reported outcomes and biomarkers for rare diseases that are not already supported by a disease-specific NIH Institute or Center
Tools, technologies and other strategies that address medication adherence in clinical settings
Tools, technologies and other strategies that address and improve community engagement
Tools and technologies that address the rapid diagnosis and/or clinical management of rare diseases
Patient empowerment tools/apps that allow users to compare their treatment and outcomes to normative populations existing treatment guidelines
Telemedicine or digital health applications that focus on research in rural populations

THANK YOU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