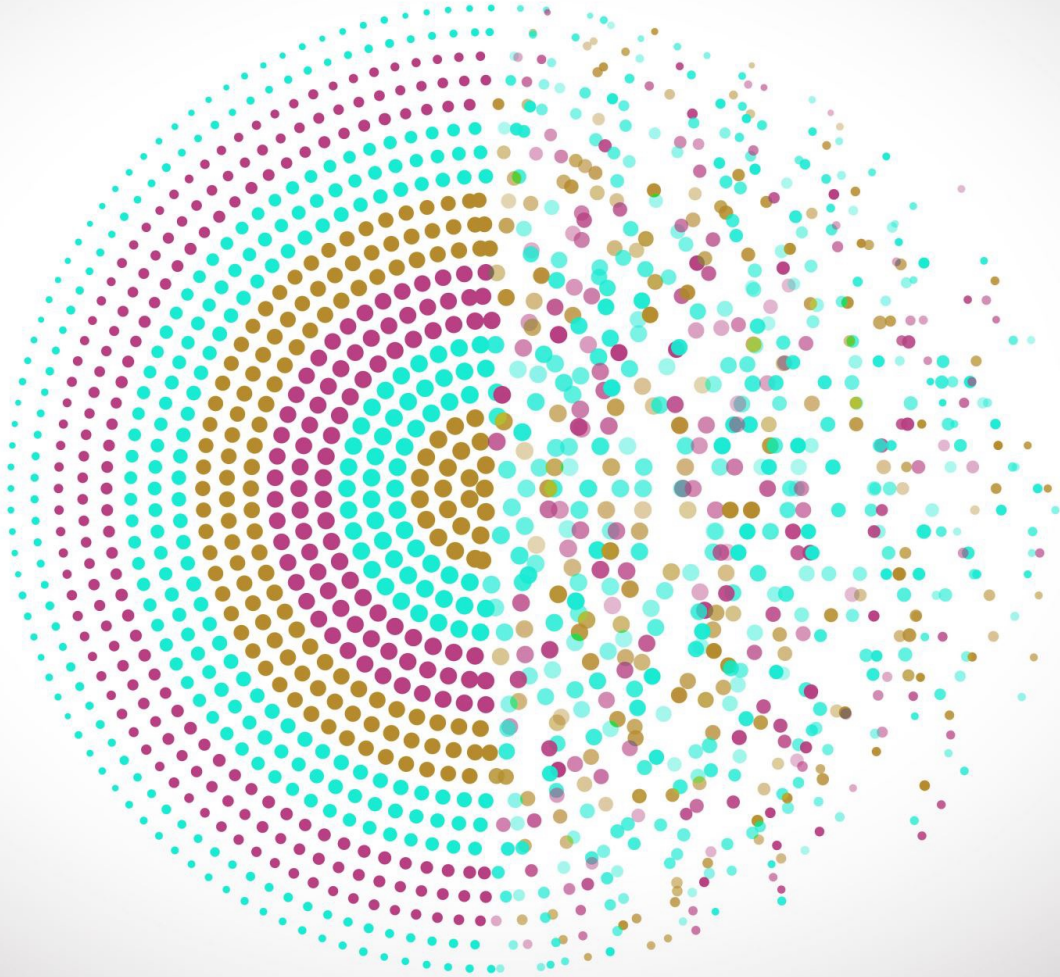
The Center for Innovative NeuroTech Advancement (CINTA) & NeuroTech Harbor (NTH) Announce the Cycle 4 Award Competition



Supported by the NIH Blueprint MedTech Program

Blueprint MedTech Incubator Hubs

- CINTA (Center tor Innovative Neurotech Advancement), a program within CIMIT (Steven Schachter, MD as PI and Paolo Bonato, PhD as co-PI from Spaulding Rehabilitation Hospital).

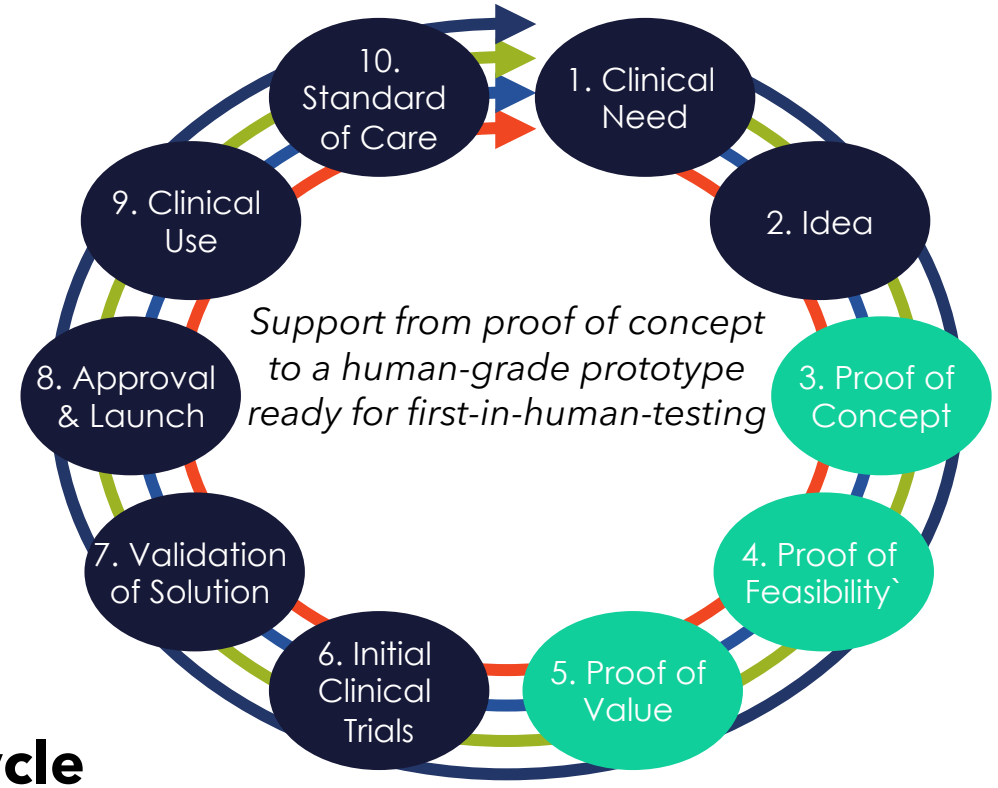
- NTH (NeuroTech Harbor), a partnership between Johns Hopkins University and Howard University (Sri Sarma, PhD as contact PI and Evar Nwulia, MD).

“Center without Walls”

Blueprint MedTech Incubator Hubs Mission

Mission

- To accelerate the development of emerging, ground-breaking technologies into first-in-human studies along the path to commercially viable, clinically focused solutions for disorders involving the nervous system.



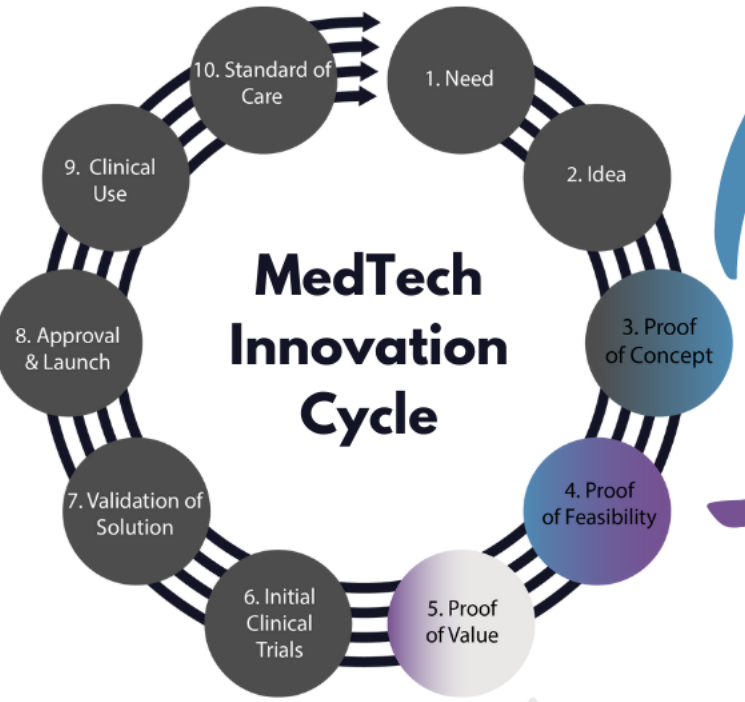
MedTech Innovation Cycle

- To catalyze translation along 4 key domains in the innovation cycle: **Technology**, **Regulatory**, **Market/Business**, **Clinical**

Blueprint MedTech Incubator Hubs Overview: Types of Awards

- **Optimizer awards**
  - Will rarely exceed $500,000 in direct costs per year for a period of up to 4 years.
  - In addition to monetary support, awardees will receive mentoring and resources and support services necessary for translation will be available as outlined above.
- **Seedling awards**
  - Provide support for six months, a $25,000 stipend, and $25,000 to hire subject matter experts.
  - Mentors will work with awardees throughout the project to help resolve identified gaps on the path to commercialization.
  - If the gaps are mitigated, project teams may become candidates for re-entry into the full optimizer award path.

Which funding path is right for my solution?



Ongoing planning and discovery takes place in 4 key domains throughout the innovation journey. Learn more about these domains and associated milestones at gaits.org.

Key Risks	Funding Path	Milestones and Tasks
Is my concept valid? I have an idea and there is a clinical need.	EXPLORATORY/ DEVELOPMENTAL RESEARCH GRANTS (e.g., R01/R21/REACH)	• Technology concept and intended use formulated • Technology feasibility studies • Experimental proof of concept validation
Will my technology work? Is there a motivated customer? I have a prototype that works as expected and can demonstrate results.	BLUEPRINT MEDTECH INCUBATOR HUB PROJECTS Blueprintneurotech.org	• Technology development project plan • Quality management system design & development • Prototype development and verification • Usability studies to optimize technology • Technology validation in pre-clinical environment
Will the technology work in humans? My solution will be ready for first-in-human studies in 1-2 years or less.	BLUEPRINT MEDTECH TRANSLATOR PROJECTS UG3/UH3, PAR-21-315; U44, PAR-21-282	• GLP Pre-clinical safety and effectiveness studies • GMP pilot production and validation • IDE or IRB • First-in-human safety and effectiveness studies

Optimizer Award Details

- Awards from NTH or CINTA will rarely exceed $500,000 in direct costs per year for a period of up to 4 years. Indirect costs will be provided at your institution's Federally negotiated rate (or 10% de minimis).
- In addition to monetary support, awardees will receive ongoing, specialized support from executive mentors experienced in developing and commercializing neurotech devices.
- Awardees will work with their executive mentor each week to focus on business, regulatory, clinical, and technical factors that may impede commercialization.

Blueprint MedTech Potential Resources

- Resources to plan and support prototype development, team building, needs assessment, and other early translational activities.
- Additional assistance from hubs and consultants (e.g., design, regulatory, reimbursement, intellectual property, commercialization, and strategic partnership issues).
- The cost of resources provided by the hubs and NIH do not need to be included in the proposed budget.
- Other resources listed on the Blueprint MedTech website

Resources Available to Investigators

Design, Prototyping, Risk Analysis
- Electronics Manufacturing
- Prototype Manufacturing
- Design Optimization and Risk
- Computational Modeling

Bench and Safety Testing
- Electrical Safety
- Electromagnetic Compatibility
- MR Testing
- Software
- Cybersecurity
- Shelf-life Testing

Biocompatibility and Animal Studies
- Biocompatibility Testing
- Materials characterization and analytical chemistry
- Sterilization testing/validation
- Preclinical – Animal Testing (GLP)
- Preclinical – Animal Testing (non-GLP)
- Cadaver Testing

Clinical
- Clinical trials
- Biostatistics
- Data Management
- Neuroethics

Resources provided by:

•Hubs	CINTA
	NTH
•Contracts	Actuated Medical
	PPD CRO

Business Development
- Public-Private Partnerships – CRA, MTA
- Entrepreneurship
- Business Development
- Market / User Research
- Commercialization

Regulatory, Compliance, Quality System
- Regulatory Advising
- QMS – Quality Management System – setup and audits
- GMP – Good Manufacturing Practice – setup and audits
- Compliance
- Legal - Intellectual Property

Participating Centers and Institutes

- National Institute of Biomedical Imaging and Bioengineering (NIBIB),
- National Center for Complementary and Integrative Health (NCCIH),
- National Eye Institute (NEI),
- National Institute on Aging (NIA),
- National Institute on Alcohol Abuse and Alcoholism (NIAAA),
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD),
- National Institute on Drug Abuse (NIDA),
- National Institute of Dental and Craniofacial Research (NIDCR),
- National Institute of Mental Health (NIMH),
- National Institute of Neurological Disorders and Stroke (NINDS), and
- Office of Behavioral and Social Sciences Research (OBSSR)
- Helping to End Addiction Long-Term (HEAL)

Applications must focus on a disorder of the nervous system in an area of interest of the NIH Participating Institutes/Centers for the Blueprint MedTech: Incubator Hubs program.

The National Institute of Child Health and Human Development (NICHD) will only accept applications related to the mission of the National Center for Medical **Rehabilitation** Research.

Applications outside the mission of these participating Institutes/Centers will not receive funding. Contact Institute Program Officer for questions about **mission fit only**.

Please forward all other questions to info@blueprintneurotech.org.

https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-medtech/blueprint-medtech-ics-and-contacts

Eligibility

The Blueprint Hubs and NIH encourage applications from women, under-represented racial and ethnic groups, as well as individuals with disabilities.

Principal Investigators (PIs) from academic institutions, industry or non-profit organizations are invited to apply. Foreign applicants may apply.

Academic PIs must hold a faculty appointment at an institution of higher education or medical center.

PIs from industry or non-academic non-profits are not required to hold a faculty appointment.

Review Process

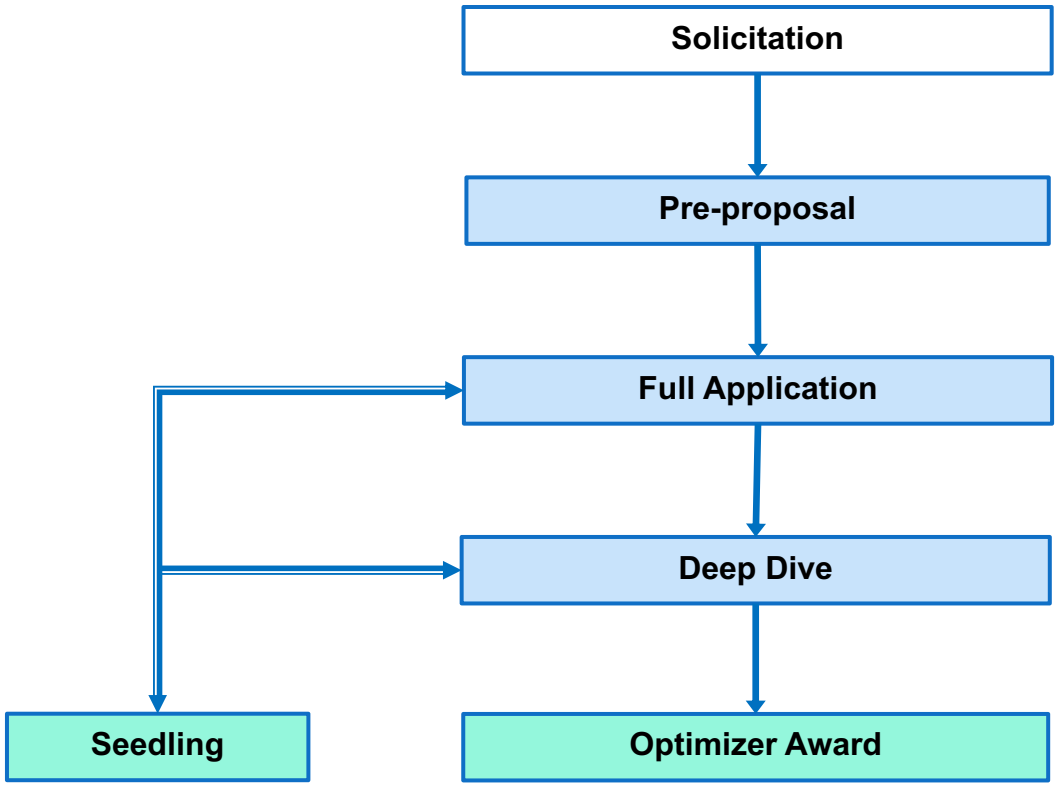
Applicants must first submit **pre-proposals**, which will undergo review by NIH program scientific staff for eligibility, including mission fit and alignment with program scope. Pre-proposals are submitted through a simple online application form equivalent to about 4 pages (CoLab).

A subset of the applicants who submit pre-proposals will be selected to submit **full proposals** which are submitted through the same online application system. The online full proposal form is equivalent to approximately 10 pages.

A subset of the applicants who submit full proposals will be selected to participate in a **"deep dive"** evaluation, which is the final stage of **due diligence** review prior to **Optimizer Award** funding decisions.

*sections of the form have word limits and there is an upload with a page limit, but there is not an overall page limit per se.

Stages of Process



*A subset of the applicants who submit full proposals will be selected to participate in an interactive "Deep Dive" evaluation, which is the final due diligence stage of review prior to funding decisions on Optimizer projects.

*All full proposals will be considered for the Seedling program if the proof-of-concept data in the full proposal is sufficient, and reviewers identify any specific weaknesses in descriptions of the:

- Commercial opportunity,
- Regulatory pathway,
- Team,
- Project Plan.

*Participants successfully completing the Seedling program may re-enter this program at the Full Application or Deep Dive stage or may be ready to apply to an NIH- Translator solicitation.

General Application Information

- Applicants should review and be familiar with the program solicitation and FAQs before completing this application.

Solicitation link: **https://blueprintneurotech.org/**

FAQ link: **https://blueprintneurotech.org/faq**

- If your project addresses a mental health disorder, you are encouraged to provide preliminary data that uses quantitative, objective measures for outcomes. Please incorporate these measures into your proposal.
- Only IRB-exempt or minimal-risk clinical studies can be proposed for funding, and only if minimal risk studies can be conducted at Georgia Tech's HomeLab, one of the core resources of the Blueprint Medtech program.

https://cacp.gatech.edu/research/accessibility/HomeLab

What is the definition of minimal risk?

Minimal Risk to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected. This category includes protocols that pose "no greater than minimal risk" according to federal regulations.

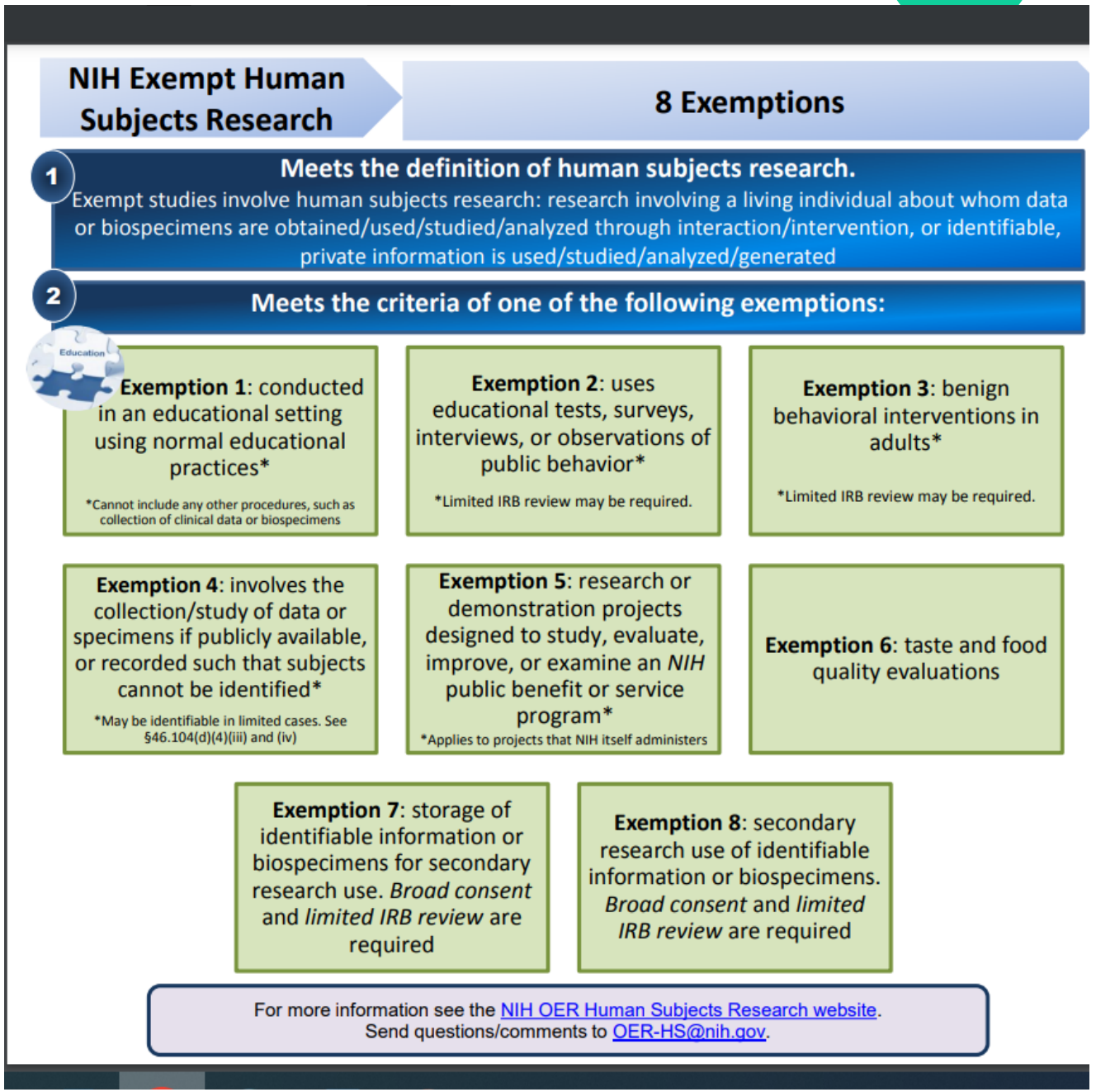
Examples of Minimal Risk are:

- Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing).
- Non-interventional studies (e.g., observational studies of behavior or nutrition).
- Survey/Questionnaire studies of a non-sensitive nature.

www.nimh.nih.gov/funding/clinical-research

NIH Definition of IRB-Exempt Human Subjects Research

https://grants.nih.gov/sites/default/files/exemption_infographic



Applications that will NOT be considered

- Products not regulated by the FDA.
- Fundamental basic/applied research prior to proof of concept.
- Device technologies that do not significantly advance the state pf the art (e.g. device technology that proposes minor modifications to FDA-approved/cleared medical device technology)
- Animal model development: all *in vivo* animal models must be well-established and characterized, and available to the applicant.
- Projects focused on technologies for functional augmentation of healthy individuals.

Pre-Proposal Application Sections

1) Applicant Information

2) Solution Information

- Medical Condition (select from list)
- Technology (select from list)
- Clinical Need & Standard of Care (<250 words)
- Stage of Technical Development (select from list)
- Solution Description (<250 words)
- Supporting Information and/or References - Upload 1 page PDF

3) Project Information

- Project Duration
- Proposed Scope of Work (<250 words)
- Regulatory Classification (select from list)
- Regulatory Pathway (<150 words)

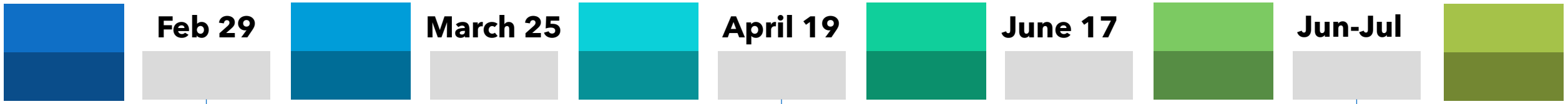
Lessons Learned from Previous Cycle Submissions

Common Reasons for Rejection

- **Stage of Maturity**
  - Too early (no proof of concept)
  - Too advanced (ready for clinical trials; candidate for UG/UH3 or U44)
- **Team Composition**
  - Lacking critical areas of expertise
  - No evidence of clinical collaboration
- **Impact**
  - Not significantly different from existing products
  - Only marginal impact on clinical condition
- **Mission fit**
  - Not priority area of NIH participating institutes/centers

Timeline

Pre-Proposals



Pre-proposals must be submitted through the online application system by 11:59 pm ET.

Applicants Notified

Full-Proposals

Invited full proposals must be submitted through the online proposal submission system.

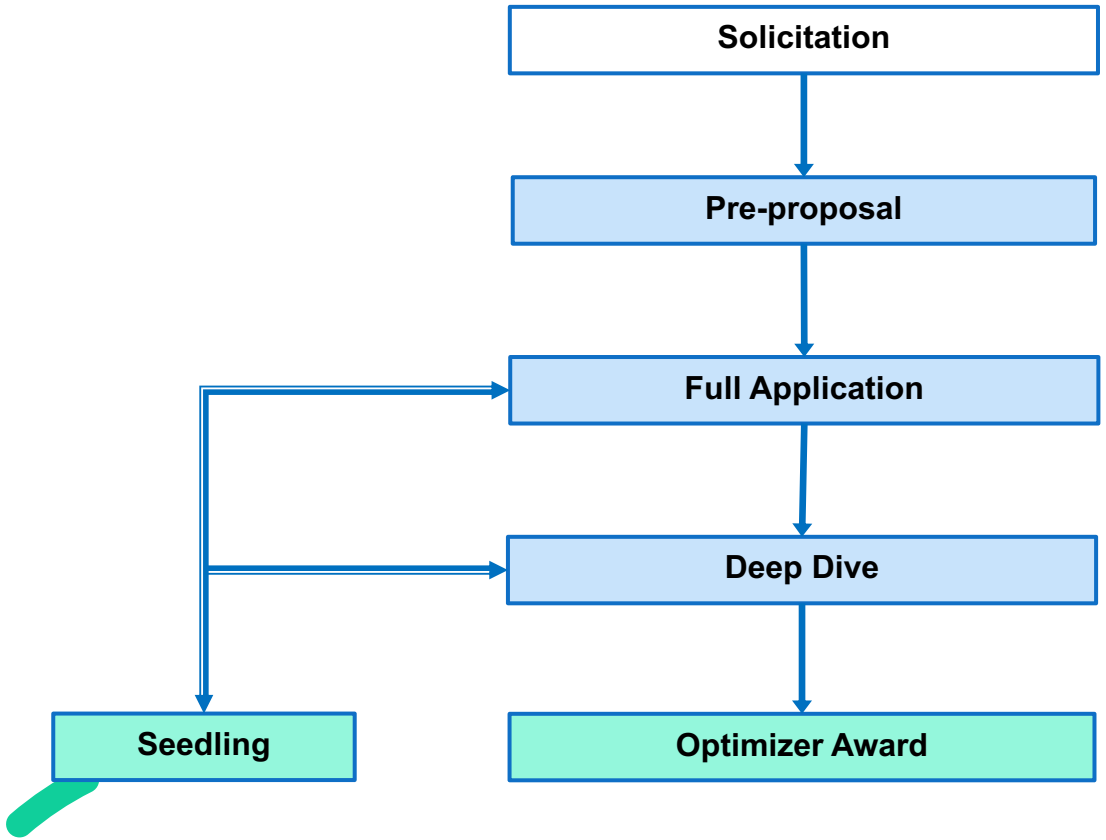
Applicants Notified

Deep Dives

Selected full proposals will proceed to an advanced, interactive "deep dive" review stage that is expected to take two weeks, during which applicants will need to commit significant effort to respond to the deep dive inquiries.

- *September-October 2024 (earliest estimate): Final projects selected for funding*
- *Two solicitation cycles per year. Next cycle announced around Summer 2024.*
- *Webinars and office hours will be available throughout the process.*

Companion Seedling Program



- A subset of all full applications will be redirected as invitations to participate in the Seedling program.
- Seedlings are akin to planning grants where the two hubs will provide training and mentoring to help applicants refine the proposal to strengthen subsequent applications to the program.

Companion Seedling Program

- Seedling program is a 6-month mentorship-based accelerator program for applicants to the BPMT full award program whose solutions have one or more weaknesses in:
  - Commercial opportunity
  - Regulatory pathway
  - Team composition
  - Project Plan
- All of which would be addressable through 6 months of work with mentors and experts in these specific gap areas.

1

Prepare innovators to submit stronger applications to for future Optimizer awards and improve their chances of being funded

2

Guide innovators proposing more clinical translational or feasibility studies to competitively submit to BPMT Translator (e.g., UG3/UH3, U44) programs

3

Guide innovators to other sources of fundings

Seedling Program Processes:

- Candidates will be interviewed by the Seedling program leadership to explore project fit with the program objectives and to gauge the team's interest in participation.
- If accepted into the program, expert mentors will be assigned to each team for individualized support.
- The team with the support of the mentor will prepare a revised budget and project plan to address identified gaps.
- Over the project period, teams will meet for 1-2 hours each week with mentors.

Summary Information

- **Optimizer awards** will rarely exceed $500,000 per year in direct costs. Indirect costs will be provided at your institution's Federally negotiated rate.
  - The initial anticipated performance period is 12 months, which can be renewed for up to an additional three 12-month periods with CINTA, NTH, and NIH approval.
  - The final aim of Hub optimizer projects should be a prototype ready for first-in-human studies.
  - Upon successful completion of the project, teams should either have non-governmental funding secured or be ready for entry into the companion translator solicitations from NIH:
    - Blueprint MedTech: Translator (UG3/UH3)
    - Blueprint Medtech: Small Business Translator (U44)

- **Seedling awards** provide support for six months, a $25,000 stipend, and $25,000 to hire subject matter experts.
  - Mentors will work with awardees throughout the project to help resolve specifically identified gaps on the path to commercialization.

Contacts and Additional Resources

Webinar Slides/Schedule: https://www.cimit.org/web/center-for-innovative-neurotech-advancement/events

FAQs: https://blueprintneurotech.org/faq

Scheduling Office Hours: Tina Cavaluzzi tcavaluzzi@jhu.edu
Availability: 15 minute sessions with faculty
Wednesday, Feb 14: 3-5 PM ET
Thursday, Feb 22: 4-6 PM ET
Wednesday, Feb 28: 3-5 PM ET

General Information: info@blueprintneurotech.org
617-643-3800

Good Luck!