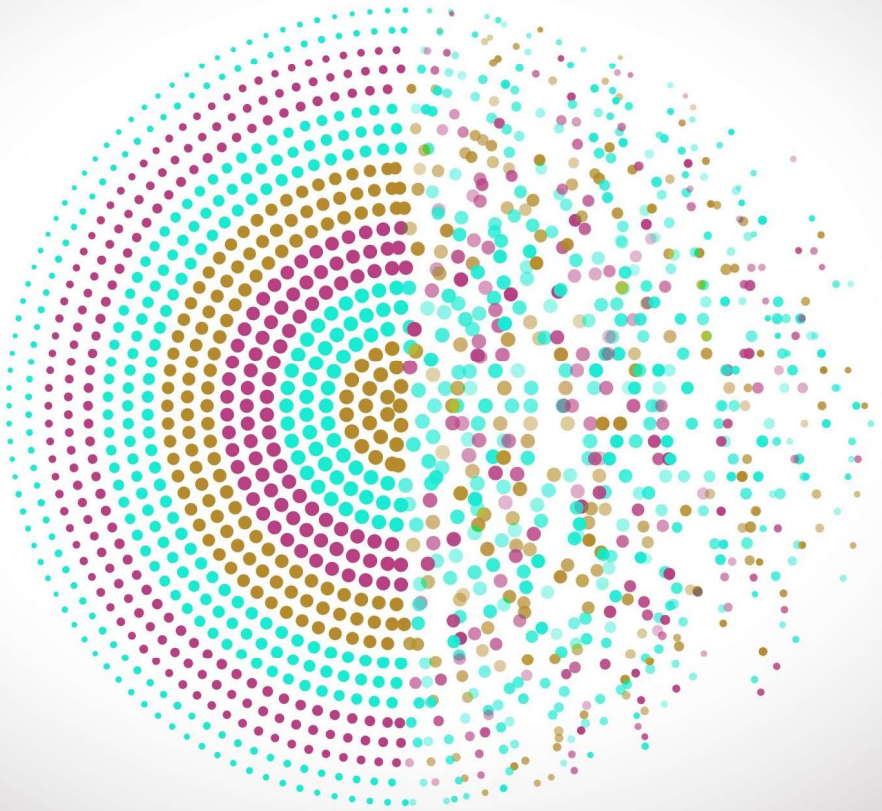
The Center for Innovative NeuroTech Advancement (CINTA) & NeuroTech Harbor (NTH) Announce the Cycle 6 Award Competition



Supported by the NIH Blueprint MedTech Incubator Hubs Program

Cycle 6 Webinar Outline

- Introduction and Background
- Updates in Cycle 6 solicitation
- Pre-proposal information
- Review Process and Timeline
- Additional resources and Office Hours Information

Blueprint MedTech Incubator Hubs

Mission

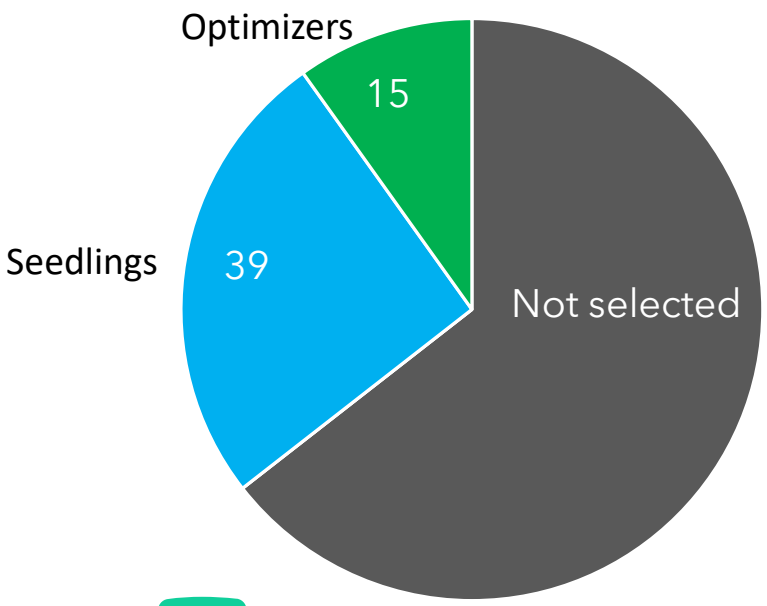
To accelerate the development of emerging, ground-breaking technologies into first-in-human studies along the path to being commercially viable, clinically focused solutions for disorders involving the nervous system.

- CINTA (Center for Innovative Neurotech Advancement), a program within Cimit (Steve Schachter, MD as PI and Paolo Bonato, PhD as co-PI from Spaulding Rehabilitation Hospital).
- NTH (NeuroTech Harbor), a partnership between Johns Hopkins University (contact PI - Sri Sarma, PhD) and Howard University (PI - Evaristus Nwulia, MD).

"Center without Walls"

Blueprint MedTech Incubator Hubs

Awards to date: **54**
Funding awarded: **$30M**

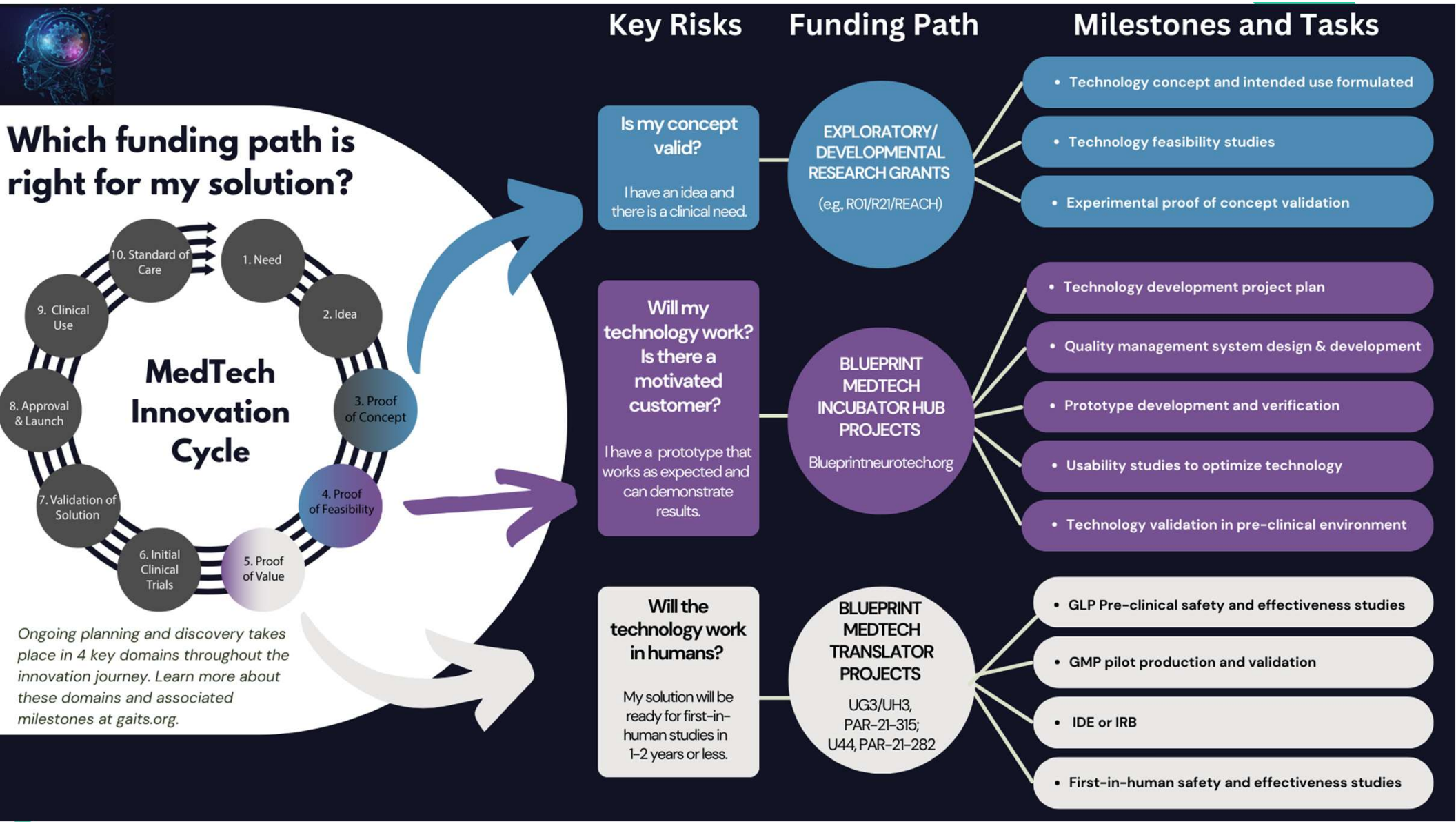


Data are from Cycles 1 thru 3 (2021 – 2023)
Not shown: Cycle 4 & 5 (2024-2025)

- In addition to funding, Hubs provide expert mentoring, oversight, and in-kind resources to innovator teams.
- Support development and de-risking of these groundbreaking technologies to the point of first-in-human testing (i.e., concluding prior to any evaluation of safety or effectiveness).
- By the conclusion of Hub funding, it is anticipated that projects will have secured non-governmental funding or be ready to apply for funding for a companion Translator solicitation from NIH (which support first-in-human evaluations of safety and effectiveness)
  - Blueprint MedTech: Translator (UG3/UH3)
  - Blueprint Medtech: Small Business Translator (U44)

Information from Previous Cycle Submissions

- One quarter of pre-proposals are from a small business <50 employees, and 2/3 are from non-academic entities
- Of invited full proposals, 1/3 have never proposed to NIH, indicating we have tapped into a new community
- Of invited full proposals, 1/3 will have received funding (Seedling or Optimizer)
- Early-stage projects (Pilot and Seedling) have a reasonable success rate: 1/3 have advanced to receive Optimizer awards


Which funding path is right for my solution?
MedTech Innovation Cycle
1. Need
2. Idea
3. Proof of Concept
4. Proof of Feasibility
5. Proof of Value
6. Initial Clinical Trials
7. Validation of Solution
8. Approval & Launch
9. Clinical Use
10. Standard of Care
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

Resources Available to Investigators listed on the Blueprint MedTech website

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 trial planning
- Biostatistics
- Data Management
- Neuroethics

Resources provided by:

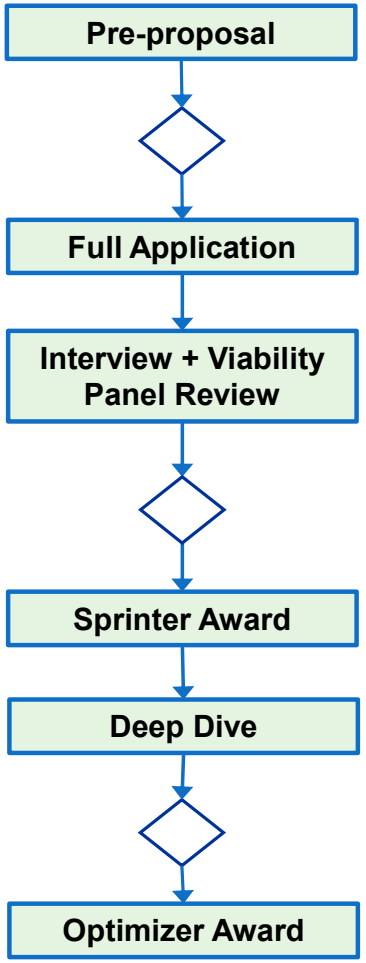
•Hubs	CINTA, NTH
•Contracts	Actuated Medical
	PPD CRO
	Venture Well

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

Update to Cycle 6 Review Process

- Applicants still submit Pre-proposal as initial step
- Selected applicants will be subsequently invited to submit a full application
- Full applications undergo Viability review which now includes **a 1-hour interview**
- Selected applicants will now receive **a 20-week Sprinter Award leading up to Deep Dive**
- Selected projects will receive an Optimizer Award



Summary of Cycle 6 Awards

- **Sprinter awards - $100,000 Total Costs**
  - Period of performance is 20 weeks and No-Cost-Extension is not allowed
  - Evaluation will be based on completion of milestones and de-risking activities

- **Optimizer awards - $1,285,000 Total Costs**.
  - Only Sprinter awardees are considered for Optimizer funding during Deep Dive
  - The initial anticipated performance period is 12 months, which can be renewed for up to an additional three 12-month periods with Hub and NIH approval.
  - Hub resources are available to complete scope of work, note funding for these resources will be included as part of total costs.
  - The final aim of Hub optimizer projects should be a prototype ready for first-in-human studies.
- Mentors are provided at no cost to applicant
- Indirect costs will be determined by your institution's federal negotiated rate or up to the de minimis rate of 15%.

Eligibility

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

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

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

Pre-proposal Areas of Interest

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**. Applications outside the mission of these participating Institutes/Centers will be not responsive to this solicitation and therefore not advance to full proposal stage.

Contact Institute Program Officer for questions about **mission fit only**, hub staff for other solicitation questions.
https://www.ninds.nih.gov/current-research/trans-agency-activities/nih-blueprint-neuroscience-research/bp-medtech#Heading3

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),
- National Center for Medical Rehabilitation Research at the *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)

Note: 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.

Pre-Proposal Application Sections

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

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

- Proposed Sprinter Scope of Work (< 100 words)
- Optimizer Project Duration
- Anticipated Optimizer Scope of Work (<250 words)
- Regulatory Classification (select from list)
- Regulatory Pathway (<150 words)

Applications that will NOT be considered

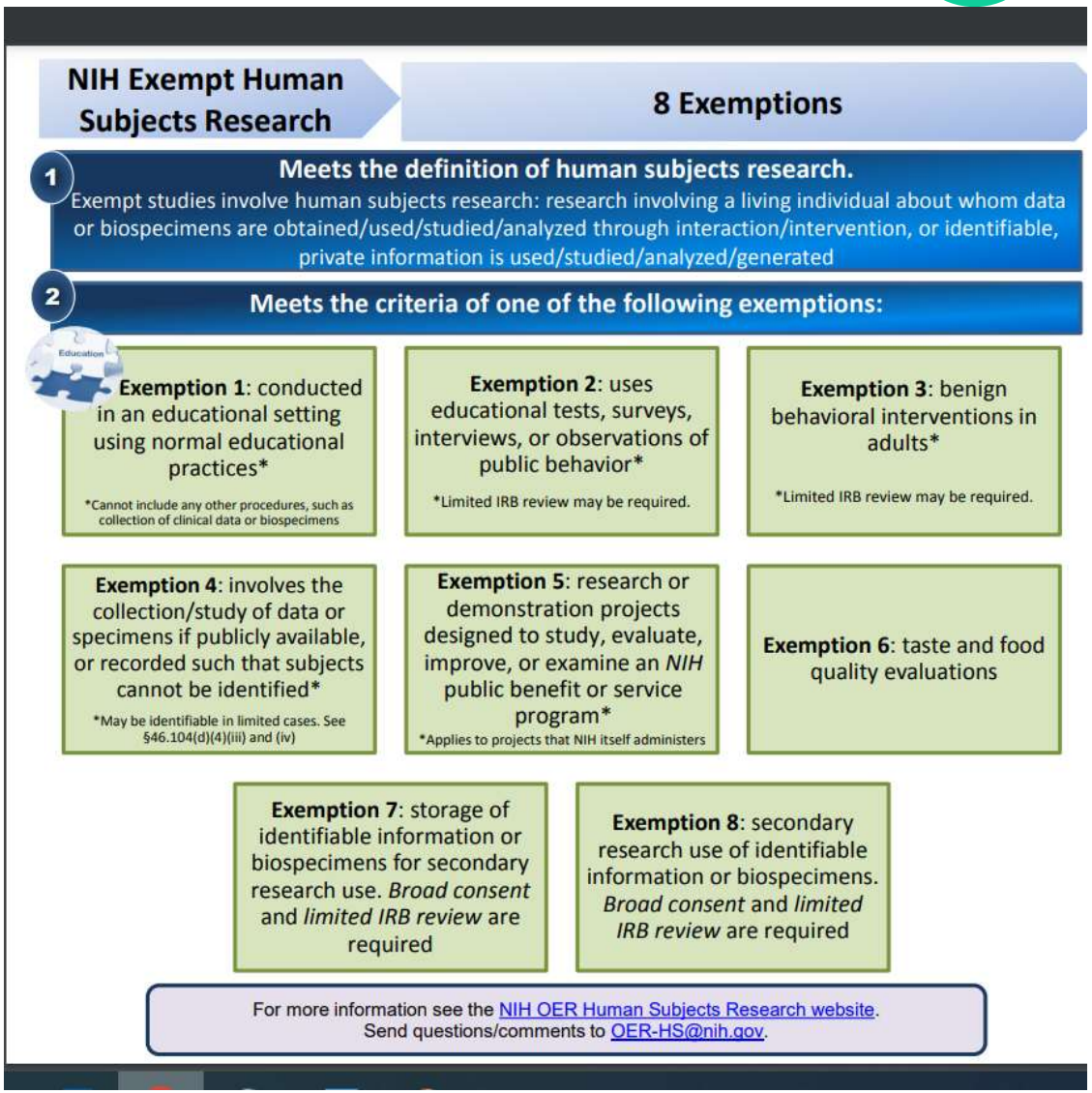
- Projects that are not well-aligned with areas of interest of the NIH participating organizations.
- Products not regulated by the FDA.
- Fundamental basic/applied research prior to proof of concept.
- Device technologies that do not significantly advance the state of the art
  (e.g. device technology 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.

Additional Application Information

- 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.
- No animal studies or human subject research can be performed using Sprinter Award funding.
- Applicants outside of the US are not eligible for hub funding, however hubs may purchase goods and services from foreign consultants and vendors in support of awarded projects.
- Only IRB-exempt or minimal-risk clinical studies can be proposed for Optimizer funding, and only if minimal risk studies can be conducted at Georgia Tech's HomeLab (https://cacp.gatech.edu/HomeLab), a resource of the Blueprint Medtech program.
- Hubs cannot support safety or effectiveness studies. Applicants should apply to the Blueprint MedTech Translator NOFOs: UG3/UH3 or U44.

NIH Definition of IRB-Exempt Human Subjects Research

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



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).
- Electrophysiological studies in healthy subjects or clinical populations (surface recordings such as EEG, ERP, MEG)
- Non-invasive imaging (e.g., MRI and fMRI) in healthy subjects or clinical populations to investigate basic mechanisms of brain function.

https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring

Summary of Cycle 6 Review Process

Applicants 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 a **full proposal (**approximately 10 pages) which is submitted through the same online application system. Applicants will be invited to a **one-hour interview** to present and discuss their solution.

A subset of applicants who submit full proposals will be selected for a $100k total cost Sprinter Award aimed to complete steps that de-risk the project. During the 20-week performance period, teams will be provided mentor support and access to hub resources.

Sprinter awardees will advance to participate in a 2-3 week **"Deep Dive"** evaluation, which is the final stage of **due diligence** review prior to **Optimizer Award** funding decisions.

Lessons Learned from Previous Cycle Submissions

Common Reasons for Rejection

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

Timeline – Part 1

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

Applicants Invited

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

Applicants Interviews

Selected full proposals will receive a Sprinter Award to be completed in a 20-week period

- *Webinars and office hours will be available throughout the process.*

Timeline – Part 2

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

Selected teams will prepare Just in time information for funding requests to NIH

Estimate of final award decisions and receipt of funding

Contacts and Additional Resources

Webinar slides and recording: https://www.cimit.org/web/center-for-innovative-neurotech-advancement/events

Solicitation link: https://blueprintneurotech.org

FAQs: https://blueprintneurotech.org/faq

All application related questions: info@blueprintneurotech.org

Office Hours scheduling:

https://calendly.com/blueprintmedtech/blueprint-medtech-cycle-6-office-hours

15 minute sessions with program leaders

- Friday, July 18: 11:30AM - 1PM ET
- Monday, July 21: 11:30AM - 1PM ET
- Thursday, July 24: 1:30 - 4PM ET
- Monday, July 28: 2:30 - 4PM ET
- Friday August 1: 11AM – 12:30PM ET

Good Luck!