

**The Center for Innovative
NeuroTech Advancement
(CINTA) & NeuroTech
Harbor (NTH) Announce
the Cycle 7 Award
Competition**



**Supported by the NIH
Blueprint MedTech
Incubator Hubs Program**





Cycle 7 Webinar Outline

- Introduction and Background
 - Updates in Cycle 7 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.



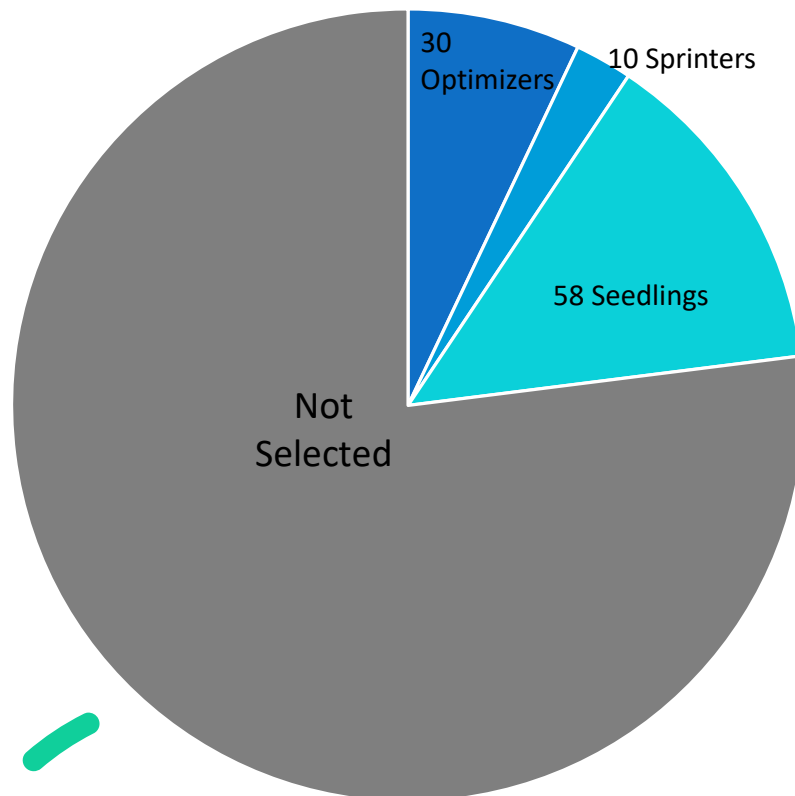
- CINTA (Center for Innovative Neurotech Advancement), a program within Cimit (Steve Schachter, MD as PI and Paolo Bonato, PhD as co-PI from Spaulding Rehabilitation Hospital).
- NTH (NeuroTech Harbor), a partnership between Johns Hopkins University (contact PI - Sri Sarma, PhD) and Howard University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

<https://www.nih.gov/nih-blueprint-neuroscience-research/blueprint-research-initiatives/blueprint-medtech>

Blueprint MedTech Incubator Hubs

Funding awarded: ~\$84M

Awards to date: 98



Data are from Cycles 1 thru 6

- Support development and de-risking of these groundbreaking technologies to the point of first-in-human testing (prior to any safety or effectiveness)
- Provide expert mentoring, oversight, and in-kind resources to innovators
- After hub funding, anticipation is projects will secure non-governmental funding and/or apply to companion Translator solicitation from NIH (which supports first-in-human evaluations of safety and effectiveness)

Blueprint MedTech: Translator (UG3/UH3)

<https://grants.nih.gov/grants/guide/pa-files/PAR-25-383.html>

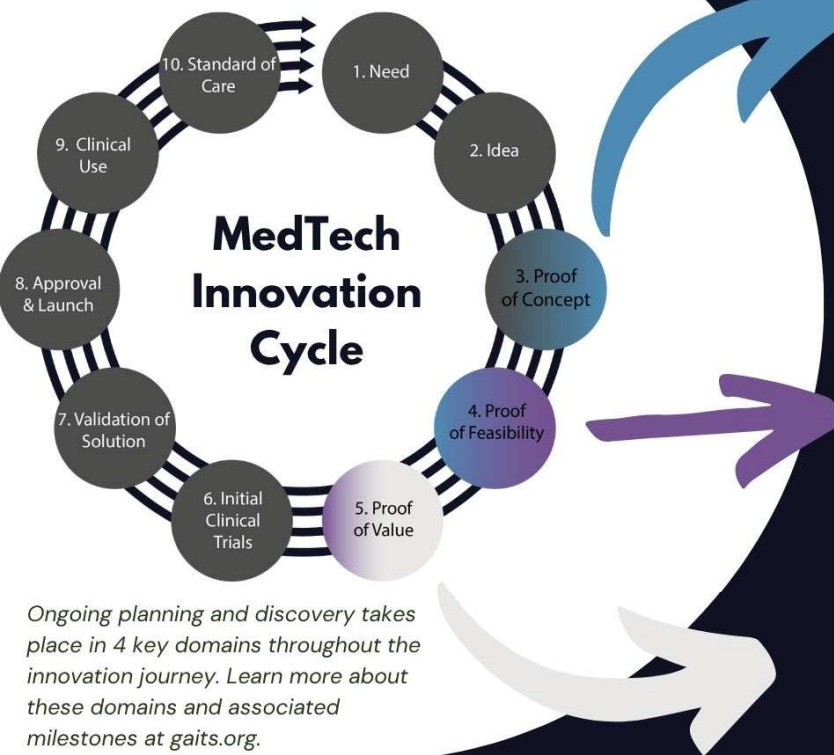


Information from Cycles 1-6

- 1 out of 4 pre-proposals from small business <50 employees & 2 out of 3 are non-academic entities
 - Of invited full proposals: 1 out of 3 first time applicants to NIH, indicating we have tapped into a new community
 - Of invited full proposals: 1 out of 3 received funding as Sprinter, Seedling, or Optimizer
 - Of Early-stage projects (Pilot and Seedling) which completed Deep Dive: 1 out of 3 have advanced to receive Optimizer
- 



Which funding path is right for my solution?



Key Risks

Is my concept valid?

I have an idea and there is a clinical need.

Will my technology work? Is there a motivated customer?

I have a proof of concept that works as expected and can demonstrate results.

Will the technology work in humans?

My solution will be ready for first-in-human studies in 1-2 years or less.

Funding Path

EXPLORATORY/
DEVELOPMENTAL
RESEARCH GRANTS
(e.g, RO1/R21/REACH)

BLUEPRINT
MEDTECH
INCUBATOR
PROJECTS

Blueprintneurotech.org

BLUEPRINT
MEDTECH
TRANSLATOR
PROJECTS

UG3/UH3,
PAR-25-383

Milestones and Tasks

- Technology concept and intended use formulated
- Technology feasibility studies
- Experimental proof of concept validation

- Technology development project plan
- Quality management system design & development
- Prototype development and verification
- Usability studies to optimize technology
- Technology validation in pre-clinical environment

- 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

(note: included in total costs of Optimizer funding request)

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

Business Development

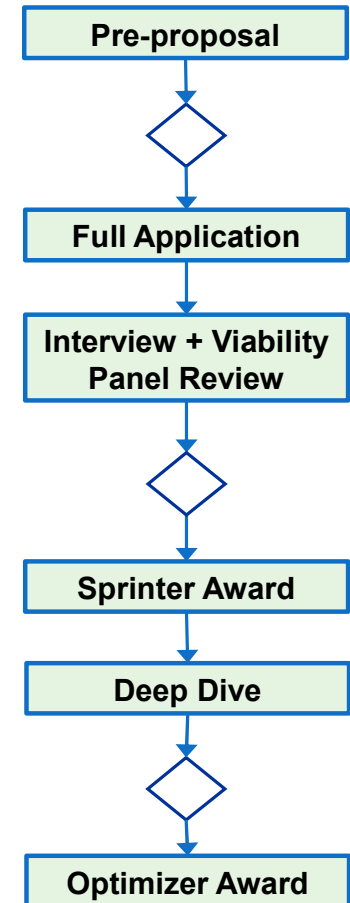
- Public-Private Partnerships – CRA, MTA
- Entrepreneurship
- Business Development
- Market / User Research
- Commercialization

Regulatory, Compliance, Quality System

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

Updates to Cycle 7 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 30-minute interview**
- Selected applicants will now receive **a 20-week Sprinter Award leading up to Deep Dive**
- Selected projects will receive an Optimizer Award for **up to 5 years of funding**





Summary of Cycle 7 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 - \$1,280,000 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 four 12-month periods with Incubator and NIH approval.
 - Incubator 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 Incubator 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 10%.
- 



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.

Contact Institute Program Officer for questions about **mission fit only**, hub staff for other solicitation questions.
<https://www.nih.gov/nih-blueprint-neuroscience-research/blueprint-research-initiatives/blueprint-medtech#Heading2>

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)
- Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative
- 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.
- Incubator cannot support safety or effectiveness studies. Applicants should apply to the Blueprint MedTech: Translator (UG3/UH3) NOFO.
- Applicants outside of the US are not eligible for incubator funding, however hubs may purchase goods and services from foreign consultants and vendors in support of awarded projects.



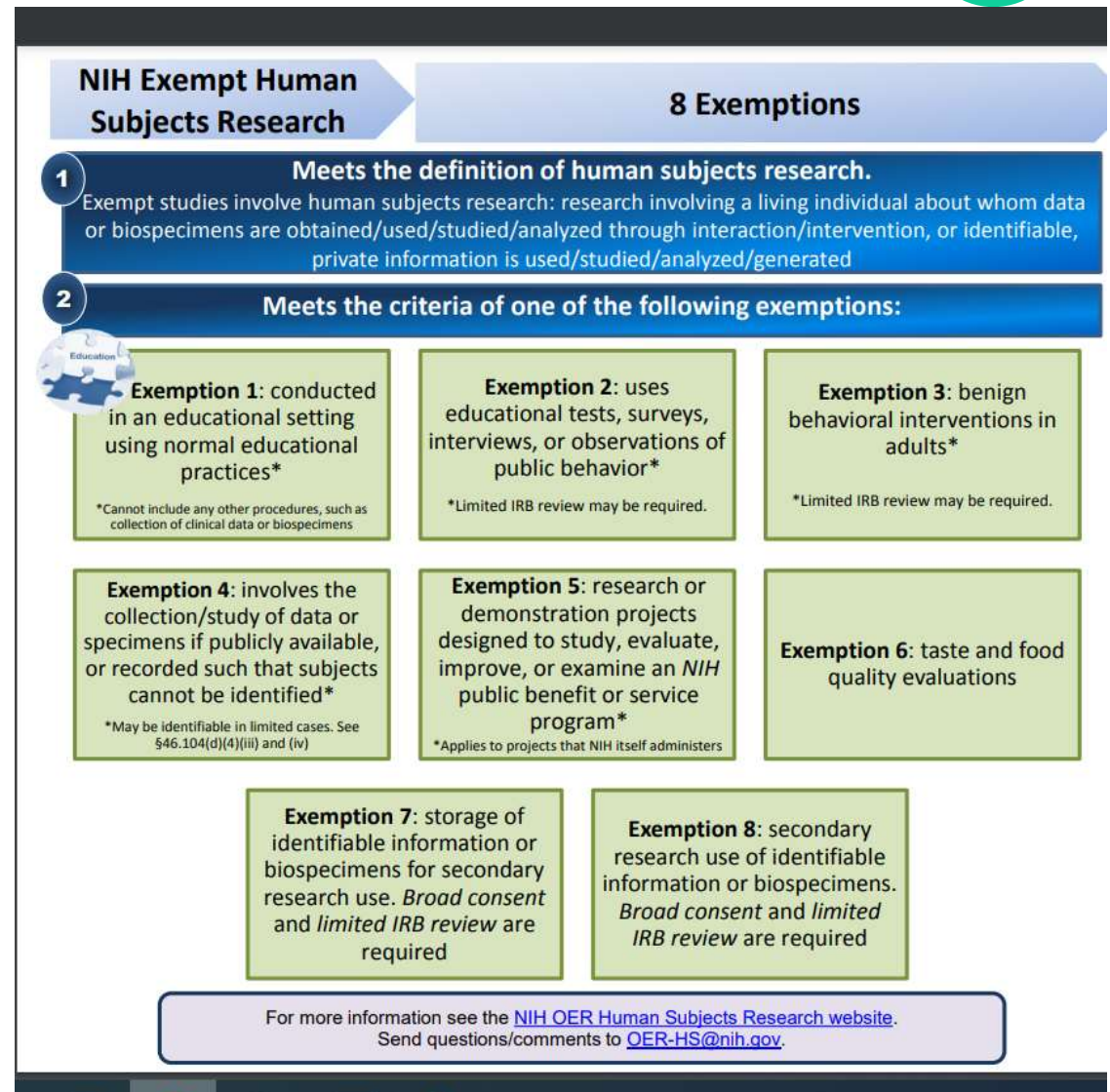


Human Subjects Research Information

- Only non-human subjects research (as determined by an IRB) or minimal-risk clinical studies can be performed with Optimizer funding
 - Examples of allowable work are:
 - Surveys/market research
 - Time-and-motion studies of clinicians performing a workflow
 - Human factors studies
 - Eligible minimal risk usability studies can be conducted at Georgia Tech's HomeLab (<https://cacp.gatech.edu/HomeLab>), a resource of the Blueprint Medtech program
- 

NIH Definition of IRB-Exempt Human Subjects Research

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



Summary of Cycle 7 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.

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 required to complete **30-minute 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)
- **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

Oct 21

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

Applicants Invited

Nov 19

Full-proposals

Dec 21

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

Feb 3 - 23
2027

Applicants Interviews

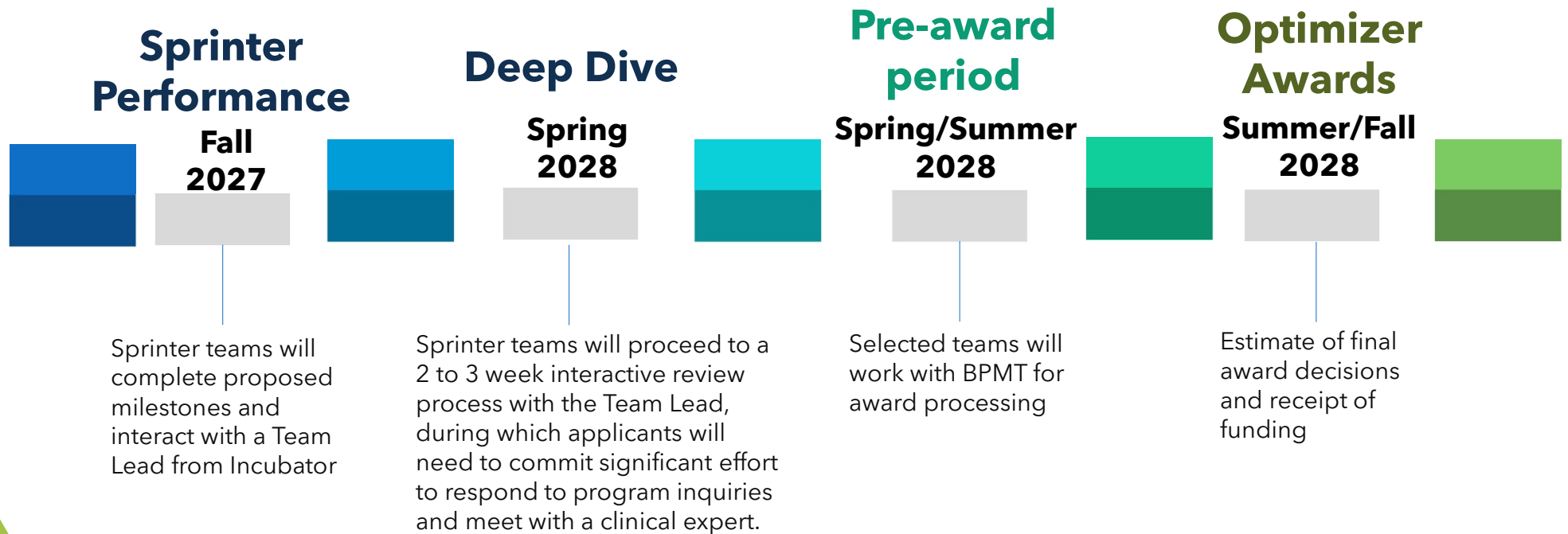
Sprinter Awards

May-Aug
2027

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





Contacts and Additional Resources

Webinar slides and recording: <https://cimit.org/initiatives/cinta/#events-cinta>

Solicitation link: <https://blueprintneurotech.org>

FAQs: <https://blueprintneurotech.org/faq>

All application related questions: info@blueprintneurotech.org

Office Hours scheduling:

<https://colab.secure-platform.com/a/solicitations/127/home>

15 minute sessions with program leaders

- October 6-8: 3 - 4PM ET
- October 13-15: 3 - 4PM ET
- October 19: 3 - 4PM ET





Good Luck!