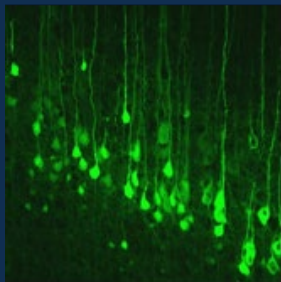


NIH **Blueprint**  
for Neuroscience Research

## NIH Blueprint MedTech: Incubator Hubs

PAR-21-314

Michael B. Wolfson, Ph.D.  
Program Director



[Blueprint-MedTech@nih.gov](mailto:Blueprint-MedTech@nih.gov)



The Blueprint MedTech program is an NIH incubator that aims to accelerate the development of cutting-edge medical devices to diagnose and treat disorders of the nervous system.

**Mission:** To catalyze the translation of novel neurotechnologies from early-stage development to first-in-human clinical studies.

**Goal:** To accelerate patient access to groundbreaking, safe, and effective medical devices.

The program will provide support to sufficiently develop and de-risk technologies to the point where additional investments are warranted from industry partners, investors, and government.



Help innovators build medical devices as close to the 'final system' as possible, providing them with resources and funding to support development of human-grade prototypes:

- 1) infrastructure for identifying the most promising technologies
- 2) funding for innovators to support product definition and development
- 3) funding for resources to assist innovators to support definition and development (e.g., prototype manufacturing, bench testing)
- 4) access to relevant expertise to advise supported innovators

This is a complicated FOA

Read it closely

Ask if you have questions



# Not Supported By This FOA

Clinical Trials NOT Allowed

Clinical evaluation of safety and effectiveness

Device technologies that are not regulated by the FDA

Use existing market approved devices for their labeled uses

Augmentation of healthy individuals

Develop tech for *fundamental study* of the nervous system

Develop animal models

Generate patentable intellectual property

Foreign institutions

This is a complicated FOA

Read it closely

Ask if you have questions



Proof-of-Concept

Development

Translation

Feasibility /  
Pivotal Study

Individual projects (Non-dilutive funding \$)

Early-stage  
(Seedlings)



Solicited by Hubs

Late-stage development

Solicited by Hubs

Non-clinical testing  
for IDE/IRB

First-in-human study

UG3/UH3      PAR-21-315  
U44 (Phase I/Phase II)      PAR-21-282

Free Resources (provided by NIH)



Design,  
Prototype,  
Bench Test



Business  
Development



Consultants &  
Industry  
Experts



Regulatory,  
Compliance,  
Quality System



Biocompatibility  
& Animal  
Studies



Clinical



External  
Oversight  
Committee



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Incubator Hubs      U54 PAR-21-314



Things NIH does	Things U54 awardees do
FOA	Solicitation
Applicant/application	Proposer/proposal
Project/center	Incubator hub
Component	Core
Review/peer reviewer	Evaluation/evaluator
Study section	Triage, Viability, Deep Dive Panels
Benchmarks for center	Milestones for subawards
Award cooperative agreement	Subcontract subawards

Innovators propose innovator subproject -> receive subawards

Resource providers propose resource subawards -> receive subawards

Resource subawards are linked to innovator subprojects

Pay attention to key words:

must and required

may, should, encouraged, anticipated, expected



# Simplified Process

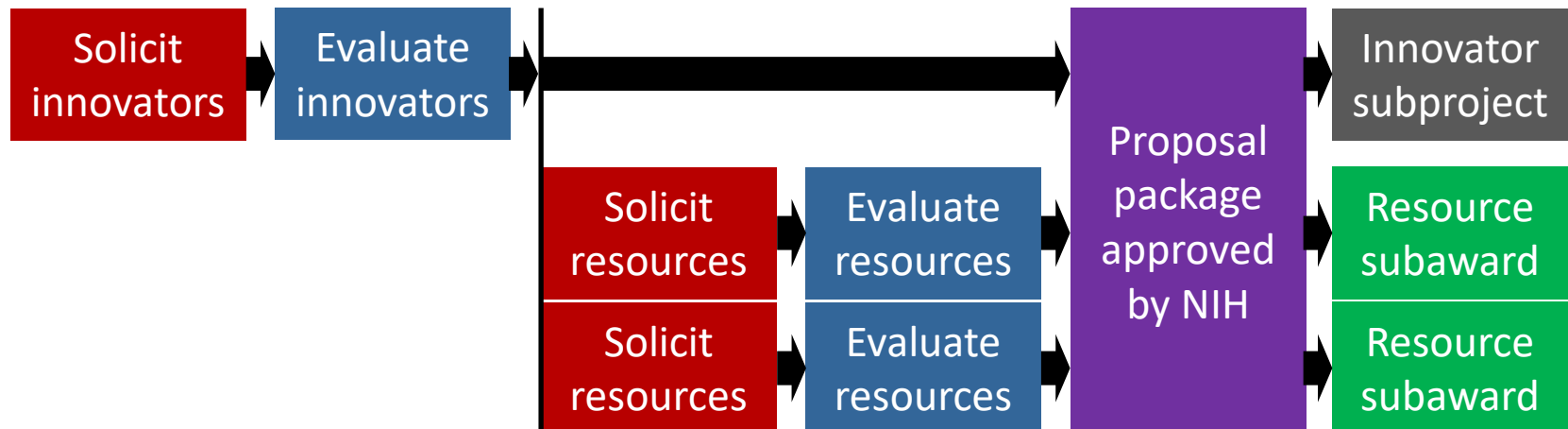
Issue a solicitation for innovator subprojects soon after award

Evaluate innovator proposals

Solicit and evaluate resource subprojects

NIH case-by-case approval

Funding for innovator subprojects and resource subawards







National leaders in facilitating the development and translation of technologies

Five Cores, integrated into a cohesive and coherent unit;  
applications must contain one of each

Led by scientific, engineering, clinical, and translational experts  
(i.e., Key individuals)

Expected to support a very broad range of innovator subprojects

Coordinate across the Blueprint MedTech consortium

Outreach Core

Evaluation Core

Innovator  
Subprojects Core

Resource  
Subawards Core

Administrative Core



Oversight of all decision-making processes

*PI(s) responsible for all decisions*

Responsible for budget, governance, policy, and quality and efficiency

Develop proposal packages

Interactions with NIH (reporting, analysis of subproject proposals)

Administer the consultant network

Other committees or subcommittees as needed

Coordinate activities across awarded Blueprint MedTech incubator hubs

Steering Committee (SC)

Outreach Core

Evaluation Core

Innovator  
Subprojects Core

Resource  
Subawards Core

Administrative Core



# Outreach Core

- Develop and host BP MedTech web content, educational material, workshops
- Manage solicitations (proposal intake, inquiries)
- Perform needs assessments to inform future solicitations
- Targeted outreach to solicit proposals from innovators with diverse backgrounds
- For each innovator subproject, foster relevant partnerships
- Bridge to industry trade associations, professional societies, and other bodies
- Host the annual BP MedTech consortium meeting
- Foster and maintain collaborations within the BP MedTech consortium

Public  
engagement

Needs  
assessments

Targeted  
outreach

Solicitations

Partnerships

Meetings

Outreach Core

Evaluation Core

Innovator  
Subprojects Core

Resource  
Subawards Core

Administrative Core



Independent evaluation of innovator and resource proposals

At least as rigorous, unbiased, and thorough as NIH peer review

Feasibility of the total lifecycle

Staged “funnel”

Recruit, train, and manage panelists

Diverse backgrounds

Entrepreneurial, technical, clinical, and scientific knowledge

May re-evaluate ongoing innovator subprojects

Outreach Core

Evaluation Core

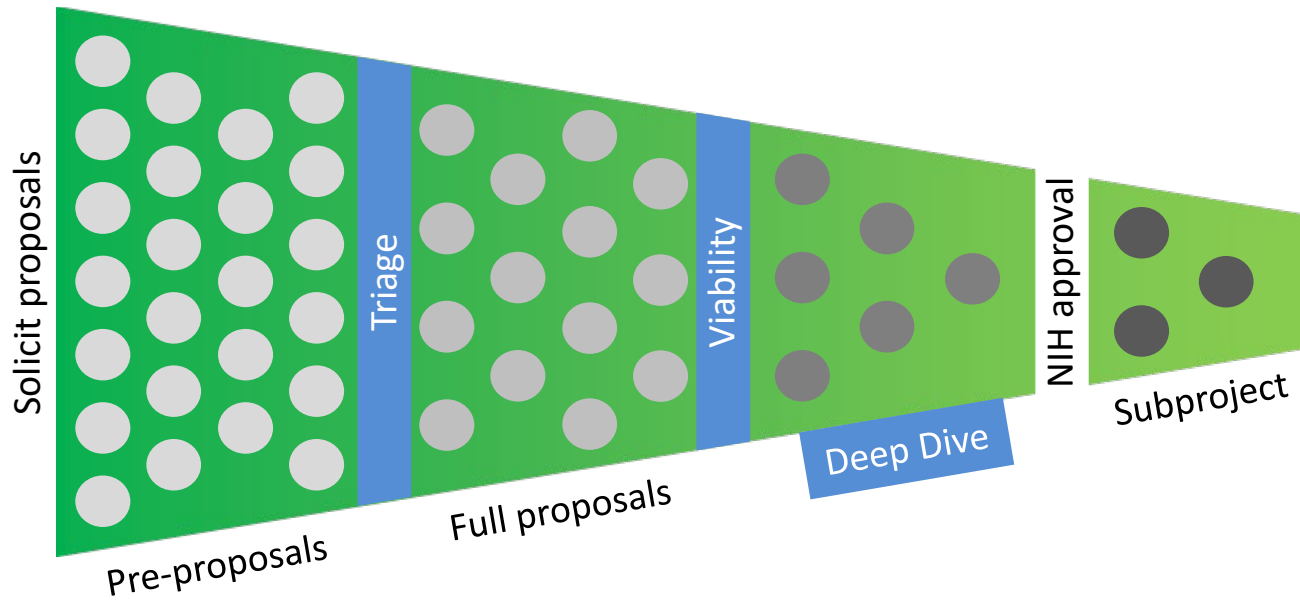
Innovator  
Subprojects Core

Resource  
Subawards Core

Administrative Core

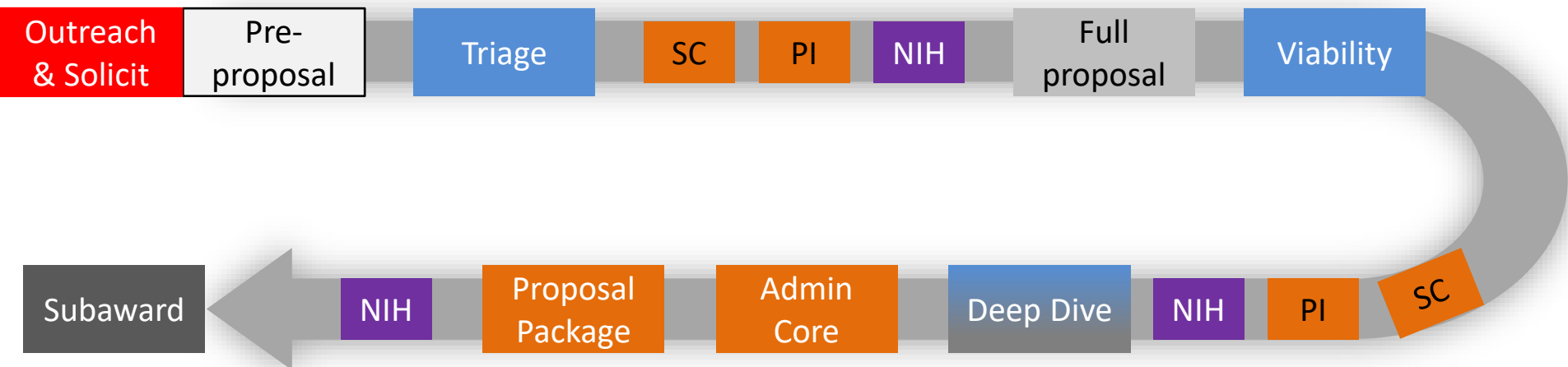
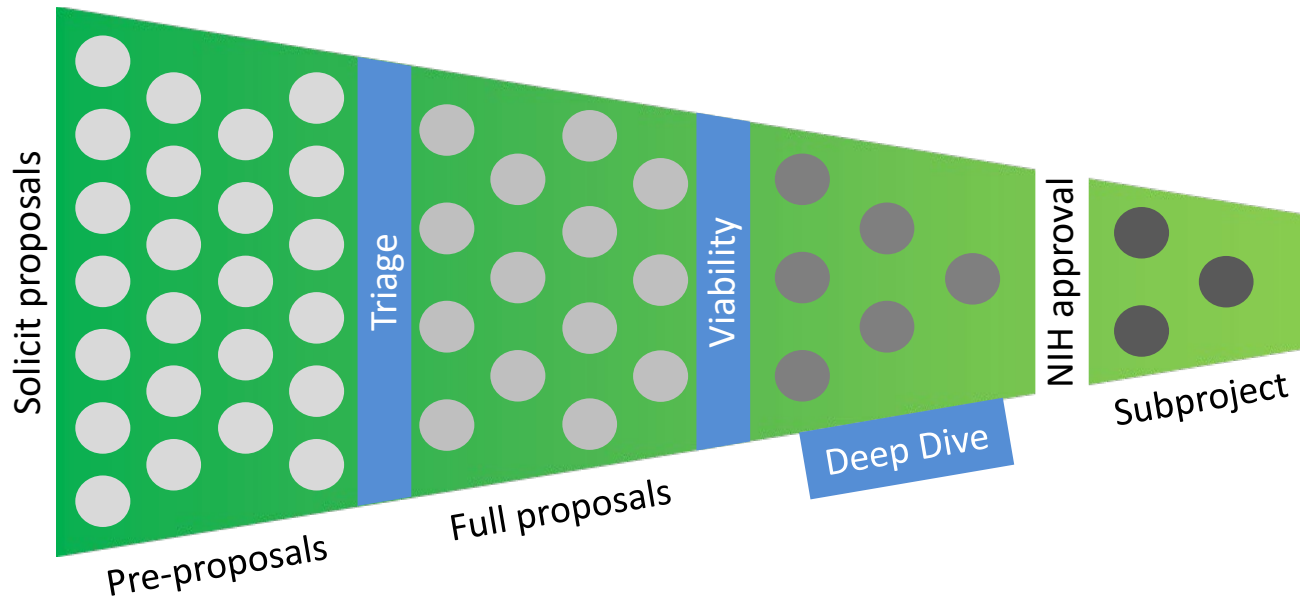


# Evaluation Core





# Evaluation Core





Manages innovator subprojects (admin and project mgt)

Monitor timelines, milestones, deliverables

Coordinate with linked resource subawards

Develop partnerships through Outreach Core

Subprojects may range (depending on maturity):

six months to four years

\$50K to \$500K direct cost/yr

May manage up to 15 innovator subprojects at a time

Subproject 1

Subproject 2

Subproject 3

Subproject 15

Award mgt.  
Project mgt.

Award mgt.  
Project mgt.

Award mgt.  
Project mgt.

...

Award mgt.  
Project mgt.

Outreach Core

Evaluation Core

**Innovator  
Subprojects Core**

Resource  
Subawards Core

Administrative Core



Selected after thorough Deep Dive

Have comprehensive supporting data based on representative bench, in vitro, and/or in vivo models

This may be in the form of a hand-built device, demonstrating feasibility in a small animal model

May not have any prior translational or entrepreneurial experience

May need “seedling” support to develop a Target Product Profile

Leave with human-grade prototype, validated and ready for entry into companion UG3/UH3 or U44 FOAs

Design freeze as close as possible to an eventual product

Detailed plans on total lifecycle of the intended product (e.g., regulatory, manufacture, reimbursement, marketing, and obsolescence)





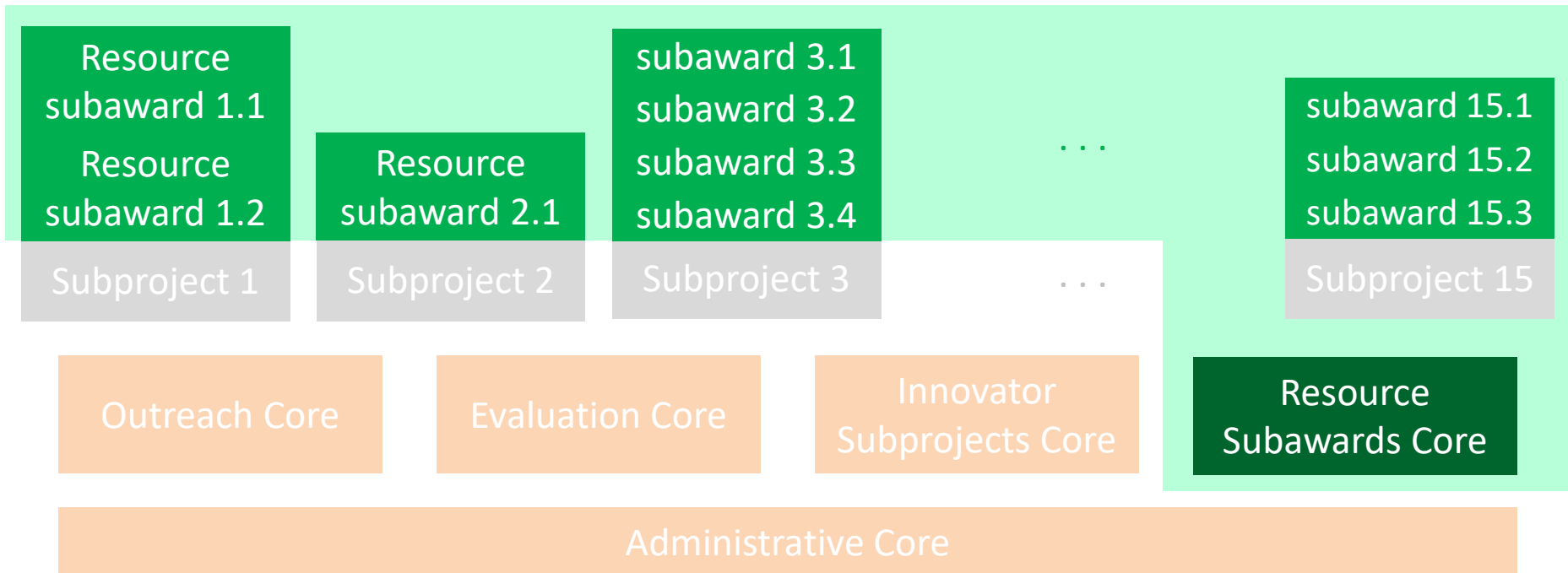
# Resource Subawards Core

Manages resource subawards (admin and project mgt)

Monitor timelines, milestones, deliverables

Each is linked to a specific innovator subproject

May need multiple resources per innovator subproject





# Potential Resources

## 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 Studies – Animal Testing (GLP)
- Preclinical Studies – Animal Testing (non-GLP)
- Cadaver Testing

## Clinical

- Clinical trials
- Biostatistics
- Data Management
- Neuroethics

Anticipated resources provided by Resource Subawards Core

Provided by other parts of BP MedTech

## Business Development

- External Oversight Committee
- 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



# Applications Must Include

All required Cores

Plan to ramp up each Core within the first year

Biosketches for all members of the Steering Committee

Letter(s) of support from institutional officials

Conflict-of-interest policy

Confidentiality policy

Plan to solicit proposals from innovators with diverse backgrounds

PI(s) commit 2.0 months per year



**[Required]** **“Draft Solicitation.pdf”** (three pages or less)  
Shovel-ready draft of the center's first solicitation

**[Required]** **“Needs Assessment.pdf”** (three pages or less)  
Preliminary needs assessment to identify areas for targeted outreach

[Optional] **“Agreement - Consultants.pdf”**

[Optional] **“Agreement - Innovators.pdf”**

[Optional] **“Agreement - Resources.pdf”**

[Optional] **“Agreement - Innovator-Resource.pdf”**



Applicants encouraged to discuss with NIH

Expected to be quantitative

Will be negotiated before award

Will be monitored over life of award

Funding may be discontinued if not met

Example benchmarks might include:

proposals received

(e.g., diversity of proposers' backgrounds, technology approach, disease/disorder, geographical region)

evaluation efficiency

(e.g., cost to evaluate proposals at each stage)

innovator subproject management

(e.g., administrative cost per project, percent of milestones met on time)

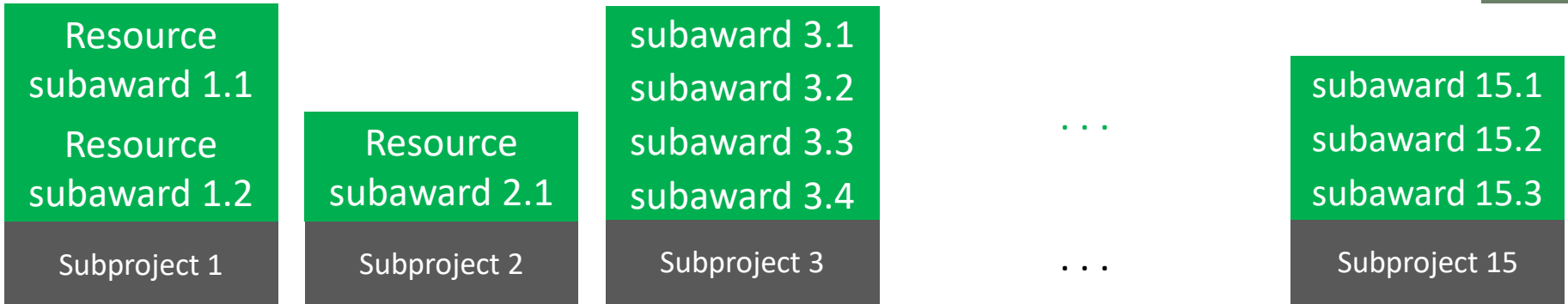
transitions out of the center

(e.g., new funding from NIH or outside investment)



Applications should request funds for full-scale operation, but ...

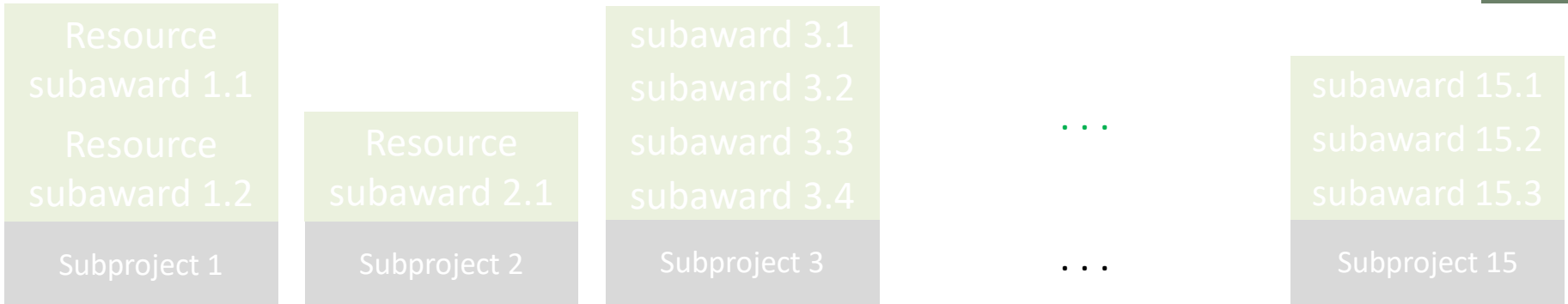
\$<sub>max</sub>





...only expect to receive funding to cover basic operations...

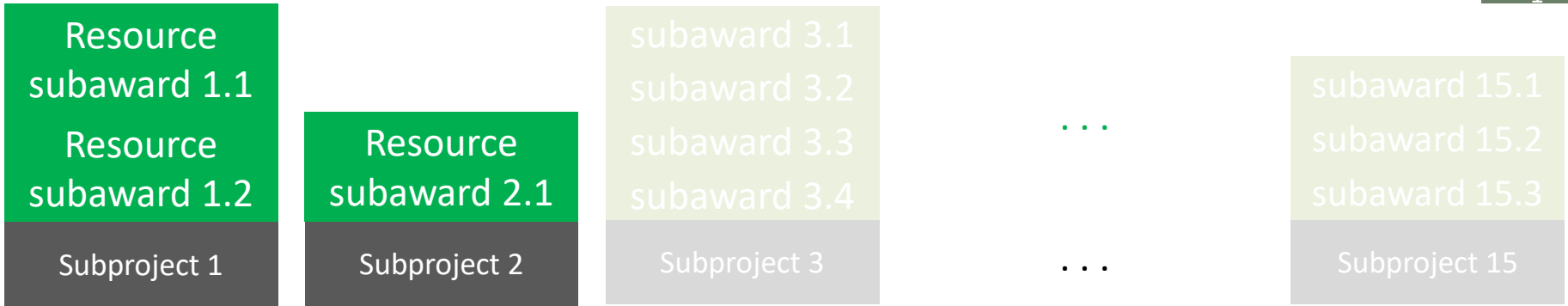
\$<sub>base</sub>





... until proposal packages are approved by NIH,  
*if funding is available*

$$\begin{matrix} \$_{\text{base}} \\ + \$_1 + \$_2 \end{matrix}$$







NIH can negotiate U54 budgets downward if needed, but not up

Application budgets are not limited but need to reflect anticipated needs

Cost of innovator and resources are not known at time of application

Assume a modest base level of activity, as if supporting

- ~20-30 proposals per year

- ~3 innovator subprojects per year

- ~1 solicitation per year

- Rotating Blueprint MedTech consortium meetings

Describe how each Core's budget would increase with each additional solicitation or subproject

Extrapolate to full scale operation (15 innovator subprojects per year)

Costs for consultant labor belongs in the relevant Core's budget



Available Component Types	Research Strategy/Program Plan Page Limits
Overall	6
Administrative Core	6
Outreach Core	6
Evaluation Core	6
Innovator Subprojects Core	3*
Resource Subawards Core	3*

\*ASSIST will allow applicants to use up to six pages, but only three are allowed by the FOA.

Applications that exceed these page limits will be considered non-responsive and will be withdrawn and not reviewed.



## Described in FOA under [Section V. Application Review Information](#)

*“a project that by its nature is not innovative may be essential to advance a field”*

### Additional Review Criteria - Overall

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

#### Review for the Overall Center

- Is the center well structured to integrate the full range of center functions? Will the center be able to harness the necessary expertise, resources, and capabilities to support early-stage technology developers as they define and demonstrate a viable product?
- Will the center be able to adequately support a broad range of innovator subprojects across interventional approaches, geographical regions, indications, and patient populations?
- Is the confidentiality policy adequate to protect the interests of innovator and resource proposers and subawardees? Is the conflict-of-interest policy adequate for an unbiased approach to evaluation and management of innovator and resource proposals and subawards?
- Does the Center provide adequate benchmarks for success? Will the proposed benchmarks be adequate to measure the impact of the center? Is the plan to ramp up in the first year realistic?

#### Review Criteria for the Administrative Core

- Has the center defined a viable governance plan? Will the center be able to prioritize its activities and adjust its scale to support new solicitations, innovator subprojects, and resource subawards? Has the center provided a pragmatic framework to work with outside parties (e.g., intellectual property approach, sample agreements under Other Attachments)?
- Is the structure, governance, and composition of the Steering Committee appropriate? Is the approach to making critical decisions appropriate (e.g., setting and evaluating subproject milestones)? Is there a reasonable plan to identify unmet needs in order to target outreach and solicitations?
- For the most promising innovator subproject proposals, will the center be able to develop a comprehensive “proposal package” of everything needed to bring the technology to the brink of a first-in-human study?

#### Review Criteria for the Outreach Core

- Is the approach to performing needs assessments adequate? Do the initial needs assessment and draft solicitation (under Other Attachments) target significant unmet need(s)? Will the draft solicitation elicit compelling proposals from an inclusive and diverse pool of proposers to address the unmet need(s)?
- Does the center have adequate plans to provide exemplary customer service to potential proposers, partners, program participants, and the public? Will the educational activities effectively prepare researchers to propose to the center's solicitations? Will the plans prime promising proposals from diverse sources at a national or international scale?
- Will the center be able to tap into and build a consultant network with appropriate breadth and depth of expertise? Will the center be able to effectively partner with other relevant parties (e.g., industry, trade groups, patient advocacy groups)? Will the center be able to serve as a central hub of the Blueprint MedTech consortium?

#### Review Criteria for the Evaluation Core



Described in FOA under [Section VI. Award Administration Information](#)

## Prior Approval of Innovator Subprojects and Resource Subawards

In addition, delayed onset studies require prior approval by NIH

## Cooperative Agreement Terms and Conditions of Award

The PD(s)/PI(s) will have the primary responsibility for:

NIH Staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards:

Areas of Joint Responsibility include:

Dispute Resolution:



Encourage participation of individuals from diverse backgrounds, including groups traditionally underrepresented in the translational workforce, such as underrepresented racial and ethnic groups, those with disabilities, those from disadvantaged backgrounds, and women

Must plan outreach to solicit proposals from innovators with diverse backgrounds

Evaluation Core to recruit a range of relevant panelists from diverse backgrounds

Steering Committee should include as many diverse perspectives as practicable

Holistic and integrated view of how enhancing diversity will be supported throughout the Blueprint MedTech center



- Yes, you need to fill details into each component in ASSIST
- Foreign components are allowed
- Support the interest of the participating Institutes and Centers across a broad range of innovator subprojects across interventional approaches, geographical regions, indications, and patient populations  
<https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-medtech/blueprint-medtech-ics-and-contacts>
- Most Steering Committee, innovator subprojects, and resource subawards should be from *outside* the participating applicant organizations
- Resource Sharing Plan does not mean resource subawards are shared outside the Blueprint MedTech consortium
- The number of awards is contingent upon NIH appropriations
- Application budgets are not limited but need to reflect the anticipated needs
- Letter of Intent is not required
- Delayed onset non-GLP animal use is anticipated
- Delayed onset human research (i.e., user preference studies) is anticipated

Additional FAQs on [BP MedTech site](#)



**Applications Due: October 20, 2021**

Scientific Merit Review: February 2022

Scientific Review Group convened by NIBIB

Advisory Council Review: May 2022

Est. Notice of Award: June 2022

Up to 5-year project period

This is a complicated FOA

Read it closely

Ask if you have questions



**Contact us:** Blueprint MedTech Mailbox

[Blueprint-MedTech@nih.gov](mailto:Blueprint-MedTech@nih.gov)

**FAQ:**

<https://neuroscienceblueprint.nih.gov/neurotherapeutics/blueprint-medtech>

**Applications Due: October 20, 2021**