Thank you for joining PRINT Proposers' Day! The presentation will begin soon.

We will make this slideshow and a video of this talk available at the PRINT program website.

ARPA⬡

PRINT: Proposer's Day
Personalized Regenerative Immunocompetent Nanotechnology Tissue

Advanced Research Projects Agency for Health (ARPA-H)

Program Manager: Dr. Ryan Spitler

Health Science Futures (HSF), Mission Office (MO)

May 7, 2024 | New Orleans, LA

The ARPA-H Model

Transforming Health for All

Amy Jenkins, PhD
Director, Health Science Future (HSF)

ARPA H

President Biden's Vision

" ARPA-H will **pursue ideas that break the mold on how we normally support fundamental research and commercial products** in this country."

" Ideas so audacious that people say they just might work only if, only if, we could try. Well, we're about to try in a big way."

— President Biden Remarks, March 18, 2022

DELIVERING BIPARTISAN PROGRESS

THROUGH PRESIDENT BIDEN'S UNITY AGENDA

- ☑ Made it easier for doctors to prescribe effective treatments for opioid addiction
- ☑ Passed a gun safety law making historic investments in youth mental health
- ☑ Launched ARPA-H to drive breakthroughs in the fight against cancer, Alzheimer's, and diabetes
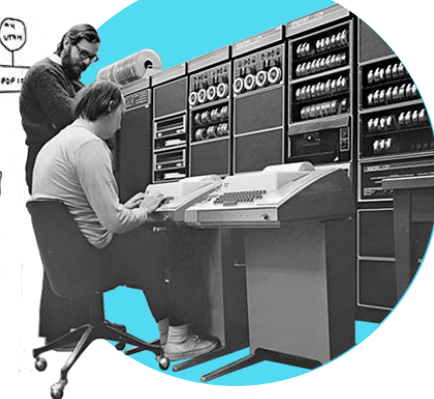- ☑ Expanded benefits and services for veterans and their survivors
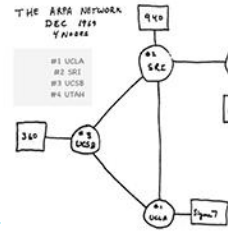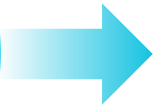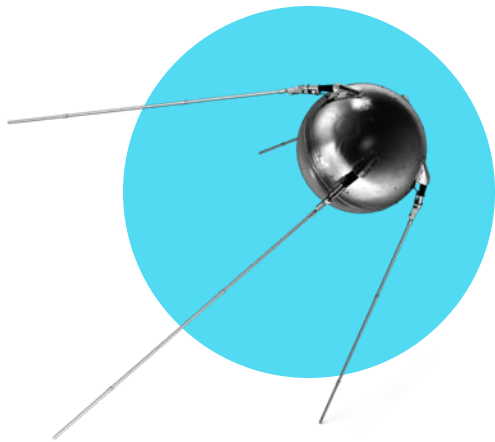
WH.GOV/SOTU

JULY 27, 2023

As Part of President Biden's Unity Agenda, Cancer Moonshot Announces Launch of New ARPA-H Program to Develop Novel Technologies for More Precise and Accurate Cancer Tumor Removal

ARPA **H**

The Promise of the ARPA-H Model

Mission

Accelerate better health outcomes for everyone.

ARPA H

# ARPA-H Organization within HHS

- Independent component of HHS within NIH; not an Institute

- ARPA-H Director reports directly to HHS Secretary

- No internal research labs; disease agnostic

- $2.5B initial appropriation; budget independent from NIH

- Generally funds contracts, not grants

- Ability to directly reimburse FDA

HHS
Secretary

NIH
Director

ARPA-H
Director

ARPA H
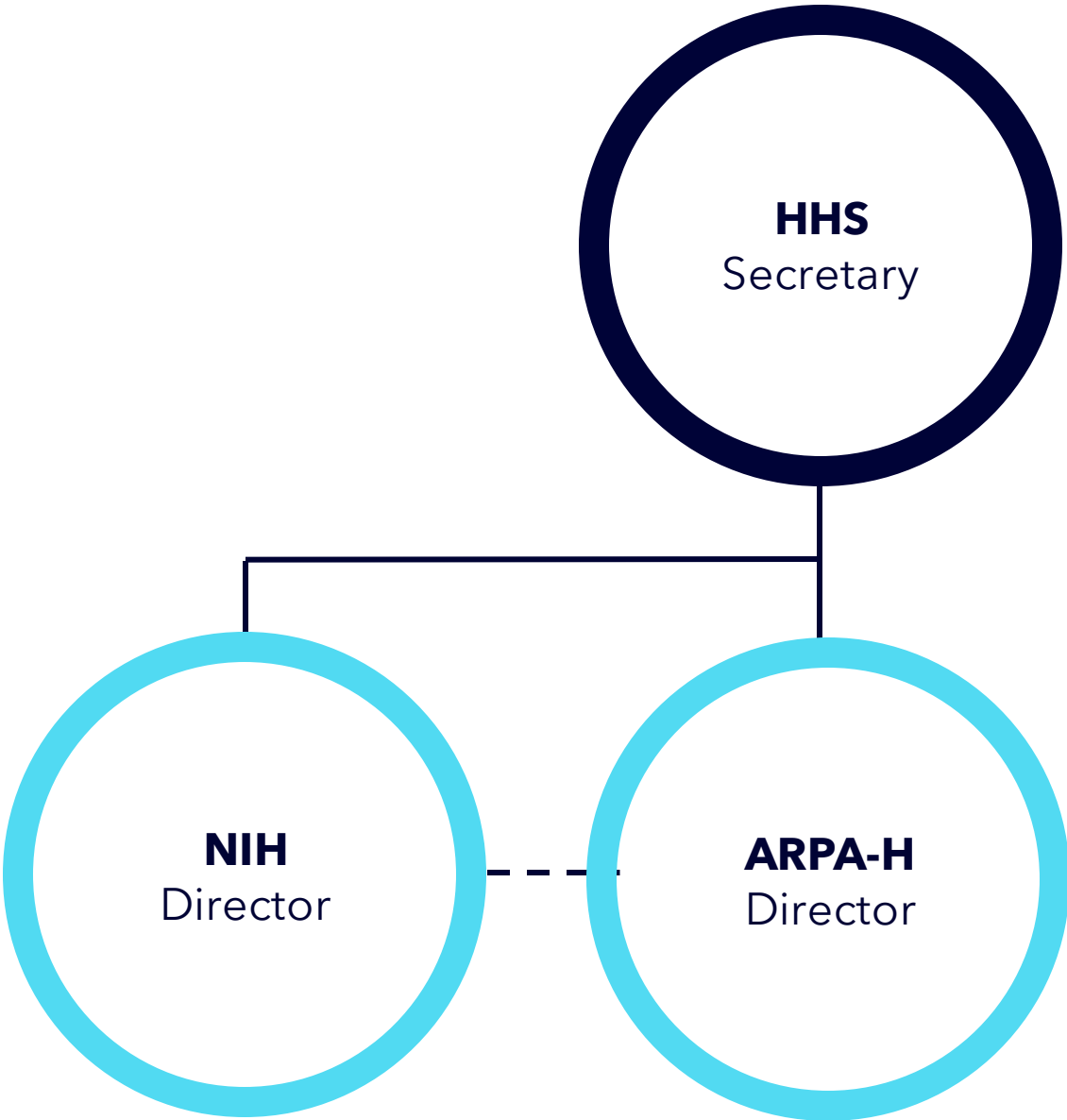
Initial Mission Focus Areas
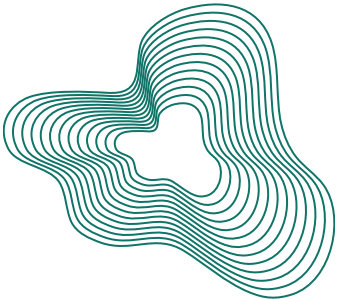
Health Science Futures

Expanding what's technically possible

Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.

Scalable Solutions

Reaching everyone quickly

Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.

Digital cellular twin capabilities that are accurate surrogates for wet lab testing and can drive training data for AI/ML tools.
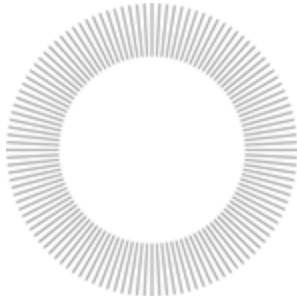
Proactive Health

Keeping people from being patients

Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans' health, whether those are viral, bacterial, chemical, physical, or psychological.

New detection modalities that are more precise, sensitive, and have broader capabilities than existing methods
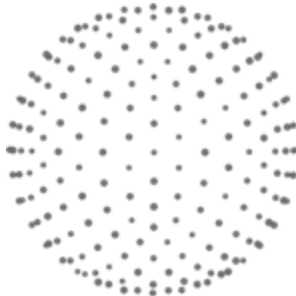
Resilient Systems

Building integrated healthcare systems

Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.

Novel techniques to **improve the efficiency and cost of manufacturing gene and cell therapeutics** from small batch to scale-up

ARPA H

ARPA-H Health Ecosystem

STAKEHOLDERS

CUSTOMERS

PERFORMERS

The Public

NIH

Healthcare Providers

Federal Partners: FDA, CMS, HRSA, et al

Patient Groups

Private Investors

Academia

Industry

NGOs

(and many others ...)

ARPA H
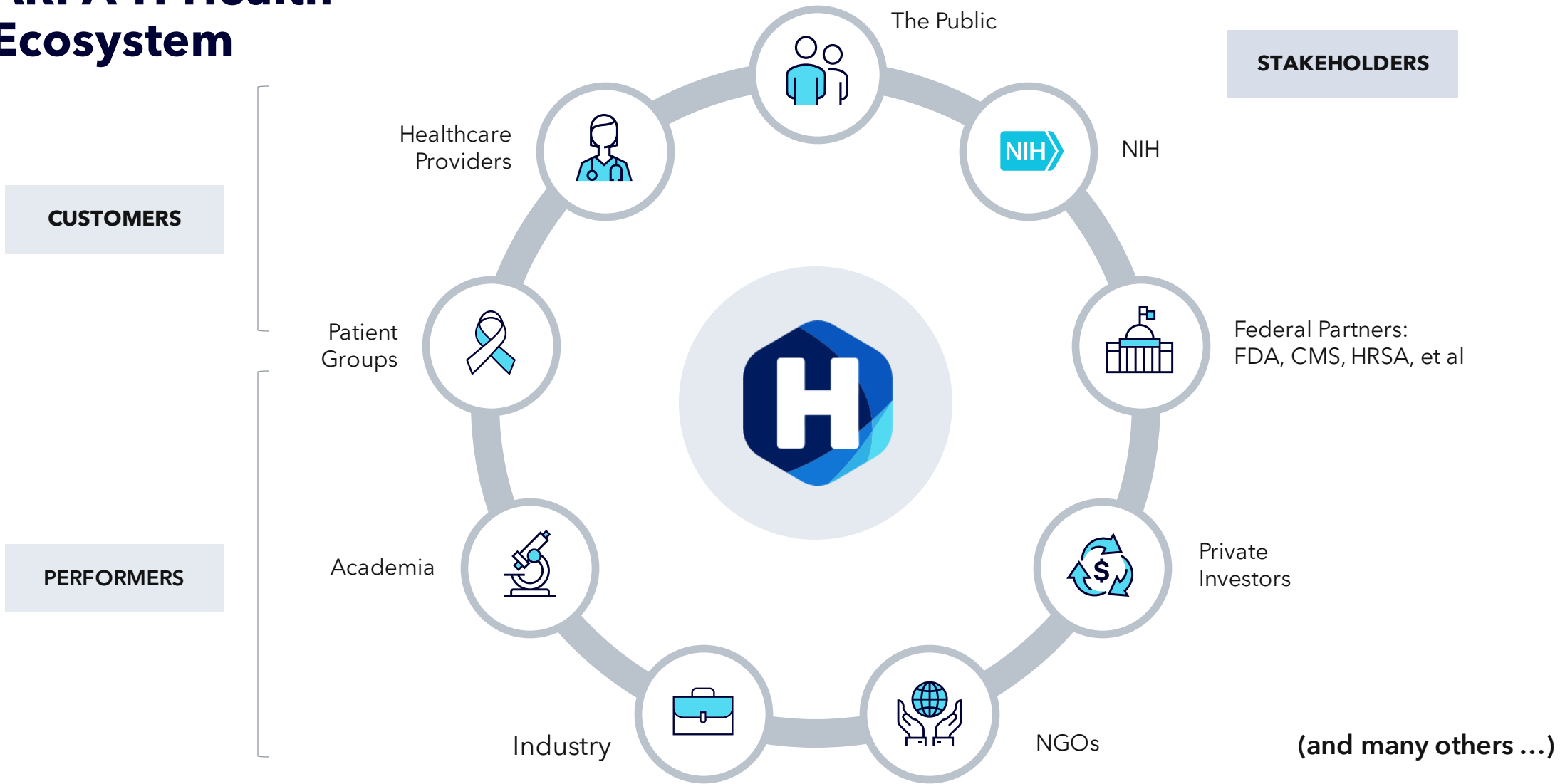
Focus Areas

Unlock new ways to collaborate and attack problems

Health Science Futures

Expand What's Technically Possible

Develop approaches that bring radically new insights and paradigms. These *innovative tools, technologies, and platforms* can apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options.

Examples include:

- Novel molecular platform approaches
  - Modulation of host systems
  - Delivery to targets with special and temporal precision
  - Mitigation of off-target effects to accelerate interventions
- Approaches to accelerate mammalian and microbial cellular engineering to enable next generation therapeutic applications.
- Interventions that target and reverse disease pathogenesis or enhance plasticity to address degenerative diseases.
- Advances in genetic, cellular, tissue, and organ replacement therapies.

ARPA**H**

Health Science Futures
Prioritize Disease Agnostic Solutions

Innovative Methods

- Use high-throughput technology and analytics to discover or test solutions across many disease states

Collaborations Across Disciplines

- Foster an environment of collaboration across disciplines to increase R&D creativity and efficacy

Adaptable Approach

- Zoom out to the big picture and focus on advances in technology that target key processes underlying a variety of disease states

Expand Possibilities of Current Solutions

- Revisit existing technology/therapies to use their power in a different way to solve outstanding health issues

ARPA H

The Program and Program Manager Flywheel

The ARPA-H portfolio is:

(1) a reflection of the PMs

(2) dynamic, and

(3) will – and should! – change frequently

PMs: 3-6 Years

Programs: 2-4 Years

PROGRAM MANAGERS

PM joins with their vision to advance health outcomes

SOLUTIONS
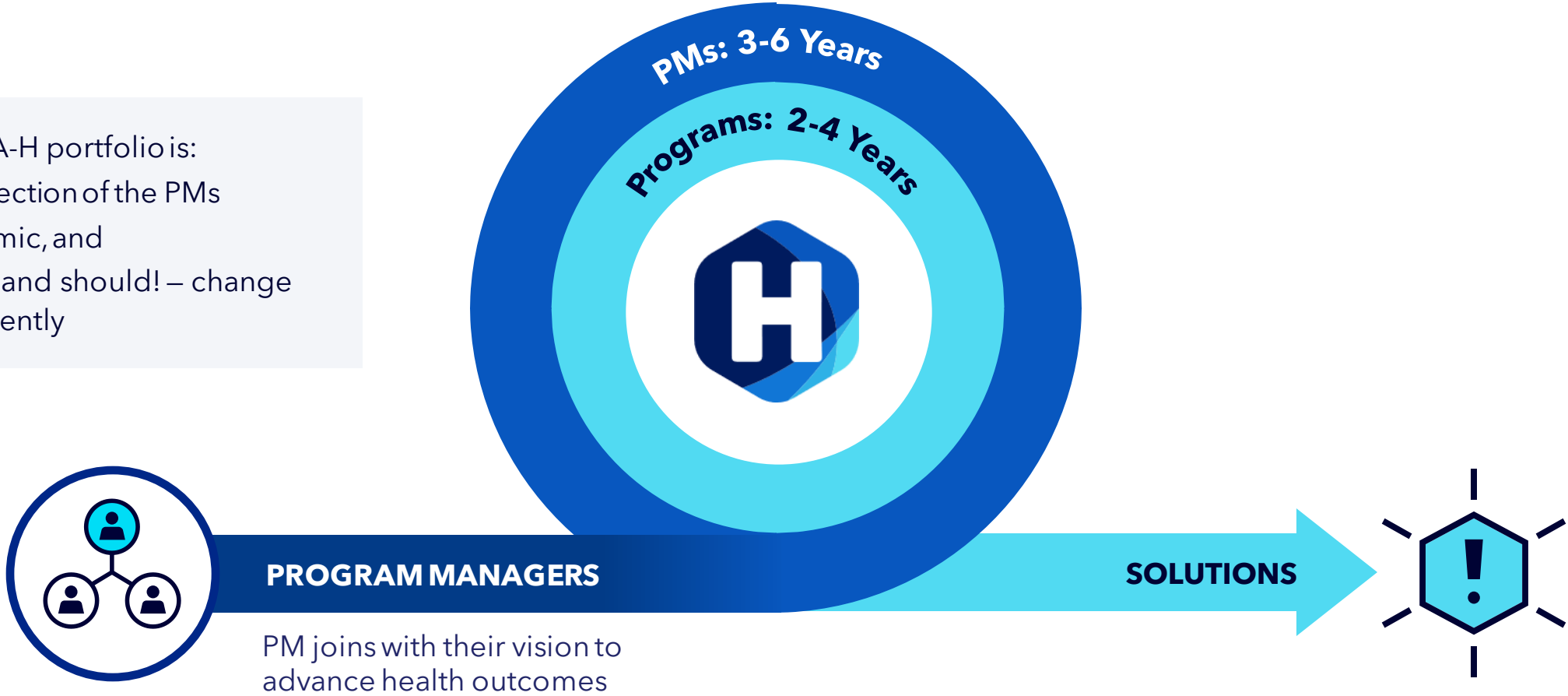
ARPA H

ARPA-H Model: Program Formation

Program Manager

Program Manager identifies a difficult health-related challenge that is ripe for solving.

Challenge

The challenge should NOT be easily solvable through traditional activities.
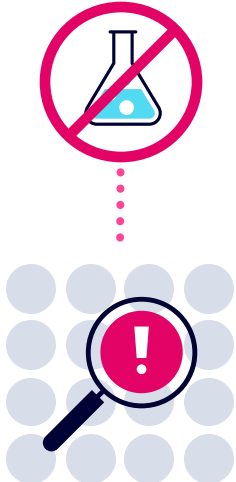
Program Launch

A Program Manager seeks — and oversees — several groups of performers aiming to solve the same problem in unique ways.

Performers

Performers compete to carry out their potential innovative solutions to the challenge
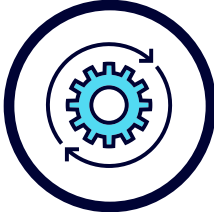
ARPA **H**

ARPA-H Model: Program Lifecycle

Launch

Program Manager
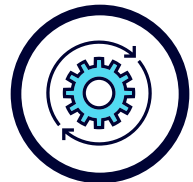Program Manager identifies a difficult health-related challenge that is ripe for solving.

Program Launch
A Program Manager seeks – and oversees – several groups of performers aiming to solve the same problem in unique ways.

Support
ARPA-H will provide contracts – not grants – for projects with well-defined endpoints. Additional support will be provided by Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.

Transition

Challenge
The challenge should NOT be easily solvable through traditional activities.

Performers
Performers compete to carry out their potential innovative solutions to the challenge.

Performance
Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals.
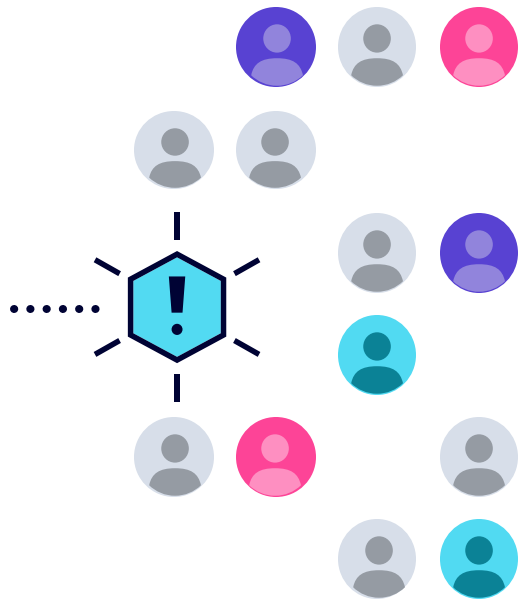
Graduation
Graduation occurs when the challenge is solved. The project then transfers to partners, who have been involved from the start and can scale the solution for large, diverse communities everywhere.

Perform

ARPA H

THIS PRESENT MOMENT USED TO BE THE UNIMAGINABLE FUTURE

Alicia Eggert
This Present Moment
2019 – 2020
Currently @ The Renwick Gallery
Washington, DC

Personalized Regenerative Immunocompetent Nanotechnology Tissue (PRINT)

Dr. Ryan Spitler

Program Manager, HSF

ARPA H

Organic Transplantation Crisis

PROBLEM: *Patients in need of organ transplants face chronic shortages, long wait lists, and the lifelong risk of transplant rejection.*

Immunosuppressive drugs
- Complications include side effects, infections, and malignancies
- Mean lifetime survival 15 – 23 years
- Drugs costs between $500 - $22,000/month

Healthcare delivery
- Process errors can result in use of diseased organs
- Challenges exist for organ transportation, organs arriving late, or damaged

Today

- 17 deaths/day in the US due to lack of organ donors
- Lifetime costs range from $600K and can exceed $1M
- Rejection rate: 10%-60%
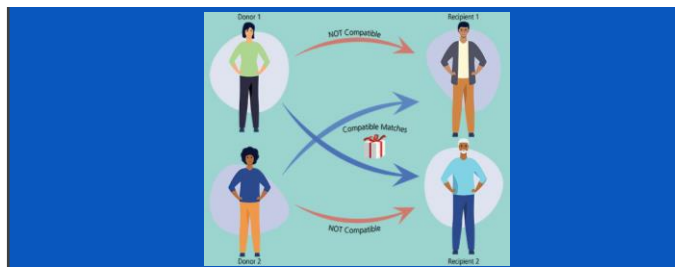
Access Challenges – Geography matters
- Unequal access to donor organs
- Differential pricing by state and hospital. A kidney transplant ranges from $15,000 - $115,000 depending where you go.
- Increased transplant center/hospital travel time results in increased risk of death and complications.

One organ donor can save up to 8 lives.

Supply and Demand
- Wait times range between 200 – 700 days, but can be years
- 45,000 transplants performed annually in the US with 120,000 patients remaining on wait lists and 7,000 died while waiting

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Vision for the Future

VISION Use state-of-the-art bioprinting technology and a regenerative medicine approach to produce personalized, on demand organs that do not require immunosuppressive drugs.

Immunocompatible Cells → Cell Manufacturing → Biofabrication → Kidney / Heart / Liver

P	**R**	**I**	**N**	**T**
Personalized	Regenerative	Immunocompetent	Nanotechnology	Tissue

ARPA**H**
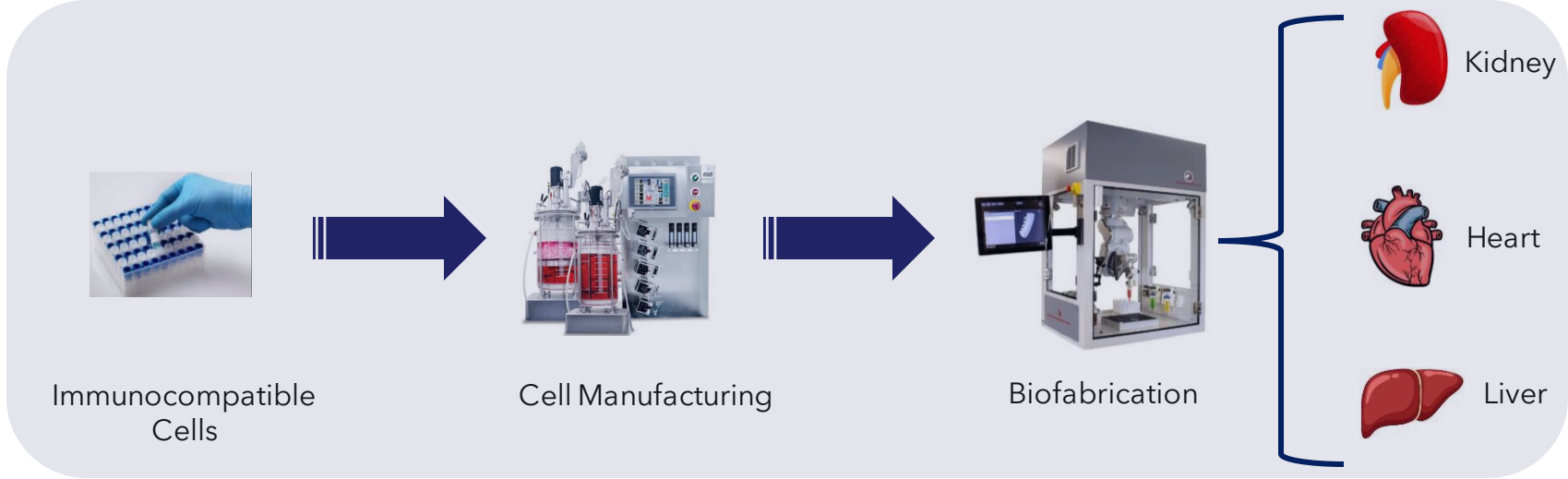
PRINT Technical Areas (TA)

TA1: Generate all necessary organ cell types

TA2: Large Scale Manufacturing of organ cell types

TA3: Organ Biofabrication and testing

PRINT will create a platform to restore healthy function to multiple organ systems and immuno-compatible to the patient to avoid rejection

Cell characterization   GMP/GLP manufacture   QA/QC   Ex vivo validation   Humanized animal testing   Restore Normal Function

ARPA H
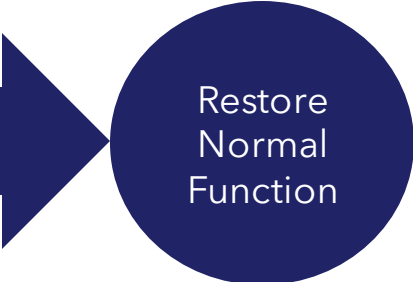
All Teams Must Choose One Organ and Address All Three TAs

- **Teams** can include academia, small business, large business, contract research organizations, manufacturers, and more!
- Teaming is considered **crucial** to accomplish the program goals and metrics.

Kidney
- TA1
- TA2
- TA3

Heart
- TA1
- TA2
- TA3

Liver
- TA1
- TA2
- TA3

Organ specific teams

TA1

TA2   TA3

ARPA H
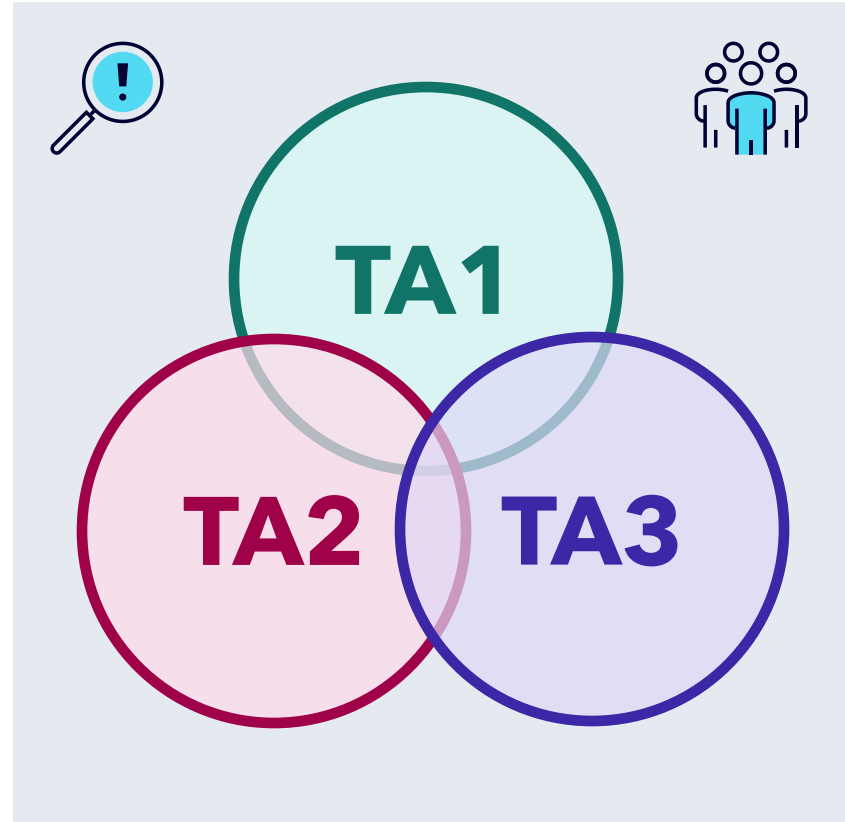
TA1: Generate All Necessary Organ Cell Types

Blood draw

Biopsy

Biobank

Problem
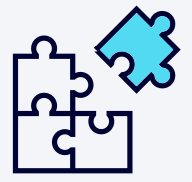
1. Some cell types are **naturally not proliferative.**
2. Not all cells have the same **multi-potent potential.**
3. Despite current expansion and differentiation protocols, **generating organ specific and a relevant number of cells remains a barrier to print an organ.**
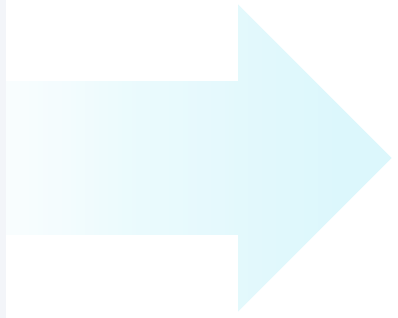
Objective
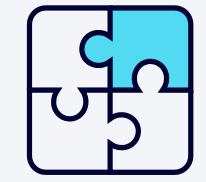
1. Select **either autologous or allogeneic cell source** which are immunocompatible
2. Demonstrate **organ specific differentiation with phenotype** (morphology + molecular markers) and **function** (assays) in vitro
3. Provide product **quality assurance (QA)**

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TA1 Metrics

Task	PRINT Phase I											
	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cell Source(s) Identified	██	██										
Develop Differentiation Protocol	██	██	██									
QA/QC			██	██	▨	▨	▨	▨	▨	▨	▨	▨
Milestones	**1.1.** Identify best in case cell source for mass production and differentiation (from biopsy, iPSCs, etc.), Criteria: cost (Target: **≤ $5,000/ billion cells**), availability, expandability (ability to manufacture ~**10 billions cells/organ**), multipotency, **>85%** viability after storage, **1.2.** Verify cell specific morphology and multipotency of the expanded cells, **1.3.** Achieve high purity (**>90%**) of defined cell types after differentiation, **1.4.** Generate all necessary cell types for the function of specific organ (Total: ~**10 billions cells/organ**), **1.5.** Demonstrate normal (**≤±20%** difference from patient derived cells) organ-relevant functions of the differentiated cells, **1.6.** Demonstrate the absence of tumorigenicity of expanded and differentiated cells in vitro.											
Deliverables	**1**. Finalized protocols for cell differentiation for all necessary cell types, high expansion, and storage conditions to create a biobank for bioprinting.											

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TA2: Large Scale Manufacturing of Organ Cell Types

Bioreactor

Patient-matched Biobank

Problem
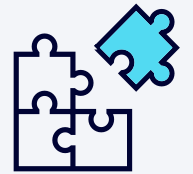
1. Scaling cell manufacturing has been **limited and inefficient.**
2. Multiple parameters are **not optimal** for cell viability i.e., culture condition, media composition.
3. Biotech companies are **reluctant to invest resources** to develop manufacturing protocols specific to cell type, cell source, and application.
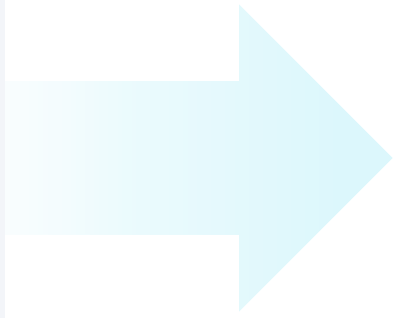
Objective
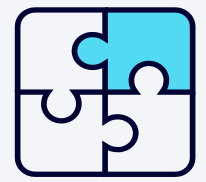
1. **Develop cell master bank** based on TA1
2. **GLP/GMP manufacturing** for small and large animal studies
3. Demonstrate **organ specific phenotype** (morphology + molecular markers) **and function** (assays) **in vitro**
4. **Provide product quality assurance (QA) and quality control (QC)** for cell characterization and safety

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TA2 Metrics

	PRINT Phase I													PRINT Phase II							
	Year 1				Year 2				Year 3					Year 4				Year 5			
Task	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
GLP Manufacturing Master Biobank				■	■	■	■	■	■	■	■	■									
GMP Manufacturing Master Biobank														■	■	■	■				
QA/QC						■	■	■	■	■	■	■		■	■	■	■				
Milestones				**1.1.** GLP manufacturing of **1 billion** cells per organ (expansion and differentiation of selected cell source) to generate all 3 organs and for small animal testing (TA3) (cost: **≤$15,000**/ billion cells) **1.2.** Demonstrate cell specific characteristics *in vitro* (quantitative metrics same as **TA1, 1.2-1.6**) **1.3.** Identify transportability and storage conditions with **≥85%** viability after storage **1.4.** Finalize QA/QC protocols											**2.1.** Scale-up GMP manufacturing of biobank cells (**10 billion** cells per organ) for *in vivo* safety and efficacy studies in large animals (cost: **≤$50,000**/ billion cells) **3.1.** Pre-IND documentation for CMC								
Deliverables				**1.** GLP manufactured cell biobank										**2.** GMP manufactured cell biobank **3.** Pre-IND enabling studies and documentation							

TA3: Organ Biofabrication and Testing

3D bioprinting

Perfusion chamber

Problem

1. 3D organ biofabrication **struggles** with complex organ structures.
2. Cell viability **during and after** printing
3. Print **speed**
4. Print **thick** and **vascularized tissues**
5. Tissue **lack suturability**
6. Existing approaches are **unable to restore normal human organ function** and **lack the biomechanical properties** necessary for implantation.

Objective
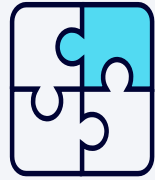
1. **Software and hardware** informed by multi-physics modeling
2. **Bioink formulation** for partial or full organ printing
3. **Printing method** for partial or full organ printing
4. **Bioreactors to mature** the bioprinted organ
5. Bioprint **vascularized tissue with active perfusion** and **organ-specific biomechanics**
6. Demonstrate bioprinted organ **function in vitro**
7. Demonstrate bioprinted organ **safety and function to sustain life** in small and large animal models
8. Demonstrate **viability, longevity,** and **immune compatibility** in a small and large animal model (3-6 months)

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TA3 Metrics-Phase I

Task	PRINT Phase I (36 months)											
	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Printing Software	██	██	██	██								
Bioreactor	██	██	██	██								
Bioink Formulation	██	██	██	██								
Printing Method			██	██	██	██						
In vitro organ efficacy assay					██	██	██	██				
Safety and efficacy in small animal								██	██	██	██	██

	Year 1	Year 2	Year 3
Milestones	**1.** Multi-physics modeling to inform 3D organ design (i.e., vascular branching, cell density, tissue layers at **≤50** µm resolution), **2.** Perfusion system that can sustain organ maturation and monitor organ function via non-invasive imaging and biochemical measurements (Maturation time **<30 days**), **3.** Develop organ-specific bioinks that are immunocompatible and support organ regeneration and function (**>99%** cell viability and non-immunogenic).	**4.1.** Hardware to achieve **~50µm** resolution, and various organ sizes that fit for both mouse and pig, **4.2.** Enable printing of anisotropic and vascularized tissue with organ specific biomechanics. (**≤±20%** difference from normal organ), **5.1.** Demonstrate organ function in a perfusion model, **5.2** Demonstrate safety and immune compatibility (**no** teratomas, rejection, toxicity, mutagenicity) in small animal model.	**6.1.** Demonstrate successful implantation of bioprinted organ in **>10** small animals, **6.2.** Demonstrate viability and longevity of the bioprinted organ in small animal model (**3-6** month survival), **6.3.** Demonstrate normal organ structure and host response postmortem.
Deliverables	**1.** Finalized print modeling software, **2.** Finalized bioreactor for active perfusion, **3.** Finalized library of bioinks.	**4.** Finalized print system, **5.** Functional organ in vitro and safety profile in vivo.	**6.** Organ function and demonstrated in humanized mice and initiate **INTERACT meeting with FDA.**

TA3 Metrics-Phase II

	PRINT Phase II (24 months)							
	Year 4				Year 5			
Task	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
IND enabling studies large animals								
Milestones	**1.1.** Demonstrate successful implantation of bioprinted organ in **>5** large animals, **1.2.** Demonstrate viability and longevity of the bioprinted organ in large animal model (**3-6 months** survival), **1.3.** Demonstrate safety (**no** teratomas, rejection, toxicity) in large animal model at **6-month** post transplantation, **1.4.** Achieve normal organ function in vivo based on organ specific parameters.				**2.1.** Postmortem IHC and molecular markers of organ structure, **2.2.** Finalize QA/QC, **2.3.** IND documentation and transition.			
Deliverables	**1.** Achieve normal organ function in a humanized pig model and survival of **3-6 months** post transplantation.				**2.** Pre-IND filing for bioprinted organ transplantation.			

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PRINT Timeline

TA1 · TA2 · TA3
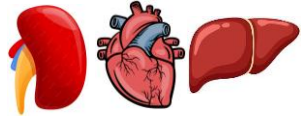
Task	PRINT Phase I												PRINT Phase II							
	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cell Source(s) Identified	■	■																		
Develop Differentiation Protocol	■	■	■																	
QA/QC (TA1)			■	■	▨	▨	▨	▨	▨	▨	▨	▨								
GLP Manufacturing Master Biobank				■	■	■	■	■	■	■	■	■								
GMP Manufacturing Master Biobank													■	■	■	■				
QA/QC (TA2)					■	■	■	■	■	■	■	■	■	■	■	■				
Printing Software	■	■	■																	
Bioreactor	■	■	■																	
Bioink Formulation	■	■	■																	
Printing Method			■	■	■	■														
In vitro organ efficacy					■	■	■	■												
In vivo safety and efficacy testing in small animal							■	■	■	■	■	■								
IND enabling large animal studies													■	■	■	■	■	■	■	■
Independent Validation					▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨				

Equity Requirements for all TAs

Equity Considerations--ARPA-H builds **equity** into program design.

- PRINT aims to make solutions accessible to **all** Americans

- PRINT enables a cost-effective organ transplantation supply chain through efficient biofabrication, eliminates lifelong side effects and comorbidities associated with anti-rejection drugs, eliminates dialysis for kidney failure patients, and leverages existing (and will create new) reimbursement mechanisms.

- **Cost** is one key metric in TA 1 and 2.

- We welcome technologies that can achieve scale up manufacture to reduce per unit cost.

If we do not intentionally, deliberately and proactively include, we unintentionally exclude.

ARPA H

PRINT Commercialization

Goal: Performer and Program Transition

- ARPA-H PATIO team
- Expert/Entrepreneur in Residence (XIR & EIR) Network
- Minimum Viable Product (MVP) Testing for Market Adoption
- Scalability with Hub and Spoke
- Venture Capital (VC) Panel
- Successful exit from PROGRAM means established path towards patient care with product(s) entering market
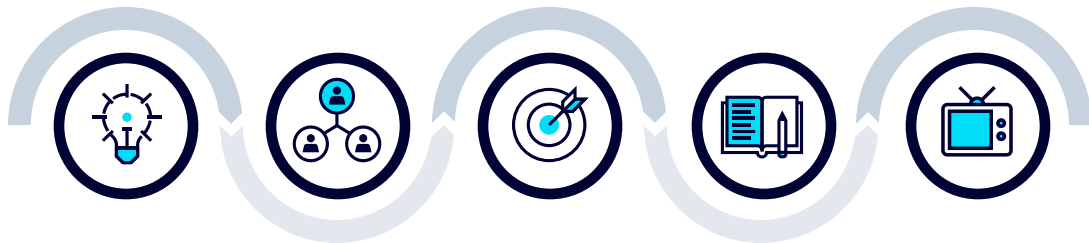
Paths to Commercialization

Government agency
- BARDA
- DARPA

And/Or

License deal with Existing Company(s)
- Launch new product(s)

New Venture(s)
- Package PRINT deliverables for
- VC fundraising

Value creation
- IP licensing agreements
- Protoypes/MVPs across biofabrication process
- Successful exit from PRINT means established path towards patient care with product(s) entering market

ARPA H

Impact of PRINT:

Chronic organ shortage...

Over 120,000 patients need a new organ:

- Only 45,000 transplants performed annually in the U.S.
- Transplant organ only lasts 20 years and is not curative.

Current Transplantation Workflow:

- Organ supply requires matched human donor
- Lifetime costs to patients can exceed over $1M
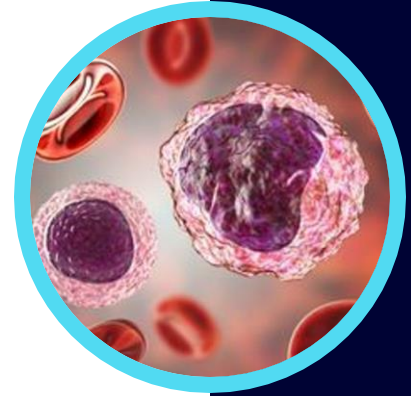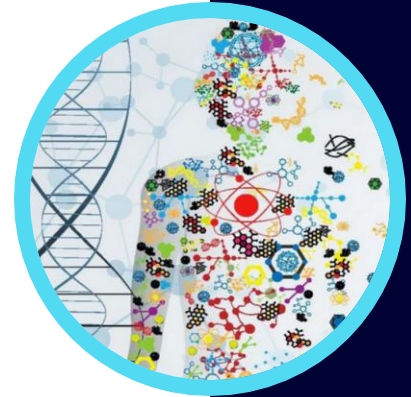
A future with organs on demand

Equity in organ access

- Biofabrication producing immuno-compatible tissues to restore normal organ function.
- All patients has access to new organs regardless of geography, background, or resources.
- *Accelerated by AI/ML-aided Biologics Design.*
- GMP production of all organ cell types.
- Biobank to enable recurring supply of cells.
- Advanced 3D organ biofabrication process that can be deployed anywhere.

ARPA H

Acquisition Details

The Application Process

Georgina Perry

Contracting/Agreements/

Other Transactions Officer

Business Innovation Division (BID)

ARPA**H**

PRINT Solicitation/Funding Opportunity Basics

Innovative Solutions Opening (ISO)

ISOs
allow for merit-based awards

ISOs
allow the Gov't to focus award decisions on technical quality

Best Ideas >
Best Price

ISOs
allow for a variety of approaches to a problem, not one singular solution

ISOs
are flexible and allow for a variety of award instruments to be considered

ARPA H

PRINT ISO Basics

Award Types

- Award type will be based on the best fit for the proposed project/solution
- Proposers will include, at the full proposal stage, the preferred award type, the ultimate decision will be made by ARPA-H
- Awards will be Cooperative Agreements and Other Transactions

Award Timeline

- Full proposal evaluations are expected to be completed by Oct 2024

- ARPA-H will begin negotiating award instruments, Statements of Work, and Terms and Conditions with the selected proposers beginning Nov 2024

Award Funding

- There is no funding limit, ceiling or range for individual awards, or an overall ceiling for the PRINT ISO
- All reasonable proposals will be evaluated and considered for award
- Awards are expected to be issued with negotiated milestones, with payments tied to actual progress/milestones accomplished

Traditional Awards

- Federal Acquisition Regulation (FAR) procurement contracts and Grants are not being contemplated for award and <u>should not</u> be proposed

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Award Types – Cooperative Agreements

Financial Assistance

- Financial assistance instrument to carry out a public purpose authorized by a U.S. law rather than to acquire supplies/services for the benefit of the Government

- Cooperative Agreements follow:

  - [2 CFR Part 200](#), [45 CFR Part 75,](#) and the [HHS Grants Policy Statement](#)

Substantial Involvement

- Includes "substantial involvement" from the federal agency (ARPA-H) that may be ongoing throughout the project

- Both parties are responsible for achieving the agreed-upon outcome, progress and results

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Award Types – Other Transactions (OTs)

What are OTs?

- ARPA-H has authority to award OTs when "*use of such authority is essential to promoting the success of the project*"

- OTs are contracts (e.g., mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality)

- OTs reflect commercial contracting rather than traditional FAR procurement contracts

OTs are collaborative

- Increased collaboration and partnership, leading to more effective use of resources and knowledge sharing.

- Free-flowing negotiations and less restrictive than FAR based procurements.

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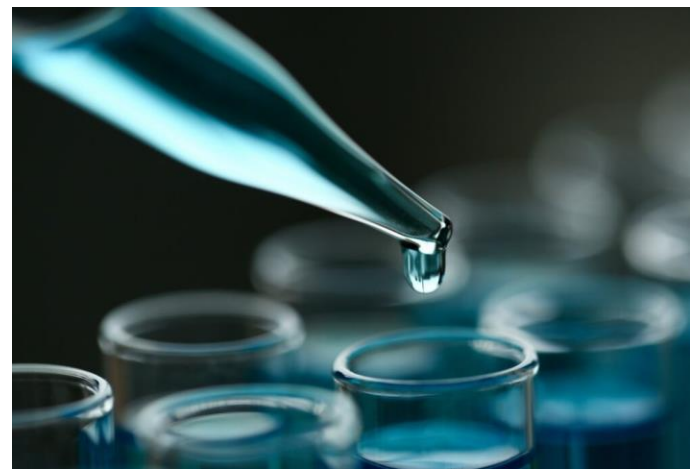
Other Transactions (OTs)

- **Pros:**
  - Many laws/regulations do not apply
    - Competition in Contracting Act; Bayh-Dole; 45 CFR 75; FAR/HHSAR; Cost Accounting Standards; Bid Protests, etc.
  - Invokes commercial practices, allowing for negotiating terms and conditions
    - May negotiate intellectual property (IP), payments, etc.
  - Streamlined award process

- **Cons:**
  - Lack the guardrails performers might desire under financial assistance or FAR contracts
    - Requires careful negotiation by sophisticated parties
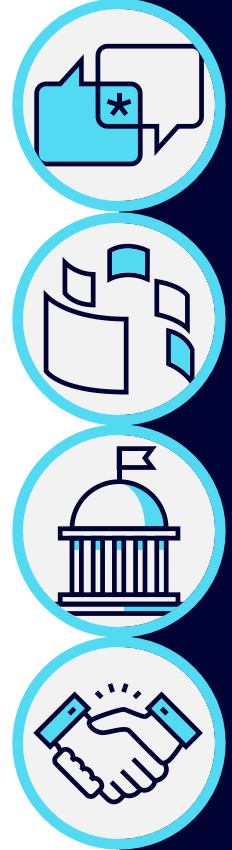
Cooperative Agreements

- **Pros:**
  - Familiar
    - Many organizations designed their systems, processes, etc. around financial assistance awards
  - Consistency among organization's award portfolio

- **Cons:**
  - Terms are largely set by law and regulation, with limited ability to negotiate
  - Include requirements that might be unappealing to a commercial entity (e.g., profit cannot be charged, ceiling on unaudited indirect rates)
  - Much more bureaucratic than OTs (e.g., submission documents, rigid reporting requirements, etc.)

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Process Overview

Solution Summary Submission

- Solution Summary submission is mandatory
- Length should not exceed **five (5)** pages (excludes cover page & ROM).
- Should include all sections as specified in the ISO.
- Evaluation criterion – scientific and technical merit.
- Submitted via the electronic Contract Proposal Submission (eCPS) website

Full Proposal

- Full proposal by invitation only
- Submitted via eCPS for OTs
- Submitted via Grants.gov for Cooperative Agreements
- Summary of Proposal & Detailed Proposal Info – no more than 30 pages in length (excludes SOW).

Evaluation and Selection

- The Government will review each conforming solution summary against criterion 1 and 2, and each full proposal against criteria 1–4 descending order of importance.
- Selection for award will be made as outlined in the ISO.

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Evaluation Criteria

1 **Overall Scientific and Technical Merit (Solution Summary and Full Proposal)**
- Innovative, feasible, achievable, and complete
- An outcome that achieves the expected goals
- Technical risk(s) identification with a feasible mitigation strategy

2 **Proposers' Capabilities and/or Related Experience (Solution Summary and Full Proposal)**
- Team expertise and experience
- Experience in managing similar efforts

ARPA**H**

Evaluation Criteria (cont.)

3 **Potential Contribution and Relevance to the ARPA-H Mission (Solution Summary and Full Proposal)**
- Future application, including unmet needs within biomedicine and to improve health outcomes
- Potential for interdisciplinary approach

4 **Reasonableness/Realism/Affordability (Full Proposal)**
- Submissions must include the specified excel spreadsheets
- Price Reasonableness - Ensure the overall price is fair and reasonable (e.g., not too high)
- Cost Realism - Proposed costs are realistic and consistent with the technical goals and SOW (e.g., too low)
- Availability/Affordability - Acquire goods or services that meet needs and are within budgetary constraints
- Intellectual Property (IP) - Impacts on the Government's ability to transition the proposed technology

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Final Guidance

Monitor SAM.gov and Grants.gov

– Any/all changes to the ISO will be made via formal amendments and posted online at SAM.gov

– No information discussed at Proposers' Day shall be construed as modifying the terms and conditions of the ISO

Conform to all ISO Requirements

– Thoroughly read the ISO

– Pay special attention to the eligibility requirements (ISO pg. 21)

– Non-conforming proposals **may not** be evaluated or considered for award
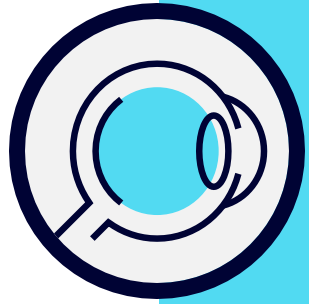
Reminders

– SF 424 Research and Related (R&R) Application for Federal Assistance

– Research and Related Senior/Key Personnel Profile

– Research and Related Personal Data

– Project Abstract Summary

Dates and Deadlines

– Solution Summary Due Date: May 28th, 2024, 9:00 AM ET

– Proposal Due Date: Aug 20th, 2024, 5:00 PM ET

Questions

– Please send to PRINT@arpa-h.gov

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Frequently Asked Questions (FAQs)

Please read the entire ISO and the FAQ's prior to submitting questions.

ISO questions will be answered via the FAQ's that get published on SAM.gov

- All inquiries shall be sent to PRINT@arpa-h.gov

- Write questions as clearly as possible

- Do not include proprietary information

- ARPA-H may re-phrase questions or consolidate similar questions for administrative purposes.

- If there is a contradiction between the FAQ and the ISO, defer to the ISO.

ARPA H

Contracts and R&D Solicitation Specifics, and Cost Proposal

Templated Spreadsheet

Emily Cortese

PRINT Business and Financial Manager

ARPA **H**

PRINT Review Process

Solution Summaries

1) Submitted via eCPS

Review will occur only after the submission deadline.

2) Compliance and Responsiveness Review
Does it adhere to the format requirements? Was it submitted on time?
Does it adhere to the technical requirements?

3) SME Reviewer Assignments Made

4) Reviews Conducted

5) PM makes a Recommendation

6) Notifications Sent
- Invite
- Not Invite

Proposals

1) Submitted via eCPS & Grants.gov

Note: Review will occur only after the submission deadline.

2) Compliance and Responsiveness Review

Does it adhere to the format requirements? Was it submitted on time?
Does it adhere to the technical requirements?

3) Federal Reviewer Assignments Made

4) Reviews & Reviewer Discussions Conducted

5) PM makes a recommendation

6) Internal review and determination

7) Notifications Selected/Not Selected

8) Negotiation

ARPA H

Approved for Public Release: Distribution Unlimited

Required Document Checklist

Cooperative Agreements

- Volume I, Technical and Management Proposal (PDF)
    - Part I: Administrative (1 page max.)
    - Part II: Detailed Proposal Information
        - Section A-E (30 pages max)
        - Section F-I (no page limit)
- Volume II, Cost Proposal (Excel)
    - *Sub-Awardee Proposals (As Applicable)*
        - *MS Excel SF-424A Budget Wrksht Research*
- Volume II, Supporting Document (PDF)
- Form 1: SF 424
- Form 2: Research and Related Senior/Key Person Profile (Expanded)
- Form 3: Research and Related Personal Data
- OCI disclosures/OCI mitigation plans
- Forward Price Rate Agreement
- Project Abstract Summary
- Human Subject Research Doc. (As Applicable)
- Vertebrate Animals Section (VAS) (As Applicable)
- Intellectual Property Representations

Other Transactions

- Volume I, Technical and Management Proposal (PDF)
    - Part I: Administrative (1 page max.)
    - Part II: Detailed Proposal Information
        - Section A-E (30 pages max)
        - Section F-I (no page limit)
- Volume II, Cost Proposal (Excel)
    - *Sub-Awardee Proposals (As Applicable)*
        - MS Excel ARPA-H Standard Cost Proposal Spreadsheet
- Volume II, Supporting Document (PDF)
- Current or Pending Support (May be included in Cost Proposal volume)
- OCI disclosures/OCI mitigation plans
- Forward Price Rate Agreement
- Human Subject Research Doc. (As Applicable)
- Vertebrate Animals Section (VAS) (As Applicable)
- Intellectual Property Representations

ARPA**H**

ARPA-H Cost Proposal Suggestions and Reminders ✅ Do's

- Provide **all** requested information on the cost proposal cover sheet in your proposal submission.
- Include:
  - A **cost estimate of total funds requested** from ARPA-H and the **amount of any cost share** (if any);
  - Per task **cost broken down by fiscal year** and phase.
  - A **summary of projected funding requirements** by month for all phases of the project.
- **Include supporting documentation** for any cost >$5,000
  - Backup may consist of a vendor quote, past purchase order/invoice, information from a website, or a detailed explanation of labor and material costs for custom made items
- Include an **itemization of Subcontracts**. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. The prime proposer is responsible for compiling and providing all subcontractor proposals and the proposal must show how subcontractor costs are applied to each phase and task. If consultants are to be used, proposer must provide consultant agreement or other document that verifies the proposed loaded daily/hourly rate.
- Make sure to **state how the proposed costs are realistic for the technical and management approach** and accurately reflect the technical goals and objectives of the solicitation.
  - **Include how the proposed costs are consistent with the proposer's Statement of Work** and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach.

ARPA H

ARPA-H Cost Proposal Suggestions and Reminders

Don'ts ✕

- Don't forget to **utilize the ARPA-H Cost Proposal Checklist**!

- **Don't change formulas given in spreadsheet**
  - If the formulas must be changed to match your business practices, please make sure the "total amount" tab accurately reflects the costs correctly

- **Don't delete a row, column, or worksheet in the spreadsheet** if it is not needed for your proposal. Just ignore or hide it.
  - Deleting will break the formulas and increase processing time.

- **Don't cost strategize!** ARPA-H recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel in order to be in a more competitive posture. ARPA-H discourages such cost strategies.

ARPA H

ARPA-H Cost Proposal Checklist

1. Are all items from Volume II, Cost Proposal) of the R&D Solicitation included on your Cost Proposal cover sheet?

2. Does your Cost Proposal include (1) a summary cost buildup by Phase, (2) a summary cost buildup by Year, and (3) a detailed cost buildup for each Phase that breaks out each task and shows the cost per month?

3. Does your cost proposal show a breakdown of the major cost items listed below: Direct Labor; Indirect Costs/Rates; Materials and/or Equipment; Subcontracts/Consultants; Other Direct Costs; Travel?

4. Have you provided documentation for proposed costs related to travel, to include purpose of trips, departure and arrival destinations and sample airfare?

5. Does your cost proposal include a complete itemized list of all material and equipment items to be purchased (a priced bill-of-materials (BOM))?

6. Does your cost proposal include vendor quotes or written engineering estimates (basis of estimate) for all material and equipment with a unit price >$5,000?

7. Does your cost proposal include a clear justification for the cost of labor (written labor basis-of-estimate (BOE)) providing rationale for the labor categories and hours proposed for each task?

8. Do you have subcontractors/consultants? If so, does your cost proposal include copies of all subcontractor/consultant technical (to include Statement of Work) and cost proposals? Do all subcontract proposals include the required summary buildup, detailed cost buildup, and supporting documentation (SOW, Bill-of-Materials, Basis-of-Estimate, Vendor Quotes, etc.)?

9. Does your cost proposal include copies of consultant agreements, if available?

10. Have all team members (prime and subcontractors) who are considered a Federally Funded Research & Development Center (FFRDC), included documentation that clearly demonstrates work is not otherwise available from the private sector AND provided a letter on letterhead from the sponsoring organization citing the specific authority establishing their eligibility to propose to Government solicitations and compete with industry, and compliance with the associated FFRDC sponsor agreement and terms and conditions?

11. Does your proposal include a response regarding Organizational Conflicts of Interest?

12. Does your proposal include a completed Data Rights Assertions table/certification?

ARPA H

Accelerated Transition

Path to Success

Chan Siv
Project Accelerator Transition
Innovation Office (PATIO) Liaison

ARPA-H

PATIO

The Advanced Research Projects Agency for Health

Project Accelerator Transition Innovation Office

ARPA H

Project Accelerator Transition Innovation Office (PATIO)

Our Mission: PATIO increases the probability that ARPA-H funded health technologies **will reach those Americans** by identifying barriers and providing transition and commercialization services to program managers and performers.

Since ARPA-H will not fund performers in perpetuity, PATIO's services increase the odds that solutions attract private investment and customers—to translate the breakthroughs

Where might the solution go after ARPA-H?
Work backwards: design with the end in mind

Large Established Company	Emerging Company with VC Backing	De Novo Startup	Health Care System
Other Gov Agency	Scaled NGO or Non-Profit	Startup NGO or Non-Profit	Fast Fail & Early Offramps

ARPA**H**

Our Capabilities

Technology Transfer and Transition Services (T3X)

Build transition-ready programs by de-risking solutions from program design through performance; runs agency SBIR/STTR program

Led by Jenica Patterson

Health Ecosystem and Engagements Team (HEET)

Create meaningful bi-directional communication between ARPA-H and America.

Led by Dan Bram

ARPANET-H (ANH)

Connect a fragmented health ecosystem through projects, events, and democratized learning

Led by Amy Lin

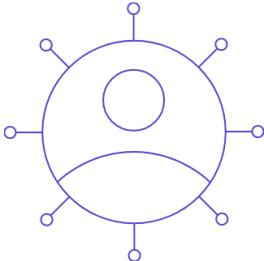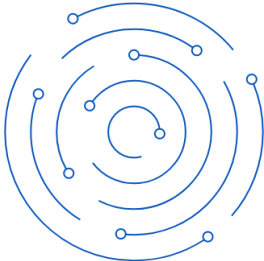PATIO is led by Craig Gravitz (Director) and Melissa Antman (Deputy Director)

ARPA **H**

Technology, Transfer and Transition Services (T3X)

Build transition-ready programs by de-risking solutions from program design through performance.

Capabilities

- **Experts in Residence (XIR) Program** External, recognized transition/commercialization experts identify and solve for blind spots of ARPA-H PMs and programs.
- **Regulatory & Reimbursement Support** Demystify and assist in navigation of these processes. Get involved early to avoid traps.
- **Due Diligence / Landscape Analyses** IP analyses, commercialization landscape to understand a particular technology, competitive landscape to understand key players in the arena, etc.
- **Small Business Program** provides funding for small businesses that possess the expertise to use innovative approaches to enable revolutionary advances in science, technology, or systems leading to developments that contribute toward the agency's mission.

Animal Subjects Research and Human Subjects Research

Tammy Salek

Assistant Director, Program Management, HSF

ARPA H

Animal Subjects Research for Proposers

POC: Lisa Mattocks, ASR Oversight Lead; lisa.mattocks@arpa-h.gov

ARPA **H**

Definition of Animal Subjects Research

What is animal
- A living or dead vertebrate
  Dead=killed for the direct purpose of conducting RDT&E or training
- A larval fish or amphibian
- An egg laying vertebrate is only an animal after hatching

What is **NOT** an animal
- An un-hatched egg
- An invertebrate
- Dead animals or parts of dead animals purchased at grocery stores or slaughterhouses

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Animal Subjects Research Regulations

Animal Welfare Act/Animal Welfare Regulations
www.nal.usda/gov/awic/animal-welfare-act

Produced by the USDA, set standards for animal care and require establishment of an Institutional Animal Care and Use Committee (IACUC)

Guide for the Care and Use of Laboratory Animals
www.ncbi.nlm.nih.gov/books/NBK54050

Produced by the NIH, provides guidelines for institutional policies, husbandry requirements, veterinary care, physical plant requirements

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Award policies

All institutions engaged in ASR must have the following in place prior to any funds being used for animal research including purchase of animals and per diem costs for animal care:

Current IACUC approved protocol

Valid assurance of the Institution engaged in the ASR

Vertebrate Animal Section completed

Interinstitutional Assurance (if applicable)

*The above **needs to be reviewed/approved** by the ARPA-H ASR oversight lead before ASR can begin*

*If any of the above **are not completed before award**, a restricted award can be issued*

ARPA H

Protocol amendments

Significant amendments require IACUC approval before implementation

- include changes that have, or have the potential to have, a negative impact on animal welfare

- some activities that may not have a direct impact on animal welfare are also considered to be significant

- Examples, including but not limited to:
  - Changes from non-survival to survival surgery
  - Changes resulting in greater pain, distress, or degree of invasiveness
  - Changes in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
  - Changes in species, study objectives, PI and anything that impacts personnel safety

Non-significant amendments do not require IACUC approval before implementation

- Examples, including but not limited to:
  - Correction of typos, grammar
  - Updates to contact information
  - Personnel changes (other than the PI) – note that there is an administrative reviewed to ensure that all personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC

ARPA H

Protocol rewrites

- IACUC approvals are good for **three (3) years** or the length of the award (whichever is shorter).

- At the three-year mark, IACUC protocols **must be re-written AND re-approved** by the IACUC.

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Non-compliance

- **Protocols are NON-COMPLIANT if:**
  - Significant amendments are implemented before IACUC approval
  - Protocol re-writes are not submitted to IACUC within the time specified by the IACUC

- In order to clear most cases of non-compliance, all performers on the protocol **must complete training** on ARPA-H animal use regulations.

- Serious cases of non-compliance may be cause to cancel the award.

ARPA**H**

Human Subject Research
for Proposers

POC: Lisa Mattocks, HSR Oversight Lead; lisa.mattocks@arpa-h.gov

Definition of Human Subjects Research

The term "human subject" can be applied to research efforts that meet <u>EITHER</u> of the following criteria

A living individual about an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **or**
- Obtains uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens

Human Subjects Research involves:

Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens

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Human Subjects Research Regulations

45 CFR Part 46 includes 4 subparts

45 CFR Part 46
(known as the "Common Rule")

The Common Rule outlines basic provisions for IRBs, informed consent, and Assurances of Compliance.

Almost all federal agencies have adopted these regulations

A the "Common Rule"

B Additional protections for pregnant women, human fetuses, and neonates

C Additional protections for prisoners

D Additional protections for children

ARPA**H**

Award policies

All institutions engaged in HSR must have the following in place prior to any funds being used for human subjects research:

☑ Current IRB approved protocol

☑ Valid Assurance of the Institution engaged in the HSR

The above needs to be reviewed/approved by the ARPA-H HSR oversight lead before HSR can begin. If any of the above are not completed before award, language needs to be inserted that prohibits the performer from engaging in HSR prior to approvals.

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IRB package

The IRB needs the following items in order to approve the research:

☑ Full protocol ☑ Informed consent document

Additional materials and training

Recruitment/advertising materials

Any sort of flyers, handouts, oral scripts, telephone screening materials, etc. used in the recruitment process

Data collection materials

Surveys, interview questions, case report form(s), written tests, etc.

Curriculum Vitae (CV) / Biosketch

A copy of the PI's CV or biosketch should be submitted to the IRB

Human Subjects Research Training

PIs and their support staff must complete human research projections training in accordance with their institution's requirements

ARPA H

IRB Determinations

- **Only an IRB or delegated official can make a determination regarding HSR.**
  – If it is determined as research involving human subjects, then one of the additional determinations will apply.

- **Exempt Research**
  – Involvement of human subjects falls under one of the "exempt" categories listed in 32 CFR 219.

Research considered not greater than minimal risk
The probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Research considered greater than minimal risk
Subjects means that the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater

ARPA H

Amendments to protocol

- An addition or change to the study design/protocol that would result in the need to change the overall human subjects designation or clinical trial designation of the grant
- The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR 46 subparts B, C, or D (i.e. pregnant women, human fetuses, and neonates; prisoners; or children)
- Any change to the study protocol that would result in an overall increase in risk level for subjects, including physical, psychological, financial, or legal or other risks.
- New information that comes to light after a study is underway, which indicates a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.

ARPA🅗

Frequently Asked Questions

Dr. Smita Bhonsale [CTR]
Science, Engineering and Technical Advisor

Dr. Yingfei Xue [CTR]
Science, Engineering and Technical Advisor

ARPA H

FAQ: Teaming

Can one group be part of multiple proposals? Can one person be part of multiple proposals?

Yes. Although there is no limit in the number of proposal one group/person can be part of, PRINT award selection is a competitive process so should a group or individual be part of multiple proposals, they will be effectively competing with themselves.

Do we have to have a partner from industry/academia/something else?

No. Teams can have participants from any mix of institutions.

Is there a limit to how many institutions can team?

No, but be sure to include detailed budget information for each institution as per the ISO and include in your proposal a program management structure that explains how the teams will be coordinated.

ARPA H

FAQ: Teaming, cont'd

Can we have multiple Principal Investigators (PIs)?

No, there will be ONE (1) PI, the rest will be Co-Investigators.

Can we change teams partway through the program?

Teaming changes may be allowed with ARPA-H's approval in response to specific needs arising from the program's progress. Requests will be dealt with on a case-by-case basis.

Will you establish teams for us? I'm looking for a partner to complement our capabilities.

We are glad that you are looking to assemble a diverse and capable team! We cannot make introductions for you, but we encourage you to talk to people at Proposers' Day and to use our teaming website, where you can submit your profile and find the contact information for potential teammates: PRINT Teaming Profiles | ARPA-H

ARPA H

FAQ: Metrics

The requirements/timeline seem aggressive. Do you really intend for us to hit these metrics?

We want you to work hard to meet them. We aim to set our goals high, with the understanding that advancements in science cannot be made without failures along the way.

What if I do not meet the metrics at one point in my project? Will you stop my project?

We have two Phases, and not all offerors are guaranteed to continue to subsequent phases. However, the metrics are not necessarily rigid Go/No-Go criteria, and instead are used to help make decisions about whether sufficient progress has been made. In other words, the answer to these questions will depend on the state of the technical program and how much progress has been made.

FAQ: Metrics, cont'd

We have an advanced prototype; can we go faster than the milestones you have scheduled?

Yes, absolutely, provided you are meeting/exceeding all technical metrics and guidelines.

Do you have any preferred technological approaches for PRINT?

We will entertain all approaches that are proposed, as long as they fit within the TA guidelines and can be used to satisfy the metrics proposed in the ISO.

What if I want to use metrics that are not mentioned in the ISO?

We are open to other approaches that would define success in each TA as long as they are a logical fit to satisfy the TA.

ARPA**H**

FAQ: Meetings and Technical

Can you meet with us to discuss our idea?

We would love to meet with you to answer questions, but we are unable to discuss concepts that a potential applicant is considering submitting to the ISO.

Can you tell us if you like our technical approach?

We will evaluate and provide feedback on technical concepts once they have been officially submitted as solution summaries/proposals.

What if I have an idea that is outside the scope of PRINT?

If your proposal is not a good fit for the PRINT program, the Mission Office-specific Innovative Solutions Openings (ISO) pursues innovative high-impact biomedical and health research proposals.

ARPA H

FAQ: International Proposers

Are foreign entities eligible for award?

ARPA-H will prioritize awards in accordance with Public Law No. 117-328 (Section 499A(n) of the PHSA). Without limiting the foregoing ARPA-H will prioritize awards to domestic entities (organization and/or individuals) that will conduct funded work in the US. However, **non-US entities may participate** to the extent such participants comply with nondisclosure agreements, security regulations, export control laws, and other governing statutes and regulations applicable under the circumstances. **Non-US entities are encouraged to collaborate with domestic US entities**. In no case will awards be made to entities organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947 (50 U.S.C. § 3059)) or entities suspended or debarred from business with the Government.

Foreign entities may be subject to a clearance review prior to beginning work on an award, whether as a prime or sub. Where the foreign entity is a sub, awards may still be made with the foreign support restricted until the clearance process is completed.

ARPA**H**

FAQ: Government Proposers

Are federal entities and federally sponsored entities eligible for award?

Federal entities and federally sponsored entities (e.g., Government/National laboratories, Federally Funded Research and Development Centers (FFRDC), University Affiliated Research Center (UARC), military educational institutions, etc.) are not eligible for award under this announcement. This includes both prime and subawards. However, ARPA-H is committed to working with its federal partners. Federal partners interested in working with ARPA-H on this program should contact PRINT@arpa-h.gov to discuss supporting this effort.

ARPA **H**

FAQ: Budget

How big can our program be? What is the overall budget for PRINT?

- Proposers are encouraged to propose a realistic, justifiable, comprehensive, and reasonable budget that aligns with the proposed solution. The proposed budget should align with the technical scope. **No budget ceiling has been established.**

- We are not able to provide budgetary details for PRINT or a target number for your budget.

- ARPA-H discourages strategies such as using only junior staff or proposing only low-risk ideas to cut costs.

Can you explain the rules around the salary cap in our cost proposal?

Since 1990, Congress has legislatively mandated a limitation on direct salary for individuals under NIH grant and cooperative agreement awards. The Consolidated Appropriations Act, 2023 (Public Law 117-328) restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. Effective January 1, 2023, the salary limitation is $221,900.

This means that the maximum for any one person in one year, for any labor category, and any level of effort, the maximum is $221,900.

ARPA H

FAQ: Intellectual Property

Who will own the IP?

Generally, the government does not take ownership of intellectual property produced under awards.

- Under **Cooperative Agreements**, performers retain ownership of IP created under an award, but the government receives a license to use the IP for federal purposes.
- For **Other Transaction Agreements**, there is more flexibility, and IP will be subject to negotiations between the proposer and ARPA-H.

At a minimum, ARPA-H wants to ensure that IP restrictions do not keep breakthrough technologies from the people who can benefit from those technologies.

Submission Timelines and Feedback – Solution Summary

Will feedback be provided for all solution summaries? When?

Feedback will be provided on all responsive summaries; we will provide brief comments on Evaluation Criteria #1, 2, and 3.

We will also provide one of three decisions:

1. ARPA-H has not selected the proposer to move forward
2. ARPA-H requests the submission of a full proposal
3. ARPA-H will contact the proposer for explanation on any unclear elements in the submitted solution summary to determine whether the summary will be selected or not

Solution summaries are due May 28th; we aim to provide feedback and notice of selection a few weeks after that date.

ARPA H

Submission Timelines and Feedback – Full Proposal

May I submit a full proposal if my solution summary is not selected? May I submit a full proposal if I do not submit a solution summary?

No, ARPA-H will only evaluate a full proposal for those offerors who submit a solution summary and are selected/invited to submit a full proposal.

Will feedback be provided for all full proposals? When?

Feedback will be provided for all full proposals; see the ISO for the selection criteria.

Full proposals are due Aug 20th. We aim to make selections by Nov; however, we expect many high-quality proposals and will take the time necessary to ensure we consider them thoroughly.

ARPA H

FAQ: Science

- **Is GLP/GMP manufacturing required for small and large animal studies?**

Yes, GLP & GMP manufacturing capability is key to the successful translation of this program and are therefore required. It is expected that cells manufactured under GLP & GMP standards (TA1 & 2) to be used in subsequent animal studies.

- **Are biobank and bioreactor required products/deliverables?**

The required deliverables for the program include cell manufacturing and restoring organ function. We envision that biobanks and bioreactors are important tools to achieve these goals. Existing or new biomanufacturing infrastructure may be leveraged in this program. In TA1, biobank may serve as one approach to generate necessary cell types. In TA2, developing master cell bank under GMP are required deliverable.

ARPA H

FAQ: Science, cont'd

- **Are there any restrictions on what types of cells or animals that can be used?**

For cell sources, you as the performers will have the freedom to choose from a variety of sources using existing or novel protocols to achieve organ functions as outlined in the metrics.

For animal testing, humanized small or large animal models are required. Small animals may include mouse or rat. Large animals may include pig or sheep.

- **Can inorganic products be used to achieve the required end result (such as artificial organ & bionic organ)?**

The final bioprinted organ products from this program will either be full size functioning organs, partial organs, or ectopic organ substitutes. Additionally, the program structure allows for non-standard organ design as long as normal organ function is achieved. However, those approaches will involve cell bioprinting. Inorganic approaches will not be considered in this ISO.

ARPA**H**

Read the ISO

The answers to many questions are in the ISO. We also link to it on our website. Make sure you've read the ISO! Final ISO will be posted soon.

Still have questions? Check the FAQ!

The PRINT FAQ will be updated periodically on our website and on sam.gov.

Still have questions that are not answered in the ISO or FAQ?

Email us at print@arpa-h.gov. If your question is relevant and generally applicable, we will publish the question and answer to the FAQ. If your question is relevant and pertains to your individual circumstances, we will try to get back to you with an answer as soon as possible.

ARPA H

Thank you for joining us today!

We will make this slideshow and a video of this talk available at the PRINT program website.

Please join us for the poster and networking session after lunch, starting at 1PM.

ARPA**H**