

**Special Notice (SN) ARPA-H-SN-24-08**  
**Proposers' Day Announcement for Advanced Research Projects Agency for Health**  
**(ARPA-H)/Health Science Futures (HSF) Office**  
**Opportunity: Engineering Of Immune Cells Inside The Body (EMBODY)**

## KEY INFORMATION

### General Information

- **Purpose:** Special Notice for Proposers' Day for ARPA-H HSF Office and Engineering Of Immune Cells Inside The Body (EMBODY)
- **Solicitation:** Promote attendance of proposers at the EMBODY Proposers' Day (see information below)

Table 1. Proposers Day Key Information	
<b>Proposers' Day</b>	April 18 <sup>th</sup> , 2024, from 11:00 AM to 2:00 PM EDT
<b>Location</b>	Virtual
<b>Website for registration</b>	<a href="#">Proposers' Day Registration</a>
<b>Registration opens</b>	April 2 <sup>nd</sup> , 2024, at 2:00 PM EDT
<b>Registration closes</b>	April 15 <sup>th</sup> , 2024, at 12:00 PM EDT
<b>Technical Point of Contact</b>	Dr. Daria Fedyukina, Program Manager, ARPA-H/HSF Office
<b>Program email</b>	<a href="mailto:EMBODY@arpa-h.gov">EMBODY@arpa-h.gov</a>
<b>Optional proposer deliverables, details below</b>	1) One (1) PDF page “teaming profile” (proposer’s capabilities, composition, research areas of interest, etc.)

## INTRODUCTION

The HSF Office of ARPA-H is sponsoring a **Proposers' Day (PD)** for the planned proposer community in support of the EMBODY program.

The PD will be held on April 18<sup>th</sup>, 2024, from 11:00 AM to 2:00 PM EDT. Advanced registration is required.

### The Proposers' Day objectives are to:

- Provide a technical overview of the EMBODY program.
- Provide information about the program to potential proposers, including details about the overall program goals, solution summary (formerly abstracts) and full proposal structure for Innovative Solutions Opening (ISO), and how they might respond to ARPA-H's solicitation.
- Share the intended scope, timeline, and scale of the EMBODY program and how the proposers, in collaboration with the ARPA-H team and resources, can accomplish the collective mission of accelerating equitable healthcare outcomes for all Americans.

The PD will include brief overview presentations by government personnel. ARPA-H will collect participant questions throughout the event and publish answers to a publicly available Frequently Asked Questions

(FAQ) site.

Attendance at this event is **not** a requirement for submission of a solution summary, full proposal, or selection for funding; however, it is anticipated that teaming arrangements will be needed to successfully innovate and integrate the critical technologies necessary to meet the EMBODY program goals. Information relayed during the PD will be made available on the HSF Office section of the ARPA-H Opportunities page: ARPA-H EMBODY as well as SAM.gov and Grants.gov.

Registration requests will only be accepted from the potential proposer community as participation is not intended for patients, patient advocates, media or a general interest audience. A separate meeting to engage these communities will be announced in the future.

## EMBODY – PROGRAM INFORMATION

This special notice is to announce and solicit attendees to the PD on April 18<sup>th</sup>, 2024, for ARPA-H's EMBODY program. The full details of the EMBODY program are in the posted draft ISO at the System for Award Management website (SAM.gov). Below is only a brief description of the full program and proposers should refer to the EMBODY ISO for more details. This SN is issued solely for information and potential new program planning purposes, and this SN does not constitute a formal solicitation for full proposals or proposal abstracts (See the full disclaimer below).

## PROJECT OBJECTIVES

The EMBODY program aims to transform engineered cell therapies for devastating, life-threatening, and hard-to-treat diseases. Recently, genetically engineered cells have emerged as revolutionary therapies to treat selected diseases and malignancies. However, *ex vivo* production of these products poses major hurdles including 1) technical complexities that require substantial patient participation, 2) lengthy wait times with a large portion of eligible patients dying or becoming ineligible while waiting for their cell therapy treatments, 3) poor access with less than 2% of U.S. hospitals having infrastructure, expertise, and experience to be able to offer these treatments, and 4) prohibitively high costs of goods per dose. EMBODY aims to solve all major *ex vivo* cell therapy challenges with one *in vivo* solution. Specifically, EMBODY seeks to develop novel off-the-shelf agents and approaches to genetically engineer immune cells *in vivo* for treating devastating diseases. EMBODY will leverage recent advances in the fields of viral vectors, gene therapies, nanoparticles, genetic engineering, genetic editing, cell/vector manufacturing, and advanced *in vitro* and *in vivo* models of the human immune system. Successful EMBODY outcomes will include platform approaches to genetically engineered immune cells *in vivo/in situ*, cost effective production methods, and preclinical validation platforms to enhance translation to clinic, as well as specific therapy candidates developed through early clinical proof of concept.

## TECHNICAL APPROACH

The EMBODY program will catalyze the discovery and development of platforms and approaches for genetically engineering immune cells *in vivo* to treat devastating disorders that may include devastating diseases like cancer, autoimmune, chronic infections, etc. The EMBODY program will also catalyze the development of low-cost production approaches and more biologically relevant and robust preclinical models to validate and efficiently translate these approaches to engineering immune cells *in vivo*. The discovery process includes two technical areas (TA):

Technical Area 1 (TA1): **Platforms and approaches for *in situ* generation of genetically engineered immune cells.** Development of cell-specific targeting approaches for immune cells. Development of genetic cargo that contains elements needed for therapeutic effects and genetic control elements, i.e., for control over gene expression, gene regulation, and gene editing. Combining the cell-specific and genetic cargo approaches to develop pharmaceutical candidates (herein, called “agents”).

Technical Area 2 (TA2): **Advanced production and validation of products developed using TA1 platforms.** Development of strategies and/or technologies to significantly reduce costs of goods of TA1 agents, ensure product scalability and high quality. Development of new or enhancement of existing advanced

physical *in vitro* and/or *in vivo* models and systems that can be used for screening, validating, and quality control of TAI agents.

## EMBODY – PROPOSERS’ DAY INFORMATION

### Proposers’ Day Participation and Deliverables

#### Teaming Profiles

Interested parties are also invited to submit a ‘teaming profile’ via the Microsoft Forms link here and below: [EMBODY Teaming Profile Form](#). The teaming profile will describe the technical competencies, team capabilities, team composition, research areas of interest, unique facilities and other capabilities, as they relate to the program, and desired technical/other competencies sought from other potential team partners. The profile will include, at a minimum:

1. Contact information, to include name, organization, email, telephone number, mailing address, and website;
2. Brief description of the proposer’s technical competencies and relevant facilities;
3. Desired technical competencies and facilities from other potential team members, if applicable.

Proposers are encouraged to submit teaming profiles via the [EMBODY Teaming Profile Form Link \(EMBODY Teaming Profile Form\)](#). Teaming profiles will be made available through a forthcoming Teaming Page on the ARPA-H EMBODY website. Specific content, communications, networking, and team formation are the sole responsibility of participants. ARPA-H does not endorse any participating organization or exercise any responsibility for improper dissemination of the team profiles.

#### Registration Information

Participants must register in advance through the registration website. The registration cutoff date is April 15<sup>th</sup>, 2024, at 12:00 PM EDT. There is no registration fee for the EMBODY Proposers’ Day. **Note that there will be no same-day registration.** An online registration form and various other meeting details can be found at the registration website, [Proposers' Day Registration](#)

PLEASE NOTE: Registration closes on April 15<sup>th</sup>, 2024, at 12:00 PM EDT.

Further administrative questions should be addressed to [embody@arpa-h.gov](mailto:embody@arpa-h.gov). Please refer to the EMBODY Proposers’ Day (ARPA-H-SN-24-08) in all correspondence. This announcement is not a request for solution summary or full proposals; any so sent will be returned.

### SIGNIFICANT DATES AND TIMES

Table 2. Proposers Day Significant Dates and Times		
Event	Date	Time
Registration opens	April 2 <sup>nd</sup> , 2024	2:00 PM EDT
Registration closes	April 15 <sup>th</sup> , 2024	12:00 PM EDT
Proposers’ Day	April 18 <sup>th</sup> , 2024	Start: 11:00 AM EDT
		End: 2:00 PM EDT

### POINTS OF CONTACT

#### Technical Point of Contact

Dr. Daria Fedyukina, Program Manager, ARPA-H/HSF Office

Email: [embody@arpa-h.gov](mailto:embody@arpa-h.gov)

All inquiries should reference “EMBODY Proposers’ Day (ARPA-H-SN-24-08)” in the subject line of the email. Prior to submitting an e-mail inquiry, please check the [General Program FAQs](#).

## **WEBINAR INFORMATION**

The link to the webinar registration confirmation will be released once registered.

## **DISCLAIMER**

This SN is issued solely for information and potential new program planning purposes; the SN does not constitute a formal solicitation for proposals or solution summaries. Submission is voluntary and is not required to propose subsequent Innovative Solutions Offering (ISO) (if any) or research solicitations (if any) on this topic. ARPA-H will not provide reimbursement for costs incurred in responding to this SN. Respondents are advised ARPA-H is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted under this SN.

The ARPA-H EMBODY Proposers’ Day will be a virtual event held on April 18, 2024, via Zoom for Government.