Special Notice (SN) ARPA-H-SN-23-02

Proposers' Day Announcement for Advanced Research Projects Agency for Health (ARPA-H)/Health Science Futures (HSF) Office Opportunity: Precision Surgical Interventions (PSI)

I. KEY INFORMATION

General Information

- **Purpose:** Special Notice for Proposers' Day for ARPA-H HSF Office and the Precision Surgical Interventions (PSI) Program
- Solicitation: Promote attendance of proposers at the PSI Proposers' Day (see information below)

Table 1. Proposers Day Key Information		
Proposers' Day	September 7 th , 2023, from 9:00 AM to 5:00 PM CT	
Location	Chicago, IL	
Website for registration	Proposers' Day Registration	
Registration opens	July 27 th , 2023, at 9:00 AM EDT	
Registration closes	August 28 th , 2023, at 12:00 PM EDT or when capacity is	
	reached, whichever comes first	
Technical Point of	Dr. Ileana Hancu, Program Manager, ARPA-H / HSF Office	
Contact		
Program email	PSI@arpa-h.gov	
Proposer deliverables,	1) One (1) physical poster (to fit within a space measuring	
details below	3.75 feet wide by 3.75 feet high - landscape layout	
	preferred)	
	2) One (1) PDF page "teaming profile" (proposer's	
	capabilities, composition, research areas of interest, etc.)	

II. INTRODUCTION

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

The PD will be held on September 7th, 2023, from 9:00 AM to 5:00 PM CT. Advanced registration is required.

The Proposers' Day objectives are to:

- Draw attention of the scientific community to the PSI technical areas.
- Provide information about the program to potential proposers, including details about the overall program goals, abstract and full proposal structure for the forthcoming* Broad Agency Announcement (BAA), and how they might respond to ARPA-H's forthcoming solicitation.

- Share the intended scope, timeline, and scale of the PSI 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.
- Provide a venue to identify potential collaborators

The PD will include brief overview presentations by government personnel; posters for potential proposers to highlight technical capabilities and promote teaming arrangements; and private sidebar meetings between the ARPA-H team and potential proposers. A limited number of sidebar meetings will be available to participants, and sidebar meetings **must** be scheduled via the registration website. 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 an abstract, 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 PSI program goals. Information relayed during the PD will be made available on the HSF Office section of the ARPA-H Opportunities page: <u>ARPA-H PSI</u> 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. Patients and patient advocates may sign up to receive future information from the PSI program about patient-specific events and updates at PSI Patient Outreach Form.

*ARPA-H will post the BAA prior to the Proposers' Day. ARPA-H anticipates posting the BAA by the end of August.

III. PSI – PROGRAM INFORMATION

This special notice is to announce and solicit attendees to the PD on September 7th, 2023, for ARPA-H's PSI program. The full details of the PSI program will be in the forthcoming PSI BAA, which will be published prior to PD. Below is only a brief description of the full program and proposers should refer to the forthcoming PSI BAA 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).

Overview

Despite recent technological advances, there are no practical solutions for some longstanding challenges faced by surgeons in the operating room. Cancer is oftentimes indistinguishable from normal tissue, and occasionally gets left behind, requiring reoperations. Critical anatomical structures such as nerves, blood vessels, lymph nodes or lymph ducts also look like surrounding tissue, and can be accidentally injured during surgeries, leading to long-term patient morbidity. The Precision Surgical Interventions ("PSI") program aims to develop technologies that will allow surgical procedures to reach their intended goals, dramatically reducing the inadvertent errors and reoperation rates. More specifically, PSI seeks to develop intraoperative end-to-end solutions for enhanced visualization of cancerous tissues. These solutions, available at

the bedside (imaging the resected specimens), or in vivo (imaging the resection cavity), will allow physicians to visualize with microscopic precision where cancer ends, enabling them to accurately complete all oncological surgeries and reduce reoperations. Secondly, PSI proposes to develop intraoperative systems that enable surgeons to better visualize critical structures in real time. Nerves, blood vessels or other anatomical structures that are not easily visible (e.g., parathyroid glands, urethra, lymph nodes, bile ducts, etc.) will be preserved, sparing patients from long-term consequences.

Technical Approach

The PSI program will develop novel intraoperative devices and tools to decrease the reoperation rate in oncological surgeries and the rate of accidental damage to critical structures in all surgeries. To accomplish this, the PSI Program is focused on two Technical Areas:

- Technical Area 1 (TA1): Cancer localization.
 - Two alternative options for this technical area exist, as described below. Proposers must select one single option.
 - o **TA1-A (In vitro pathology):** Development of end-to-end solutions, including devices and software, for intraoperative microscopic imaging of a resected specimen and automated image classification. Use of existing staining agents, or development and optimization of new staining agents, that can be *used once the specimen is removed from the body*, are also allowed under this aim.
 - o **TA1-B** (In vivo pathology): Development of end-to-end solutions, including devices and software, for intraoperative microscopic imaging of the resection cavity and automated image classification. Use of existing, Food and Drug Administration (FDA)-approved contrast agents, as well as development and optimization of new contrast agents, capable of labeling the cancer cells or the cells in the tumor microenvironment (*in vivo*) are also allowed under this aim.
- Technical Area 2 (TA2): Healthy structure localization. Development of devices and software capable of sensing structures of interest at their depth, integrated with surgical tools and/or surgical workflow. Use of existing, FDA-approved contrast agents, as well as development and optimization of new contrast agents capable of labeling the structures of interest *in vivo*, are also allowed under this aim.

Proposal details: Performers will have the option of submitting proposals that address TA1-A or TA1-B or TA2. Among the TA1 options, at comparative quality, TA1-B will be preferred over TA1-A. A group (e.g., a contrast agent or digital pathology developer) may participate in two proposals but cannot be the *prime (contact)* proposer on both. Proposals may only address TA1-A, TA1-B, or TA2, with the single exception of a combined response to TA1-B and TA2, in which a significant component of the technical solution (e.g., microscopy method or contrast agent) addresses both Technical Areas.

Proposals that only provide parts of the solutions above (i.e., just an agent, or just a device, or just a classification algorithm), and not an end-to-end solution, will be deemed non-conforming and rejected without further review.

Program Structure

The PSI program will be accomplished over 2 sequential Phases of increasing technical complexity. PSI Phase 1 for all TAs is 24 months. PSI Phase 2 for all TAs is 36 months. Attendees of the PD should consider the timeline and program structure as well as the metrics information in the forthcoming BAA within their posters and teaming profiles.

IV. PSI – PROPOSERS' DAY INFORMATION

Proposers' Day Participation and Deliverables

This Special Notice and Proposers' Day include two specific opportunities for prospective proposers to identify team members:

Posters

Interested attendees and/or proposers are invited to request space for one poster (to fit within a space measuring 3.75 feet wide by 3.75 feet high - landscape layout preferred) that summarizes their interests and capabilities. A style guide and further directions pertaining to the poster will be provided upon your registration acceptance. At PD, proposers will be split in 3 categories (contrast agents, devices and software) and will have one hour to stand by the poster, present their work and answer questions from interested parties. Posters will be accepted on a first-come, first-served basis, until the maximum possible number of submissions given the space constraint for the PD is reached, considering relevance and diversity of presenters. Interested attendees must identify their intention to present a poster during registration. Poster presentations are restricted to those attending the meeting.

Teaming Profiles

Interested parties are also invited to submit a 'teaming profile' via the Microsoft Forms link here and below: <u>PSI Teaming Profile Form</u>. 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 PSI Teaming Profile Form Link (PSI Teaming Profile Form), no later than 12:00 PM EDT on September 8th, 2023. Teaming profiles will be made available through a forthcoming Teaming Page on the ARPA-H PSI 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. Due to in-person and webinar capacity limitations, in-person registration is limited to 130 participants. The registration

cutoff date is August 28th, 2023, at 12:00 PM EDT, or once attendance capacity is met, whichever comes first. There is no registration fee for the PSI 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, <u>Proposers' Day Registration</u>

Upon entry to the physical meeting, all attendees will be required to present valid, Government-issued photo identification. Individuals who are unable to register because the deadline has passed, or capacity has been reached for the PD or for the optional sidebar meetings will be added to a waitlist. If slots remain open after registration closes or become available due to cancellations, the slots will be filled on a first-come, first-served basis from the waitlist.

PLEASE NOTE: Registration closes on August 28th, 2023, at 12:00 PM EDT.

Further administrative questions should be addressed to <u>PSI@arpa-h.gov</u>. Please refer to the PSI Proposers' Day (ARPA-H-SN-23-02) in all correspondence. <u>This announcement is not a request for abstracts or full proposals; any so sent will be returned.</u>

V. SIGNIFICANT DATES AND TIMES

Table 2. Proposers Day Significant Dates and Times			
Event	Date	Time	
Registration opens	July 27 th , 2023	9:00 PM EDT	
Registration closes	August 28 th , 2023	12:00 PM EDT*	
Proposers' Day	September 7 th , 2023	Start: 9:00 AM CT	
		End: 5:00 PM CT	

^{* 12:00} PM EDT, or when capacity is reached, whichever comes first

VI. POINTS OF CONTACT

Technical Point of Contact

Dr. Ileana Hancu, Program Manager, ARPA-H / HSF Office

Email: PSI@arpa-h.gov

All inquiries should reference "PSI Proposers' Day (ARPA-H-SN-23-02)" in the subject line of the email. Prior to submitting an e-mail inquiry, please check the <u>PSI FAQs</u>.

VII. WEBINAR INFORMATION

The link to the webinar registration confirmation will be released once registered. The registration will be limited to a first-come, first-served basis and the same from the waitlist.

VIII. 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 proposal abstracts. Submission is voluntary and is not required to propose subsequent Broad Agency Announcements (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.