

Office of Biomedical Advanced Research and Development Authority
(BARDA) Division of Research, Innovation & Ventures (DRIVE)

Special Instructions 013 Issuance for Easy Broad Agency
Announcement (EZ-BAA) BAA-20-100-SOL-0002

**Adding Area of Interest (AOI) #7:
ImmuneChip+**



**DRIVE Contracting Office
200 C Street SW
Washington, DC 20201**

I. INTRODUCTION AND OVERVIEW INFORMATION

A. Development Opportunity Objective:

Under these Special Instructions 013, BARDA is adding AOI #7 as part of its EZ-BAA (BAA-20-100-SOL-0002). Under this AOI, we are seeking abstract submissions for the following:

AOI #7: ImmuneChip+

BARDA is requesting abstract submissions to support the development of advanced *in vitro* platforms that recapitulate components of vital human tissues and the immune system and their interactions. Abstract submissions that qualify for this funding will focus on engineering 3-D *in vitro* human microphysiological tissues (e.g. lung, liver, gut, or heart tissue) and immune system tissues on a single platform, while adding in-line sensors for continuous tissue monitoring and utilizing platform materials suitable for automated manufacturing. Specifically, Respondents should add immune system responsiveness to an existing, validated *in vitro* human tissue model (e.g. lung, liver, gut, or heart) and/or model infection with a viral, bacterial, or fungal pathogen, while demonstrating continuous monitoring of the tissues and capability for automated manufacturing of the platform. Respondents should consider the following when submitting their abstract:

- 1) Utilizing previously developed and validated MPS models of the human tissue and functionally enhance them by integrating relevant components of the human immune system (e.g. immune effector and/or regulatory cells) in a controlled way. Preliminary data should discuss the validation protocol within a single laboratory or multiple laboratories.
- 2) All MPS should mimic architecture, organization, multi-tissue interfaces, physiology, and disease pathology of the native human tissue.
- 3) All vital tissue-immune system MPS must be viable and functional for at least four weeks. Evidence of such achievement for previously developed tissue chips should be included in all proposals.
- 4) Proposed use cases may, but are not required, to center on infection of human lung tissue with a pathogen such as influenza or SARS-CoV-2. Proposals to utilize pseudoviruses will be considered.
- 5) The use of transformed or immortalized cell lines is discouraged. The use of primary cells, organ explants, or pluripotent stem cells, e.g., iPSC, is encouraged. Multipotent or unipotent stem cells also may be utilized where appropriate. Applicants should not use animal cells.
- 6) Choosing platform material(s) that are appropriate for automated production of the chips. Success will be demonstrated by using machinery to fabricate and assemble physical components of the platform and produce at least 25 platforms within 24 hours (without cell culture).

- 7) Each platform should include at least two different types of built-in biochemical sensors that enable continuous or near-continuous monitoring of the developing tissues for at least four weeks. Preference will be given to proposals focusing on monitoring physiologically relevant biomarkers, e.g. cytokines rather than the physical environment. Applicants should discuss the clinical value of the observed biomarkers.
- 8) Quantitative milestones and benchmarks should be described in the Research Strategy.
- 9) All awarded projects may be reviewed quarterly by an internal review committee comprised of federal staff from BARDA, NCATS, and NASA.

The desired project outcomes are the following:

Biological:

- 1) Integration of proposed disease models, where appropriate, with other organ systems to understand how tissue interactions influence disease pathogenesis, comorbidities, and treatment.
- 2) Inclusion of multiple immune elements (e.g., lymphocytes, macrophages, neutrophils, or mucosa-associated lymphoid tissue).
- 3) Accurate reflection of human host-pathogen interactions, where appropriate.

Functionality:

- 1) Demonstration of reliable operation of a minimum of two different types of built-in biochemical sensors that enable continuous or near-continuous monitoring of the developing tissues. Reliability should be assessed across the time domain (at least four weeks of continuous operation) and across multiple platforms, based on signal persistence or loss, and signal to noise ratio (if relevant).
- 2) Essential characteristics of the tissue models including all or some of the following features: (1) multicellular architecture that represents characteristics of the chosen tissue; (2) functional representation of normal and/or diseased human biology; (3) reproducible and viable operation under physiological conditions in culture for a minimum of four weeks; and (4) accurate representation of normal and/or disease phenotypes.
- 3) A bioengineered platform with spatial and temporal control of the cellular microenvironment, while enabling continuous monitoring through at least two built-in biochemical sensors for probing (direct in-cell measurements) and sampling (testing and continuous data collection and analysis) of the system.
- 4) Ability to identify new or test existing candidate therapeutics, where appropriate.

Scalability and Manufacturing:

- 1) Choice of extracellular matrix material based on relevant biological properties

and the potential downstream effects.

- 2) Biomaterials that can avoid confounding characteristics, e.g., the elastomer polydimethylsiloxane (PDMS) binds hydrophobic drugs or reagents, which decreases the intended concentration, and can leach the endocrine disruptor cyclosilane into the medium.
- 3) Manufacturing scale-up should be demonstrated by providing evidence of reproducible automated production and, ideally, assembly, of at least 25 platforms within 24 hours. Production should occur under GLP condition, if relevant to the project and envisioned end use of the platform.

B. Eligible Respondents & Scope Parameters:

These Special Instructions 013 are open to all responsible sources as described in the EZ-BAA. IMPORTANT NOTE: Interested vendors **must** submit a request to schedule a market research call to ImmuneChipBARDA@hhs.gov to be considered for award. This request should include the project title, key project staff, and a brief description of the proposed project. Interested parties who do not submit this request will not be eligible for consideration.

AOI #7 will be open for abstract submissions through 2:00PM ET on 30 June 2021, unless otherwise extended. Additionally, award(s) expected to be made under these Special Instructions 013 will be less than \$750,000 in total Government funding. Funding is limited, so we encourage any interested vendors to reach out to ImmuneChipBARDA@hhs.gov as soon as possible before submitting an abstract.

Abstract submissions that do not conform to the requirements outlined in the EZ-BAA may be considered non-responsive and will not be reviewed. To clarify, an entity must have an active registration with <https://beta.sam.gov> at the time of submission to be reviewed. If not, submissions will not be reviewed and will be rejected. Please do not attempt to submit an abstract if your registration is not active in <https://beta.sam.gov>.

C. Number of Awards:

Multiple awards are anticipated and are dependent upon the program priorities, scientific/technical merit of submissions, how well submissions fit within the goals of the AOI, and the availability of funding. The program funding is subject to change based on the Government's discretion.

D. Special Instructions Application Process:

These Special Instructions 013 will follow the same submission process and review procedures as those established under the EZ-BAA. For complete details, please read the EZ-BAA solicitation in its entirety.

DRIVE takes the protection of Respondent information very seriously to ensure that

such information is safeguarded in full compliance with all applicable regulations and law. In addition to the “DRIVE Safeguarding of Information” procedures explained in the EZ-BAA, by submitting an abstract to this area of interest the Respondent expressly acknowledges that they are consenting to the disclosure of protected source selection information contained in the abstract to NIH and NASA personnel who may participate in the review and evaluation process. Abstracts not selected for award by BARDA may be shared internally with NIH and NASA for consideration of other funding opportunities. NIH and NASA will not disclose any abstract information outside of the federal government.

Respondents further acknowledge that they may be contacted by NIH or NASA personnel regarding information contained in their submissions for market research purposes. NIH and NASA have agreed not to disclose any protected source selection information contained in the Respondent’s abstract with non-governmental personnel absent specific consent by the Respondent, unless such disclosure is required by law. By submitting an abstract to this research area of interest, Respondent consents and agrees to these protocols.