NATIONAL CANCER INSTITUTE (NCI) SMALL BUSINESS INNOVATION RESEARCH (SBIR) INNOVATIVE CONCEPT PHASE I AWARD PROGRAM SOLICITATION NO. 75N98026R00109

Closing Date: September 21, 2026

IMPORTANT DEADLINES AND INSTRUCTIONS

Deadline for Receipt of Proposals: Proposals must be received before 5:00 PM Eastern Daylight Time on September 21, 2026. All proposals must be submitted using the electronic contract proposal submission (eCPS) website, as discussed in Section 7 of this solicitation. Please read the entire solicitation carefully prior to submitting your proposal. **Please note that White Papers will not be requested or accepted in response to this solicitation.**

Deadline for Receipt of Questions: As discussed in Section 7 of this solicitation, all questions should be submitted by **August 1, 2026** via e-mail to ncioasbir@mail.nih.gov. After that time, questions will be addressed as time permits, and at the discretion of the NCI Office of Acquisitions. Questions will be shared with the public through a solicitation amendment to ensure fair competition. Do not include sensitive information in questions submitted.

For additional information, read the SBIR/STTR Policy Directive issued by the Small Business Administration: https://www.sbir.gov/about/policies

Please note the inclusion of a new proposal requirement: Appendix J – Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries. Reference SECTION 12 – APPENDICES within this solicitation, read the document in full, and include a completed disclosure form within your business proposal.

For information about this solicitation, the primary point of contact is listed below:

National Institutes of Health ncioasbir@mail.nih.gov

Issued by: Office of Acquisition and Logistics Management, National Institutes of Health.

Table of Contents

1 INTRODUCTION 4

2 PROGRAM DESCRIPTION 5

2.1 Objectives 5
2.2 Three Phase Program 5
2.3 I-Corps™ at NIH 5

3 DEFINITIONS 6

3.1 General Definitions 6
3.2 Definitions (Relating to R&D) 11

4 PROPOSAL FUNDAMENTALS 15

4.1 Introduction 15
4.2 Offeror Eligibility and Performance Requirements 15
4.3 HHS Annual SBIR Application/Proposal Limit 15
4.4 SBIR/STTR Performance Benchmarks for Progress towards Commercialization 15
4.5 Multiple Principal Investigators 16
4.6 Joint Ventures and Limited Partnerships 17
4.7 Majority Ownership in Part by Multiple Venture Capital, Hedge Fund, and Private Equity Firms 17
4.8 Conflicts of Interest 17
4.9 Market Research 17
4.10 Debriefing 17
4.11 Registrations and Certifications 17
4.12 Promotional Materials, URLs, and Other Media 18
4.13 Prior, Current, or Pending Support of Similar Proposals or Awards 19
4.14 Reporting Matters Involving Fraud, Waste, and Abuse 19
4.15 Technical and Business Assistance / State Assistance 19
4.16 Payment 20
4.17 Proprietary Information 20
4.18 Identification and Marking of SBIR Technical Data in Contract Reports and Deliverables 20

5 CONTRACT REQUIREMENTS 21

5.1 NIH Policy on Enhancing Reproducibility Through Rigor and Transparency 21
5.2 CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015) 21
5.3 Animal Welfare 22
5.4 PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015) 22
5.5 Required Education in the Protection of Human Research Participants 22
5.6 Copyrights 23
5.7 Technical Data Rights 23
5.8 Patents and Invention Reporting 23
5.9 Management and Sharing of Research Data 24
5.10 Other Contract Requirements 24

6 METHOD OF EVALUATION 26

6.1 Evaluation Process 26
6.2 Award Decisions 28
6.3 Technical Evaluation Criteria 29

7 PROPOSAL SUBMISSION 31

..... 31
7.1 Questions 31
7.2 Limitation on the Length of the Technical Proposal 31
7.3 Submission, Modifications, Revision, and Withdrawal of Proposals 31

8 PROPOSAL PREPARATION AND INSTRUCTIONS 32

8.1 Introduction 32
8.2 Proposal Instructions 32
8.3 Technical Proposal Cover Sheet 34
8.4 Abstract of Research Plan and Public Health Relevance 34
8.5 Technical Proposal Content Generated by Small Business Offeror 34
8.6 Enhancing Reproducibility through Rigor and Transparency 36
8.7 Research Involving Vertebrate Animals 37
8.8 Human Subjects and Clinical Trials Information Form 38

1) Human Specimens and/or Data 38
2) Human Subjects Research with an Exemption from Federal Regulations 38
3) Protection of Human Subjects 39

8.9 Content of the Pricing Proposal 39

9 ANTICIPATED SCHEDULED AND NUMBER OF AWARDS 40

10 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES 40

11 TECHNICAL TOPIC DESCRIPTION(S) 41

National Cancer Institute (NCI) 41

12 ATTACHMENT(S) AND APPENDICES 44

1 INTRODUCTION

The National Cancer Institute (NCI) invites small business concerns to submit research proposals under this Phase I Small Business Innovation Research (SBIR) contract solicitation. Firms with the capability to conduct research and development (R&D) in the health-related topic areas referred to below and described more fully in Section 11.0, and to commercialize the results of that R&D, are encouraged to participate.

The topic areas that are being sought under this solicitation are:

- **Topic 1:** Development of therapeutic or preventative technologies for treatment or prevention of **Pediatric Cancers and/or Rare Cancers.**

  For this solicitation rare cancers with a 5-year survival rate of less than 50% are encouraged**.**

- **Topic 2:** Development of devices, diagnostic technologies, or digital health tools for treatment, detection, and diagnosis of **Pediatric Cancers and/or Rare Cancers.**

  For this solicitation, rare cancers with a 5-year survival rate of less than 50% are encouraged.

The National Cancer Institute is soliciting proposals from small business concerns who are looking for an opportunity to perform a few key activities to demonstrate proof-of-concept and feasibility of untested but potentially transformative, game-changing research and development (R&D) technologies to help cancer patients, providers and caregivers, in conjunction with Small Business Innovation Research (SBIR) program objectives. The NCI has established a high-risk, high-reward SBIR "Innovative Concept Award" Program for this purpose.

Preliminary data is not required; however, the ideas should have sound scientific premise either based on the offeror's own research or literature evidence. Proposals will need to identify an anticipated product that will be developed and clearly lay out the anticipated development path. Proposals will need to clearly identify the clinical problem and cancer type(s) that the proposal will focus on with adequate justification. In addition, the offerors should propose experiments to obtain initial de-risking and proof-of-concept data.

Note: Non-exempt Human subjects research will not be supported under this solicitation.

Phase I Concept Award contractors will be informed of the opportunity to apply for Phase II. Only one Phase II award may result from a single Phase I SBIR contract. The United States Department of Health and Human Services (HHS) is not obligated to make any awards under this solicitation. All awards are subject to the availability of funds. HHS is not responsible for any monies expended by the offeror before award of any contract.

2 PROGRAM DESCRIPTION

2.1 Objectives

The statutory purpose of the SBIR program is to strengthen the role of innovative SBCs in Federally-funded research or research and development (R/R&D). Specific program purposes are to: (1) stimulate technological innovation; (2) use small business to meet Federal R/R&D needs; (3) foster and encourage participation by emerging and undercapitalized SBCs in technological innovation and, (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth.

The basic design of the NCI SBIR program is in accordance with the Small Business Administration (SBA) SBIR Program Policy Directive dated May 3, 2023. This Phase I SBIR contract solicitation strives to encourage scientific and technical innovation in areas specifically identified by the NCI. The guidelines presented in this solicitation reflect the flexibility provided in the Policy Directive to encourage proposals based on scientific and technical approaches most likely to yield results important to the NCI and to the private sector.

2.2 The Concept Award and Three Phase Program

The Concept Award program is unique to the NCI. The objective of the NCI Concept Award Program is to support exploration of untested but potentially transformative ideas that may radically change the way the cancer community can prevent, diagnose, treat, and manage pediatric and/or rare cancers. This initial $300,000 Concept Award funding is intended to allow small businesses to perform key de-risking research activities and generate proof-of-concept and feasibility data that lay the groundwork to support additional Federal funding opportunities. Phase I Concept Award contractors will be informed of the opportunity to apply for Phase II.

Phase I: Feasibility

The objective of Phase I is to determine the scientific or technical feasibility and commercial merit of the proposed research or R&D efforts and the quality of performance of the small business concern, prior to providing further Federal support in Phase II.

Phase II: Full R/R&D Effort

The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal.

Phase III: Commercialization Stage without SBIR Funds

The objective of Phase III is for the small business concern to pursue, with non-SBIR funds, the commercialization objectives resulting from the outcomes of the research or R&D funded in Phases I and II. Phase III may be funded by non-Federal sources of capital or may be funded by follow-on non-SBIR Federal funding agreements.

2.3 I-Corps™ at NIH

Offerors are encouraged to consider participation in the I-Corps™ at NIH program following an award.

The I-Corps™ at NIH program is designed to complement activities within the scope of an initial SBIR award. This opportunity is specifically aligned with the statutorily mandated purpose of the SBIR program to "increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity, and economic growth" (48 CFR 1819.7301).

The program teaches researchers how to gain a clearer understanding of the value of their inventions in the marketplace, and ultimately how to advance their technologies from the research lab into the commercial world, helping to accelerate the commercialization of new products and services derived from NIH SBIR awards.

See https://seed.nih.gov/I-Corps-at-NIH for further information on this program.

3 DEFINITIONS

3.1 General Definitions

The following definitions from the SBA Policy Directive and the Federal Acquisition Regulation (FAR) apply for the purposes of this solicitation:

8(a) firm - A small business concern that is participating in the Small Business Administration's 8(a) Business Development Program for firms that are owned and controlled at least 51% by socially and economically disadvantaged individuals.

Affiliate - This term has the same meaning as set forth in 13 CFR part 121—Small Business Size Regulations, section 121.103. How does SBA determine affiliation? (Available at http://www.ecfr.gov/cgi-bin/text-idx?SID=b02d16dbfcddf646e5c0728d5e632a61&mc=true&node=se13.1.121_1103&rgn=div8). Further information about SBA's affiliation rules and a guide on affiliation is available at www.SBIR.gov and www.SBA.gov/size.

Animal - Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

Applicant - The organizational entity that qualifies as an SBC at all pertinent times and that submits a contract proposal or a grant application for a funding agreement under the SBIR Program.

Awardee - The organizational entity receiving an SBIR Phase I award, SBIR Phase II, or Phase III award. An "SBIR Awardee."

Commercialization - The process of developing products, processes, technologies, or services and the production and delivery (whether by the originating party or others) of the products, processes, technologies, or services for sale to or use by the Federal government or commercial markets.

Computer Database. A collection of data recorded in a form capable of being processed by a computer. The term does not include Computer Software.

Computer Programs. A set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

Computer Software - Computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer Software does not include Computer Databases or Computer Software Documentation.

Computer Software Documentation. Owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the Computer Software or provide instructions for using the software.

Consultant - An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, awardees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

Contract - An award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefore.

Cooperative Agreement - A financial assistance mechanism used when substantial Federal programmatic involvement with the awardee during performance is anticipated by the issuing agency. The Cooperative Agreement contains the responsibilities and respective obligations of the parties.

Covered Individual - Covered Individual Per NOT-OD-26-074, Notice of Information: Policy Changes to SBIR and STTR Foreign Disclosure and Risk Management, released on April 20, 2026, a "Covered Individual" means an individual who –

A) Contributes in a substantive, meaningful way to the scientific development project proposed to be carried out with a research and development award from a Federal research agency; or

B) Is identified by the small business in the application as senior key personnel (i.e., individuals who contribute to the scientific development or execution of a project in a substantive, measurable way).

Covered Small Business Concern - A small business concern that:

(1) Was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on the date on which it submitted an application in response to a solicitation under the SBIR program; and

(2) Is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms on the date of the SBIR award.

Data - All recorded information, regardless of the form or method of recording or the media on which it may be recorded. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

eCPS - The Electronic Contract Submission (eCPS) website is a component of the Government's integrated, secure system for the electronic submission, capture, tracking, and review of contract proposals. The eCPS website will be the only way to submit proposals under this solicitation. See the Section on Proposal Submissions for further information.

Essentially Equivalent Work - Work that is substantially the same research, which is proposed for funding in more than one contract proposal or grant application submitted to the same Federal agency or submitted to two or more different Federal agencies for review and funding consideration; or work where a specific research objective and the research design for accomplishing the objective are the same or closely related to another proposal or award, regardless of the funding source.

Feasibility - The practical extent to which a project can be performed successfully.

Federal Agency - An executive agency as defined in 5 U.S.C. § 105, and a military department as defined in 5 U.S.C. 102 (Department of the Army, Department of the Navy, Department of the Air Force), except that it does not include any agency within the Intelligence Community as defined in Executive Order 12333, section 3.4(f), or its successor orders.

Federal Laboratory - As defined in 15 U.S.C. § 3703, means any laboratory, any federally funded research and development center, or any center established under 15 U.S.C. §§ 3705 & 3707 that is owned, leased, or otherwise used by a Federal agency and funded by the Federal Government, whether operated by the Government or by a contractor.

Foreign Country of Concern - The term "foreign country of concern" means the People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the Secretary of State. https://www.sbir.gov/foreign_disclosures

Fraud, Waste, and Abuse -

Fraud includes any false representation about a material fact or any intentional deception designed to deprive the United States unlawfully of something of value or to secure from the United States a benefit, privilege, allowance, or consideration to which an individual or business is not entitled.

Waste includes extravagant, careless or needless expenditure of Government funds, or the consumption of Government property, that results from deficient practices, systems, controls, or decisions.

Abuse includes any intentional or improper use of Government resources, such as misuse of rank, position, or authority or resources.

Form, Fit, and Function Data - Data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For Computer Software it means data identifying source, functional

characteristics, and performance requirements, but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

Funding Agreement - Any contract, grant, or cooperative agreement entered into between any Federal agency and any SBC for the performance of experimental, developmental, or research work, including products or services, funded in whole or in part by the Federal Government.

Funding Agreement Officer - A contracting officer, a grants officer, or a cooperative agreement officer.

Grant - A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the Federal agency anticipates no substantial programmatic involvement with the awardee during performance.

Government Purpose - Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations or sales or transfers by the United States Government to foreign governments or international organizations. Government Purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Technical Data or Computer Software for commercial purposes or authorize others to do so.

HUBZone Small Business Concern - A small business concern that appears on the List of Qualified HUBZone (Historically Underutilized Business Zone) Small Business Concerns maintained by the Small Business Administration (13 CFR 126.103).

Innovation - Something new or improved, having marketable potential, that includes the development of new technology, the refinement of existing technology, or the development of new applications for existing technology.

Intellectual Property - The separate and distinct types of intangible property that are referred to collectively as "Intellectual Property," including but not limited to: patents, trademarks, copyrights, trade secrets, and mask works.

Joint Venture - See 13 CFR 121.103(h) for further information.

Key Personnel - The principal investigator/project manager and any other person considered to be essential to work performance.

Operations, Maintenance, Installation, or Training Purposes (OMIT) Data - Data that is necessary for operation, maintenance, installation, or training purposes (but not including detailed manufacturing or process data).

Principal Investigator/Project Manager - The one individual designated by the applicant to provide the scientific and technical direction to a project supported by the funding agreement.

Program Solicitation - A formal solicitation for proposals issued by a Federal agency that notifies the small business community of its R/R&D needs and interests in broad and selected areas, as appropriate to the agency, and requests proposals from SBCs in response to these needs and interests.

Proprietary Information - Information that constitutes a trade secret or other confidential commercial or financial information.

Prototype - A product, material, object, system, or process, or a model thereof, that is in development, regardless of whether it is in tangible, electronic, graphic or other form, at any stage of development prior to its intended ultimate commercial production and sale. The term "Prototype" includes Computer Programs embedded in hardware or devices.

SBIR Computer Software Rights - The Federal Government's rights during the SBIR/STTR Protection Period in specific types of SBIR/STTR Data that are Computer Software.

A. The Federal Government may use, modify, reproduce, release, perform, display, or disclose SBIR/STTR Data that are Computer Software within the Government. The Federal Government may exercise SBIR/STTR Computer Software Rights within the Government for:
    a. Use in Federal Government computers;
    b. Modification, adaptation, or combination with other Computer Software, provided that the Data incorporated into any derivative software are subject to the rights in § 3(ee) of the SBIR/STTR Policy Directive and that the derivative software is marked as containing SBIR/STTR Data;

c. Archive or backup; or
d. Distribution of a computer program to another Federal agency, without further permission of the Awardee, if the Awardee is notified of the distribution and the identity of the recipient prior to the distribution, and a copy of the SBIR/STTR Computer Software Rights included in the Funding Agreement is provided to the recipient.

B. The Federal Government shall not release, disclose, or permit access to SBIR/STTR Data that is Computer Software for commercial, manufacturing, or procurement purposes without the written permission of the Awardee. The Federal Government shall not release, disclose, or permit access to SBIR/STTR Data outside the Government without the written permission of the Awardee unless:
   a. The non-Governmental entity has entered into a non-disclosure agreement with the Government that complies with the terms for such agreements outlined in § 8 of the SBIR/STTR Policy Directive; and
   b. The release or disclosure is—
      i. To a Federal Government support service contractor or their subcontractor for purposes of supporting Government internal use or activities, including evaluation, diagnosis and correction of deficiencies, and adaptation, combination, or integration with other Computer Software provided that SBIR/STTR Data incorporated into any derivative software are subject to the rights in § 3(ee) of the SBIR/STTR Policy Directive; or
      ii. Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul.

SBIR Data - All Data developed or generated in the performance of an SBIR or STTR award, including Technical Data and Computer Software developed or generated in the performance of an SBIR or STTR award. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

SBIR/STTR Data Rights - The Government's license rights in properly marked SBIR/STTR Data during the SBIR/STTR Protection Period as follows: SBIR/STTR Technical Data Rights in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software and SBIR/STTR Computer Software Rights in SBIR/STTR Data that is Computer Software. Upon expiration of the protection period for SBIR/STTR Data, the Government has a royalty-free license to use, and to authorize others to use on its behalf, these Data for Government Purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these Data by third parties. The Government receives Unlimited Rights in all Form, Fit, and Function Data, OMIT Data, and unmarked SBIR/STTR Data.

SBIR Participants - Business concerns that have received SBIR awards or that have submitted SBIR proposals/applications.

SBIR/STTR Protection Period - The period of time during which the Government is obligated to protect SBIR/STTR Data against unauthorized use and disclosure in accordance with SBIR/STTR Data Rights. The SBIR/STTR Protection Period begins at award of an SBIR/STTR Funding Agreement and ends not less than twenty years from that date. (See § 8(b)(4) of the SBIR/STTR Policy Directive).

SBIR Technical Data Rights - The Federal Government's rights during the SBIR/STTR Protection Period in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software. (1) The Government may, use, modify, reproduce, perform, display, release, or disclose SBIR/STTR Data that are Technical Data within the Federal Government; however, the Federal Government shall not use, release, or disclose the data for procurement, manufacture or commercial purposes; or release or disclose the SBIR/STTR Data outside the Government except as permitted by paragraph (2) below or by written permission of the Awardee. (2) SBIR/STTR Data that are Technical Data may be released outside the Federal Government without any additional written permission of the Awardee only if the non-Governmental entity or foreign government has entered into a non-disclosure agreement with the Federal Government that complies with the terms for such agreements outlined in § 8 of this Policy Directive and the release is: (i) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul; (ii) To a Government support services contractor in the performance of a Government support services contract for internal Government use or activities, including evaluation, diagnosis or modification provided that SBIR/STTR Technical Data incorporated into any derivative Data are subject to the rights in paragraph (ii), and the release is not for commercial purposes or manufacture; (iii) To a foreign government for purposes of information and evaluation if required to serve the interests of the U.S. Government; or (iv) To non-Government entities or individuals for purposes of evaluation.

Service-Disabled Veteran-Owned Small Business Concern - A small business concern note less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and, the management and daily business operations of

which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such a veteran. Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

Small Business Concern (SBC) - A concern that meets the requirements set forth in 13 CFR 121.702:

To be eligible for award of funding agreements in the SBA's Small Business Innovation Research (SBIR) program, a business concern must meet the requirements of paragraphs (a) and (b) below:

(a) *Ownership and control.*

(1) An SBIR awardee must:

(i) Be a concern which is more than 50% directly owned and controlled by one or more individuals (who are citizens or permanent resident aliens of the United States), other small business concerns (each of which is more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States), or any combination of these; OR

(ii) Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these (for agencies electing to use the authority in 15 U.S.C. 638(dd)(1)); OR

(iii) Be a joint venture in which each entity to the joint venture must meet the requirements set forth in paragraph (a)(1)(i) or (a)(1)(ii) of this section. A joint venture that includes one or more concerns that meet the requirements of paragraph (a)(1)(ii) of this section must comply with § 121.705(b) concerning registration and proposal requirements

(2) No single venture capital operating company, hedge fund, or private equity firm may own more than 50% of the concern.

(3) If an Employee Stock Ownership Plan owns all or part of the concern, each stock trustee and plan member is considered an owner.

(4) If a trust owns all or part of the concern, each trustee and trust beneficiary is considered an owner.

(b) *Size.* An SBIR awardee, together with its affiliates, will not have more than 500 employees.

Small Disadvantaged Business Concern - Consistent with 13 CFR 124.1002, means a small business concern under the size standard applicable to the acquisition, that: is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by one or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States; and, each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and, the management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Socially and Economically Disadvantaged Individual - See 13 CFR 124.103 and 124.104.

Subcontract - Any agreement, other than one involving an employer-employee relationship, entered into by an awardee of a funding agreement calling for supplies or services for the performance of the original funding agreement.

Technical Data - Recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including Computer Software Documentation and Computer Databases). The term does not include Computer Software or financial, administrative, cost or pricing, or management information, or other data incidental to contract or grant administration. The term includes recorded Data of a scientific or technical nature that is included in Computer Databases.

United States - Means the 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of

Palau.

Unlimited Rights - The Government's rights to access, use, modify, prepare derivative works, reproduce, release, perform, display, disclose, or distribute Data in whole or in part, in any manner and for any purpose whatsoever, and to have or authorize others to do so

Women-Owned Small Business Concern - A small business concern that is at least 51% owned by one or more women, or in the case of any publicly owned business, at least 51% of the stock is owned by women, and women control the management and daily business operations.

3.2 Definitions (Relating to R&D)

Autopsy Materials - The use of autopsy materials is governed by applicable Federal, state, and local law and is not directly regulated by 45 CFR part 46.

Child - The NIH Policy on Inclusion of Children defines a child as an individual under the age of 18 years (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html). The intent of the NIH policy is to provide the opportunity for children to participate in research studies when there is a sound scientific rationale for including them, and their participation benefits children and is appropriate under existing Federal guidelines. Thus, children must be included in NIH conducted or supported clinical research unless there are scientific or ethical reasons not to include them. This policy is separate from considerations of protections and consent for children to participate in research**.**

Clinical Research - NIH defines human clinical research as research with human subjects that is:

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes:
   (a) mechanisms of human disease,
   (b) therapeutic interventions,
   (c) clinical trials, or
   (d) development of new technologies.

(2) Epidemiologic and behavioral studies.

(3) Outcomes research and health services research.

Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

Clinical Trial - NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

If the answers to **all** four questions below are **yes**, the study meets the definition of a Clinical Trial:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

See Appendix H.1 Instructions, Human Subjects, and Clinical Trials Information Form, Section 1.4. Clinical Trial Questionnaire, for further information and references for understanding this definition. Appendix H.1. is located in Section 12 – Appendices of this solicitation.

Human Subjects - The HHS regulations "Protection of Human Research Subjects" 45 CFR part 46, (administered by OHRP) define a human subject as a living individual about whom an investigator conducting research obtains:

- Data through *intervention* or *interaction* with the individual; or,
- Identifiable private information.

Individually Identifiable Private Information - According to its guidance for use of coded specimens, OHRP generally considers private information or specimens to be *individually identifiable* as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through *coding* systems. Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding system.

Interaction includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f)).

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(f)).

Investigational Device Exemption (IDE) - An IDE is a regulatory submission that permits clinical investigation of devices. This investigation is exempt from some regulatory requirements. The term "IDE" stems from the description in 21 CFR 812.1.

Investigator - The OHRP considers the term investigator to include anyone involved in conducting the research. OHRP does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in the conduct of the research. However, if the individuals who provide *coded* information or specimens also collaborate on other activities related to the conduct of the research with the investigators who receive such information or specimens, they will be considered to be involved in the conduct of the research. (See OHRP's Guidance on Research Involving Coded Private Information on Biological Specimens.)

Manufacturing-related R&D as a result of Executive Order 13329 - Encompasses improvements in existing methods or processes, or wholly new processes, machines or systems. Four main areas include:

- Unit process level technologies that create or improve manufacturing processes including:
  - Fundamental improvements in existing manufacturing processes that deliver substantial productivity, quality, or environmental benefits.
  - Development of new manufacturing processes, including new materials, coatings, methods, and associated practices.
- Machine level technologies that create or improve manufacturing equipment, including:
  - Improvements in capital equipment that create increased capability (such as accuracy or repeatability), increased capacity (through productivity improvements or cost reduction), or increased environmental efficiency (safety, energy efficiency, environmental impact).
  - New apparatus and equipment for manufacturing, including additive and subtractive manufacturing, deformation and molding, assembly and test, semiconductor fabrication, and nanotechnology.
- Systems level technologies for innovation in the manufacturing enterprise, including:
  - Advances in controls, sensors, networks, and other information technologies that improve the quality and productivity of manufacturing cells, lines, systems, and facilities.
  - Innovation in extended enterprise functions critical to manufacturing, such as quality systems, resource management, supply change integration, and distribution, scheduling and tracking.
- Environment or societal level technologies that improve workforce abilities, productivity, and manufacturing competitiveness, including:
  - Technologies for improved workforce health and safety, such as human factors and ergonomics.
  - Technologies that aid and improve workforce manufacturing skill and technical excellence, such as educational systems incorporating improved manufacturing knowledge and instructional methods.
  - Technologies that enable integrated and collaborative product and process development, including computer-aided and expert systems for design, tolerancing, process and materials selection, life-cycle cost estimation, rapid prototyping, and tooling.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be *individually identifiable* (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. (45 CFR 46.102(f))

- **Coded -** With respect **to private information** or human biological specimens, *coded* means that:
  - Identifying information (such as name or social security number) that would enable the investigator to readily

ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e., the code); and

- A key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

Research that involves only coded private information/data or coded human biological specimens may not constitute human subjects research under the HHS human subjects regulations (45 CFR 46) if:

- The specimens and/or information/data are not obtained from an interaction/intervention with the subject specifically for the research; and
- The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain (e.g., the researcher's access to subject identities is prohibited).

Individuals who provide coded information or specimens for proposed research and who also collaborate on the research involving such information or specimens are considered to be involved in the conduct of human subjects research.

(See the following guidance from the Office for Human Research Protections (OHRP) for additional information and examples: http://www.hhs.gov/ohrp/policy/cdebiol.html.)

Research or Research and Development (R/R&D) - Any activity that is:

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;
- A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Research Involving Vertebrate Animals:

All research involving live vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy).

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), which is incorporated by reference. If using live vertebrate animals, HHS policy requires that offerors address the criteria in the Vertebrate Animal Section (VAS) of the Technical Proposal. Each of the criteria must be addressed in the VAS portion of the Technical Proposal. For additional information see Office of Laboratory Animal Welfare – Vertebrate Animals Section and use Contract Proposal VAS Worksheet.

Research Involving Human Subjects: All research involving human subjects, to include use of identifiable human biological specimens and human data, shall comply with the applicable federal and state laws and agency policy/guidelines for human subject protection.

Exemptions. The following six categories of research meet the basic definition of human subjects research but are considered to be exempt from the HHS human subject regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

  (i) Research on regular and special education instructional strategies; or

  (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

  (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) Procedures for obtaining benefits or services under those programs;

(iii) Possible changes in or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) If wholesome foods without additives are consumed; or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

See Appendix H.1 Instructions, Human Subjects and Clinical Trials Information Form, Section 1.3. Exemption Number, for additional guidance. Appendix H.1. can be located in Section 12 – Appendices of this solicitation.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules - Any recipient performing research involving recombinant or synthetic nucleic acid molecules and/or organisms and viruses containing recombinant or synthetic nucleic acid molecules shall comply with the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, dated April 2016 as amended. The guidelines can be found at: https://www.federalregister.gov/documents/2016/04/15/2016-08810/national-institutes-of-health-nih-office-of-science-policy-osp-recombinant-or-synthetic-nucleic-acid.

Recombinant or synthetic nucleic acid molecules are defined as:

(i) Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;

(ii) Nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or,

(iii) Molecules that result from the replication of those described in (i) or (ii) above.

Sex - Refers to the classification of research subjects in either or both of two categories: male and female. In some cases, representation is unknown, because sex composition cannot be accurately determined (e.g. pooled blood samples or stored specimens without sex designation). In addition, sex classification is based on the self- reporting of participants enrolled in the research study. Investigators should consider the scientific goals of their study when requesting this information.

Valid Analysis - This term means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are: allocation of study participants of both sexes

(males and females) and from different groups to the intervention and control groups by an unbiased process such as randomization; unbiased evaluation of the outcome(s) of study participants; and use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex, race, and/or ethnicity.

4 PROPOSAL FUNDAMENTALS

4.1 Introduction

The proposal must provide sufficient information to demonstrate to the evaluator(s) that the proposed work represents an innovative approach to the investigation of an important scientific or engineering problem and is worthy of support under the stated criteria. The proposed research/research and development must be responsive to the topic area. Anyone contemplating submission of a proposal should determine that: (a) the technical approach has a reasonable chance of meeting the topic objective; (b) this approach is innovative, not routine, with potential for commercialization; and (c) the proposing firm has the capability to implement the technical approach, i.e., has or can obtain people and equipment suitable to the task.

4.2 Offeror Eligibility and Performance Requirements

To receive SBIR funds, each awardee must qualify as a small business concern (SBC) at the time of award and at any other time set forth in SBA's regulations at 13 CFR 121.701-121.705. Each applicant must qualify as a small business for research or research and development purposes and certify to this on the Cover Sheet of the proposal. Additionally, each awardee must submit a certification stating that it meets the size, ownership and other requirements of the SBIR Program at the time of award, and at any other time set forth in SBA's regulations at 13 CFR 121.701-705.

A minimum of two-thirds of the research or analytical effort must be performed by the awardee. The percentage of work will be measured by total contract costs. Services obtained from Contract Research Organizations (CROs), Contract Development and Manufacturing Organizations (CDMOs), and similar entities may be treated as vendor procurements where the entity is providing routine or commercial services and is not responsible for the scientific or technical direction of the project. In such cases, the associated costs may be included as part of the small business concern's performance of work.

The principal investigator must be primarily employed with the SBC. Primary employment means that more than one half (50%) of the employee's time is spent with the small business. Primary employment with the SBC precludes full-time employment at another organization.

All research or research and development work must be performed by the SBC and its subcontractors in the United States.

Based on rare and unique circumstances, deviations from these performance requirements may occur, and must be approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager/Coordinator.

4.3 HHS Annual SBIR Application/Proposal Limit

In accordance with NOT-OD-26-073, Notice of Information: Implementation of HHS Annual SBIR/STTR Application/Proposal Limit, and 15 U.S.C. § 638, as amended, HHS will accept a maximum of nine new, renewal, resubmission, or revision applications (including grants, cooperative agreements, and contract proposals) from a Small Business Concern, including its affiliates, in a fiscal year. This policy applies to all SBIR and STTR activity codes. **The maximum amount of nine submissions per Small Business Concern per fiscal year includes any combination of the aforementioned submission types.**

4.4 SBIR/STTR Performance Benchmarks for Progress towards Commercialization

Phase I to Phase II Transition Rate Benchmark: In accordance with guidance from the SBA, the HHS SBIR/STTR Program is implementing the Phase I to Phase II Transition Rate benchmark required by the SBIR/STTR Reauthorization Act of 2011 and the SBIR and STTR Extension Act of 2022. The benchmark establishes a minimum number of Phase II awards the company must have received relative to a given number of Phase I awards received during the 5-fiscal year time period. The Transition Rate is calculated as the total number of SBIR and STTR Phase II awards a company received during the past 5 fiscal years divided by the total number of SBIR and STTR Phase I awards it received during the past 5 fiscal years excluding the most recently completed year. The Transition Rate requirement, agreed upon and established by all 11 SBIR agencies, was published for public comment in a Federal Register Notice on October 16, 2012 (77 FR 63410) and amended on May 23, 2013 (78 FR

30951).

- For SBIR and STTR Phase I applicants that have received more than 20 Phase I awards over the past 5 fiscal years (excluding the most recently-completed fiscal year): Companies that do not meet or exceed the benchmark minimum Transition Rate of 0.25 will not be eligible to apply for a Phase I, Fast-Track, or Direct Phase II (if available) award for a period of one year from the date of the application submission. This requirement does not apply to companies that have received 20 or fewer Phase I awards over the prior 5-fiscal year period.
- For application deadlines that fall on or after April 5, 2023: For SBIR and STTR Phase I applicants that have received more than 50 Phase I awards over the past 5 fiscal years (excluding the most recently-completed fiscal year): Companies that do not meet or exceed the benchmark minimum Transition Rate of 0.5 will not be eligible to receive more than 20 total Phase I and Phase II awards for a period of one year from the date on which such determination is made. This requirement does not apply to companies that have received 50 or fewer Phase I awards over the 5-fiscal year period.

On June 1 of each year, SBA will identify the companies that fail to meet minimum performance requirements. SBA calculates individual company Phase I to Phase II Transition Rates using SBIR and STTR award information across all federal agencies. SBA will notify companies and the relevant officials at the participating agencies. More information on the Phase I to Phase II Transition Rate requirement is available at SBIR.gov.

Phase II to Commercialization Benchmark: In accordance with guidance from the SBA, the HHS SBIR/STTR Programs are implementing the Phase II to Commercialization Rate benchmark for Phase I applicants, as required by the SBIR/STTR Reauthorization Act of 2011 and the SBIR and STTR Extension Act of 2022. The Commercialization Rate Benchmark was published in a Federal Register notice on August 8, 2013 (78 FR 48537), with a reopening of the comment period published on September 26, 2013 (78 FR 59410).

- For companies that have received more than 15 Phase II awards from all agencies over the past 10 fiscal years (excluding the two most recently completed fiscal year): Companies that meet this criterion must show an average of at least $100,000 in revenues and/or investments per Phase II award or at least 0.15 (15%) patents per Phase II award resulting from these awards during the past 10- fiscal year period. Applicants that fail this benchmark will not be eligible to apply for New Phase I, Fast-track or Direct Phase II (if applicable) awards for a period of one year. This requirement does not apply to companies that have received 15 or fewer Phase II awards over the 10-fiscal year period, excluding the two most recently completed fiscal years.
- For application deadlines that fall on or after April 5, 2023: For companies that have received more than 50 Phase II awards from all agencies over the past 10-fiscal years (excluding the two most recently completed Fiscal Year): Companies that meet this criterion must show an average of at least $250,000 of aggregated sales and investment per Phase II award over the past 10-fiscal year period. Applicants that fail this benchmark will not be eligible to receive more than 20 total Phase I and Phase II awards for a period of one year from the date on which such determination is made. This requirement does not apply to companies that have received 50 or fewer Phase II awards over the 10-fiscal year period, excluding the two most recently completed fiscal years.
- For application deadlines that fall on or after April 5, 2023: For companies that have received more than 100 Phase II awards from all agencies over the past 10-fiscal years (excluding the two most recently completed Fiscal Year): Companies that meet this criterion must show an average of at least $450,000 of aggregated sales and investment per Phase II award over the past 10-fiscal year period. Applicants that fail this benchmark will not be eligible to receive more than 20 total Phase I and Phase II awards for a period of one year from the date on which such determination is made. This requirement does not apply to companies that have received 100 or fewer Phase II awards over the 10-fiscal year period, excluding the two most recently completed fiscal years.

On June 1 of each year, SBA will identify the companies that fail to meet minimum performance requirements. SBA will notify companies and the relevant officials at the participating agencies. More information on the Phase II to Commercialization requirement is available at SBIR.gov.

4.5 Multiple Principal Investigators

The NIH provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. Ultimately, the decision to submit a proposal using multiple PIs versus a single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project. At least one proposed PI must be primarily employed with the applicant, as discussed in Section 4.2 “Offeror Eligibility and Performance Requirements.”

4.6 Joint Ventures and Limited Partnerships

Joint ventures and limited partnerships are eligible, provided that each entity to the joint venture qualifies as a small business in accordance with the Small Business Act. Refer to the definition of "Small Business Concern" and "Joint Venture" in Section 3.1 "General Definitions," for further information.

4.7 Majority Ownership in Part by Multiple Venture Capital, Hedge Fund, and Private Equity Firms

Small businesses that are owned in majority part by multiple venture capital operating companies (VCOCs), hedge funds, or private equity funds **are** eligible to submit proposals for opportunities under this solicitation, but **are required to submit a "SBIR Application VCOC Certification" at time of their application submission** per the SBIR Policy Directive. Download the "SBIR Application VCOC Certification.pdf" at the NIH SBIR Forms webpage. Answer the 3 questions and check the certification boxes. The authorized business official must sign the certification. The signed SBIR Application VCOC Certification must be submitted as part of the Pricing Proposal.

Applicant small business concerns who are NOT owned in majority part by multiple venture capital operating companies (VCOCs), hedge funds, or private equity funds, as described above, should NOT fill out a "SBIR Application VCOC Certification" and should NOT attach it to their application package.

4.8 Conflicts of Interest

Contract awards to firms owned by or employing current or previous Federal Government employees could create conflicts of interest for those employees which may be a violation of federal law. Proposing firms should contact the cognizant Ethics Counselor from the employee's Government agency for further guidance if in this situation.

4.9 Market Research

Base SBIR award funding will not support any market research or studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable. However, refer to Section 2.3 I-Corps™ at NIH and Section 4.14 Technical and Business Assistance / State Assistance for potential opportunities for specialized supplemental funding to support commercialization efforts.

For purposes of the SBIR program, "market research" is the systematic gathering, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

4.10 Debriefing

SBIR procurements are 'other competitive procedures' as outlined in FAR § 6.102 and 15 U.S.C. 638. Thus, there is no procurement statute or regulation requiring debriefing in the SBIR procurement process. However, the NCI will provide a debriefing to an unsuccessful offeror that submits a written request within 3 calendar days of being notified that its proposal was not selected for award. Be advised that an offeror that fails to submit a timely request is not entitled to a debriefing, although untimely debriefing requests may be accommodated at the Government's discretion.

4.11 Registrations and Certifications

Registration in the System for Award Management (SAM) – Required Prior to Proposal Submission

Proposing firms must be registered in the System for Award Management (SAM) at https://www.sam.gov. The registration should reflect "Purpose of Registration: All Awards" and not "Purpose of Registration: Federal Assistance Awards Only."

SAM allows firms interested in conducting business with the federal government to provide basic information on business capabilities and financial information. It is in the firm's interest to visit SAM and ensure that all the firm's data is up to date

to avoid delay in award.

Proposals do not need to include proof of SAM registration – however, proposals should note the company's Unique Entity Identifier (UEI), so that the Government may verify active SAM registration at any time.

SBA Company Registry – Required Prior to Proposal Submission (Include Proof of Registration in Business Proposal)

All applicants to the SBIR and STTR programs are required to register at the SBA Company Registry **prior to proposal submission** and **attach proof of registration**. Completed registrations will receive a unique SBC Control ID and .pdf file. If applicants have previously registered, you are still **required to attach proof of registration**. The SBA Company Registry recommends verification with SAM (see above) but a SAM account is not required to complete the registration. In order to be verified with SAM, your email address must match one of the contacts in SAM. If you are unsure what is listed in SAM for your company, you may verify the information on the SAM site.

Follow these steps listed below to register and attach proof of registration to your application:

- Navigate to the SBA Company Registry.
- If you are a previous SBIR/STTR awardee from any agency, search for your small business by Company Name, EIN/Tax ID, UEI, or Existing SBIR/STTR Contract/Grant Number in the search fields provided. Identify your company and click "Proceed to Registration".
- Download and save your SBA registry PDF locally. The name will be in the format of SBC_123456789.pdf, where the 9-digit number reflects your firm's SBC Control ID.

A copy of the completed SBA Company Registration for your organization must be submitted as part of your Business Proposal.

Funding Agreement Certification & Life Cycle Certifications – Required Prior to Award and During Contract Life Cycle

The SBA SBIR/STTR Policy Directive requires the collection of certain information from firms at time of award and during the award life cycle through use of the SBIR Funding Agreement Certification and the SBIR Life Cycle Certification, which can be viewed here: https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm.

The Funding Agreement Certification is required at the time of award and may also be required at any other time that has been identified and incorporated into the contract delivery schedule.

The Life Cycle Certification is required prior to final payment on the award and may also be required at any other time that has been identified and incorporated into the contract delivery schedule.

These certifications do not need to be included in your original proposal.

Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries

All offerors must complete and submit the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries form (referred to as the "Disclosure Form" hereafter) as part of your Business Proposals which is incorporated as a linked attachment under Solicitation APPENDIX J. Offerors are required to disclose all funded and unfunded relationships with foreign countries, using the Disclosure Form, for all owners and covered individuals. **Covered Individual Per NOT-OD-26-074,** Notice of Information: Policy Changes to SBIR and STTR Foreign Disclosure and Risk Management, released on April 20, 2026, a "Covered Individual" means an individual who –

A) Contributes in a substantive, meaningful way to the scientific development project proposed to be carried out with a research and development award from a Federal research agency; or

B) Is identified by the small business in the application as senior key personnel (i.e., individuals who contribute to the scientific development or execution of a project in a substantive, measurable way).

4.12 Promotional Materials, URLs, and Other Media

Promotional and non-project related discussion is discouraged, and additional information provided via Universal Resource Locator (URL) links or on computer disks, CDs, DVDs, video tapes or any other medium will not be accepted or considered in the proposal evaluation.

4.13 Prior, Current, or Pending Support of Similar Proposals or Awards

A small business concern may not submit both a contract proposal and a grant application for essentially equivalent work (*see definition in Section 3.1*) in response to multiple HHS SBIR solicitations and funding opportunity announcements. The only exception is that a grant application is allowed to be submitted after a contract proposal has been evaluated and is no longer being considered for award.

It is permissible, with proposal notification, to submit proposals containing essentially equivalent work for consideration under another federal program solicitation in addition to one HHS solicitation or funding opportunity announcements for the SBIR program. The small business concern must make appropriate disclosures within the proposal cover sheet and Appendix C.

IMPORTANT – It is unlawful to enter into contracts or grants requiring essentially equivalent effort. If there is any question concerning prior, current, or pending support of similar proposals or awards, it must be disclosed to the soliciting agency or agencies as early as possible.

4.14 Reporting Matters Involving Fraud, Waste, and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or through the Inspector General's Hotline. The toll-free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office
of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

4.15 Technical and Business Assistance / State Assistance

Technical and Business Assistance (TABA)

NIH offers distinct technical and business assistance (TABA) programs to NIH SBIR and STTR awardees. Find more information at https://seed.nih.gov/support-for-small-businesses/technical-business-assistance-program. These programs offer specialized support to help small businesses to identify and address their most pressing product development needs.

If you would like to utilize a TABA funding, you are required to include these costs in your budget and to provide a detailed budget justification. TABA funding can support new or existing staff, vendors, consultants, or subawards to perform activities consistent with the goals below.

You may request up to $6,500 per Phase I project (across all years). For this solicitation, technical and business assistance costs may be in addition to the $300,000 base R&D budget.

Refer to Section 8 for how to include this in your Pricing Proposal.

If requesting technical and business assistance costs**, include this as an Other Direct Cost line item in your Appendix C budget**, and in the follow-on pages to Appendix C, include a **detailed** description of the technical or business assistance that your vendor/s or staff will provide, including the name of the vendor/s or staff and the expected benefits and results of the technical or business assistance provided. A letter of support from the vendor or staff describing their qualifications and services to be provided is recommended to be included in the Business Proposal along with Appendix C.

Technical assistance is limited to services that comply with 15 U.S.C. § 638(q):

> To provide small business concerns engaged in SBIR or STTR projects with technical and business assistance services, such as access to a network of scientists and engineers engaged in a wide range of technologies, product sales, IP protections, market research, market validation, development of regulatory plans, manufacturing plans, or access to technical and business literature available through on-line data bases, for the purpose of assisting such concerns in—
>
> (A) making better technical decisions concerning such projects;
>
> (B) solving technical problems which arise during the conduct of such projects;
>
> (C) minimizing technical risks associated with such projects;

(D) developing and commercializing new commercial products and processes resulting from such projects; and

(E) screening for potential foreign involvement in technology development or commercialization activities.

State Assistance

Many states have established programs to provide services to those small business firms and individuals wishing to participate in the Federal SBIR/STTR Program. These services vary from state to state. Contact your State SBIR Support office for further information.

4.16 Payment

The Government shall make payments, including invoice and contract financing payments, by electronic funds transfer (EFT). As a condition to any payment, the contractor is required to register in the System for Award Management (SAM).

Payments on fixed price contracts may be made based on the satisfactory completion, receipt, and acceptance of contract deliverables. It is anticipated that contracts awarded under this solicitation will require the submission and acceptance of technical progress reports that will result in authorization of interim payments. Final payment will be made after completion of all contract activities.

4.17 Proprietary Information

Information contained in unsuccessful proposals will remain the property of the applicant. The Government may, however, retain copies of all proposals. Public release of information in any proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information is provided by an applicant in a proposal, which constitutes a trade secret, proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law. This information must be clearly marked by the applicant with the term "confidential proprietary information" and identified by asterisks (*).

For Phase I proposals, also note each page number that contains proprietary information in the appropriate field in Appendix A. For Phase II proposal, please include the following language at the beginning of the "Content of the Technical Element" section of the proposal: "These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages of this proposal." **Do not include proprietary information in your Statement of Work. This document will be included in any awards resulting from this solicitation, and therefore subject to Freedom of Information Act disclosure.**

4.18 Identification and Marking of SBIR Technical Data in Contract Reports and Deliverables

After award, to preserve the SBIR data rights of the awardee, the legend (or statements) used in the SBIR Data Rights clause included in the SBIR contract must be affixed to any submissions of technical data developed under that SBIR contract. Any SBIR/STTR Data delivered by the Awardee, and in which the Awardee intends to limit the Federal Government's rights to SBIR/STTR Data Rights, must be delivered with restrictive markings. The Federal Government assumes no liability for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR Data without markings. The Awardee or its subcontractors or suppliers shall conspicuously and legibly mark all such SBIR/STTR Data with the appropriate legend.

(1) The authorized legend shall be placed on each page of the SBIR/STTR Data. If only portions of a page are subject to the asserted restrictions, the SBIR/STTR Awardee shall identify the restricted portions (e.g., by circling or underscoring with a note or other appropriate identifier). With respect to SBIR/STTR Data embodied in 194 Computer Software, the legend shall be placed on:

a. the printed material or media containing the Computer Software; or
b. the transmittal document or storage container. The legend shall read as follows:

"SBIR/STTR DATA RIGHTS Funding Agreement No. _____ Award Date _____ SBIR/STTR Protection Period _____ SBIR/STTR Awardee ____ SBIR/STTR Awardee Address _____ This is SBIR/STTR Data (or

is Computer Software or a Prototype that embodies or includes SBIR/STTR Data) to which the SBIR/STTR Awardee has SBIR/STTR Data Rights and to which the Federal Government has received SBIR/STTR Technical Data Rights (or SBIR/STTR Computer Software Rights) during the SBIR/STTR Protection Period and rights of use for Government Purposes after the SBIR/STTR Protection Period, as those terms are defined in the SBIR/STTR Funding Agreement. Awards issued by the U.S. Department of Energy are subject to Unlimited Rights after the SBIR/STTR Protection Period, as that term is defined in the SBIR/STTR Funding Agreement. Any reproduction of SBIR/STTR Data or portions of such data marked with this legend must also reproduce the markings." (End of Legend)

(2) Data submitted without correct or appropriate markings may be corrected within 6 months from the date the data is delivered.

Relation to patents. Nothing regarding SBIR/STTR Data Rights in this clause shall imply a license to or imply a requirement to license to the Federal Government any patent to a Subject Invention (as defined under the Bayh-Dole Act implemented at 37 CFR 401) made under an SBIR/STTR award.

5 CONTRACT REQUIREMENTS

Upon award of a contract, the contractor will be required to make certain legal commitments through acceptance of Government contract clauses. This Section discusses which clauses will be included in a contract resulting from this solicitation, if applicable to the project being proposed.

5.1 NIH Policy on Enhancing Reproducibility Through Rigor and Transparency

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103 , "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102 , "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor- reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

5.2 CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c)above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH,

terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare). (End of clause)

5.3 Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: https://olaw.nih.gov/policies-laws/phs-policy.htm.

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, which is incorporated by reference.

5.4 PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal- wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.
b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.
c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).
d. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part. (End of clause)

5.5 Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated August 25, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:
The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and

any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

5.6 Copyrights

With prior written permission of the Contracting Officer, the awardee may copyright material developed with HHS support. HHS receives a royalty-free license for the Federal Government and requires that each publication contain an appropriate acknowledgment and disclaimer statement.

5.7 Technical Data Rights

Allocation of SBIR/STTR Data Rights.

1) An SBC retains ownership of all SBIR/STTR Data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR Data that are not granted to the Federal Government in accordance with the SBIR/STTR Policy Directive. These rights of the SBC do not expire.
2) During the SBIR/STTR Protection Period, the Federal Government receives SBIR/STTR Technical Data Rights in appropriately marked SBIR/STTR Data that is Technical Data or any other type of Data other than Computer Software; and SBIR/STTR Computer Software Rights in appropriately marked SBIR/STTR Data that is Computer Software.
3) After the protection period, the Federal Government may use, and authorize others to use on its behalf, for Government Purposes, SBIR/STTR Data that was protected during the SBIR/STTR Protection Period. Awards issued by the U.S. Department of Energy are subject to Unlimited Rights after the expiration of the SBIR/STTR Protection Period.
4) The Federal Government receives Unlimited Rights in Form Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

5.8 Patents and Invention Reporting

Small business firms normally may retain the principal worldwide patent rights to any invention developed with Government support. The Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain limited circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 USC 205, the Government will not make public any information disclosing a Government-supported invention to allow the awardee to pursue a patent.

The reporting of inventions is accomplished by submitting information through the Edison Invention Reporting System for those Awarding Components participating in "Interagency Edison", or iEdison. The NIH has developed the iEdison electronic invention reporting system to assist contractors in complying with invention reporting requirements. NIH requires contractors to use iEdison, which streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected.

Inventions must be reported promptly—within two months of the inventor's initial report to the contractor organization.

This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 U.S.C. 202, and may result in loss of the rights of the small business concern, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

Inquiries or information about invention reporting or requirements imposed by 37 CFR 401 may also be directed to:

Office of Policy for Extramural Research Administration, Division of

Extramural Inventions and Technology Resources, National Institutes of Health (NIH)
6705 Rockledge Drive, MSC 7980
Bethesda, MD 20892-7980
Phone: (301) 451-4235
Fax: (301) 480-0272
E-mail: hammerslaa@mail.nih.gov

5.9 Management and Sharing of Research Data

Note: This policy applies to all NIH contracts, regardless of dollar value or level or type of funding, degree of funding (whole or partial), or type of NIH funding mechanism, that are expected to generate research data.

NIH encourages, to the maximum extent practicable, the sharing of final research data to expedite the translation of research results into knowledge, products, services, and/or procedures to improve the human health condition. This contract is anticipated to generate such research data. Therefore, the Offeror shall submit to the Contracting Officer (CO) its Data Management and Sharing Plan, which also includes genomic data, as an attachment to its technical proposal or state why such data sharing is not possible. SBIR and STTR recipients may retain the rights to data generated during the performance of an SBIR or STTR award for up to 20 years after the award date, per the SBIR Program Policy Directive. An Offeror's Data Management and Sharing Plan, including those that include genomic data, will no longer undergo peer review but be subject to NIH Program staff review and acceptance prior to award. NIH's Data Management and Sharing Policy may be found at the following Web site:

NOT-OD-21-013: Final NIH Policy for Data Management and Sharing.

NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources are found at: https://grants.nih.gov/policy/sharing.htm.

5.10 Other Contract Requirements

The outline that follows is illustrative of the types of generally-applicable clauses required by the Federal Acquisition Regulations that will be included in contracts resulting from this solicitation. This is not a complete list of clauses to be included, nor does it contain specific wording of these clauses. An award document reflecting all contract requirements applicable to your proposal will be made available prior to award.

a. **Technical Progress Reporting.** Contractors will be required to submit periodic technical progress reports throughout the period of performance, to be specified by the Awarding Component. On fixed-price contracts, payments may be tied to delivery and acceptance of these technical progress reports. For all contracts, final payment will not be made until all reports and deliverables included in the contract have been delivered and accepted by the Government.

   If reports are required to be submitted in electronic format, they must be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

   The Contractor shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

b. **Inspection.** Work performed under the contract is subject to Government inspection and evaluation at all reasonable times.

c. **Audit and Examination of Records.** The Contracting Officer and the Comptroller General, or a fully authorized representative of either, shall have the right to examine and audit all records and other evidence sufficient to reflect properly all costs claimed to have been incurred or anticipated to be incurred directly or indirectly in performance of this contract.

d. **Default.** The Government may terminate the contract if the contractor fails to perform the work contracted.

e. **Termination for Convenience.** The contract may be terminated at any time by the Government if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.

f. **Disputes.** Any dispute concerning the contract which cannot be resolved by agreement shall be decided by the Contracting Officer with right of appeal.

g. **Acknowledgement of Federal Funding.** The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

h. **Items Unallowable Unless Otherwise Provided.** Unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs: purchase or lease of any interest in real property; special rearrangement or alteration of facilities; purchase or lease of any item of general purpose office furniture or equipment regardless of dollar value; travel to attend general scientific meetings; foreign travel; non-expendable personal property with an acquisition cost of $1,000 or more.

i. **Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.** The Contractor shall not use contract funds for (1) any abortion; (2) the creation of a human embryo or embryos for research purposes; or (3) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Additionally, Federal funds shall not be used for the cloning of human beings.

j. **Use of Funds for Conferences, Meetings and Food.** The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval. In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

k. **Use of Funds for Promotional Items.** The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

l. **Equal Opportunity.** The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

m. **Equal Opportunity for Veterans.** The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran.

n. **Equal Opportunity for Workers with Disabilities.** The contractor will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.

o. **Anti-Kickback Procedures.** The contractor is prohibited from offering or accepting any money, gifts, things of value, etc. for the purpose of improperly obtaining or rewarding favorable treatment in connection with a federal contract or subcontract and shall have procedures in place to prevent and detect violations.

p. **Covenant Against Contingent Fees.** No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.

q. **Gratuities.** The contract may be terminated by the Government if any gratuities have been offered to any representative of the Government to secure the contract**.**

r. **Patent Infringement.** The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

s. **Employment Eligibility Verification.** The contractor shall be enrolled as a Federal Contractor in E-Verify and verify all employees assigned to the contract as well as all new employees hired by the contractor.

t. **Needle Exchange.** The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

u. **Limitation on Use of Funds for Promotion of Legalization of Controlled Substances.** The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

v. **Dissemination of False or Deliberately Misleading Information.** The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

w. **Anti-Lobbying.** Pursuant to the current appropriations act, except for normal and recognized executive legislative relationships, the contractor shall not use any contract funds for (i) publicity or propaganda purposes; (ii) the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself; or (iii) payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

x. **Gun Control.** The contractor shall not use contract funds in whole or in part to advocate or promote gun control.

y. **Restriction on Pornography on Computer Networks.** The contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

6 METHOD OF EVALUATION

All proposals will be evaluated and judged on a competitive basis. Each proposal will be judged on its own merit. The NCI is under no obligation to fund any proposals.

6.1 Evaluation Process

Using the technical evaluation criteria specified below, a panel of experts knowledgeable in the disciplines or fields under review will evaluate proposals for scientific and technical merit. This peer review panel will be composed primarily of experts from outside the Federal Government, in accordance with 42 CFR 52h. The review panel provides a rating for each proposal and makes specific recommendations related to the scope, direction and/or conduct of the proposed research.

To ensure an efficient and rigorous review process in the context of high proposal volume, the Government may employ a multi-stage peer review approach consistent with practices used across Federal SBIR/STTR programs and other research funding mechanisms.

Under this approach, all complete proposals will undergo an initial preliminary evaluation (triage) conducted by qualified scientific and technical reviewers. This preliminary evaluation will assess proposals against the core technical evaluation criteria outlined in Section 6.3.

Based on this preliminary assessment, approximately 50 percent of proposals may be triaged and not advanced to full panel discussion. Proposals selected for triage will be those determined to be noncompetitive or that do not demonstrate sufficient potential to meet the program's objectives.

Consistent with NIH peer review practices, triaged proposals:

- Will not receive full panel discussion
- Will not be assigned a final overall score
- Will receive summary reviewer comments

Proposals that are not triaged will advance to full peer review evaluation, where they will be discussed, scored, and considered for technical acceptability.

The Government reserves the right to adjust the proportions of proposals triaged based on submission volume and programmatic needs.

The peer review technical evaluation panel will also determine whether each proposal is Technically Acceptable or Technically Unacceptable. If a proposal is not found Technically Acceptable by a majority of the peer review panel members, then the proposal cannot be considered further for award, pursuant to 42 CFR 52h.

A **Technically Acceptable** vote indicates that the evaluator determined that the proposal, as written, demonstrates sufficient technical understanding and capabilities to perform the technical objectives set forth in the solicitation, and clearly documents that the Offeror can successfully perform all the tasks required in the Statement of Work (SOW). Note: *A determination of technical acceptability does not mean that the proposal will result in an award, it only means that the NIH Awarding Component is able to consider the proposal for award.*

A **Technically Unacceptable** vote indicates that the evaluator determined that the proposal contains major deficiencies which are so material as to preclude resolution except through major revisions and additions. A deficiency is defined as a material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

NCI program staff will conduct a second level of review of all proposals found Technically Acceptable by the peer review panel, and will take into consideration all factors set forth in Section 6.2 Award Decisions.

Evaluators will also be instructed to comment on the compliance of a proposal with applicable HHS and NIH policies, such as those listed below. If the Government is interested in funding a proposal, but a concern is noted with one of these policies, the offeror company will be afforded the opportunity to address the concerns through negotiation and proposal revisions. If the offeror company is not able to submit a proposal revision that is found acceptable in terms of these policies, then the proposal may not be considered further for award.

- Human Subject Protection http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- Animal Welfare http://grants.nih.gov/grants/oer_offices/olaw.htm
- Data Management and Sharing Plan https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview
- Biohazards/Select Agents/Recombinant DNA http://grants.nih.gov/grants/guide/notice-files/not95- 209.html
- Dual Use Research of Concern: http://phe.gov/s3/dualuse/Documents/oversight-durc.pdf

Evaluation of Data Management and Sharing Plan

An Offeror's plan for the management and sharing of final research data (Data Management and Sharing Plan) shall be assessed for appropriateness, adequacy, and reasonableness.

SBIR and STTR recipients may retain the rights to data generated during the performance of an SBIR or STTR award for up to 20 years after the award date, per the SBIR Program Policy Directive.

If an Offeror's proposal does not include a Data Management and Sharing Plan (Plan) or if the Plan in an Offeror's proposal is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the Plan is still considered "unacceptable" by the Government after discussions, the Offeror may not be further considered for award.

6.2 Award Decisions

The NCI will make awards to the offerors based on the following considerations:

- Technical Evaluation (see Section 6.3, below);
- Areas of high programmatic relevance;
- Programmatic balance (i.e., balance among areas of research);
- Availability of funds;
- Cost/price reasonableness; and,
- Security risk as assessed by the HHS Due Diligence Program.

Denial of Awards

Offerors and awardees are encouraged to consider whether their entity's relationships with foreign countries of concern will pose a security risk. Per the Small Business Innovation and Economic Security Act (the Act), HHS cannot make an award under the SBIR program if it is determined the small business concern submitting the proposal has any of the following:

- an owner or covered individual that is party to a malign foreign talent recruitment program
- a business entity, parent company, or subsidiary located in the People's Republic of China or another foreign country of concern
- an owner or covered individual that has a foreign affiliation with a research institution located in the People's Republic of China or another foreign country of concern
- a security risk connecting the small business concern to an entity, including any affiliates of the entity, or individual on—
  - the UFLPA Entity List maintained by the Department of Homeland Security;
  - the Non-SDN Chinese Military-Industrial Complex Companies List of the Office of Foreign Assets Control maintained by the Department of the Treasury;
  - the Section 889 Prohibition List established under section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115–232; 132 Stat. 1917) and maintained by the Department of Defense;
  - the list of Chinese Military companies required under section 1260H of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (10 U.S.C. 113 note) and maintained by the Department of Defense;
  - the Military End User List maintained by the Bureau of Industry and Security of the Department of Commerce;
  - the Entity List maintained by the Bureau of Industry and Security of the Department of Commerce;
  - the List of Equipment and Services maintained by the Federal Communications Commission; or
  - the Withhold Release Orders and Findings List maintained by U.S. Customs and Border Protection;
- a security risk with a primary source that is classified
- a security risk that the federal agency determines warrants a denial

If an award cannot be made due to a security risk, HHS will advise the small business concern that a security risk was found that required denial of award and indicate which category listed above necessitated the denial.

NIH will not provide offerors the opportunity to address any identified security risks prior to award.

Receipt of an award decision denying a proposal due to an identified security risk does not prohibit the small business concern from being eligible for an award in a subsequent award cycle.

6.3 Technical Evaluation Criteria

Proposals will be evaluated based on the criteria outlined below – subfactors are of equal importance:

FACTORS FOR PROPOSALS	WEIGHT
Scientific Rationale and Approach • Demonstration of sound scientific rationale including identification of an existing unmet medical need and clinical problem for pediatric and/or rare cancer, with adequate justification of the proposed technological solution based either on the offeror's own research or literature evidence. ○ Demonstration of a strong scientific premise (*i.e.*, Sufficiency of proposed strategy to ensure a robust and unbiased approach, as appropriate for the work proposed. Adequacy of proposed plan to address relevant biological variables, including sex, for studies in vertebrate animals.) • Overall strategy, methodology, and analyses are well-reasoned and appropriate to accomplish the specific aims of the project. For early-stage technology development, the strategy should be designed to establish de-risking project feasibility and proof of concept. • Identification of potential problems, risk management, and alternative strategies. • Benchmarks for success presented which will establish feasibility and mitigate risks for future development efforts.	20%

FACTORS FOR PROPOSALS	WEIGHT
Potential for Innovation and Impact • Demonstration of a novel idea that proposes to test new targets, tools, and approaches to change diagnosis, prevention, and treatment paradigms in rare and/or pediatric cancers. • Projects demonstrate high creativity and new innovative thinking approaches. • Potential to target an important problem or a critical barrier to progress in the field. • Transformative potential for significant change in understanding, diagnosis, or treatment of rare and/or pediatric cancers, considering consequences for the field and size of the community affected. For example, a paradigm-shifting or novel idea to test new targets, tools, and/or approaches that would change diagnosis, prevention, and/or treatment paradigms in rare and/or pediatric cancers.	50%
Commercialization Potential • A clear unmet medical need exists in the identified rare or pediatric cancer space for which the proposed technology may solve. • The proposed research activity has the potential to lead to a marketable product or process in the proposed cancer space. Expectation is not to have an immediate short-term product; however, a clear deliverable should be identified and described in relation to the long-term product development strategy. • Assuming the technical objectives are achieved, development of the proposed technology into a commercial product would offer significant advantages over existing approaches, methodologies, instrumentation, or interventions currently utilized in clinical practice.	20%
Personnel and Resources • The qualifications of the proposed Principal Investigators, Project Directors, supporting staff and consultants, their experience in the scientific area being proposed, and the appropriateness of the leadership approach (including the designated roles and responsibilities, governance, and organizational structure). • The adequacy and suitability of the proposed facilities, equipment, and research environment	10%

Technical reviewers will base their conclusions only on information contained in the proposal. It cannot be assumed that reviewers are acquainted with the firm or key individuals or any referenced experiments. All relevant supporting data such as journal articles, literature, including Government publications, etc., should be contained or referenced in the proposal and will count toward the page limit.

7 PROPOSAL SUBMISSION

7.1 Questions

Offerors with questions regarding this solicitation must submit them in writing to ncioasbir@mail.nih.gov. To ensure that the Government has sufficient time to respond, questions should be submitted by **August 1, 2026**. The Government may issue an amendment to this solicitation which publishes its responses to questions submitted. The Government anticipates that responses would be published in sufficient time for interested offerors to consider them prior to submission of a proposal.

7.2 Limitation on the Length of the Technical Proposal

The Technical Proposal shall consist of ATTACHMENT 1 – TECHNICAL PROPOSAL FORM, as well as applicable NIH Biosketches for key personnel, Letters of Support, and up to one page of OPTIONAL preliminary data/figures. Any information that exceeds the character limits set forth in the ATTACHMENT 1 – TECHNICAL PROPOSAL FORM will be redacted and not considered during evaluation. Any additional information provided other than the ATTACHMENT 1 – TECHNICAL PROPOSAL FORM, the NIH Biosketches, Letters of Support, and up to 1 page of preliminary data/figures will be redacted and not considered during evaluation. Do not insert figures or images in other areas of the TECHNICAL PROPSAL FORM aside from the OPTIONAL preliminary data/figures page.

Note, the Technical Proposal must be uploaded as one file. NIH Biosketches, Letters of Support, and OPTIONAL preliminary data/figures must be combined into one file along with ATTACHMENT 1 – TECHNICAL PROPOSAL FORM.

7.3 Submission, Modifications, Revision, and Withdrawal of Proposals

(a) Offerors are responsible for submitting proposals to the electronic Contract Proposal Submission (eCPS) website at https://ecps.nih.gov/ by the date and time specified on the first page of this solicitation.

Offerors must use this electronic transmission method. No other method of proposal submission is permitted.

(b) Instructions on how to submit a proposal into eCPS are available at: https://ecps.nih.gov/HowToSubmit. Offerors may also reference Frequently Asked Questions regarding online submissions at https://ecps.nih.gov/faq.

1. Be advised that registration is required to submit a proposal into eCPS and registration may take several business days to process.

2. Separation of Technical and Business Proposals

   The proposal must be uploaded in 3 parts: Technical Proposal, Human Subjects and Clinical Trials Information Form, and Business Proposal.

   The Technical Proposal shall be created as described in Section 7.3 and Section 8.
   The Technical Proposal must consist of a single PDF file.

   The PHS Human Subjects and Clinical Trials Information Form shall consist of Item 2, as described in Section 8.12. A link to this form is found in Section 13 Appendices. **This form – Appendix H.2. – is required for every proposal submission.** If your proposal does not involve Human Subjects or Clinical Trials, you must still note this on the form and submit the form. If applicable, Appendix H.3. – Study Record must be attached to Appendix H.2., as described in the Instructions set forth in Appendix H.1. **Note: Non-exempt Human subjects research will not be supported under this solicitation.**

   The Business Proposal shall consist of the items as described in Section 8.2. The Business Proposal must consist of a single PDF file. Offerors may also choose to submit an optional Excel Workbook spreadsheet providing a cost breakdown, in addition to the single PDF file.

3. Proposal Naming Conventions

To aid the Government in the efficient receipt and organization of your proposal files, please follow the following file naming conventions:

a. The language entered into the 'Proposal Name' field in eCPS for your proposal submission should include, in order: (1) the name of the Small Business Offeror; and, (2) the last name of the Principal Investigator/Project Director.

   Examples are provided below, supposing a company named "XYZ Company" and a Principal Investigator with the last name of "Smith":

   - XYZ Company_ Smith

b. Files uploaded for your proposal submission should include, in order: (1) the name of the Small Business Offeror; (2) the last name of the Principal Investigator/Project Director; and, (3) the section of the proposal that the file represents (i.e., Technical, Business, or Human Subjects Form).

   Use the format set forth in the examples below when naming your files, prior to uploading them into eCPS:

   Technical Proposal: XYZ Company_Smith_Technical.pdf

   Human Subjects and Clinical Trials Information Form: XYZ Company_Smith_HumanSubjectsForm.pdf

   Business Proposal: XYZ Company_Smith_Business.pdf

(c) Any proposal, modification, or revision, that is not received prior to the exact time specified for receipt of proposals is "late" and will not be considered for award.

(d) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the eCPS website by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation closing date, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(e) Proposals may be withdrawn by written notice at any time before award. A copy of withdrawn proposals will be retained in the contract file.

8 PROPOSAL PREPARATION AND INSTRUCTIONS

8.1 Introduction

It is important to read and follow the proposal preparation instructions carefully. Pay special attention to the requirements concerning Human Subjects and use of Vertebrate Animals if your project will encompass either item.

8.2 Proposal Instructions

A complete proposal consists of the following:

Technical Proposal

- **ATTACHMENT 1 – TECHNICAL PROPOSAL FORM**

  This Attachment has been uploaded and posted alongside the solicitation document. It consists of the following:

  - Submission Checklist
  - Proposal Cover Sheet
  - Abstract of the Research Plan and Public Health Relevance

    (This information will be placed in a publicly accessible database if the project is funded – do not

include proprietary information.)

- Technical Proposal Content
  (See Section 8.5 for further instructions)
- Statement of Work
  (This information will be included in final awarded contracts and is therefore subject to the Freedom of Information Act – do not include proprietary information.)

- OPTIONAL – **One Page** of Preliminary Data/Figures

  Not required.

  You may choose to create no more than 1 page of supplemental data or figures that would help to establish feasibility.

  Combine with the ATTACHMENT 1 – TECHNICAL PROPOSAL FORM, NIH Biosketches, and Letters of Support for your Technical Proposal Submission.

- **NIH Biosketches**

  Complete an NIH Biosketch for all key personnel.

  Template available here: https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx

  Combine with ATTACHMENT 1 – TECHNICAL PROPOSAL FORM, as well as optional 1-page of data/figures if desired, and Letters of Support for your Technical Proposal Submission.

- OPTIONAL – Letters of Support

  Include relevant Letters of Support for key collaborations, resources, and commercial interest/translation.

  Combine with ATTACHMENT 1 – TECHNICAL PROPOSAL FORM, as well as the optional 1-page of data/figures if desired, and NIH Biosketches for your Technical Proposal Submission.

The proposal submission website will only accept a single PDF document as the Technical Proposal. Only the single Technical Proposal file will be considered during Technical Evaluation.
The above documents must be merged/attached/combined into one file.

Human Subjects and Clinical Trials Information Form and Attachments (Appendix H.2.)

Business Proposal

- Pricing Proposal (Appendix C) – Individual Pricing Proposal should be completed for the base research project. The individual pricing proposal should be combined together into the final Business Proposal along with the documentation/appendices below.
  (See Section 12, Appendices, for a hyperlink to this template)
- Proof of Registration in the SBA Company Registry
  (Refer to Section 4 for Directions)
- Completion of the SBIR.gov commercialization report.
  Please reference Performance Benchmark Requirements | SBIR - The Commercialization Rate Benchmark section details the report and links out to: Guide_for_completing_commercialization_Report_SBIR_Gov.pdf. Applicants must confirm that they are in compliance and indicate the date they updated the report (or that they have not received a previous Phase II award).
- Summary of Related Activities (Appendix F)
  (See Section 12, Appendices, for a hyperlink to this template)
- SBIR Application VCOC Certification, **if applicable**
  (See Section 4 to determine if this applies to your organization)
- Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries form (see Appendix J)

IMPORTANT -- While it is permissible, with proposal notification, to submit identical proposals or proposals containing a significant amount of essentially equivalent work for consideration under numerous federal program solicitations, it is unlawful to enter into contracts or grants requiring essentially equivalent effort. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies as early as possible. Refer to Proposal Cover Sheet and Appendix C.

8.3 Technical Proposal Cover Sheet

Complete the Proposal Cover Sheet as the first page of the proposal. No other coversheet should be used. If submitting a proposal reflecting Multiple Principal Investigators/Project Directors (PIs/PDs), the individual designated as the Contact PI should be entered here.

8.4 Abstract of Research Plan and Public Health Relevance

Do not include any proprietary information as abstracts of successful proposals will be published by NCI. The abstract should briefly discuss the problem or opportunity that the offerors are trying to solve, highlight the innovation of the proposed technology and how it will change the clinical and research paradigm, and briefly discuss the activities proposed in the proposal. Summarize anticipated results and potential commercial applications of the proposed research.

Include at the end of the Abstract a brief description (two or three sentences) of the relevance of this research to public health. In this description, be succinct and use plain language that can be understood by a general, lay audience.

8.5 Technical Proposal Content

NOTE: Prior to preparing the Technical Proposal Content, offerors should refer to the specific research Topic in Section 11 to tailor the proposed research plan to the description, goals, anticipated activities, and budget set forth for the specific Topic.

The Technical Proposal Content covers the following items.

A) **Identification and Significance of the Problem or Opportunity**

Provide a clear statement of the specific technical problem or opportunity to be addressed in the proposed research. Use this section to demonstrate the scientific rationale behind the proposed technology, including identification of an existing unmet medical need, clinical problem, and rare/pediatric cancer type that the proposal will focus on. Limit your response to 4500 characters at 10pt font.

Refer to **Section 8.6 Enhancing Reproducibility through Rigor and Transparency**, and address those points, as applicable.

B) **Proposed Technological Solution**

Describe the proposed solution to the identified unmet medical need. Justify how the proposed technology is ideally suited to solve the stated problem using the offeror's own research or by citing appropriate literature evidence. Limit your response to 4500 characters at 10pt font. Preliminary data are not required but can be included/referred to in an optional 1-page (maximum) document to establish project feasibility, which must be attached or combined with ATTACHMENT 1 - TECHNICAL PROPOSAL FORM provided.

C) **Innovation**

Highlight the disruptive innovation of the proposed research project in developing approaches to change diagnosis, prevention, and treatment paradigms in rare and/or pediatric cancers. Discuss the transformative potential of the project for significant change compared to current standard of care paradigms. Include subsections that discuss creative thinking approaches and project risk reward ratio analyses. Limit your response to 9000 characters at 10pt font.

D) **Approach and Methodology**

Set forth technical objectives and describe a logical approach for meeting the objectives through clearly identified tasks, in a well-developed experimental design.

Technical Objectives and Milestones shall be included at a high level in the **Statement of Work section,** which comes further down in the TECHNICAL PROPOSAL FORM template. In contrast, in this section of the proposal, the offeror should include more detailed and/or confidential information that is not appropriate for inclusion in the final contract award, which is generally releasable to the public, to allow for sufficient technical evaluation of the proposed project.

Discuss the methods, models, systems, and assays to be used to achieve each objective/task.

Discuss anticipated challenges and plans to address weaknesses in prior research. Identify

potential problems and alternative strategies.

Define measurable benchmarks for success which will establish feasibility and mitigate risks for future development efforts. Milestones should include quantitative parameters so that the progress and success of the project can be assessed. Milestones should link to clear product development goals, even at an early-stage.

Explicitly describe the role and time allocated towards the project for each key personnel. If a co-PI/PD is proposed, include a Multiple PI/PD Leadership Plan. Biosketches should still be included separately from this section and combined with ATTACHMENT 1 – TECHNICAL PROPOSAL FORM.

Limit your response to 13,500 characters at 10pt font.

Refer to **Section 8.6 Enhancing Reproducibility through Rigor and Transparency**, and address those points, as applicable.

E) **Product Discovery and Development**

Clearly define a deliverable (expectation is not to have an immediate short-term commercial product) to be achieved with the Concept Award funding and how this deliverable will fit into a whole long-term product development strategy. Successful execution of Concept Award proposals should help de-risk the technology for potential future Federal funding opportunities. Limit your response to 4500 characters.

F) **Potential Commercial Application**

Define the unmet medical need that exists in the identified rare and/or pediatric cancer space for which the proposed technology may solve. Use this section to identify a plausible commercial path and need for a product to be developed. Describe the market as it currently exists and how your product/service may enter and compete. Include the potential barriers to market entry and how you expect to overcome them. Describe the strategy for protecting your innovation (such as status of and/or potential for intellectual property or market exclusivity, etc.). Limit your response to 4,500 characters.

NOTE: For any small business applicant that has received an SBIR Phase II award issued by NIH or any other Federal Government agency, please include the company's commercialization history:

- The company commercialization history must document the extent to which the company was able to secure additional non-SBIR / STTR funding to develop concepts resulting from previous Phase II SBIR awards.
- For each Phase II award, the history must include: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of non-SBIR / STTR funding; and (6) commercialization status of each Phase II award.

G) **Resources**

Discuss the resources available and accessible to the offeror that will enable the team to successfully complete the proposed research project, including facilities, equipment, and research environment. Limit your response to 4,500 characters.

H) **Authentication of Key Biological and/or Chemical Resources**

Outline below the main biological/chemical resources to be utilized in this project and any authentication procedures. Limit your response to 1,500 characters.

I) **Scientific Data Sharing**

The NIH has a longstanding commitment to making the results of NIH-funded Federal research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets. Further guidance is available here: https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview

SBIR and STTR recipients may retain the rights to data generated during the performance of an SBIR or STTR award for up to 20 years after the award date, per Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Policy Directive. An acceptable Data Management and Sharing (DMS) Plan can reference and incorporate these data rights. Further information about SBIR and STTR data rights are enumerated here: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_18/18.5.5_administrative_requirements.htm#Intellec
Limit your response to 1500 characters.

J) **References** (1 page maximum)

All relevant supporting data such as journal articles, literature, including Government publications, etc., should be contained or referenced in the proposal and will count toward the page limit.

K) **Statement of Work**

Technical Objectives and Milestones shall be included at a high level in the **Statement of Work section.** The Statement of Work will be included in the final contract award document, to set forth the parameters of the activities that are being conducted under the contractual agreement, and as such, are generally releasable under the Freedom of Information Act. Therefore, do not include proprietary/confidential information.

Follow instructions within the template provided, including, for example: a timeline broken down by objectives and milestones, and defining measurable benchmarks for success including quantitative parameters so that the progress and success of the project can be assessed.

Refer to **Section 8.7 Research Involving Vertebrate Animals** and include a Vertebrate Animals Section as required if the project proposed includes vertebrate animals.

L) **NIH Biosketches**

Complete an NIH Biosketch for all key personnel.

Template available here: https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx

Combine with ATTACHMENT 1 – TECHNICAL PROPOSAL FORM, as well as optional 1-page of data/figures if desired, for your Technical Proposal Submission.

NIH Biosketches should reflect the qualifications of the proposed Principal Investigators, Project Directors, supporting staff and consultants, and their experience in the scientific area being proposed.

Paragraph D), above, should include a discussion of the appropriateness of the leadership approach of how personnel will be used for this project (including the designated roles and responsibilities, governance, and organizational structure).

M) **Letters of Support**

Include relevant Letters of Support highlighting key collaborations, resources, and commercial interest.

8.6 Enhancing Reproducibility through Rigor and Transparency

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103. Specifically, the offeror shall describe the information below within the Detailed Approach and Methodology section of the technical proposal:

a. Describe the scientific premise for the Technical Proposal. The scientific premise is the research that is used to form the basis for the proposed research. Offerors should describe the general strengths and weaknesses of the

prior research being cited by the offeror as crucial to support the proposal. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.

b. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

c. Explain how relevant biological variables, including sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

8.7 Research Involving Vertebrate Animals

If it is intended that live vertebrate animals will be used during performance of this contract the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH.

The following criteria must be addressed in the "Vertebrate Animals Section" within the **Statement of Work** attachment**:**

Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the VAS, see http://grants.nih.gov/grants/olaw/vertebrate_animal_section.htm. For additional guidance see the *Worksheet for Review of the Vertebrate Animal Section under Contract Proposals*, http://grants.nih.gov/grants/olaw/VAScontracts.pdf.

The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that offeror organizations proposing to use vertebrate animals file a written **Animal Welfare Assurance** with the Office of Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy defines "animal" as "any live vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

In accordance with the PHS Policy, offerors must establish an **Institutional Animal Care and Use Committee (IACUC)**, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. No PHS award for research involving vertebrate animals will be made to an offeror organization unless that organization is operating in accordance with an approved **Animal Welfare Assurance** and provides **verification that the IACUC has reviewed and approved** the proposed activity in accordance with the PHS Policy. This information should be addressed in the Technical Proposal section on Vertebrate Animals.

Proposals may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that

accepts responsibility for compliance with the PHS Policy. Foreign offeror organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

The PHS Policy stipulates that an offeror organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program, see: http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, unless a deviation is justified for scientific reasons in writing by the investigator, see: https://www.avma.org/KB/Policies/Documents/euthanasia.pdf . This policy does not affect applicable state or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 U.S.C. 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163, e- mail: olaw@mail.nih.gov.

For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301–496–7163). The PHS Policy is available on the OLAW website at: http://www.grants.nih.gov/grants/olaw/olaw.htm.

8.8 Human Subjects and Clinical Trials Information Form

All proposal submissions must include Appendix H.2 – Human Subjects and Clinical Information Form. Attachments must also be included if applicable, based on the nature of your project.

Please review Appendix H.1. - INSTRUCTIONS, HUMAN SUBJECTS AND CLINICAL TRIALS **INFORMATION FORM**, found in Section 13 – Appendices, which is the last page of this solicitation.

Then, download and complete **Appendix H.2. – HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM,** found in Section 13 – Appendices, which is the last page of this solicitation. This form must be included in every proposal.

If your project involves Human Subjects, even if the project is exempt from Federal Regulations, then completion of Appendix H.2. will also require **Appendix H.3. – STUDY RECORD**, which is an attachment to Appendix H.2., and can be found in Section 12 – Appendices, which is the last page of this solicitation.

Through these forms, each proposal must address the Human Subjects Research, Inclusion, and Clinical Trials policies which are included in this solicitation, as applicable to your project.

If there is not a specific place identified within Appendix H.2. or Appendix H.3. for a particular issue concerning Human Subjects protection, Inclusion, or Clinical Trials policies discussed in this solicitation, include your response as an attachment in the "Other Requested Information" field on the Human Subjects and Clinical Trials Information form.

1) Human Specimens and/or Data

If your project does not meet the definition of human subjects research, but involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved. There is a field in the Human Subjects and Clinical Trials Information form to attach this explanation. To help determine whether your research is classified as human subjects research, refer to the Research Involving Private Information or Biological Specimens flowchart.

2) Human Subjects Research with an Exemption from Federal Regulations

If **all** of your proposed human subjects research meets the criteria for one or more of the human subjects exemption categories, identify which exemptions you are claiming and justify why your proposed research meets the criteria for the exemptions you have claimed. This justification should explain how the proposed research meets the exemption criteria and should not merely repeat the criteria or definitions themselves. This exemption justification must be attached to the Human Subjects and Clinical Trials Information form using the **"Other Requested Information"** field.

3) *Protection of Human Subjects*

A. Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.270-4(a) (December 2015)

- The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: http://www.hhs.gov/ohrp/index.html .These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.
- The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.
- Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)-(6) are exempt from complying with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.
- Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.
- In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).
- Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.
- The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB. If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval prior to human subjects work beginning. Upon obtaining FWA approval, submit the approval notice to the Contracting Officer. (End of provision)

Proof of an approved or active FWA should be attached to the Human Subjects and Clinical Trials Information form using the "Other Requested Information" field.

Non-exempt Human subjects research will not be supported under this solicitation.

8.9 Content of the Pricing Proposal

Complete the Pricing Proposal (Appendix C). Some items in the Pricing Proposal may not apply to the proposed project. Provide enough information to allow the Government to understand how you plan to use the requested funds if a contract is awarded.

- List all personnel by name as well as by number of hours dedicated to the project as direct labor. If a position will be filled at a later date, it is acceptable to list the job title and indicate that it is To Be Determined (TBD).
- Cost for travel funds must be justified and related to the needs of the project. Describe reason for travel, location

of travel, number of travelers, and number of nights of lodging in the Description fields in Appendix C.

- Cost sharing is permitted for proposals under this solicitation; however, cost sharing is not required nor will it be an evaluation factor.
- All subcontractor costs and consultant costs must be detailed at the same level as prime contractor costs in regards to labor, travel, equipment, etc. Provide detailed substantiation of subcontractor costs in your cost proposal. Enter this information in the Explanatory Material section of the on-line cost proposal form.
- **NIH Policy on Threshold for Negotiation of General and Administrative (G&A)/Indirect Costs (IDC) Rates for SBIR proposals** – SBIR offerors who propose a G&A/IDC rate of 40 percent of total direct costs or less will not be required to negotiate Final Indirect Rates with the NIH Division of Financial Advisory Services (DFAS), or other cognizant auditing agency. However, awarding Contracting Officers may require offerors to document how they calculated their IDC rate(s) in order to determine that these costs are fair and reasonable. Furthermore, the Division of Financial Advisory Services (DFAS) will retain the authority to require well-documented proposals for G&A/IDC rates on an *ad hoc* basis. If the SBC has a currently effective negotiated indirect cost rate(s) with a Federal agency, such rate(s) shall be used when calculating proposed G&A/IDC costs for an NIH proposal. (However, the rate(s) must be adjusted for IR&D expenses, which are not allowable under HHS awards.)

  SBCs are reminded that only actual G&A/IDC costs may be charged to projects. If awarded at a rate of 40 percent or less of total direct costs, the rate used to charge actual G&A/ID costs to projects cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate(s) with DFAS.
- Offerors submitting proposals may include the amount of up to $6,500 per year for technical assistance as discussed and outlined in Section 4.14 of the solicitation. Include a detailed description of the technical or business assistance that your vendor/s or staff will provide, including the name of the vendor/s or staff and the expected benefits and results of the technical or business assistance provided. A letter of support from the vendor or staff describing their qualifications and services to be provided is recommended.
- **Prior, Current, or Pending Support of Similar Proposals or Awards**.

  If a proposal submitted in response to this solicitation is for **essentially equivalent work** (as defined in this solicitation) as another proposal that was funded, is now being funded, or is pending with a Federal agency, you must make the appropriate certification on the proposal cover sheet, as well as provide the following information in Appendix C:

  1) Name and address of the Federal Agency(s) or HHS Component, to which a proposal was submitted, will be submitted, or from which an award is expected or has been received.
  2) Date of proposal submission or date of award.
  3) Title of proposal.
  4) Name and title of principal investigator for each proposal submitted or award received.
  5) Title, number, and date of solicitation(s) under which the proposal was submitted, will be submitted, or under which award is expected or has been received.
  6) If award was received, state contract number.
  7) Specify the applicable topics for each SBIR/STTR proposal submitted or award received.

9 ANTICIPATED SCHEDULE AND NUMBER OF AWARDS

Award Schedule:

- Question submission deadline – August 1, 2026
- Proposal Submission Deadline – September 21, 2026 at 5:00 PM Eastern Daylight Time
- Awards Anticipated – April 2027

Anticipated Number of Awards: 15 - 20

10 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Health science research literature is available at academic and health science libraries throughout the United States.

Information retrieval services are available at these libraries and Regional Medical Libraries through a network supported by the National Library of Medicine. To find a Regional Medical Library in your area, visit http://nnlm.gov/ or contact the Office of Communication and Public Liaison at publicinfo@nlm.nih.gov, (301) 496-6308.

Other sources that provide technology search and/or document services include the organizations listed below. They should be contacted directly for service and cost information.

National Technical Information Service
1-800-553-6847
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National Technology Transfer Center

11 TECHNICAL TOPIC DESCRIPTION(S)

NATIONAL CANCER INSTITUTE (NCI)

The NCI is the Federal Government's principal agency established to conduct and support cancer research, training, health information dissemination, and other related programs. As the effector of the National Cancer Program, the NCI supports a comprehensive approach to the problems of cancer through intensive investigation in the cause, diagnosis, prevention, early detection, and treatment of cancer, as well as the rehabilitation and continuing care of cancer patients and families of cancer patients. To speed the translation of research results into widespread application, the National Cancer Act of 1971 authorized a cancer control program to demonstrate and communicate to both the medical community and the general public the latest advances in cancer prevention and management. The NCI SBIR program acts as NCI's catalyst of innovation for developing and commercializing novel technologies and products to research, prevent, diagnose, and treat cancer.

Potential offerors should not exceed the budget set forth for the Topic(s), inclusive of all total costs (direct costs, facilities and administrative (F&A)/indirect costs, and fee).

Concept awards are intended to provide funds to perform a few key activities to demonstrate proof-of-concept and feasibility and lay the groundwork for future research and development. Phase I Concept Award contractors will be informed of the opportunity to apply for Phase II. Concept awards are not intended to support continuation of already established and advanced research programs. Thus, preliminary data is not required; however, the ideas should have sound scientific premise either based on the applicant's own research or literature evidence. These awards are focused on development of innovative products and technologies; thus, the anticipated product that will be developed should be identified and a development path should be clearly laid out.

NCI Topic(s)

This solicitation invites proposals in the following areas:

- **Topic 1:** Development of therapeutic or preventative technologies for treatment or prevention of **Pediatric Cancers and/or Rare Cancers.**

  For this solicitation rare cancers with a 5-year survival rate of less than 50% are encouraged**.**

- **Topic 2:** Development of devices, diagnostic technologies, or digital health tools for treatment, detection, and diagnosis of **Pediatric Cancers and/or Rare Cancers.**

  For this solicitation, rare cancers with a 5-year survival rate of less than 50% are encouraged.

- Fast track proposals will not be accepted.
- Direct-to-Phase II proposals will not be accepted.
- Non-exempt Human subjects research are not allowed.
- Budget (total costs, per award): Up to $300,000 for up to 12 months with an additional $6,500 for TABA if requested.

The NCI SBIR program encourages small businesses developing highly innovative and transformative technologies that have the potential to create new scientific paradigms, establish entirely new and improved approaches to significantly improve cancer research, prevention, detection, and care in pediatric and/or rare cancers to apply for the NCI SBIR Innovative Concept Award.

Summary

Background

About 9,550 children in the United States under the age of 15 will be diagnosed with cancer in 2025 (https://www.cancer.org/cancer/cancer-in-children/key-statistics.html). Cancer is the leading cause of death from disease in children ages 1 to 14 in the US after infancy.

Similarly, as a group, rare cancers are the leading cause of cancer deaths in the United States (https://rarecancer.org/). For the purposes of this solicitation, a rare cancer is defined in accordance with the U.S. Food and Drug Administration (FDA) Orphan Drug Act as a malignancy with a total U.S. prevalence of fewer than 200,000 individuals. Prevalence estimates should be supported by authoritative data sources (e.g., SEER) or where direct estimates are not available, by scientifically justified epidemiologic approximations based on published literature. This definition is intended to capture clinically and biologically relevant rare cancer populations that may not be fully represented in existing rare disease databases. Applications must clearly describe how the proposed technological approach has the potential to result in a meaningful improvement in patient survival and/or to address areas of significant unmet medical need where the current standard of care has demonstrated limited progress. Access the NCI Surveillance, Epidemiology, and End Results Program (SEER) database (https://seer.cancer.gov/) for more information regarding 5-year cancer survival rates.

Because of smaller patient populations and challenging development pathways, development of new technologies focused on pediatric and rare cancers lag significantly compared to other major cancers. Innovative and transformative solutions focused on prevention, diagnosis, detection, and treatment in both pediatric cancers and rare cancers are urgently needed. Rather than just the tried and tested approaches that have not led to much success and progress, bold and "out of the box" ideas that are still based on sound scientific premise are needed to make a significant impact in the prevention, diagnosis, treatment, and care of patients with pediatric and/or rare cancer. Thus, the NCI SBIR Development Center has developed the NCI SBIR Innovative Concept Award program to encourage the development of high-risk innovative and disruptive technologies.

The Concept Award program will provide funding to small businesses to explore the technical feasibility and demonstrate

proof of concept for the development of highly innovative therapies, devices, diagnostic tools, or preventive strategies focused on pediatric and rare cancers. The focus is on innovation and "out of the box" ideas that have not been tried and tested before. So, preliminary data is not required; however, proposed ideas should have sound scientific premise either based on the offeror's own research or referenced literature evidence. Offerors are eligible to apply if they have disruptive ideas based on sound scientific premise with a potential to make an impact in these cancers.

The goal of the funding is for offerors to generate de-risking technical data that provides key proof of concept validation. We also want the offerors to explore the commercial potential and development path of the technology during the award period. In addition to funding, the program will also provide additional business and commercialization resources including entrepreneurship training to explore and refine the business model and commercialization plan.

We expect that once the technology is de-risked and the offerors have gained some preliminary data, they will be more competitive for additional R&D funding.

Offerors must be Small Business Concerns, as defined in Section 3.2 Definitions, within this solicitation. However, National Cancer Institute recognizes that many innovations originate in universities and research institutions, and therefore we invite academic researchers working on translational technologies to consider applying either via setting up a small business or by partnering with an existing small business. Please refer to Sections 4.2 and 4.10 of this solicitation for requirements for collaborations and requirements for registrations and certifications. Since outstanding research is conducted at a broad spectrum of institutions, this Funding Opportunity Announcement encourages applications from researchers from all institutions.

Project Goals

The goal of this solicitation is to encourage small businesses to propose "out of the box" ideas to demonstrate "proof of concept" for the development of innovative technologies to make a transformative impact in prevention, diagnosis, treatment, and care of pediatric or rare cancer patients. To be considered innovative, projects must have the potential to transform the way research is conducted through the development of novel tools or technologies or lead to major improvements in pediatric and rare cancer care through the development of highly innovative therapies, diagnostic tools, or preventive strategies. Projects that primarily focus on optimization, hardening, or obvious extrapolations of established technology might be less competitive. For example, the following types of projects would **not** be considered innovative and would not be responsive:

- Therapeutics targeting genes and pathways with FDA-approved agents or agents in late clinical stage unless the novel approach mitigates known issues with approved agents
- Screening, diagnostic, and monitoring approaches already in clinical use
- Continuation of already funded SBIR/STTR projects

Proposals are encouraged for the development of innovative approaches focused on detection, prevention, and treatment of pediatric or rare cancers. The solicitation is agnostic to the type of technologies and modalities as long as they are highly innovative and reflect ideas substantially improved from current state of the art. Projects supported by this program should not be low risk, or incremental improvements to established technologies. These could include but not limited to novel therapeutics and prevention approaches, therapeutic devices, drug delivery approaches, and devices focused on early diagnosis, prognosis, and treatment response.

Proposals are solicited for all innovative ideas – **not limited to the ones above** – if they are focused on detection, prevention, and treatment of pediatric cancers or rare cancers. Projects are anticipated to have a high risk of failure with concomitant high reward. Commercial potential is evaluated by assuming the continued development of technology is successful, regardless of the inherent risk of the project.

The awards will support initial exploration of untested but potentially transformative ideas that may radically change the way we understand, prevent, diagnose, treat, and manage rare or pediatric cancers. These Concept Awards are intended to provide funds to perform key de-risking activities to demonstrate proof-of-concept and feasibility and lay the groundwork for future Federal funding opportunities. Concept awards are not intended to support continuation of already established and advanced research programs. Thus, preliminary data is **not required**; however, the ideas should have sound scientific premise either based on the offeror's own research or literature evidence. These awards are focused on development of innovative products and technologies; thus, the anticipated product that will be developed should be identified and a development path should be clearly laid out.

Activities and deliverables proposed by the offerors would differ based on their technology types and stage of development. However, the offerors should ensure that they clearly identify the clinical problem and cancer type(s) that the proposal will focus on with adequate justification. In addition, the offerors should propose experiments to obtain initial de-risking and proof-of-concept data and at the completion of the project present a report with the results of the experiments to the NCI. Examples of activities and deliverables that could be proposed include (but are not limited to) the following:

Therapeutic Projects: The offeror could propose most or all of these activities for pediatric or rare cancers.

- Target validation
- Optimized drug candidate screening
- Identification of lead and lead candidate optimization
- In vivo efficacy studies
- Preliminary PK/PD studies

Device Development Projects: The offeror could propose most or all of these activities for pediatric or rare cancers.

- Evaluation and justification of clinical need
- Product concept and protype development
- Early feasibility studies
- Phantom validation
- *In vivo* validation studies
- Software development (if needed)
- Biocompatibility, sterility, and safety studies

Diagnostics Development Projects: The offeror could propose most or all of these activities for pediatric or rare cancers.

- Biomarker optimization and qualification
- Assay development and optimization
- Define assay performance and analytic validation
- Sensitivity, specificity, and reproducibility
- Validation studies in deidentified clinical samples

12 ATTACHMENT(S) and APPENDICE(S)

ATTACHMENT(S)

ATTACHMENT 1 – TECHNICAL PROPOSAL FORM

Fillable PDF

APPENDICES

NIH BIOSKETCH

MS Word (https://grants.nih.gov/grants/forms/biosketch-blank-format-rev-10-2021.docx)

APPENDIX C — PRICING PROPOSAL

MS Word (http://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixC.docx)
PDF (http://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixC.pdf)

APPENDIX F — SUMMARY OF RELATED ACTIVITIES

MS Word (http://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixF.docx)
PDF (http://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixF.pdf)

APPENDIX H.1 — INSTRUCTIONS, HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

PDF (https://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixH.1.pdf)

APPENDIX H.2 — HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

Fillable PDF (https://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixH.2.pdf)

***Due to large file size, Appendix H.2 - Human Subjects and Clinical Trials Information Form, and Appendix H.3. – Study Record, can only be **opened** in Internet Explorer. However, you may **download** them from any browser, then view them once you have saved them onto your computer. ***

APPENDIX H.3. — STUDY RECORD, ATTACHMENT TO HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

Fillable PDF (https://grants.nih.gov/grants/funding/SBIRContract/ContractAppendixH.3.pdf)

***Due to large file size, Appendix H.2 - Human Subjects and Clinical Trials Information Form, and AppendixH.3. – Study Record, can only be **opened** in Internet Explorer. However, you may **download** them from any browser, then view them once you have saved them onto your computer. ***

DISCLAIMER: Reference to these software packages neither constitutes nor should be inferred to be an endorsement or recommendation of any product, service, or enterprise by the National Institutes of Health, any other agency of the United States Government, or any employee of the United States Government. No warranties are stated or implied.

APPENDIX J – Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries

All offerors must disclose all funded and unfunded relationships with foreign countries, using the Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries form (referred to as the "Disclosure Form" hereafter), for all owners and covered individuals. **Covered Individual Per NOT-OD-26-074,** Notice of Information: Policy Changes to SBIR and STTR Foreign Disclosure and Risk Management, released on April 20, 2026, a "Covered Individual" means an individual who –

A) Contributes in a substantive, meaningful way to the scientific development project proposed to be carried out with a research and development award from a Federal research agency; or

B) Is identified by the small business in the application as senior key personnel (i.e., individuals who contribute to the scientific development or execution of a project in a substantive, measurable way).

Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries – Post-Award Reporting Requirements

Contractors are responsible for monitoring their relationships with foreign countries of concern post-award, for any changes that may impact previous disclosures. SBCs receiving an award under the SBIR program are required to submit an updated Disclosure Form to report any of the following changes to NIH throughout the duration of the award:

- any change to a disclosure on the Disclosure Form;
- any material misstatement that poses a risk to national security; and
- any change of ownership, change to entity structure, or other substantial change in circumstances of the SBC that NIH determines poses a risk to national security.

Updated Disclosure Forms are required within 30 days of any change in ownership, entity structure, covered individual, or other substantive changes in circumstance, as described above.

If the contractor reports a covered foreign relationship that meets any of the risk criteria prohibiting funding described in this solicitation, NIH may withhold funding until the covered relationship has been dissolved. The contractor will be required to submit documentation verifying the relationship has been terminated. If the risk cannot be resolved, NIH may deem it necessary to terminate the award for material failure to comply with the federal statutes, regulations, or terms and conditions of the federal award. Contractors are encouraged to monitor their covered foreign relationships post-award and avoid entering into relationships, both funded and unfunded, that may pose a security risk and jeopardize their ability to retain their award.

Agency Recovery Authority and Repayment of Funds

An SBC will be required to repay all amounts received from NIH under the award if either of the following

determinations are made upon assessment of a change to their disclosure:

- the SBC makes a material misstatement that NIH determines poses a risk to national security; or
- there is a change in ownership, change in entity structure, or other substantial change in circumstances of the SBC that NIH determines poses a risk to national security.

The required Disclosure Form (in MS Word and PDF), including additional information and instructions on how to complete the form, can be found at the following url:
https://grants.nih.gov/grants/forms/all-forms-and-formats/required-disclosures-foreign-affiliations-or-relationships