Announcement of Requirements and Registration for the

National Heart, Lung, and Blood Institute (NHLBI)

Air You Wear Challenge

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Authority: 15 U.S.C. 3719

Billing Code: HHS-CAOD-2021-NHLBI-001

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DESCRIPTION

Subject of the Challenge

Over 1.5 million Americans are prescribed supplemental oxygen for use outside the hospital for a range of medical conditions. Although there are different options available for how outpatients receive supplemental oxygen, the issues associated with the therapeutic goals and optimal use of home oxygen continue to be considered and are not considered solved. Patients consistently express concerns around the following issues particularly: having an oxygen supply be lighter and more portable, making it last longer, and ensuring that they get the amount ("flow rate") that is needed.

To address these issues, the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH) is sponsoring the Air You Wear Challenge - a two phase challenge with a total prize purse of $500,000 to help teams with compelling

ideas to develop and demonstrate proof of concept for their innovative approaches for providing supplemental oxygen to outpatients, while promoting activity in the field and awareness of this problem to the wider community. The NHLBI is interested in providing more supplemental oxygen options to outpatients. Proposed approaches can be for new devices, modifications to existing technologies, or something else entirely.

The goal of this challenge is to broadly stimulate research and development of processes and technologies that actively address the different outpatient issues associated with use of supplemental oxygen. People who use supplemental oxygen and their loved ones are anxious for new options that are lighter, more portable, longer-lasting, and capable of providing the required oxygen level (flow-rate). If you have actionable ideas for how to improve the portability, flow rate, or duration of home oxygen supplies, the NHLBI wants to hear about them.

Dates

- Challenge launch — June 24, 2021
- Phase 1 competition period — June 24, 2021 - September 30, 2021
- Phase 1 submissions due — September 30, 2021
- Phase 1 judging — September - November 2021
- Phase 1 winner(s) announced — December 2021
- Phase 2 development period — February 2022 – September 14, 2022
- Phase 2 submissions due — September 14, 2022
- Phase 2 judging — September - November 2022
- Phase 2 winner(s) announced — November 2022

Statutory Authority to Conduct the Challenge

The general purpose of the NHLBI is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood

products and the management of blood resources (42 U.S.C. 285b). The mission of the NHLBI is to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives. In order to fulfill its mission, the NHLBI stimulates basic discoveries about the causes of disease, enables the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public. The NHLBI Strategic Vision specifically encompasses an objective to develop and optimize novel diagnostic and therapeutic strategies to prevent, treat, and cure heart, lung, blood, and sleep diseases. The NHLBI is conducting this Challenge under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Reauthorization Act of 2010, as amended [15 U.S.C. § 3719]. In line with these authorities, this Challenge will lead to innovation in outpatient supplemental oxygen use.

PRIZES

Amount of the Prize and Other Assistance

This two-phase challenge will award a total prize purse of $500,000. At the end of Phase 1, up to eight (8) finalists (whether an individual, team of individuals, or entity), proposing the most compelling and impactful solutions, will each receive $50,000. Only Phase 1 finalists will be invited to participate in Phase 2, and they are strongly encouraged to use their prize money to help develop a working prototype and/or demonstration of the proposed approach during the Phase 2 development period. At the end of Phase 2, up to three (3) winners will be awarded first, second, and third prizes of $60,000, $30,000, and $10,000 respectively for the best prototypes/demonstrations.

Phase 1 finalists will have equal access to subject matter experts during the Phase 2 development period to ensure that development work is well-aligned with patient needs. At the end of Phase 2, participants may be offered introductions or networking opportunities to help them get to the next stage of development. Phase 2 winners will also be recognized through a winners' webinar and announcement on the NHLBI website. Finally, as with all NIH funding applicants, all challenge participants can

receive NIH assistance in developing applications to compete for other NIH funding opportunities.

Award Approving Official

The Award Approving Official will be Gary H. Gibbons, M.D., Director of the National Heart, Lung, and Blood Institute (NHLBI).

Payment of the Prize

Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. If the Participants submit as a team, the prize will be awarded in one payment to the designated team leader. HHS/NIH will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, or any part of it, for any reason, and/or (b) not award any prizes if no entries are deemed worthy.

RULES

Eligibility Rules for Participating in the Challenge

(1) To be eligible to win a prize under this Challenge, a Participant (whether an individual, team of individuals, or entity)

a) Shall have registered to participate in the Challenge under the rules promulgated by the National Heart, Lung, and Blood Institute (NHLBI) as published in this announcement;
b) Shall have complied with all the requirements set forth in this announcement;
c) In the case of a private entity, shall be incorporated in the United States and also maintain a primary place of business in the United States. In the case of an individual, whether participating singly or in a group, shall be a citizen or

permanent resident of the United States. However, non-U.S. citizens and non-permanent residents can participate as members of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and non-permanent residents are not eligible to win monetary prizes (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced.

d) Shall not be a federal entity or federal employee acting within the scope of their employment.
e) Shall not be an employee of the Department of Health and Human Services (HHS), or any other component of HHS, acting in their personal capacity.
f) Shall, if employed by a federal agency or entity other than HHS or any component of HHS, consult with an agency ethics official to determine whether the federal ethics rules will limit or prohibit the acceptance of a prize under this Challenge.
g) Shall not be a judge of the Challenge, or any other party involved with the design, production, execution, or distribution of the Challenge, or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child).
h) Shall be at least 18 years old at the time of submission

(2) Federal grantees may not use federal funds from a grant award to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(3) Federal contractors may not use federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(4) Federal awardees may not use federal funds from an Other Transaction (OT) award to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(5) By participating in this Challenge, each Participant (whether an individual, team of individuals, or entity) agrees to assume any and all risks and waive claims against the federal government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct,

indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

(6) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no Participant (whether an individual, team of individuals, or entity) participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

(7) By participating in this Challenge, each Participant (whether an individual, team of individuals, or entity) agrees to indemnify the federal government against third party claims for damages arising from or related to Challenge activities.

(8) A Participant (whether an individual, team of individuals, or entity) shall not be deemed ineligible because the Participant used federal facilities or consulted with federal employees during the Challenge if the facilities and employees are made available to all Participants participating in the Challenge on an equitable basis.

(9) By participating in this Challenge, each Participant (whether an individual, team of individuals, or entity) warrants that he, she, or it is the sole author or owner of, or has the right to use, any copyrightable works that the submission comprises, that the works are wholly original with the Participant (or is an improved version of an existing work that the Participant has sufficient rights to use and improve), and that the submission does not infringe any copyright or any other rights of any third party of which the Participant is aware.

(10) By participating in this Challenge, each Participant (whether an individual, team of individuals, or entity) grants to the NIH an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly the contents of the following fields of the Participant's submission on the web or elsewhere. For Phase 1 participants: Eligibility, Project plan, Supplemental Information, and a summary prepared by NHLBI of the contents of the remaining submission fields.

For Phase 2 participants: the video if submitted; or if not submitted, then an NHLBI-prepared summary of the remaining submission fields. Participants will have the opportunity to review and approve all NHLBI-prepared summaries. Additionally, by participating in this Challenge, each Participant (whether an individual, team of individuals, or entity) grants to the NIH a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the submission throughout the world. Each Participant will retain all other intellectual property rights in their submission, as applicable. To participate in the Challenge, each Participant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of the Participant's rights to the federal government. Participants will *not* be required to transfer their intellectual property rights to NIH; however, by participating in this Challenge, Participants grant to the federal government the *nonexclusive licenses* recited herein.

(11) Each Participant (whether an individual, team of individuals, or entity) agrees to follow all applicable federal, state, and local laws, regulations, and policies.

(12) Each Participant (whether an individual, team of individuals, or entity) in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each Participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

JUDGING CRITERIA

Basis Upon Which Winners Will be Selected

Phase 1 of the NHLBI Air You Wear Challenge will select up to eight (8) finalists who will each be awarded a prize and then invited to participate in Phase 2 of the challenge. Phase 2 will then select up to three (3) winners who will be awarded a first, second, or third place prize. The submissions will be reviewed by federal employees serving as judges, who will select the winners, subject to a final decision by the Award Approving Official.

Basis Upon Which Submissions Will Be Evaluated

The criteria that will be used to score submissions and assist with the selection of the Phase 1 finalists and Phase 2 winners are provided below:

Phase 1 Judging Criteria

Criteria		**Description**	**Weight**	
Proposal Quality		Is the submission complete and responsive? Is the writing clear, concise, and compelling? Are the ideas and information presented thoughtfully and in an easy-to-follow manner?		5
Idea	Feasibility	Is the idea practical? How easy would it be to implement? What barriers, if any, might there be to widespread adoption among patients, prescribers, and suppliers?	20	55
	Impact	How impactful is this idea? Does it have potential for use in other applications?	20	
	Innovation	How creative is the overall idea? Does it attempt to solve the problem with a different approach or using different tools?	15	
Project Plan		Is the submitted project plan realistic, clear, and well-thought out? Does it identify the major hurdles that must be overcome for successful prototype development? Does the project plan clearly outline the activities and milestones that must occur in order to successfully demonstrate the prototype at the end of 30 weeks?		25
Team		Does the team have the necessary skills and expertise required to execute the project plan? Does the team have adequate access to resources and other experts, as needed?		15

Phase 2 Judging Criteria

Criteria	Description	Weight
Oxygen Delivery Capability	Does the approach deliver supplemental oxygen as intended? How well does the prototype or demonstration address the key issues of weight, portability, duration, and flow rate?	50
User adoption	Why will this technology enjoy widespread adoption of this approach? Form factor, etc.	15
Commercial Potential	What is the commercial potential for this approach? Are there any issues that would affect its widespread adoption? Does this technology have potential for use in other applications?	15
Next Steps	What are the next steps for further development of this technology? What are the likely major hurdles and how would they be addressed?	10
Creativity	Does the solution deliver supplemental oxygen in a new and different manner from existing approaches? Does the form factor or the solution overall present an elegant, new option to users? Did the team overcome any development hurdles in a creative, novel manner?	10

HOW TO ENTER

Registration Process

Interested competitors may locate an announcement of this challenge at challenge.gov which will forward them to the official challenge page at www.herox.com/AirYouWear. At the HeroX official challenge page, competitors may create a HeroX account and then click "Solve This Challenge" to complete their challenge registration. Once registered, competitors will use the HeroX platform and the Challenge Submission Form to complete and submit their proposed solution.

Registrations must be submitted on the challenge page, www.herox.com/AirYouWear, *by 5:00pm EST on September 30, 2021.*

Submission Requirements

Each submission for this challenge must be complete in order to be considered. If participants submit as a team or as an entity, they should identify a team leader who will serve as a point of contact and submit on behalf of the team. Only complete and correctly formatted submissions will be reviewed. Detailed instructions on the submission are listed below and also available on the challenge website at www.herox.com/AirYouWear.

Participants cannot use the logo or official seal of the Department of Health and Human Services (HHS); the National Institutes of Health (NIH); or the National Heart, Lung, and Blood Institute (NHLBI). Participants cannot claim federal government endorsement of their submissions.

All submissions must be submitted on the challenge page, www.herox.com/AirYouWear. *Submissions for Phase 1 are due by 5:00pm EST on September 30, 2021. Submissions for Phase 2 are due by 5:00pm EST on September 14, 2022.*

Submission Details

Phase 1 Submission Form

Field	Description	Format
Team	For each team member: please list their names, their roles/expertise, and their email addresses. Please note who is the team leader/primary point of contact.	Formatted text (3000 characters max)
Eligibility	Please confirm that you meet the eligibility requirements for this challenge:	Y/N
Overview	Please provide an overview of your proposed approach: • What is your idea and why will it work?	Formatted text

	• How will it improve the patient's experience? • How does your idea differ from current solutions to supplemental oxygen for outpatients?	(1500 characters max)
Feasibility	Please discuss the feasibility of your idea: • What is the supporting evidence or scientific rationale for it? • What do you estimate is the technical maturity of your approach? (is it something completely new, something based on pre-existing technology, or something else) • How practical is your idea and how easy will it be for patients to use? • Is this something that will cost about the same as existing solutions? • What are potential barriers to its widespread adoption?	Formatted text (6000 characters max)
Impact	Please discuss the potential impact of your proposed approach: • How will it address one or more of the major patient concerns regarding supplemental oxygen? (lightweight/portable, lasts longer, and delivers the needed flow rate) • Is there potential for this approach to be used in other related or adjacent applications?	Formatted text (6000 characters max)
Innovation	How is your proposed approach different from existing solutions? Does the proposed approach use a novel technology, an existing technology in a novel way, or something else?	Formatted text (3000 characters max)
Project Plan	Please provide a complete project plan, timeline, and supporting budget. If you are a Phase 1 winner, you will be expected to execute against your project plan. Be sure to address: • How you will be able to make a demonstrable prototype within the 30 week development period • What are the major milestones and what will be the biggest hurdle in successfully developing and demonstrating your technology. How are you planning to address this hurdle? • The resources and expertise that you will need to successfully develop your proposed approach. If there are resources and/or expertise needed that are currently not available to your team, how do you plan to address these gaps?	Formatted text (4500 characters max)

Supplemental Information	Please upload any supporting files, such as design files, team bios or CV's, etc.	Upload files

Phase 2 Submission Form

Field	Description	Format
Overview	Please provide an overview of Phase 2 development work: • What are the key findings/results? • How did your results meet your expectations? • What are your next steps?	Formatted text (2000 characters max)
Performance	Please discuss in detail how your technology works. Also, please share how your approach performed in terms of: • Oxygen delivery • Weight and portability • Duration of use • Flexibility for different patient needs	Formatted text (9000 characters max)
Usability	Please discuss the advantages your technology offers to patients. Are there potential barriers to widespread adoption by patients?	Formatted text (6000 characters max)
Commercial Potential	Discuss your technology's potential for commercial success. What do you foresee as possible hurdles to commercial development? Are there other applications where this technology might be used?	Formatted text (3000 characters max)
Next Steps	What are the next steps for further development of your technology? What additional resources will you need to support those next steps?	Formatted text (3000 characters max)
Creativity	Looking at your developed solution and the development process to arrive at this point, please discuss how your solution and process demonstrate creativity by addressing at least the following points: • How is your technology different from existing supplemental oxygen options? • Why will users view this as an attractive and new option?	Formatted text (2000 characters max)

	• If you ran into any unexpected development problems, do you believe you overcame them in unusual or innovative ways?	
Video - 1	Please provide the link to a video that shows your technology in action. Be sure to show both set-up and operation steps.	Link
Video - 2	This second video is optional. Please provide a link to a 30-90 second video that is suitable for general public viewing. NIH NHLBI is interested in having this content to be able to create montages or other assets that help build awareness of this issue and of other relevant activities in the space.	Link
Supplemental Information	Please upload any supporting files, such as design files, data sets, etc.	Upload files

ADDITIONAL INFORMATION

Supplementary Information

These academic resources have been provided to educate the competitors about the context of the challenge's targeted problem:

1. Optimizing Home Oxygen Therapy. An Official American Thoracic Society Workshop Report | Annals of the American Thoracic Society
    a. The report is also accessible at this separate link: Optimizing Home Oxygen Therapy. An Official American Thoracic Society Workshop Report
2. Burden and Unmet Needs with Portable Oxygen in Patients on Long Term Oxygen Therapy | Annals of the American Thoracic Society | Articles in Press

An additional element of this challenge is to promote further research and attention to the overarching field of supplemental oxygen for outpatients. To achieve this end, the challenge will promote other development opportunities, such as those afforded through Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) and the NHLBI Innovation Office. Participants will be encouraged to pursue some of these other opportunities and may receive NIH support in developing

applications to compete for other NIH funding opportunities. Links to these two organizations are available, respectively, below:

1. NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs
2. NHLBI Innovation Office

For Further Information Contact: NHLBI_Challenge@nhlbi.nih.gov

Gary H. Gibbons, M.D.

Director, National Heart, Lung, and Blood Institute

June 24, 2021

Date