

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Announcement of Requirements and Registration for “Shape of Health: An Obesity Prevention Game”

**AGENCY:** Office on Women’s Health, Office of the Assistant Secretary for Health, Department of Health and Human Services.

*Subject of Challenge Competition:* The Office on Women’s Health (OWH) is seeking new ways to get health messages out to women and girls. According to the CDC, two out of every three women in the United States are overweight or obese.<sup>1</sup> This extra weight can lead to many diseases, such as heart disease, diabetes, and many cancers. Obesity results from a combination of causes and contributing factors, including individual factors such as behavior and genetics. Some examples of behaviors that affect weight include diet, physical activity, inactivity, and stress. Improving behaviors in these areas can help women and girls maintain a healthy weight.

Furthermore, American children today are increasingly unhealthy at earlier ages. According to the 2014 National Health and Nutrition Examination Survey (NHANES), of girls ages 2–19, 16 percent were overweight and 17.1 percent were obese.<sup>2</sup> Many children and teens do not eat properly or exercise enough and as a result, childhood obesity and diabetes are increasingly prevalent. Children with obesity may experience immediate health consequences that can lead to weight-related health problems in adulthood. In addition to physical health problems, overweight and obese children can be targets of social discrimination that can lead to low self-esteem and hinder social and academic functioning.

Video games are a unique medium to boost knowledge and skills and can lead to behavior change through exploration of cause and effect in a virtual environment. According to a Robert Wood Johnson project called “Health Games Research,” it was found that digital games can be effective in improving children’s health in multiple health topics including physical fitness, health promotion, and disease management.<sup>3</sup> Additional evidence suggests adult learning and behavior change is also possible through gaming.

A study in *JMIR Serious Games* found that women with a higher baseline readiness to change experienced improvement in BMI and nutrition with game play.<sup>4</sup>

Your challenge with this competition is to create an interactive video game with focus on obesity prevention or weight control for women or girls. The game you create will be shared with the general public. The game must address an evidence-based obesity prevention or control strategy. You must show that the game is unlike currently available offerings. The game must be made publically available at no cost as either a web-based or mobile based game available on a widely accessible platform.

For more information about obesity prevention or control strategies and guidelines view the CDC’s resource here: <https://www.cdc.gov/obesity/resources/strategies-guidelines.html>.

The competition has three phases. All eligible submissions will be evaluated and separate prizes will be awarded for each of the three phases.

#### Registration Process for Participants

Participants will be able to register and submit a submission on [challenge.gov](https://challenge.gov). Participants can find out more information at <https://www.challenge.gov>. All submissions will be made through the [challenge.gov](https://www.challenge.gov) website.

*Dates:* Submissions will be accepted starting January 15, 2019. The submission period for Phase 1 will end on March 15, 2019. The Phase 2 (In-Person Presentation) submission period will be on a date TBD in 2019. The prize winners will be announced at the completion of each phase.

Entries not in compliance with the submission requirements outlined below will be ineligible for further review and prize award. During the open submission period, participants must submit the following information to enter the Shape of Health competition:

#### Phase 1 (Concept Development)

The first stage of the competition aims to attract a large range of ideas and game developers. The target submission of the first stage will be the conceptualization of the most promising and/or unique game to help support behavior change around physical activity and/or nutrition to prevent obesity in women

or girls. The submissions should aim to demonstrate that the proposed game will be accessible to the general public, developed from evidence-based prevention or control techniques, and engaging for women or girls.

The Phase 1 Submission shall include a comprehensive description of the proposed game in 5 pages or less, including:

1. A one-paragraph executive summary that clearly states how the game will target obesity prevention or control determinants and be developed for a women or girls audience;
2. Link evidence to support the obesity determinant chosen and the theoretical basis for the game (will your game change behavior? improve knowledge? something novel? etc.);
3. A descriptive overview of how the participant arrived at their idea, and why the approach is unlike anything already available;
4. A draft storyboard of the game that describes the game components; and
5. An assessment describing the participant’s ability to execute the proposed solution through Phase 2 and to completion.

Your Shape of Health competition concept submission must be uploaded in [challenge.gov](https://challenge.gov).

Participants may also choose to include additional determinants that contribute to obesity not discussed in the provided resources. If additional determinants are included, the participant should include a short description of how these determinants may contribute to obesity and how this game will address these determinants.

Up to 10 selections will be made in Phase 1 to continue on to Phase 2.

#### Phase 2 (In-Person Presentation)

Phase 2 of the competition builds upon the work of Phase 1 and is focused on prototyping the game, and providing an in-person presentation to a panel of judges. The participants should demonstrate both the evidence base for the intervention and its viability.

The in-person presentation must include a description of how the following components are incorporated into the game:

- Relates to women or girls;
- Targets a determinant of obesity;
- and
- Engages the player

Selected participants must build out the storyboard submitted in Phase 1 to become a visual presentation of game play. The visual presentation of game play must be recorded into a video and available through a private YouTube link. OWH expects that the participants provide an in-person presentation,

<sup>1</sup> <https://www.cdc.gov/nchs/fastats/obesity-overweight.htm>

<sup>2</sup> <https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity>.

<sup>3</sup> <http://healthgamesresearch.org/our-publications/research-briefs/Game-Changer>.

<sup>4</sup> Shiyko, M., Hallinan, S., Seif El-Nasr, M., Subramanian, S., & Castaneda-Sceppa, C. (2016). Effects of Playing a Serious Computer Game on Body Mass Index and Nutrition Knowledge in Women. *JMIR Serious Games*, 4(1), e8. <http://doi.org/10.2196/games.4977>.

which includes a demonstration of the recorded presentation of game play.

Submissions must be free of security threats and/or malware. Participants agree that HHS may conduct testing on the submission to determine whether malware or other security threats may be present. HHS may disqualify the submission if, in HHS' judgment, the software may damage government or others' equipment or operating environment or if the game, in HHS' judgment, is inconsistent with HHS' public health mission, utilizes software or other technologies without appropriate licenses, or any other reason deemed necessary.

The expectation is that each team will use the prize money from Phase 1 for at least one person to travel to Washington, DC to deliver the in-person presentation.

Up to 2 selections will be made in Phase 2 to continue on to Phase 3

### Phase 3 (Final Development)

Phase 3 builds upon the work of Phase 2 and is focused on the final development of the proposed game and making it available to the general public. Entrants are required to ensure that proper obesity prevention or control determinants are included in the final game. Participants are encouraged to discuss the proper obesity prevention or control determinants with OWH in order to make sure that they are included in the final game.

*Basis upon Which Winners Will Be Selected:* A panel composed of subject-matter experts will judge eligible Shape of Health competition entries. The panel will make winner selections based upon the criteria outlined below and in compliance with the *HHS Competition Judging Guidelines*.

One winner may be selected from each category (1 women's health and 1 girls' health).

### Phase 1 Scoring Criteria

All Criteria are scaled 1–5, with 1 being the lowest score on each dimension and 5 being the highest score on each dimension. Scores are weighted by the proportion of each dimension and then aggregated to create a final score.

1. Viability of storyboard (30%)
  - 1 = Storyboard is not likely to be developed into a working game/5= Storyboard is likely to be able to developed into a working game
2. Application of research (20%)
  - 1 = Storyboard does not address evidence-based obesity prevention or control determinants/5 = Storyboard addresses evidence-based obesity prevention or control

- determinants
3. Relevancy of storyboard (20%)
  - 1 = Storyboard does not address obesity from a women/girls' health perspective/5 = Storyboard addresses obesity from a women/girls' health perspective
4. Originality of storyboard (15%)
  - 1 = Storyboard does not take a novel approach/5 = Storyboard takes a novel approach
5. Likelihood of adoption (15%)
  - 1 = Proposed game is not likely to be used by women/girls/5 = Proposed game is likely to be used by women/girls.

### Phase 2 Scoring Criteria

All Criteria are scaled 1–5, with 1 being the lowest score on each dimension and 5 being the highest score on each dimension. Scores are weighted by the proportion of each dimension and then aggregated to create a final score. Judging criteria for Phase 2 include:

1. Viability of game (30%)
  - 1 = Demo is not likely to be developed into a working game/5= Demo is likely to be developed into a working game
2. Application of research (20%)
  - 1 = Game does not address evidence-based obesity prevention or control determinants/5 = Game addresses evidence-based obesity prevention or control determinants
3. Relevancy of game (20%)
  - 1 = Game does not address obesity from an women/girls' health perspective/5 = Game addresses obesity from a women/girls' health perspective
4. Originality of game (15%)
  - 1 = Game does not take a novel approach/5 = Game takes a novel approach/35. Likelihood of adoption (15%)
    - 1 = Game is not likely to be used by women/girls/5 = Game is likely to be used by women/girls

### Phase 3 Scoring Criteria (Pass/Fail)

The final prize money will be provided when the game:

- Is complete;
- includes the proper obesity prevention or control determinants; and
- is available to the general public on a widely accessible platform.

### Amount of the Prize

- In Phase 1 (Concept Development), participants will compete for a \$20,000 prize pot from which up to 10 submissions may be selected to receive a \$2,000 prize each.
- In Phase 2 (In-person Demo), the 10 participants from Phase 1 will compete

for a \$70,000 prize pot. The following prizes may be awarded:

- Two First Place winners of \$20,000 (one girls' health, one women's health)
- Two Second Place winners of \$10,000 (one girls' health, one women's health)
- Two Third Place winners of \$5,000 (one girls' health, one women's health)
- In Phase 3 the First Place winners from Phase 2 may each be awarded an additional \$55,000.
- All winners will be notified via email.

*Eligibility Rules for Participating in the Competition:* To be eligible to win a prize under this competition, an individual, group, or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by HHS;

(2) Shall have complied with all the requirements under this section;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States;

(4) May not be a Federal entity or Federal employee acting within the scope of their employment (all non-HHS Federal employees must consult with their agency Ethics Official to determine whether the Federal ethics rules will limit or prohibit the acceptance of a COMPETES Act prize);

(5) Shall not be a Federal employee working on their applications or submissions during assigned duty hours;

(6) May not be an HHS employee;

(7) May not be any other individual or entity associated with the development, evaluation, or administration of the Shape of Health competition or members of such persons' immediate families (spouses, children, siblings, parents), and persons living in the same household as such persons, whether or not related;

(8) A Federal grantee may not use Federal funds to develop submissions unless consistent with the purpose of their grant award;

(9) A Federal contractor may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission;

(10) Must be an individual or team comprised only of members 18 years of age or older;

(11) Shall not be deemed ineligible because the individual or entity used federal facilities or consulted with

federal employees during a competition if the facilities and employees are made equitably available to all individuals and entities participating in the competition;

(12) Must provide a statement agreeing to indemnify the federal government against third party claims for damages arising from or related to competition activities;

(13) Must provide a statement agreeing to assume 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 prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

(14) HHS has hereby waived the requirement for participants to obtain liability insurance in a specified amount for this competition. Participants are advised to consult with appropriate advisors to determine what amounts of insurance may be necessary for their own liability protection.

(15) Shall not be currently on the Excluded Parties List (<https://www.epls.gov>).

#### Additional Requirements

Entrants shall not use the OWH or HHS logos or official seals in their submissions, and must not claim endorsement.

HHS reserves the right to cancel, suspend, and/or modify the Shape of Health competition, or any part of it, for any reason, at HHS' sole discretion.

**Payment of the Prize:** Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

#### Intellectual Property (IP)

- Each entrant retains full ownership and title in and to their submission. Entrants expressly reserve all intellectual property rights not expressly granted under this publication notice.

- By participating in the competition, each entrant hereby irrevocably grants to HHS a limited, non-exclusive, royalty-free, worldwide license and right to reproduce, publically perform, publically display, and use the submission for internal HHS business and to the extent necessary to administer the competition, and to publically perform and publically display the submission, including,

without limitation, for advertising and promotional purposes relating to the competition.

- Record Retention and FOIA:** All materials submitted to HHS as part of a submission become HHS records and cannot be returned. Any confidential commercial information contained in a submission should be designated at the time of submission. Participants will be notified of any Freedom of Information Act requests for their submissions in accordance with 45 CFR 5.65.

#### SUPPLEMENTARY INFORMATION:

Information on obesity prevention and control in women and girls can be found at:

<https://www.cdc.gov/obesity/resources/strategies-guidelines.html>

<https://www.womenshealth.gov/a-z-topics/overweight-obesity-and-weight-loss>

<https://www.girlshealth.gov/nutrition/healthyweight/>

Details on the Shape of Health competition may be found at [challenge.gov](http://challenge.gov).

**FOR FURTHER INFORMATION CONTACT:** Ann Abercrombie at [Ann.Abercrombie@hhs.gov](mailto:Ann.Abercrombie@hhs.gov).

Dated: November 28, 2018.

**Brett Giroir,**

ADM, Assistant Secretary for Health.

[FR Doc. 2018-27653 Filed 12-20-18; 8:45 am]

**BILLING CODE 4150-33-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of an Exclusive Patent License: "Multifunctional RNA Nanoparticles and Methods of Uses" and "RNA/DNA Hybrid Nanoparticles Modified With Single Stranded RNA Toeholds and Uses Thereof"

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patent Applications listed in the Supplementary Information section of this notice to Sixfold Biosciences Inc., ("Sixfold") of Walnut, California.

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before January 7, 2019 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jasmine Yang, Sr. Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 Email: [jasmine.yang@nih.gov](mailto:jasmine.yang@nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Intellectual Property

##### A. Multifunctional RNA Nanoparticles and Methods of Uses

1. U.S. Provisional Patent Application (Application No. 61/878,758) filed September 17, 2013, HHS Reference No.: E-765-2013-0-US-01
2. PCT Application (Application No. PCT/US2014/056007) filed September 17, 2014, HHS Reference No.: E-765-2013-0-US-02
3. European Patent Application (Application No. 14780963.6) filed September 17, 2014, HHS Reference No.: E-765-2013-0-EP-03
4. Australian Patent Application (Application No. 2014321443) filed September 17, 2014, HHS Reference No.: E-765-2013-0-AU-04
5. Canadian Patent Application (Application No. 2,924,509) filed September 17, 2014, HHS Reference No.: E-765-2013-0-CA-05
6. Japanese. Patent Application (Application No. 2016-543964) filed September 17, 2014, HHS Reference No.: E-765-2013-0-JP-05
7. US Patent Application (Application No. 15/022,530) filed March 16, 2016, HHS Reference No.: E-765-2013-0-US-07

##### B. RNA/DNA Hybrid Nanoparticles Modified with Single Stranded RNA Toeholds and Uses Thereof

1. U.S. Provisional Patent Application (Application No. 62/294,848) filed February 12, 2016, HHS Reference No.: E-078-2016-0-US-01
2. PCT Application (Application No. PCT/US2017/017661) filed February 13, 2017, HHS Reference No.: E-078-2016-0-US-02
3. US Patent Application (Application No. 16/076,878) filed August 9, 2018, HHS Reference No.: E-078-2016-0-US-03
4. European Patent Application (Application No. 17706653.7) filed September 12, 2018, HHS Reference No.: E-078-2016-0-EP-04

The patent rights in these inventions have been assigned and/or exclusively