

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary of Health (OASH)

Announcement of Requirements and Registration for ‘KidneyX: Artificial Kidney Prize Phase Two’

Authority: 15 U.S.C. 3719

The Kidney Innovation Accelerator (KidneyX) is a partnership between the U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN). KidneyX is launching the Artificial Kidney Prize to radically improve treatment options for people with kidney disease who may eventually require renal replacement therapy. Working together, HHS and ASN are executing a series of prize competitions to incentivize a wide variety of stakeholders (including to individuals, communities, businesses, institutions, and non-profit organizations) to develop innovative solutions to prevent, diagnose, and/or treat kidney diseases. KidneyX seeks to improve the lives of people with kidney diseases by expediting the development of drugs, devices, biological products, and other therapies across the spectrum of kidney care, from prevention to diagnosis to treatment.

To date, KidneyX has completed five prize competitions that have awarded prizes to over 65 innovators across the world. Through this announcement, HHS and ASN are announcing KidneyX’s prize competition, “KidneyX: Artificial Kidney Prize Phase 2” (referred to herein as “the Competition”). In this competition, cash prizes will be offered to increase the number of innovators with diverse expertise addressing critical issues in kidney health. Every KidneyX prize competition will define a technology need that would improve kidney care, without a pre-conceived notion of what the solutions should be, and ask entrants to find solutions. For these competitions, we encourage applicants -- think better, think bold, think big.

The Artificial Kidney Prize is built on the foundational belief that innovators from a range of backgrounds must bring multidisciplinary expertise and collaborations to develop solutions that replicate kidney function and improve the lives of people with kidney diseases, their families, and care partners.

This prize competition is being run under the authority of section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), as added by the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358). HHS and ASN reserve the right to change or update this announcement at any time.

Dates for the Artificial Kidney Prize Phase 2

Track One Submission period begins: August 11, 2022

Track One Submission period ends: October 28, 2022, at 4:59 p.m. EDT

Track Two Submission period begins: August 11, 2022

Track Two Submission period ends: January 28, 2023, at 4:59 p.m. EDT

Sections of this announcement:

- A. Background
- B. Subject of the Prize Competition
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- D. Registration and Submission Requirements
- E. Eligibility, Evaluation Criteria, and Judging
- F. Additional Competition Rules, Terms, and Conditions

A. Background

The kidney maintains homeostasis through physiological functions that include filtration of bloodstream, reabsorption of nutrients and water, regulation of pH, concentration of electrolytes, hormone production, and secretion of waste products. Given significant scientific advances that could supplement kidney health, such as adjustments in lifestyle and nutrition, pharmaceuticals, and other interventions that could mitigate many of the lost functions associated with kidney failure, even if an artificial kidney, xenotransplant, or other type of wearable/implantable kidney does not address all of the natural kidney functions, it may still offer a life-saving and life-enhancing solution. However, innovation will be challenging; an artificial kidney would ideally include the various and essential different cell types that mediate the physiological functions of the kidney such as volume regulation and waste secretion and excretion, all seamlessly integrated to maintain homeostasis and being necessary for life.

There are thirty-seven million Americans and more than 850 million people worldwide living with kidney diseases. Current treatment methods have not changed significantly in more than 60 years and cost more than \$100 billion per year in the United States, alone.

Innovation is urgently needed with 22 patients dying each day while awaiting kidney transplant and a 50% mortality rate within the first five years of treatment for dialysis patients. People living with kidney diseases that have advanced to end-stage require kidney replacement therapies, either as bridges to transplantation or lifelong solutions, that increase survival and improve quality of life.

B. Subject of the Prize Competition

This Artificial Kidney Prize builds on the past KidneyX Artificial Kidney Prize competition (phase 1) but is distinct in its goal to accelerate the development of continuous kidney replacement therapies as transformational treatment options beyond current dialysis methods. For phase 2, artificial kidneys may be considered as wearable or implantable constructs as options for kidney replacement therapy. Xenotransplants, including chimera, or other non-human organ platforms, may also be considered.

This Competition solicits submissions that support innovations in regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology to either advance the development of an artificial kidney prototype or create enabling tools or components that address critical challenges for developing an artificial kidney platform. Each submission will address one of the two tracks included in this competition:

Track One (*Accelerating the prototype of a wearable or implantable artificial kidney or xenotransplant*): The development of a prototype bioartificial kidney derived solely from innovations in regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology, or,

Track Two (*Tools or Components that enable the development of an artificial kidney*): The development of enabling tools or components derived solely from innovations in regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology that accelerate the development of any artificial kidney or xenotransplantation platforms.

With the Artificial Kidney Prize, HHS and ASN intend to stimulate the market for further kidney health innovation, drawing greater participation and capital.

Entrants to **Track One (*Accelerating the prototype of a wearable or implantable artificial kidney or xenotransplant*)** must describe the application of innovations in regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology in the development of a prototype bioartificial kidney. Applicants must link achievement of future objectives described in the submission to progression of a prototype along a pathway and timeline towards first-in-human studies. Applicants must also describe how people with lived experiences of kidney disease have or will provide input in the design and/or evaluation of a prototype.

Entrants to **Track Two (*Tools or Components that enable the development of an artificial kidney*)**, must clearly describe how their tools or components adapt innovations from the regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology communities to solve a specific challenge for developing xenotransplanted, bioartificial, biomechanical, and/or other implantable or wearable platforms for kidney replacement therapy. These could include tools or components that optimize efficiency and scalability of regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology methodology to enable development of an artificial kidney platform, such as applications of artificial intelligence, machine learning, gene editing, and gene circuits. Scientists and innovators who work outside the kidney space and have innovations that can be applied to overcoming the barriers for developing an artificial kidney, are particularly welcome.

Entrants to either Track of the Competition are recommended to consider the Kidney Health Initiative's *Technology Roadmap for Innovative Approaches to Renal Replacement Therapy* (https://www.asn-online.org/g/blast/files/KHI_RRT_Roadmap1.0_FINAL_102318_web.pdf), which describes examples of kidney functions and components that regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology approaches could address to realize a kidney replacement, including:

- Fully integrated wearable or implantable artificial kidney platforms.
- Access that connects an artificial kidney platform to the blood circuit.
- Biological and immunological modulation that supports non-immunogenicity and functionality of an artificial kidney platform.
- Continuous monitoring of an artificial kidney platform to assess reliability and safety.
- Filtrate transport and drainage of an artificial kidney to remove excess filtrate after processing.
- Connectivity for filtration, processing, and exterior drainage of an artificial kidney.
- Solutions that manufacture the minimal cohort of cells necessary for an artificial kidney with scalable production.
- Xenotransplants.

Entrants to Track Two of the Competition are encouraged to address one or more of these aspects, as well as describe other solutions, with a clear pathway for integration into an artificial kidney platform.

For both Tracks, eligibility is limited to solutions that support development of an artificial kidney with the rationale clearly described in the submission.

C. Prize Competition Structure

Phase 1 and Phase 2 of the Artificial Kidney Prize may award up to \$14,400,000. In Phase 1, HHS distributed \$3,900,000 in prizes across six (6) winners.

In Phase 2, HHS may award up to \$8,000,000 in prizes. In Phase 2, ASN may award up to \$2,500,000 in prizes.

For Phase 2, KidneyX will select up to nine (9) winners total, which includes up to three (3) winners for Track One and up to six (6) winners for Track Two.

For Track One, up to three (3) winners will each receive an equal share of: up to \$3,000,000 from HHS and up to \$1,500,000 from ASN.

For Track Two, up to six (6) winners will each receive an equal share of: up to \$5,000,000 from HHS and up to \$1,000,000 from ASN.

Artificial Kidney Prize Phase 2

Artificial Kidney Prize Phase 2 (referred to herein as “the Competition”) solicits innovative applications of regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology in (1) either the development of a prototype bioartificial kidney (Track One) or (2) in the development of enabling tools or components that accelerate the development of artificial kidney platforms (Track Two). This Competition is open to past Artificial Kidney Prize Phase 1 entrants and prize winners, as well as any other entrants who meet the eligibility requirements defined in Sections E and F of this announcement. In their submissions, entrants are asked to provide justification for their approach, and to include potential partners or collaborators that would enable artificial kidney development.

Entrants’ solutions to Track One of the Competition, *Accelerating the prototype of a bioartificial kidney*, should include clear descriptions of their development plans for a prototype bioartificial kidney, including a pathway and future timeline towards first-in-human studies. Submissions could be supported by pre-clinical (bench or animal) or clinical data demonstrating the potential of the approach to support the reliability, effectiveness and functionality of a wearable or implantable bioartificial kidney.

Entrants’ solutions to Track Two of the Competition, *Tools or Components that enable the development of an artificial kidney*, should include clear descriptions of the challenge and barrier faced by artificial kidney developers. This should focus the rationale and data that support the application of a regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology-based solution as tools or components that enables development of an artificial kidney platform.

Winners will be recommended by the judges according to the evaluation criteria defined in Section E of this announcement. At the discretion of ASN and HHS, KidneyX will select up to nine (9) winners: up to three (3) in Track One and up to six (6) winners in Track Two as specified in Section C: Prize Competition Structure in this document. Technical support for the Competition winners will also include a range of informational resources to encourage and facilitate collaboration, navigate regulatory and commercial considerations, and incorporate patient input into solution development.

As part of their submission, Competition entrants agree to have brief synopses or abstracts of their submissions published by the KidneyX partnership.

D. Registration and Submission Requirements

“To be eligible to win a cash prize purse under this section, an individual or entity -- (1) shall have registered to participate in the prize competition under any rules promulgated by the head of an agency.” 15 U.S.C. § 3719(g)(1). To participate in the Competition, entrants must:

1. Register for the competition.
2. Enter a submission on the Competition website;
3. Comply with all requirements in this announcement and on the Competition website;
4. Provide affirmation upon submission to the Competition that the entrant is eligible under the Eligibility section below;
5. Each entrant (whether an individual, group of individuals, or entity) agrees to:
 1. Assume any and all risks and waive claims against the Federal government, its related entities (as defined in the America COMPETES Reauthorization Act, as amended), and ASN; 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 Competition, whether the injury, death, damage, or loss arises through negligence or otherwise;
 2. Indemnify the Federal government and ASN against third-party claims for damages arising from, or related to, Competition activities, patents, copyrights, and trademark infringements; and
 3. Comply with and abide by the official rules, terms, and conditions noted in this announcement and on the Competition website, as well as the decisions of HHS and ASN which shall be final and binding in all respects.

Registration requirements

“To be eligible to win a cash prize purse under this section, an individual or entity -- (1) shall have registered to participate in the prize competition under any rules promulgated by the head of an agency.” 15 U.S.C. § 3719(g)(1). Registration is required to participate in the competition. Registration must be completed prior to submission.

Registration and contact information

- Team, entity, or individual name
- Team lead (Team, entity, or individual lead and primary contact)
Name, Email, Phone Number, Affiliation
- Additional team members
Name Email, Phone Number, Affiliation

Registration information should be submitted to the KidneyX website at <https://www.kidneyx.org/akp>. This will submit a copy via e-mail to: kidneyx@asn-online.org and kristen.honey@hhs.gov.

Submission requirements

Submission Track One: Accelerating the prototype of a bioartificial kidney

- Abstract
 - **Submission title.** Provide the title of your submission. (10 words maximum)
 - **Submission headline.** Provide a one-sentence “elevator pitch” description summarizing your solution. (15 words maximum)

- **Technical abstract.** Summarize how your bioartificial kidney solution applies regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology innovations and how future objectives in the submission advance progress of the prototype towards first-in-human trials, in a way that is accessible for non-scientific readers. (500 words maximum)
- **Team description.** Describe how your team uses the expertise of each member, including details of past and current collaborations between members, in a way that is accessible for non-scientific readers. (300 words maximum)
- **Documentation**
 - **Functionality replication:** Scientific or technical justification that the prototype bioartificial kidney will safely and continuously replicate one or more kidney functions. (See Section B for an example list of kidney functions)
 - Examples**
 - Clear description of kidney functions that the solution addresses.
 - Design and performance targets of each functional areas that the solution addresses.
 - Rationale that the work described in the submission will achieve or advance performance towards relevant functional areas.
 - Timelines for achieving milestones.
 - **Integration of patient preferences, perspectives, and considerations:** The degree to which people with kidney diseases or their care partners have provided and/or will provide feedback into the design and evaluation of the prototype.
 - **Development pathway of a bioartificial kidney:** The degree to which the work described in the submission aligns with bioartificial kidney development milestones. Entrants should include plans that further develop their prototype beyond the work described in the submission with future milestones, timelines, and decision criteria that lead to animal and first-in-human studies, including collaborations with additional expertise.
 - **Development progress and plan:** The degree of progress achieved to-date with supporting data, relative to funding received.
 - **Team Science/collaboration:** The degree of confidence in the team to develop a prototype bioartificial kidney, including complementarity of the individual expertise within the team and level-of-effort needed to successfully execute the plan described in the submission.

Submission Track Two: Components and tools that enable the development of an artificial kidney

- **Abstract**
 - **Submission title.** Provide the title of your submission. (10 words maximum)
 - **Submission headline.** Provide a one-sentence “elevator pitch” description summarizing your solution. (15 words maximum)
 - **Technical abstract.** Summarize how the enabling tools or components applies regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology innovations in a manner that solves a specific challenge for developing artificial kidney platforms, in a way that is accessible for non-scientific readers. (500 words maximum)

- **Team description.** Describe how your team uses the expertise of each member, including details of past and current collaborations between members, in a way that is accessible for non-scientific readers. (300 words maximum)
- Documentation
 - **Catalyzing the development to a bioartificial kidney:** The justification that the tools or components described in the submission applies regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology as a discrete solution to a specific challenge and enables development of an artificial kidney platform, beyond established scientific methods and technology. Entrants should include plans to collaborate with other innovators and experts for further integration into the development an artificial kidney platform.
 - **Proof of concept:** The likelihood that the application of regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or synthetic biology innovations towards the development of tools or components will address specific challenges and enable the development of an artificial kidney platform.
 - **Team Science and collaboration:** Complementarity of the individual expertise within the team to develop the enabling tools or components, including level-of-effort needed to successfully execute the plan described in the submission.

Documentation should be a maximum of 10 pages; however, additional content may be included in an appendix. The appendix is not guaranteed to receive review by the judging panel but may provide helpful context or clarification. Documentation should be submitted as a PDF and formatted with 1-inch margins (2.5 cm), using Times New Roman font with minimum 12-point size for prose, and 10-point font for tables and charts.

Submissions must be received during the open submissions period of the Competition in order to be eligible.

Once submitted, a submission may not be altered during the open submissions period.

Upon submission, entrants will be asked to affirm they have read, understand, and fully agree to the Competition Rules, Terms, and Conditions.

E. Eligibility, Evaluation Criteria, and Judging

Eligible entrant profile

The Artificial Kidney Prize Phase Two is open to both U.S. and international entrants. To be eligible to receive any monetary prizes, entrants (whether an individual, group of individuals, or an entity), must register for the Competition and designate an individual or entity as the official entrant. Pursuant to section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), as added by the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358), to be eligible to receive monetary prizes awarded by HHS, in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States, and in the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States. An entrant that is a non-U.S. citizen, non-permanent resident, or non-U.S.-incorporated entities or places of business may be eligible to receive certain monetary prizes awarded by ASN, at the discretion of ASN and provided the entrant meets all other requirements as stated in the additional Competition rules, terms, and conditions.

While it is the desire of ASN and HHS that entrants from all over the world be able to participate in the Competition, ASN and HHS reserve the right to exclude from participating or from winning, citizens of any nation that prohibits or restricts the Competition from proceeding as set forth herein, or that imposes requirements, including, without limitation, registration or bonding of the Competition, or translation of the Official Rules, Terms, and Conditions. Monetary prizes will be awarded to the extent allowed under U.S. law, including U.S. trade and economic sanctions and U.S. government restrictions on dealing with specified parties. In particular, entrants are not eligible to receive any monetary or nonmonetary prize in the Competition if they are a resident or entity designated by the United States Treasury's Office of Foreign Assets Control (see <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> for additional information). Complete eligibility requirements are noted in Section F below.

Evaluation criteria and judging

A multi-disciplinary judging panel will evaluate eligible submissions; depending on the volume of submissions received, an expert panel may conduct an initial review of eligible submissions and determine a sub-set for judge evaluation. Based on their evaluation, the judging panel will recommend winners; the HHS Award Approving Official will approve the winners of the HHS prize money, while an ASN representative will approve the winners of the ASN prize money.

The HHS Award Approving Official will be RADM Michael Iademarco, Deputy Assistant Secretary for Health (Science and Medicine).

Submissions will be evaluated using the following four (4) criteria for Track One, Accelerating the prototype of a bioartificial kidney:

1. **Functionality replication:** The degree to which patient input has framed the targeted functions and design of the prototype. The degree of confidence that the plans for bioartificial kidney prototype will achieve critical kidney functions safely and continuously. See [2018 Kidney Health Initiative RRT roadmap](#) for examples of kidney functionality.
2. **Level of innovation:** The degree to which the submission demonstrates a novel adaptation of regenerative medicine, cellular engineering, systems biology, and/or synthetic biology in the development of a prototype bioartificial kidney.

3. **Preliminary proof of concept:** The likelihood that future objectives are achievable in advancing a prototype of a bioartificial kidney towards animal studies, first-in-human studies, and/or clinical trials.
4. **Development progress and plan:** The amount of progress completed relative to funding received, the rigor of plans, and the confidence in the team to execute. The degree of patient engagement in the design and/or evaluation of a prototype. Plans that describe the work needed beyond the submission should include future critical milestones, timelines, and collaborations to achieve animal studies, first-in-human studies, and clinical trials.

Submissions will be evaluated using the following four (4) criteria for Track Two, Components and tools that enable the development of an artificial kidney:

1. **Tool utility:** The degree of justification and confidence that the enabling tool or component(s) address a critical challenge in the development of an artificial kidney platform. See [2018 Kidney Health Initiative RRT roadmap](#) for examples of kidney functionality.
2. **Level of innovation:** The degree to which the submission identifies a barrier in the development of an artificial kidney platform and describes how an enabling tool can be created through an adaptation of regenerative medicine, cellular engineering, systems biology, and/or synthetic biology, beyond established scientific methods and technology.
3. **Preliminary proof of concept:** The likelihood of success that the application of regenerative medicine, cellular engineering, systems biology, and/or synthetic biology concepts towards the development of an enabling tool or component can be created to address a challenge in developing an artificial kidney platform.
4. **Development progress and plan:** The amount of progress completed relative to funding received, the rigor of plans, and the confidence in the team to execute. Plans that describe the work needed beyond the submission include future critical milestones and collaborations.

To achieve KidneyX programmatic goals, ASN and HHS may consider the breadth of solution types when selecting winners from the top-scoring submissions recommended by the judging panel.

F. Additional Competition Rules, Terms, and Conditions

Pursuant to section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3719), as added by the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358):

1. The Competition is open to all legal entities and individuals (non-felons) over the age of 18, subject to the additional eligibility requirements listed below. Eligibility is subject to verification by HHS and ASN before monetary prizes are awarded.
2. An individual or entity shall have registered to participate in the Competition under the rules promulgated by HHS and ASN in this announcement. Entrants shall have complied with all of the requirements in this announcement.
3. Entrants are not eligible to receive any monetary or non-monetary prize in the Competition if they are a person or entity designated or sanctioned by the United States Treasury's Office of Foreign Assets Control (see <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> for additional information).
4. Note on awards: Monetary prizes provided by ASN for the Competition will be awarded separately from HHS monetary prizes. Please refer to the "Prize Competition Structure" section of these Rules, Terms, and Conditions for additional information on HHS and ASN prizes.
 - a. *HHS monetary prizes*: To be eligible to win prize money from HHS under the Competition, a private entity shall be incorporated in and maintain a primary place of business in the United States; and an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States. **Note:** Non-U.S. citizens and nonpermanent residents can participate as a member of a team that otherwise satisfies the eligibility criteria. Non-U.S. citizens and non-permanent residents are not eligible to win a monetary prize (in whole or in part) from HHS. Their participation as part of a winning team, if applicable, may be recognized when the results are announced.
 - b. *ASN monetary prizes*: At the discretion of ASN, non-U.S. citizens, non-permanent residents, or non-U.S. incorporated entities or places of business, may be eligible to receive certain monetary prizes awarded by ASN under the Competition.
5. HHS and ASN employees directly supporting the development or execution of the Competition, support contractors directly supporting the Competition, reviewers, and judges are ineligible to compete in this Competition. Likewise, members of their immediate family (spouses, children, step-children, siblings, step-siblings, parents, step-parents), and persons living in the same household, whether or not related, are not eligible to participate in any portion of this Competition. Note: The members of an individual's household include any other person who shares the same residence as such individual for at least three months out of the year.
6. Individuals and entities, otherwise eligible to win a monetary or non-monetary prize, may form and submit a team entry; however, each team member must be clearly identified in the team's submission form for the team to be eligible. Failure to follow this procedure as outlined in this announcement will disqualify the contest submission. Team winnings, as determined by the Competition sponsor, will be distributed to the designated team lead for further distribution to team members. In the event a dispute regarding the identity of the entrant who actually submitted the entry cannot be resolved to HHS and ASN's satisfaction, the affected entry will be deemed ineligible. If the submission includes the work of any third party (such as third-party content or open source code), the entrant must identify the work and be able to provide, upon the request of HHS and ASN, documentation of all appropriate licenses and releases for such third-party works. If the entrant cannot provide documentation of all required licenses and releases, HHS and

ASN reserve the right to disqualify the applicable submission, or direct the entrant to secure the licenses and releases for HHS and ASN's benefit within three (3) days of notification of the missing documentation and allow the applicable submission to remain in the Competition.

7. Entrants to this Competition must agree to be bound by the rules of the Competition, agree that the winner selection decisions for the Competition are final and binding, and acknowledge that their submissions may be the subject of a Freedom of Information Act (FOIA) request and that they are responsible for identifying and marking all business confidential and proprietary information in their submissions.
8. Entrants selected as monetary prize winners must submit all required taxpayer identification and bank account information required to complete an electronic payment of the monetary prize. Failure to provide HHS or ASN required documents for electronic payment within 30 days of notification by HHS or ASN will result in a disqualification of the winning entry.
9. Entrants in the Competition agree, as a condition for winning a monetary or non-monetary prize, to complete and submit all required winner verification documents to HHS or ASN within 3 business days of notification. Failure to return all required verification documents per return instructions by the date specified in the notification may be a basis for disqualification of the winning entry.
10. Entrants to the Competition must agree and consent, as a condition for receiving a monetary or non-monetary prize, to the use of their name, affiliation, city and state, likeness or image, comments, and a short synopsis of their winning solution as a part of HHS and ASN's promotion of this Competition.
11. Entrants must own or have access at their own expense to a computer, an Internet connection, and any other electronic devices, documentation, software, or other items that entrants may deem necessary to create and enter a submission.
12. The following entrants (including any individuals participating as part of a team or entity) are not eligible regardless of whether they meet the criteria set forth above:
 - a. Any HHS employee.
 - b. Any Federal entity or Federal employee acting within the scope of his or her employment or otherwise prohibited by Federal law. Federal employees should consult their agency ethics officials to determine whether the federal ethics rules will limit or prohibit acceptance of a prize under the Competition. Note: Federal ethical conduct rules may restrict or prohibit federal employees from engaging in certain outside activities; any federal employee not excluded under this paragraph seeking to participate in this Competition outside the scope of employment should consult the respective agency's ethics official prior to developing a submission.
 - c. Any individual or entity that used Federal funds to develop a submission, unless such use is consistent with the purpose of the Federal award. Federal award recipients who use Federal funds to develop their Competition submissions must also obtain written prior approval from the appropriate grants management or program officer and provide documentation of prior approval upon request by HHS. If a Federal award recipient using Federal funds enters and wins this Competition, the monetary prize must be treated as program income for purposes of the original Federal award in accordance with the award terms and conditions and applicable HHS grant policies and regulations, including 45 CFR part 75. Federal contractors may not use Federal funds from a contract to develop a submission for the Competition, or to fund efforts in support of a Competition submission.

- d. An individual or entity that is determined to be on the GSA Excluded Parties List (www.sam.gov) is ineligible to receive a monetary or non-monetary prize award and will not be selected as a Competition winner.
13. An entrant (whether an individual, group of individuals, or entity) shall not be deemed ineligible because entrants used Federal facilities or consulted with Federal employees during the Competition if the facilities and employees are made available to all entrants participating in the Competition on an equitable basis.
14. By participating in this competition, each entrant (whether an individual, group of individuals, or entity) agrees to indemnify the Federal government against third party claims for damages arising from or related to competition activities.
15. By participating in this competition, each entrant (whether an individual, group of individuals, or entity) agrees to assume any and all risks and waive claims against the Federal government and its related entities (as defined in the America COMPETES Reauthorization Act, as amended), 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 competition, whether the injury, death, damage, or loss arises through negligence or otherwise.
16. Each entrant (whether an individual, group of individuals, or entity) agrees to follow all applicable federal, state, and local laws, regulations and policies.
17. Use of Marks: Except as expressly set forth in the Competition Rules, Terms, and Conditions, entrants shall not use the names, trademarks, service marks, logos, insignias, trade dress, or any other designation of source or origin subject to legal protection, copyrighted material or similar intellectual property ("Marks") of the organizers or other Competition partners, sponsors, or collaborators in any way without such party's prior written permission in each instance, which such party may grant or withhold at its sole and absolute discretion.
18. By participating in the Competition, each entrant represents, warrants, and covenants that entrants are the sole authors, creators, and owners of the submission; and that:
 - a. The entrant's submission:
 - i. Is not the subject of any actual or threatened litigation claim
 - ii. Does not, and will not, violate or infringe upon the intellectual property rights, privacy rights, publicity rights, or other legal rights of any third party
 - iii. Does not, and will not, contain any harmful computer code (sometimes referred to as "malware," "viruses," or "worms")
 - b. The submission and entrant's use of the submission does not, and will not, violate any applicable laws or regulations of the United States.

Entrants must comply with and abide by these Official Rules, Terms and Conditions and the decisions of HHS and ASN which shall be final and binding in all respects. HHS and ASN reserve the right to disqualify any submission that HHS and ASN in their discretion, deem to violate these Official Rules, Terms and Conditions.

Payment of the prize

Monetary prizes awarded under this competition will be paid by electronic funds transfer and may be subject to local, state, and/or Federal income taxes. HHS and ASN will comply with the Internal Revenue Service withholding and reporting requirements, where applicable. Prizes offered by ASN will be paid directly by ASN to prize recipients, and prize money offered by HHS will be paid directly by HHS to prize recipients. If ASN fails to pay any portion of the monetary prize it has indicated it intends to pay, HHS does not have the legal authority to pay the amount on their behalf.

Publicity release

By participating in the Competition, each entrant hereby irrevocably grants to HHS and ASN the right to the use of their name, affiliation, city and state, likeness or image, and a short synopsis of their winning solution as a part of HHS and ASN's promotion of this Competition, as stated in the Eligibility section.

Disqualification

HHS and ASN reserve the right in their discretion to disqualify any entrant who is found to be tampering with the entry process or the operation of the Competition, the Competition website, or other Competition-related websites; to be acting in violation of these Official Rules, Terms and Conditions; or to be acting in an unsportsmanlike or disruptive manner, or with the intent to disrupt or undermine the legitimate operation of the Competition; or to annoy, abuse, threaten, or harass any other person; and HHS and ASN reserve the right to seek damages and other remedies from any such person to the fullest extent permitted by law.

Links to third-party websites

The Competition website may contain links to third-party websites that are not owned or controlled by HHS and ASN. HHS and ASN do not endorse or assume any responsibility for any such third-party sites. If you access a third-party website from the Competition website, you do so at your own risk and expressly relieve HHS and ASN from any and all liability arising from use of any third-party website content.

Notice to winners

Attempts to notify Competition winners will be made using the email address associated with the Team Lead's account listed in the submission. HHS and ASN are not responsible for email or other communication problems of any kind.

If, despite reasonable efforts, a potential Competition winner does not respond within three (3) business days of the first notification attempt regarding selection as a Competition winner (or a shorter time as exigencies may require), or if the notification is returned as undeliverable to such entrant, that entrant may forfeit the entrant's winner status and any associated prizes, and an alternate Competition winner may be selected.

If any potential winner is found to be ineligible, has not complied with these Official Rules, Terms and Conditions, or declines the applicable prize for any reason prior to award, such potential winners will be disqualified, and alternate winners may be selected.

Intellectual Property (IP) rights

Entrants retain all ownership in intellectual property of their submissions, subject to the licenses referenced herein.

- Entrants are free to discuss their submissions and their ideas or technologies that it contains with other parties, are encouraged to share ideas and technologies publicly, are encouraged to collaborate or combine with other teams to strengthen their solutions, and are free to contract with any third parties. Entrants should be aware that any agreement signed or obligation undertaken in regard to their participation in the Competition that conflicts with the Competition rules, terms, and conditions may result in disqualification of the entrant's submission.
- By participating in the Competition, each entrant (whether an individual, group 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 entrant (or is an improved version of an existing work that the entrant 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 entrant is aware. In addition, each entrant grants to HHS an irrevocable, paid-up, royalty-free nonexclusive worldwide license to reproduce, publish, post, link to, share, and display publicly the submission and related synopses or abstracts on the web or elsewhere, and a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the solution throughout the world for federal purposes. Winners must also grant to the federal government and others acting on its behalf, a fully paid, nonexclusive, irrevocable, worldwide license in any copyrightable works that the submission comprises, including the right to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly said copyrightable works. By participating in the Competition, each entrant hereby grants an irrevocable and royalty-free license to HHS and ASN to store, access, modify, reproduce, and distribute submissions in perpetuity. Each entrant will retain all other intellectual property rights in their submissions, as applicable. To participate in the competition, each entrant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of the entrant's rights to the Federal government. To receive an award, entrants will not be required to transfer their intellectual property rights to HHS, but entrants must grant to the Federal government the nonexclusive licenses recited herein.

- Each entrant also warrants that the work is free of security threats and/or malware.
- Each entrant is responsible for consulting with legal counsel of his/her/its choice as to whether publication of his/her/its abstract will jeopardize his/her/its ability to secure patent protection of his/her/its invention. Neither HHS nor ASN shall be liable for any loss of IP rights or protection that results from publication of any entrant's abstract by the KidneyX partnership.
- All materials submitted to HHS as part of a submission become HHS agency records.
- If the submission includes any third party works (such as third party content or open source code), the entrant must be able to provide, upon request, documentation of all appropriate licenses and releases for use of such third party works. If the entrant cannot provide documentation of all required licenses and releases, HHS and ASN reserve the right, at their sole discretion, to disqualify the submission.

Dates and deadlines

HHS and ASN reserve the right to modify any dates or deadlines set forth in this announcement.

Competition termination

HHS reserves the right to cancel, suspend, and/or modify the Competition, or any part of it, for any reason, at HHS's sole discretion. HHS reserves the right not to award any prizes if no entries are deemed worthy. ASN may also discontinue its participation in the Competition at its discretion. If ASN elects to discontinue its participation, every effort will be made to announce that decision promptly on the KidneyX.org website.

General liability release

By participating in the Competition, each entrant hereby agrees that:

Without limiting the generality of foregoing releases, HHS and ASN are not responsible for incomplete, illegible, misdirected, misprinted, late, lost, postage-due, damaged, or stolen entries or prize notifications; or for lost, interrupted, inaccessible, or unavailable networks, servers,

satellites, Internet Service Providers, websites, or other connections; or for miscommunications, failed, jumbled, scrambled, delayed, or misdirected computer, telephone, cable transmissions or other communications; or for any technical malfunctions, failures, difficulties, or other errors of any kind or nature; or for the incorrect or inaccurate capture of information, or the failure to capture any information.

These Official Rules, Terms and Conditions cannot be modified except by HHS and ASN in their absolute discretion. The invalidity or unenforceability of any provision of these Official Rules, Terms and Conditions shall not affect the validity or enforceability of any other provision. In the event that any provision is determined to be invalid or otherwise unenforceable or illegal, these Official Rules, Terms and Conditions shall otherwise remain in effect and shall be construed in accordance with their terms as if the invalid or illegal provision were not contained herein.

Insurance

Based on the subject matter of the Competition, 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 Competition participation, no entrant (whether an individual, group of individuals, or entity) participating in the Competition is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Competition. Entrants are encouraged to consult with their own advisors with respect to the level of insurance that is prudent for each entrant.

Privacy, data security, ethics, and compliance

Entrants are required to identify and address privacy and security issues in their proposed projects and describe specific solutions for meeting them. In addition to complying with appropriate policies, procedures, and protections for data that ensures all privacy requirements and institutional policies are met, use of data should not allow the identification of the individual from whom the data was collected.

Entrants are responsible for compliance with all applicable federal, state, local, and institutional laws, regulations, and policies. These may include, but are not limited to, Health Information Portability and Accountability Act (HIPAA) protections, Department of Health and Human Services (HHS) Protection of Human Subjects regulations, and Food and Drug Administration (FDA) regulations. If approvals (e.g., from an Institutional Review Board) will be required to initiate any activities associated with submission development in Phase 1 or 2 of the Competition, it is recommended that entrants apply for approval at or before that phase's submission deadline. The following links are intended as a starting point for addressing potentially applicable regulatory requirements but should not be interpreted as a complete list of resources on these issues:

HIPAA

Main link: <http://www.hhs.gov/ocr/privacy/index.html>

Summary of the HIPAA Privacy Rule:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html>

Summary of the HIPAA Security Rule:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html>

Human Subjects—HHS

Office for Human Research Protections: <http://www.hhs.gov/ohrp/index.html>

Protection of Human Subjects Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Policy & Guidance: <http://www.hhs.gov/ohrp/policy/index.html>

Institutional Review Boards & Assurances: <http://www.hhs.gov/ohrp/assurances/index.html>

Human Subjects—FDA

Clinical Trials:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>

Office of Good Clinical Practice:

<https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials>

Consumer Protection—Federal Trade Commission

Bureau of Consumer Protection: <https://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection>.

Exercise

The failure of HHS and ASN to exercise or enforce any right or provision of these Official Rules, Terms and Conditions shall not constitute a waiver of such right or provision.

Governing law

All issues and questions concerning the construction, validity, interpretation, and enforceability of these Official Rules, Terms and Conditions shall be governed by and construed in accordance with U.S. Federal law as applied in the federal courts of the District of Columbia if a complaint is filed by any party against HHS and ASN.

Privacy policy

By participating in the Competition, each entrant hereby agrees that occasionally, HHS and ASN may also use the entrant's information to contact the entrant about federal Competition and innovation related activities, and acknowledges that the entrant has read and accepted the Privacy Policy published on the Competition website.

Additional terms that are part of the rules, terms and conditions

Participation in the Competition constitutes the entrant's full and unconditional agreement to these Official Rules, Terms and Conditions. By entering, an entrant agrees that all decisions related to the Competition that are made pursuant to these Official Rules, Terms and Conditions are final and binding, and that all such decisions are at the sole discretion of HHS and/or ASN.

The ASN Privacy Policy is located here: <https://www.asn-online.org/terms/privacy.aspx>. Note: the information collected by ASN is not governed by or part of any federal data collection process, and is solely the policy of the privately operated ASN.

Winner list, Official rules, and Contact

To obtain a list of winners (after the conclusion of the Competition) or a copy of these Official Rules, Terms and Conditions, send a self-addressed envelope with the proper postage affixed to: American Society of Nephrology, 1401 H St NW Suite 900, Washington, DC 20005. Please specify "Winner List" or "Rules, Terms and Conditions" and the name of the specific Competition in your request.

For Further Information Contact:

Kristen Honey, Ph.D. (Kristen.Honey@hhs.gov, 202-853-7680) or kidneyx@asn-online.org.