

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Office of the Chief Technology Officer (OCTO)

Announcement of Requirements and Registration for 'KidneyX Artificial Kidney Prize Phases 1-2'

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). HHS and ASN plan to hold a series of KidneyX prize competitions to develop innovative solutions that can prevent, diagnose, and/or treat kidney diseases. Prize competitions challenge individuals, communities, businesses, institutions, and non-profit organizations, among others, to achieve defined goals in a defined timeframe. In KidneyX prize competitions, HHS and ASN plan to offer cash prizes and other incentives to increase the number and variety of problem-solvers addressing critical issues in kidney health. Every KidneyX prize competition will define a problem, without a pre-conceived notion of what the solution(s) should be, and ask participants to find solutions. Think better, think bold, think big.

Through this announcement (also referred to herein as “the Official Rules, Terms, and Conditions”), HHS and ASN are announcing KidneyX’s prize competition, “KidneyX Artificial Kidney Prize” (referred to herein as “the Competition”). KidneyX is launching the Artificial Kidney Prize to radically improve treatment options for people who may otherwise require dialysis or a transplant.

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 1**

Submission period begins: October 30, 2020

Submission period ends: March 24, 2021 at 4:59 p.m. ET

Winners announced by: July 2021

**Anticipated dates for the Artificial Kidney Prize Phase 2**

Submission period begins: October 1, 2021

Submission period ends: June 17, 2022 at 4:59 p.m. ET

Winners announced by: October 2022

**Sections of this announcement:**

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

**A. Background**

37 million Americans and more than 850 million people worldwide live with kidney disease. Current treatment methods have not changed significantly in more than 60 years and cost more than \$100 billion per year in the U.S. alone.

Innovation is urgently needed with 13 patients dying each day while waiting for a kidney transplant, and those on dialysis facing a 50% mortality rate within the first three years of treatment. People living with kidney diseases need kidney replacement therapies, either as bridges to transplantation or lifelong solutions, that increase survival and restore quality of life. However, innovation is also incredibly difficult; a functioning kidney is built from over 20 different cell types that seamlessly integrate to maintain homeostasis. The Artificial Kidney Prize is built on the foundational belief that solvers from a range of backgrounds must bring multidisciplinary expertise and collaborative skills to develop solutions that replicate kidney function and improve the lives of patients with kidney diseases, their families, and caregivers.

The Kidney Innovation Accelerator (KidneyX), a public-private partnership between the U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN), is accelerating innovation in the prevention, diagnosis, and treatment of kidney diseases. KidneyX seeks to improve the lives of patients by expediting the development of drugs, devices, biologics, and other therapies across the spectrum of kidney care. To date, KidneyX has completed three prize competitions that have awarded over \$4,000,000 to innovators.

#### **B. Subject of the Prize Competition**

The Artificial Kidney Prize builds on past KidneyX competitions but is distinct in its goal to accelerate the development of continuous renal replacement therapies that provide transformational treatment options beyond current dialysis methods. For this competition, artificial kidneys may be considered as wearable, implantable, bioengineered, developed as a xenotransplant or chimera organ, or other approaches not yet conceived.

The Competition aims to bring these artificial kidney solutions toward human clinical trials with a greater level of maturity, functionality, and potential for patient impact than is currently possible. With the Artificial Kidney Prize, HHS and ASN intend to stimulate the market for further kidney health innovation, drawing greater participation and capital.

To mimic the natural kidney, future artificial kidneys will need to integrate a spectrum of core functions from a wide variety of scientific and engineering disciplines into a system. 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](https://www.asn-online.org/g/blast/files/KHI_RRT_Roadmap1.0_FINAL_102318_web.pdf)) describes some of the specific scientific advances that urgently need to be addressed to realize a functioning artificial kidney including:

- Blood Filtration (filtering blood to remove waste and excess fluid)
- Electrolyte Homeostasis (maintaining appropriate levels of key minerals in the blood)
- Fluid Regulation (regulating the amount of and/or removing excess fluid)
- Toxin Removal and Secretion (removing, limiting or preventing toxins in the bloodstream)

- Filtrate Transport and Drainage (removing excess filtrate after processing; connectivity issues for filtration, processing, and exterior drainage)

The *Technology Roadmap* further describes “system enablers” or technological approaches to perform these functions using expertise from a combination of cellular, molecular, materials, electronic and other scientific and engineering disciplines. System enablers cited in the *Technology Roadmap* include:

- Renal replacement therapy access (vascular, peritoneal dialysis, blood circuit),
- Biomaterials development,
- Biological and immunological modulation,
- Function and safety monitoring, and
- Other technologies.

Entrants to the Artificial Kidney Prize are encouraged to address one or more of these aspects, and the Competition also remains open to entrants proposing solutions that advance artificial kidneys in other ways. Eligibility is limited to solutions that support development of an artificial kidney.

### **C. Prize Competition Structure**

The Competition (October 2020 through October 2022) will award up to \$10 million. Up to \$4,000,000 in Phase 1 prizes will be distributed across up to eight (8) Phase 1 winners, at the discretion of HHS and ASN. For Phase 2, up to \$6,000,000 in prizes will be distributed to winners at the discretion of HHS and ASN. Up to \$2,500,000 in prizes will be awarded by HHS over Phases 1-2; up to \$7,500,000 in prizes will be awarded by ASN over Phases 1-2. Eligibility to receive monetary prizes is further detailed in Sections E and F of this announcement.

#### *Phase 1*

Phase 1 seeks demonstrated performance including proof of concept data for component or integrated prototype solutions that advance development of artificial kidneys, as defined in Section B, above. Entries should include detailed development plans for solutions that enable and advance the functionality, effectiveness, and/or reliability of artificial kidneys. Phase 1 will be open to all entrants who meet the eligibility requirements defined in Sections E and F of this announcement. In their submissions, entrants are asked to include bench or animal study data and justification for how their solution could advance and integrate with artificial kidneys (see Section D of this announcement for further details). Submissions open on October 30, 2020 and close at 4:59 p.m. ET on March 24, 2021.

Winners will be recommended by the judges according to the evaluation criteria defined in Section E of this announcement. Up to \$4 million in Phase 1 prizes will be distributed across up to eight (8) Phase 1 winners, at the discretion of HHS and ASN. Technical support available to entrants includes 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, Phase 1 entrants agree to have brief synopses or abstracts of their submissions published by the KidneyX partnership. Phase 1 will be administered by Luminary Labs, LLC (Luminary Labs). Luminary Labs has been contracted to assist and support HHS and ASN in organizing and managing the Competition.

### *Phase 2*

Phase 2 focuses on initial integration of prototype solutions into an artificial kidney, or advancement of already integrated prototype solutions that advance development of artificial kidneys, as defined in Section B, above. Entrants' solutions should be supported by pre-clinical (bench or animal) or clinical data demonstrating the potential of the prototype for successful support of the reliability, effectiveness and/or functionality of wearable and/or implantable artificial kidneys. Phase 2 will be open to Phase 1 entrants, 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 prototype design, and to include potential partners or collaborators that would enable artificial kidney development toward human clinical trials. Submissions open on October 1, 2021 and close at 4:59 p.m. ET on June 17, 2022.

Winners will be recommended by the judges according to the evaluation criteria defined in Section E of this announcement. Up to \$6 million in Phase 2 prizes will be distributed across Phase 2 winners, at the discretion of HHS and ASN. Technical support in Phase 2 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, Phase 2 entrants agree to have brief synopses or abstracts of their submissions published by the KidneyX partnership.

### **D. Registration and Submission Requirements**

Phase 1 opens on October 30, 2020. Open submissions will last from this date through the close of open submissions, currently scheduled for 4:59 p.m. ET on March 24, 2021

#### *Registration*

To participate in the Competition, entrants must:

1. Register on Luminary Lightbox™ on the Competition website;
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. Agree to:
  - a. Assume any and all risks and waive claims against the Federal government, its related entities, ASN, and Luminary Labs; 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 their participation in the Competition, whether the injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arises through negligence or otherwise;
  - b. Indemnify the Federal government, ASN, and Luminary Labs against third-party claims for damages arising from, or related to, Competition activities, patents, copyrights, and trademark infringements; and

- c. 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.

Anticipated submission requirements

Registration and contact information:

- Team name
- Team lead and primary contact  
*Name / Email / Phone Number / Affiliation*
- Additional team members  
*Name / Email / Phone Number / Affiliation*

Submission:

- **Abstract:** *The abstract may be published after the Phase 1 submission deadline.*
  - **Submission title.** Provide the title of your submission. (10 words maximum)
  - **Submission headline.** Provide a one-sentence “elevator pitch” description summarizing your solution. (30 words maximum)
  - **Solution area(s).** Select which area(s) your solution addresses, or describe in “other.”  
*[Blood filtration; Electrolyte homeostasis; Fluid regulation; Toxin removal and secretion; Filtrate transport and drainage; Renal replacement therapy access (vascular, peritoneal dialysis, blood circuit); Biomaterials development; Biological and immunological modulation; Function and safety monitoring; Other solutions not already defined - please describe]*
  - **Technical abstract.** Summarize your solution and justification for how it could advance the functionality, effectiveness, or reliability of artificial kidneys. (500 words maximum)
  - **Patient abstract.** Describe your solution, and how it could impact and improve the lives of patients, in a way that is accessible for non-scientific readers. (300 words maximum)

Documentation:

- **Approach summary:** An overview of the proof of concept and development plan, including the problem(s) the solution is solving and how it advances the state of innovation for artificial kidneys.
- **Solution description:** A description of the kidney function(s) the enabling solution could advance or support in artificial kidneys. This should also include rationale for maturity, safety, and effectiveness claims, such as data from testing (benchtop or beyond) or other proof of concept evidence. *Each submission must include at least one clear visual (preferably a video file) of the actual proof of concept that demonstrates functionality.*
- **Patient perspective:** A summary of patient input in the development process, and a description of how it impacts and improves both patient quality of life as well as clinical outcomes.
- **Research and development:** A summary of past progress, current development status (including existing IP), and a detailed development plan for continued iteration, testing, and safety evaluation in Phase 2 of the Competition, and/or beyond.
- **Artificial kidney integration:** A description of potential partnerships or intentions/plans for future collaborative efforts, and an approach for integration with other solutions or further development of integrated solutions in the next 3-4 years, including a strategy to address potential intellectual property (IP) issues.

- **Program management:** A description of past funding and how it has been used to advance development to date. This section should also include a forward-looking budget, timeline, and roadmap to achieve future regulatory approvals and manufacturing at scale.
- **Team description:** A description of the team including: areas of expertise, as well as experience/success developing analogous solutions.

Documentation should be a maximum of 20 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. Open submissions officially begin on October 30, 2020. Open submissions will last from this date through the close of open submissions, currently scheduled for 4:59 p.m. ET on March 24, 2021. Once submitted, a submission may not be altered during open submissions.

Upon submission, entrants will be asked to affirm they have read, understand, and fully agree to the Competition Rules, Terms, and Conditions, including granting an irrevocable and royalty-free license to HHS, ASN, and Luminary Labs to store, access, modify, reproduce, and distribute submissions in perpetuity, however, entrants retain ownership of their concepts, including any software, designs, research, or other intellectual property (IP) that they develop in connection therewith. Please refer to “Intellectual property (IP) rights” in Section F for more information.

In advance of the Phase 2 submission period, HHS and ASN may update this announcement with additional details.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact: Luminary Labs, 61 Broadway, Suite 2800, New York, NY 10006 or by email: [kidneyx@asn-online.org](mailto:kidneyx@asn-online.org). Entrants who use a TDD or a TTY may call the Federal Relay Service (FRS), toll free, at 1-800-877-8339. If Luminary Labs provides an accommodation or auxiliary aid to an individual with a disability in connection with the entry submission process, the entry remains subject to all other requirements and limitations in these Official Rules, Terms, and Conditions.

## **E. Eligibility, Evaluation Criteria, and Judging**

### *Eligible entrant profile*

The Artificial Kidney Prize is open to both U.S. and international participants. To be eligible to receive any monetary prizes, participants, whether participating singly or as a team, must register for the Competition on Luminary Lightbox™ 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, an entrant must be a citizen or permanent resident of the United States, or a legal entity with its primary place of business in the United States. An entrant that is a non-U.S. citizen, nonpermanent resident, or non-U.S.-based legal entity may be eligible to win a

monetary prize awarded by ASN, at the discretion of ASN and provided the entrant meets all other eligibility 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 US law, including US trade and economic sanctions and US 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 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; a representative of HHS will approve the distribution of HHS prize money, while an ASN representative will approve the distribution of ASN prize money.

Submissions will be evaluated using the following seven, equally-weighted criteria below.

- **Functionality replication:** The degree of confidence in the enabling solution to safely replace or support one or more kidney functions, and the ability to sustain continuous functionality over time. (See [2018 Kidney Health Initiative RRT roadmap](#) for specific targets by functionality.)
- **Integration potential:** The degree to which the submission demonstrates potential utility in serving as a foundational enabling element of an artificial kidney, and clearly outlines plans to collaborate with other innovators and experts in further development.
- **Technical maturity:** The likelihood based on bench or animal testing results or other justification that the enabling solution could integrate with nascent artificial kidney solutions or receive approval to begin FIH clinical trials within 3-4 years from submission.
- **Patient impact:** The potential for the solution to improve quality of life and clinical outcomes for a broad spectrum of patients (e.g., those with differing access to care, comorbidities).
- **Innovation:** The level of advancement beyond established scientific methods and technology (e.g., advances in materials, biocompatibility, power utilization, size/weight, sensors, long-term patency).
- **Development progress and plan:** The amount of progress completed relative to funding received, the rigor of plans for continued development in Phase 2, and the confidence in the team to execute.
- **Commercial viability:** The potential and timeframe for the enabling solution as part of an integrated artificial kidney to attract external investment, be produced sustainably at scale, and obtain payer reimbursement once commercialized.

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

#### F. Additional Competition Rules, Terms, and Conditions

##### Eligibility

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, ASN, and Luminary Labs in accordance with the description provided on the Competition website. Entrants shall have complied with all of the requirements on the official Competition website.
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 "Monetary Prizes" section of these Rules, Terms, and Conditions for additional information on HHS and ASN prizes.
5. *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 but will not be eligible to win a monetary prize from HHS (in whole or in part); however, their participation as part of a winning team, if applicable, may be recognized when results are announced.
6. *ASN monetary prizes:* At the discretion of ASN, non-U.S. citizens/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.
7. HHS and ASN employees directly supporting the development or execution of the Competition and support contractors directly supporting the development or execution of the Competition, Luminary Labs and its contractors (with the express exception of Luminary Labs' authorized solver community), 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.
8. 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 on the team's submission form for the team to be eligible. Failure to follow this procedure as outlined on the Competition website 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, and/or Luminary Labs, documentation of all appropriate licenses and released for such third-party works. If the entrant cannot provide documentation of all required licenses and relates, HHS and ASN reserve the right to disqualify the applicable submission, or direct the entrant to secure the licenses and relates 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.

9. 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.
10. 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 Luminary Labs, HHS, or ASN required documents for electronic payment within 30 days of notification by Luminary Labs, HHS, or ASN will result in a disqualification of the winning entry.
11. 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 Luminary Labs, HHS, or ASN within 3 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.
12. 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.
13. 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.
14. 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 his/her 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 grant award, or other applicable Federal funds awarding document. If a grantee using Federal funds enters and wins this Competition, the monetary prize must be treated as program income for purposes of the original grant in accordance with applicable Office of Management and Budget Circulars. 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.
15. An individual or entity shall not be deemed ineligible under these eligibility rules because the individual or entity used Federal facilities or consulted with Federal employees during a Competition if the facilities and employees are made available to all individuals and entities participating in the Competition on an equitable basis.

16. Each individual (whether participating singly or in a group) or entity (whether participating singly or in a group with other individuals and/or entities) 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.
  - c. An individual or entity that is determined to be on the GSA Excluded Parties List ([www.sam.gov](http://www.sam.gov)) is ineligible to receive a monetary or non-monetary prize award and will not be selected as a Competition winner.

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 and Luminary Labs reserve the right to disqualify any submission that HHS and ASN and/or Luminary Labs in their discretion, deem to violate these Official Rules, Terms and Conditions.

#### Monetary prizes

For Phases 1 and 2 of the Competition, up to \$10,000,000 in total prize funds are available. HHS will award up to \$2,500,000 in prizes during Phases 1-2, and ASN will separately award up to \$7,500,000 in prizes during Phases 1-2.

The total monetary prizes for Phase 1 of the Competition will be up to \$4,000,000. The judging panel will recommend up to eight (8) monetary prize winners according to official Phase 1 evaluation criteria. The Phase 1 monetary prizes will be distributed across the Phase 1 winners. Contestants to the Competition must agree and consent, as a condition for receiving a monetary prize, to the use of their name, affiliation, city and state, likeness or image, and an abstract of their winning solution as a part of HHS and ASN's promotion of this Competition, as stated in the Eligibility section, and below in the Publicity Release sections.

If any potential winner is found to be ineligible, has not complied with the Official Rules, Terms and Conditions, or declines the monetary prize for any reason prior to award, an alternate winner may be selected.

The total monetary prizes for Phase 2 of the Competition will be up to \$6,000,000. The judging panel will recommend winners according to official Phase 2 evaluation criteria. The Phase 2 prizes will be distributed across Phase 2 winners, at the discretion of HHS and ASN.

Monetary prizes awarded under Phases 1 and 2 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 and Luminary Labs 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 or Luminary Labs. HHS and ASN and Luminary Labs 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 and / or Luminary Labs from any and all liability arising from use of any third-party website content.

#### Notice to winner(s)

Attempts to notify Phase 1 and Phase 2 winner(s) will be made using the email address associated with the Team Lead's Luminary Lightbox™ account. HHS and ASN and Luminary Labs are not responsible for email or other communication problems of any kind.

If, despite reasonable efforts, a potential Phase 1 or Phase 2 winner does not respond within three (3) days of the first notification attempt regarding selection as a Phase 1 or Phase 2 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 Phase 1 or Phase 2 winner status and any associated prizes, and an alternate Phase 1 or Phase 2 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 participant (whether participating singly or in a group) warrants that he or she 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 participant is aware. 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 nor Luminary Labs shall be liable for any loss of IP rights or protection that results from publication of any entrant's abstract by the KidneyX partnership. In addition, each participant (whether participating singly or in a group) and each entity grants to HHS an irrevocable, paid-up, royalty-free non exclusive worldwide license to reproduce, publish, post link to, share, and display publicly (e.g., on websites) the submission and related synopses or abstracts. To participate in the Competition, each entrant must warrant that there are no legal obstacles to providing the above-referenced nonexclusive licenses of participant rights to the federal government. To receive an award, winners must grant to the federal government a nonexclusive, non transferable, 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 and Luminary Labs to store, access, modify, reproduce, and distribute submissions in perpetuity. Each entrant also warrants that the work is free of security threats and/or malware.
- 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 these Official Rules, Terms and Conditions or otherwise governing the Competition.

#### 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, ASN, and Luminary Labs 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 and the type of work that it will possibly require, entrants are not required to obtain liability insurance or demonstrate financial responsibility in any specified amount for claims by a third party for death, bodily injury, or property damage or loss resulting from an activity carried out in connection with participating in a prize competition, but 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: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191>.

#### ***Consumer Protection—Federal Trade Commission***

Bureau of Consumer Protection: <http://business.ftc.gov/privacy-and-security>.

#### **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, and the laws of the State of New York as applied in the New York state courts in New York City if a complaint is filed by any party against Luminary Labs.

#### **Privacy policy**

By participating in the Competition, each entrant hereby agrees that occasionally, HHS and ASN and Luminary Labs 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**

Please review the Luminary Lightbox Terms of Service at <<http://www.LuminaryLightbox.com/terms>> for additional rules that apply to your participation in the Competition and more generally your use of the Competition website. Such Terms of Service are incorporated by reference into these Official Rules, Terms and Conditions. If there is a conflict between the Terms of Service and these Official Rules, Terms and Conditions, the latter terms shall control with respect to this Competition only.

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 ASN and/or Luminary Labs.

Luminary Labs collects personal information from entrants to the Competition. The information collected is subject to the Privacy Policy located here: <<http://www.LuminaryLightbox.com/privacy>>

#### **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: Luminary Labs,

61 Broadway, Suite 2800, New York, NY 10006. Please specify "Winner List" or "Rules, Terms and Conditions" and the name of the specific Competition in your request.

**For Further Information Contact:**

**Kidneyx@asn-online.org.**