

1 **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

2 Office of the Assistant Secretary of Health (OASH)

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

5 Authority: 15 U.S.C. 3719

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

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

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

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

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37 **Dates for the Artificial Kidney Prize Phase 2**

38 Track One Submission period begins: August 11, 2022

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

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41 Track Two Submission period begins: August 11, 2022

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

43
44 **Sections of this announcement:**

45 A. Background

46 B. Subject of the Prize Competition

47 C. Prize Competition Structure

48 D. Registration and Submission Requirements

49 E. Eligibility, Evaluation Criteria, and Judging

50 F. Additional Competition Rules, Terms, and Conditions

51

52 **A. Background**

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

64
65 There are thirty-seven million Americans and more than 850 million people worldwide living with
66 kidney diseases. Current treatment methods have not changed significantly in more than 60
67 years and cost more than \$100 billion per year in the United States, alone.

68
69 Innovation is urgently needed with 22 patients dying each day while awaiting kidney transplant
70 and a 50% mortality rate within the first five years of treatment for dialysis patients. People
71 living with kidney diseases that have advanced to end-stage require kidney replacement
72 therapies, either as bridges to transplantation or lifelong solutions, that increase survival and
73 improve quality of life.

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

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

82
83 This Competition solicits submissions that support innovations in regenerative medicine, cellular
84 engineering, tissue engineering, systems biology, and/or synthetic biology to either advance the
85 development of an artificial kidney prototype or create enabling tools or components that
86 address critical challenges for developing an artificial kidney platform. Each submission will
87 address one of the two tracks included in this competition:

88
89 **Track One (*Accelerating the prototype of a wearable or implantable artificial kidney or***
90 ***xenotransplant*):** The development of a prototype bioartificial kidney derived solely from
91 innovations in regenerative medicine, cellular engineering, tissue engineering, systems biology,
92 and/or synthetic biology, or,

93
94 **Track Two (*Tools or Components that enable the development of an artificial kidney*):**
95 The development of enabling tools or components derived solely from innovations in
96 regenerative medicine, cellular engineering, tissue engineering, systems biology, and/or
97 synthetic biology that accelerate the development of any artificial kidney or xenotransplantation
98 platforms.

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

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

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

123
124 Entrants to either Track of the Competition are recommended to consider the Kidney Health
125 Initiative's *Technology Roadmap for Innovative Approaches to Renal Replacement Therapy*
126 (https://www.asn-online.org/g/blast/files/KHI_RRT_Roadmap1.0_FINAL_102318_web.pdf),
127 which describes examples of kidney functions and components that regenerative medicine,
128 cellular engineering, tissue engineering, systems biology, and/or synthetic biology approaches
129 could address to realize a kidney replacement, including:

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

142
143 Entrants to Track Two of the Competition are encouraged to address one or more of these
144 aspects, as well as describe other solutions, with a clear pathway for integration into an artificial
145 kidney platform.

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

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150 **C. Prize Competition Structure**

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

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155 In Phase 2, HHS may award up to \$8,400,000 in prizes. In Phase 2, ASN may award up to
156 \$2,100,000 in prizes.

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

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161 For Track One, up to three (3) winners will each receive an equal share of: up to \$3,200,000
162 from HHS and up to \$1,300,000 from ASN.

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164 For Track Two, up to six (6) winners will each receive an equal share of: up to \$5,200,000 from
165 HHS and up to \$800,000 from ASN.

166 **Artificial Kidney Prize Phase 2**

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168 Artificial Kidney Prize Phase 2 (referred to herein as “the Competition”) solicits innovative
169 applications of regenerative medicine, cellular engineering, tissue engineering, systems biology,
170 and/or synthetic biology in (1) either the development of a prototype bioartificial kidney (Track
171 One) or (2) in the development of enabling tools or components that accelerate the
172 development of artificial kidney platforms (Track Two). This Competition is open to past
173 Artificial Kidney Prize Phase 1 entrants and prize winners, as well as any other entrants who
174 meet the eligibility requirements defined in Sections E and F of this announcement. In their
175 submissions, entrants are asked to provide justification for their approach, and to include
176 potential partners or collaborators that would enable artificial kidney development.
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178 Entrants’ solutions to Track One of the Competition, *Accelerating the prototype of a wearable or*
179 *implantable artificial kidney or xenotransplant*, should include clear descriptions of their
180 development plans for a prototype bioartificial kidney, including a pathway and future timeline
181 towards first-in-human studies. Submissions could be supported by pre-clinical (bench or
182 animal) or clinical data demonstrating the potential of the approach to support the reliability,
183 effectiveness and functionality of a wearable or implantable bioartificial kidney.
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185 Entrants’ solutions to Track Two of the Competition, *Tools or Components that enable the*
186 *development of an artificial kidney*, should include clear descriptions of the challenge and barrier
187 faced by artificial kidney developers. This should focus the rationale and data that support the
188 application of a regenerative medicine, cellular engineering, tissue engineering, systems
189 biology, and/or synthetic biology-based solution as tools or components that enables
190 development of an artificial kidney platform.
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192 Winners will be recommended by the judges according to the evaluation criteria defined in
193 Section E of this announcement. At the discretion of ASN and HHS, KidneyX will select up to
194 nine (9) winners: up to three (3) in Track One and up to six (6) winners in Track Two as
195 specified in Section C: Prize Competition Structure in this document. Technical support for the
196 Competition winners will also include a range of informational resources to encourage and
197 facilitate collaboration, navigate regulatory and commercial considerations, and incorporate
198 patient input into solution development.
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200 As part of their submission, Competition entrants agree to have brief synopses or abstracts of
201 their submissions published by the KidneyX partnership.

202 **D. Registration and Submission Requirements**

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

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- 208 1. Register for the competition.
 - 209 2. Enter a submission on the Competition website;
 - 210 3. Comply with all requirements in this announcement and on the Competition website;
 - 211 4. Provide affirmation upon submission to the Competition that the entrant is eligible under
212 the Eligibility section below;
 - 213 5. Each entrant (whether an individual, group of individuals, or entity) agrees to:
 - 214 1. Assume any and all risks and waive claims against the Federal government, its
215 related entities (as defined in the America COMPETES Reauthorization Act, as
216 amended), and ASN; except in the case of willful misconduct, for any injury,
217 death, damage, or loss of property, revenue, or profits, whether direct, indirect, or
218 consequential, arising from participation in this Competition, whether the injury,
219 death, damage, or loss arises through negligence or otherwise;
 - 220 2. Indemnify the Federal government and ASN against third-party claims for
221 damages arising from, or related to, Competition activities, patents, copyrights,
222 and trademark infringements; and
 - 223 3. Comply with and abide by the official rules, terms, and conditions noted in this
224 announcement and on the Competition website, as well as the decisions of HHS
225 and ASN which shall be final and binding in all respects.
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227 **Registration requirements**

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

232 **Registration and contact information**

- 233
- 234 • Team, entity, or individual name
 - 235 • Team lead (Team, entity, or individual lead and primary contact)
Name, Email, Phone Number, Affiliation
 - 236 • Additional team members
237 *Name Email, Phone Number, Affiliation*

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

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242 **Submission requirements**

243 Submission Track One: Accelerating the prototype of a bioartificial kidney

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

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- **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.

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

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- 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)

297 ○ **Team description.** Describe how your team uses the expertise of each member,
298 including details of past and current collaborations between members, in a way that
299 is accessible for non-scientific readers. (300 words maximum)
300

- 301 • Documentation
 - 302 ○ **Catalyzing the development to a bioartificial kidney:** The justification that the
303 tools or components described in the submission applies regenerative medicine,
304 cellular engineering, tissue engineering, systems biology, and/or synthetic biology
305 as a discrete solution to a specific challenge and enables development of an
306 artificial kidney platform, beyond established scientific methods and technology.
307 Entrants should include plans to collaborate with other innovators and experts for
308 further integration into the development an artificial kidney platform.
 - 309 ○ **Proof of concept:** The likelihood that the application of regenerative medicine,
310 cellular engineering, tissue engineering, systems biology, and/or synthetic biology
311 innovations towards the development of tools or components will address specific
312 challenges and enable the development of an artificial kidney platform.
 - 313 ○ **Team Science and collaboration:** Complementarity of the individual expertise
314 within the team to develop the enabling tools or components, including level-of-
315 effort needed to successfully execute the plan described in the submission.
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317 Documentation should be a maximum of 10 pages; however, additional content may be
318 included in an appendix. The appendix is not guaranteed to receive review by the judging panel
319 but may provide helpful context or clarification. Documentation should be submitted as a PDF
320 and formatted with 1-inch margins (2.5 cm), using Times New Roman font with minimum 12-
321 point size for prose, and 10-point font for tables and charts.
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323 Submissions must be received during the open submissions period of the Competition in order
324 to be eligible.
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326 Once submitted, a submission may not be altered during the open submissions period.
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328 Upon submission, entrants will be asked to affirm they have read, understand, and fully agree to
329 the Competition Rules, Terms, and Conditions.
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332 **E. Eligibility, Evaluation Criteria, and Judging**

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334 **Eligible entrant profile**

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

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

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361 **Evaluation criteria and judging**

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

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

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

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374 1. **Functionality replication:** The degree to which patient input has framed the targeted
375 functions and design of the prototype. The degree of confidence that the plans for
376 bioartificial kidney prototype will achieve critical kidney functions safely and continuously.
377 See [2018 Kidney Health Initiative RRT roadmap](#) for examples of kidney functionality.

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379 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.

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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.

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

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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.

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

412 **F. Additional Competition Rules, Terms, and Conditions**
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414 Pursuant to section 24 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C.
415 3719), as added by the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358):

- 416 1. The Competition is open to all legal entities and individuals (non-felons) over the age of
417 18, subject to the additional eligibility requirements listed below. Eligibility is subject to
418 verification by HHS and ASN before monetary prizes are awarded.
- 419 2. An individual or entity shall have registered to participate in the Competition under the
420 rules promulgated by HHS and ASN in this announcement. Entrants shall have complied
421 with all of the requirements in this announcement.
- 422 3. Entrants are not eligible to receive any monetary or non-monetary prize in the
423 Competition if they are a person or entity designated or sanctioned by the United States
424 Treasury’s Office of Foreign Assets Control (see [http://www.treasury.gov/resource-](http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx)
425 [center/sanctions/SDN-List/Pages/default.aspx](http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx) for additional information).
- 426 4. Note on awards: Monetary prizes provided by ASN for the Competition will be awarded
427 separately from HHS monetary prizes. Please refer to the “Prize Competition Structure”
428 section of these Rules, Terms, and Conditions for additional information on HHS and
429 ASN prizes.
 - 430 a. *HHS monetary prizes*: To be eligible to win prize money from HHS under the
431 Competition, a private entity shall be incorporated in and maintain a primary
432 place of business in the United States; and an individual, whether participating
433 singly or in a group, shall be a citizen or permanent resident of the United States.
434 **Note:** Non-U.S. citizens and nonpermanent residents can participate as a
435 member of a team that otherwise satisfies the eligibility criteria. Non-U.S.
436 citizens and non-permanent residents are not eligible to win a monetary prize (in
437 whole or in part) from HHS. Their participation as part of a winning team, if
438 applicable, may be recognized when the results are announced.
 - 439 b. *ASN monetary prizes*: At the discretion of ASN, non-U.S. citizens, non-
440 permanent residents, or non-U.S. incorporated entities or places of business,
441 may be eligible to receive certain monetary prizes awarded by ASN under the
442 Competition.
- 443 5. HHS and ASN employees directly supporting the development or execution of the
444 Competition, support contractors directly supporting the Competition, reviewers, and
445 judges are ineligible to compete in this Competition. Likewise, members of their
446 immediate family (spouses, children, step-children, siblings, step-siblings, parents, step-
447 parents), and persons living in the same household, whether or not related, are not
448 eligible to participate in any portion of this Competition. Note: The members of an
449 individual’s household include any other person who shares the same residence as such
450 individual for at least three months out of the year.
- 451 6. Individuals and entities, otherwise eligible to win a monetary or non-monetary prize, may
452 form and submit a team entry; however, each team member must be clearly identified in
453 the team’s submission form for the team to be eligible. Failure to follow this procedure as
454 outlined in this announcement will disqualify the contest submission. Team winnings, as
455 determined by the Competition sponsor, will be distributed to the designated team lead
456 for further distribution to team members. In the event a dispute regarding the identity of
457 the entrant who actually submitted the entry cannot be resolved to HHS and ASN’s
458 satisfaction, the affected entry will be deemed ineligible. If the submission includes the
459 work of any third party (such as third-party content or open source code), the entrant
460 must identify the work and be able to provide, upon the request of HHS and ASN,
461 documentation of all appropriate licenses and releases for such third-party works. If the
462 entrant cannot provide documentation of all required licenses and releases, HHS and

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

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

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

549
550 Entrants must comply with and abide by these Official Rules, Terms and Conditions and the
551 decisions of HHS and ASN which shall be final and binding in all respects. HHS and ASN
552 reserve the right to disqualify any submission that HHS and ASN in their discretion, deem to
553 violate these Official Rules, Terms and Conditions.

554 **Payment of the prize**

555 Monetary prizes awarded under this competition will be paid by electronic funds transfer and
556 may be subject to local, state, and/or Federal income taxes. HHS and ASN will comply with the
557 Internal Revenue Service withholding and reporting requirements, where applicable. Prizes
558 offered by ASN will be paid directly by ASN to prize recipients, and prize money offered by HHS
559 will be paid directly by HHS to prize recipients. If ASN fails to pay any portion of the monetary
560 prize it has indicated it intends to pay, HHS does not have the legal authority to pay the amount
561 on their behalf.
562
563

564 **Publicity release**

565 By participating in the Competition, each entrant hereby irrevocably grants to HHS and ASN the
566 right to the use of their name, affiliation, city and state, likeness or image, and a short synopsis
567 of their winning solution as a part of HHS and ASN's promotion of this Competition, as stated in
568 the Eligibility section.
569

570 **Disqualification**

571 HHS and ASN reserve the right in their discretion to disqualify any entrant who is found to be
572 tampering with the entry process or the operation of the Competition, the Competition website,
573 or other Competition-related websites; to be acting in violation of these Official Rules, Terms
574 and Conditions; or to be acting in an unsportsmanlike or disruptive manner, or with the intent to
575 disrupt or undermine the legitimate operation of the Competition; or to annoy, abuse, threaten,
576 or harass any other person; and HHS and ASN reserve the right to seek damages and other
577 remedies from any such person to the fullest extent permitted by law.
578

579 **Links to third-party websites**

580 The Competition website may contain links to third-party websites that are not owned or
581 controlled by HHS and ASN. HHS and ASN do not endorse or assume any responsibility for any
582 such third-party sites. If you access a third-party website from the Competition website, you do
583 so at your own risk and expressly relieve HHS and ASN from any and all liability arising from
584 use of any third-party website content.
585

586 **Notice to winners**

587 Attempts to notify Competition winners will be made using the email address associated with the
588 Team Lead's account listed in the submission. HHS and ASN are not responsible for email or
589 other communication problems of any kind.
590

591 If, despite reasonable efforts, a potential Competition winner does not respond within three (3)
592 business days of the first notification attempt regarding selection as a Competition winner (or a
593 shorter time as exigencies may require), or if the notification is returned as undeliverable to such
594 entrant, that entrant may forfeit the entrant's winner status and any associated prizes, and an
595 alternate Competition winner may be selected.
596

597 If any potential winner is found to be ineligible, has not complied with these Official Rules,
598 Terms and Conditions, or declines the applicable prize for any reason prior to award, such
599 potential winners will be disqualified, and alternate winners may be selected.
600

601 **Intellectual Property (IP) rights**

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

- 604
- 605 • Entrants are free to discuss their submissions and their ideas or technologies that it
606 contains with other parties, are encouraged to share ideas and technologies publicly, are
607 encouraged to collaborate or combine with other teams to strengthen their solutions, and
608 are free to contract with any third parties. Entrants should be aware that any agreement
609 signed or obligation undertaken in regard to their participation in the Competition that
610 conflicts with the Competition rules, terms, and conditions may result in disqualification
611 of the entrant's submission.
 - 612 • By participating in the Competition, each entrant (whether an individual, group of
613 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

614 wholly original with the entrant (or is an improved version of an existing work that the
615 entrant has sufficient rights to use and improve), and that the submission does not
616 infringe any copyright or any other rights of any third party of which the entrant is aware.
617 In addition, each entrant grants to HHS an irrevocable, paid-up, royalty-free
618 nonexclusive worldwide license to reproduce, publish, post, link to, share, and display
619 publicly the submission and related synopses or abstracts on the web or elsewhere, and
620 a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have
621 practiced for or on its behalf, the solution throughout the world for federal purposes.
622 Winners must also grant to the federal government and others acting on its behalf, a fully
623 paid, nonexclusive, irrevocable, worldwide license in any copyrightable works that the
624 submission comprises, including the right to reproduce, prepare derivative works,
625 distribute copies to the public, and perform publicly and display publicly said
626 copyrightable works. By participating in the Competition, each entrant hereby grants an
627 irrevocable and royalty-free license to HHS and ASN to store, access, modify,
628 reproduce, and distribute submissions in perpetuity. Each entrant will retain all other
629 intellectual property rights in their submissions, as applicable. To participate in the
630 competition, each entrant must warrant that there are no legal obstacles to providing the
631 above-referenced nonexclusive licenses of the entrant's rights to the Federal
632 government. To receive an award, entrants will not be required to transfer their
633 intellectual property rights to HHS, but entrants must grant to the Federal government
634 the nonexclusive licenses recited herein.

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

647 **Dates and deadlines**

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

649 **Competition termination**

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

655 **General liability release**

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

657 Without limiting the generality of foregoing releases, HHS and ASN are not responsible for
658 incomplete, illegible, misdirected, misprinted, late, lost, postage-due, damaged, or stolen entries
659 or prize notifications; or for lost, interrupted, inaccessible, or unavailable networks, servers,
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664 satellites, Internet Service Providers, websites, or other connections; or for miscommunications,
665 failed, jumbled, scrambled, delayed, or misdirected computer, telephone, cable transmissions or
666 other communications; or for any technical malfunctions, failures, difficulties, or other errors of
667 any kind or nature; or for the incorrect or inaccurate capture of information, or the failure to
668 capture any information.
669

670 These Official Rules, Terms and Conditions cannot be modified except by HHS and ASN in their
671 absolute discretion. The invalidity or unenforceability of any provision of these Official Rules,
672 Terms and Conditions shall not affect the validity or enforceability of any other provision. In the
673 event that any provision is determined to be invalid or otherwise unenforceable or illegal, these
674 Official Rules, Terms and Conditions shall otherwise remain in effect and shall be construed in
675 accordance with their terms as if the invalid or illegal provision were not contained herein.
676

677 **Insurance**

678 Based on the subject matter of the Competition, the type of work that it will possibly require, as
679 well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or
680 loss potentially resulting from Competition participation, no entrant (whether an individual, group
681 of individuals, or entity) participating in the Competition is required to obtain liability insurance or
682 demonstrate financial responsibility in order to participate in this Competition. Entrants are
683 encouraged to consult with their own advisors with respect to the level of insurance that is
684 prudent for each entrant.
685

686 **Privacy, data security, ethics, and compliance**

687 Entrants are required to identify and address privacy and security issues in their proposed
688 projects and describe specific solutions for meeting them. In addition to complying with
689 appropriate policies, procedures, and protections for data that ensures all privacy requirements
690 and institutional policies are met, use of data should not allow the identification of the individual
691 from whom the data was collected.
692

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

703 **HIPAA**

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

705 Summary of the HIPAA Privacy Rule:

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

707 Summary of the HIPAA Security Rule:

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

709 **Human Subjects—HHS**

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

711 Protection of Human Subjects Regulations:
712 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

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

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

715 **Human Subjects—FDA**

716 Clinical Trials:

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

718 Office of Good Clinical Practice:

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

721 **Consumer Protection—Federal Trade Commission**

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

724 **Exercise**

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

727

728 **Governing law**

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

733

734 **Privacy policy**

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

739

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

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

745

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

749

750 **Winner list, Official rules, and Contact**

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

756

757 **For Further Information Contact:**
758 Kristen Honey, Ph.D. (Kristen.Honey@hhs.gov, 202-853-7680) or kidneyx@asn-online.org.