

All of Us Research Program Engagement and Retention Innovators (OT2) Q&A

1. The solicitation states “NIH intends to fund at least one (1) award for FY2019.” Does the government anticipate more than one award? If multiple awardees, how does the government foresee dividing the work? How will multiple awardees work together?
We may give more than one award. Additionally, multiple organizations can apply jointly under a single award. If multiple awardees are selected, they will be expected to work collaboratively to achieve the intended outcome.
2. Are multiple PIs allowed?
Yes
3. What will be required for subcontract budgets? Will detailed, itemized budgets be required at the time of application?
Enough details and information must be provided for reviewers to connect subcontract budgets to the activities performed. Additionally, as per page 3 in the funding opportunity announcement “Budget detail should be specific enough for the reviewers to understand the connection between the funds requested and activity to be conducted.”
4. The notice stated questions may be submitted via email, to Dr. Dara Richardson-Heron, All of Us Research Program, for programmatic objectives, or to Ms. Irene Haas, All of Us Research Program Agreements Officer, National Center for Advancing Translational Sciences (NCATS), for award mechanism and application submission matters, both at AllofUsEngagement@nih.gov. Can you please clarify if there is a specific due date for question submittal?
We encourage you to submit any questions well in advance of the submission deadline to allow ample time for response and incorporation into application as needed. Questions may be submitted until the final application submission date.
5. Is there an organization currently conducting this work (i.e., an incumbent)? If so, will the work be transitioned from the incumbent to the new awardee?
Yes, we currently have several national engagement partners. Details regarding how the transition process will occur, will be made after awardees have been selected.
6. Can the government provide guidance on required travel to NIH (Washington DC) or elsewhere?
Please refer to the “Budget” section of the award, page 10, second paragraph.
“Application PI/PDs and key personnel should plan for several weekly calls and team meetings as needed over the course of the award. In addition, three members from the awardee should plan and budget for up to four trips annually to Bethesda, MD, for All of Us Research Program Steering Committee and other strategic meetings.”
7. Would you please explain the application review process in more detail?
Please refer to the “Review Process” section of the award, page 5.

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Applications will be evaluated for responsiveness to the Funding Opportunity requirements and merit by an appropriate review group convened by the NIH.

Reviewers will evaluate applications based on the following:

1. Experience
2. Quality of Submission
3. Engagement Approach including Measurable Commitments
4. Proficiency in categories of expertise described in the application:
 - a. Community engagement
 - b. Provider engagement
 - c. Experiential learning
 - d. Multicultural engagement
 - e. Digital engagement
5. Innovation
6. Proposed Commitment to the Project
7. Past Performance
8. Key Personnel & Experience
9. Cost Proposal

Applicants may receive a brief written summary of the review. Successful applicants will undergo a negotiation process for award determination.

8. Are the criteria listed under the Application Review: Evaluation Process section ranked? Are they equally weighted?

The award mechanism used for this funding opportunity is other transactions. Standard peer review rankings do not apply. As stated in this section on page 6, programmatic priority will be given to applicants who have demonstrated experience and success working with and reaching into communities historically underrepresented in biomedical research as defined in the Funding Opportunity Purpose section.

9. Is cost sharing/match required for award?

No.

10. In the Instructions for Application Submission, "OTA-19-004" is listed as the FOA number to enter in ASSIST. Double checking, is that the correct number to use when this announcement came out under 19-003?

Yes, "**OTA-19-004**" is the correct number to use when submitting an application in ASSIST in response to this announcement.

11. Is there a total cost cap? It appears that \$8M is the direct cost cap. Can you please clarify if the budget is \$8 million direct costs TOTAL over 5 years or \$8 million direct costs PER YEAR for 5 years (i.e. \$40 million total)? It appears to be written differently in different places.

Please refer to the "Budget" section of the award, page 10, third paragraph. The budget is not expected to exceed \$8M in direct costs annually.

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12. Reference: Overview Information, Funds Available, Page 2

The overview information states that applicant direct costs should not exceed \$8M and the key date states the anticipated project period is 5 years. Does the government expect that applicant direct costs should not exceed \$8M per year or that applicant direct costs should not exceed \$8M over the total project period of 5 years?

“The total budget will be based on funds available, but not expected to exceed \$8M per year in direct costs.” (page 10) [note that on page 2 the text referring to funds is missing per year after \$8M].

13. Reference: Required Application Instructions, Page 3

Would the government clarify the not to exceed 2-page limit on the cost proposal includes the budget detail and accompanying price narrative?

Yes, per the instructions the cost proposal should not exceed 2 pages. This includes budget details and accompanying price narrative.

14. Reference: Purpose and Objective, Page 7

The purpose and objectives references “these experiences”. Can you please provide previous examples, so we can gain clarity around these experiences?

Here are two examples of engagements that the program uses currently: a virtual reality engagement for participants to explore concepts about precision medicine and a pebble art engagement that uses pebbles of different colors to represent the three data types that each participant brings to the program: their environment, their life style, and their genetics.

In addition, on May 6th, 2018, the program launched nationally with activities from 7 launch sites simulcasted throughout the day. One activity that took place at each launch event was an art exhibit where a local artist created a large portrait for the national event. On the day of the event, visitors were encouraged to pose for a small picture that was printed out and placed on one side of the larger portrait. When hundreds of small pictures were collected, they formed a visual collage of event-goers at each event. This was used to demonstrate the importance of community for the program.

An important note: the examples above are what is available now. The purpose of this award is not to create a continuation of existing materials, but create new, innovative engagements the program does not currently use.

15. When a participants are teaming in a submission will an award be given to each teaming organization or does one need to serve as the PI and backbone?

When multiple organizations apply jointly, there will be one primary applicant organization. There may be multiple-PIs from various organizations however one PI must serve as the main contact for NIH communication. The contact PI must be affiliated with the primary applicant organization. Generally, the primary applicant organization would be eligible for receipt of a potential award.

16. Do you anticipate that a significant portion of the engagement materials will be subject to IRB approval or are these mostly outside of the IRB?

Yes, all participant-facing collateral requires IRB approval.

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17. What has been successful and what do you see at the biggest gaps in AoU community engagement so far?
- a. Community partner awards
 - i. Involving both communities and individuals during the beginning phase of engagement design.
 - b. Community ambassadors
 - i. Leveraging the trust Community Partners have with their communities has been successful.

In terms of gaps:

- Engagements that can be easily deployed to people where they are as well as local partners deeply embedded with participant communities
- Engagements that build continuous, sustained relationships
- Leveraging local interactions
- Focusing on retaining/reengaging participants
- Non-digital engagements
- Digital engagements for people not familiar with digital engagements
- Engagements created using game-based design

18. Has AoU established enrollment targets and recruitment milestones for the various communities sought after in the study?

Our targets are 75% of UBR participants and 50% racial and ethnic minorities.

19. How closely linked do engagement technologies need to be to existing AoU technology systems and partners?

Many of them will be stand alone and will be utilized separately (i.e. if being utilized at a conference, etc.), however many will need to be integrated into our current systems.

20. Should we include participant incentives in our response if we feel they are needed or are those covered somewhere else?

This particular funding announcement is not involved in recruiting participants. The focus of this announcement is engagement. Participants who are enrolled in the program who decide to be physically measured and who decide to give blood and urine samples are offered a one-time compensation of value up to \$25 for their time and effort. This compensation would not be provided by awards under this announcement and should not be included in the budget request.

It is the Department's policy that government funds shall not be used to purchase promotional items when they are not a necessary expense in relation to the scope of the award.

Promotional items including, but not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags should not be included in the budget request for these awards.

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21. What has been learned so far about community education as a core component of study recruitment?
What has been learned is the importance of leveraging the knowledge, skills, expertise of the Community Partners.
22. We applied for a previous AoU RFP, but OT-PM-19-003 has stated purposes that we can meet. We covered these elements in our previous proposal. Are you sharing proposals internally, or do we need to apply again for this funding opportunity?
No, we are not sharing proposals internally. You will need to follow the instructions and submit a new proposal for this funding opportunity (OT-PM-19-003).
23. Given the scope of this request, would you please consider extending the due date for the proposal to April 15?
No, we cannot extend the funding opportunity deadline.
24. Engagement suggests that this award excludes a focus on recruitment of participants. Is that correct? If so, is recruitment then addressed in the marketing/communications award?
We do hope that any work done under this award interests participants in learning more about and hopefully joining the program, but this award focuses on engagement. Recruitment is being done by our Health Care Provider Organizations and Direct Volunteer Partners.
25. The ASSIST proposal structure has a field to upload a multi-PI leadership plan (MPI) if the proposal is submitted as an MPI application. Will an MPI leadership plan be required, and will the plan count against the 26-page application maximum?
If an application has multiple PIs, the applicants must submit an MPI plan. This plan will not count against the 26-page limit as long as the plan is submitted in the ASSIST proposal MPI Leadership Plan field.
26. Can food costs be included in the budget? Our experience in working with community member organizations is that conducting work, such as during consultation, over a meal is expected.
Refreshments are not allowable costs. Meals might be allowable during a working meeting if they are consistently provided in accordance with the applicant organization's policies. Any funding request for meals must meet HHS rules, be fully justified, and be approved by NIH in advance
27. May applications include more than one PI from one organization?
Yes, but one of these PIs must be listed as the contact PI.
28. Can you elaborate on the provider engagement and the retention aspects of the application?
Providers are integral to the program's success. We have been working with providers to make them aware of the program and encourage them to help engage people in the program. Providers can, for example, tout the potential benefits of precision medicine. We also want to make participants aware that, as with any long-term study, the longer participants stay in the program, the more beneficial their participation will be.
29. Can engagement participants be given a stipend for their time?
Compensation for individuals involved in engagement/education activities can be provided. Applicants considering providing compensation must specify the anticipated level of

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compensation, justification for the applicable funding levels and activities to be conducted. (Additionally, please refer to question 20 regarding participant incentives.)

30. I understand small businesses are eligible for this FOA. Is this true? If so, do you have any advice to small business owners?
Yes, small businesses are eligible for this funding opportunity. The advice for small business owners is the same as for all applicants—to review the OT policy guide for this program and the funding opportunity. All applicants should pay close attention to the program requirements listed in the announcement.
31. Should the submitted budget be for the full \$8 million or a portion of that? If a proposed intervention is more than \$8 million, will it be reviewed/eligible for funding?
The budget should be relevant to the activities the applicant plans to conduct in each year. If the planned activity costs only \$6 million direct costs, then the applicant's budget total should be \$6 million direct costs. If an application's budget exceeds the \$8 million direct costs funding cap in a year, the application will not be eligible for funding.
32. You shared a list of your community partners. Are those ongoing partners throughout the life of the award?
We hope to have ongoing relationships with all the people with whom we have connected that are interested in the program. Some partners receive funding and others do not, and the hope is that all partners will continue to work with *All of Us*. However, we cannot guarantee ongoing partnerships throughout the life of the award.
33. Should the budget be for the entire five-year project period, or only for the first year?
The budget should be for the full five years of the award.
34. If my company has demonstrated experience and success engaging underrepresented communities in other arenas, but not biomedical research, should we still apply?
Yes, you should submit an application. We are seeking applications from anyone with demonstrated experience and success in engaging underrepresented communities. Potential applicants that can address the needs listed in the funding opportunity should apply.
35. May awardees seek additional outside funding to supplement the award?
For this funding opportunity, cost sharing or matching is not required. However, organizations are permitted to seek partnerships that provide in-kind or cost-sharing support. If such contributions are included, they should be described in the application along with details on how these funds and/or resources will be utilized.
36. If we share a proposal that includes ideas for all of the five areas of need, but only three are considered of interest by the reviewers, would you consider awarding for the three?
You should submit an application that focuses specifically on your area(s) of expertise. If you submit ideas for all five areas but only three are of interest to the reviewers, we may decide to provide funding to implement activities in the three areas that are most appropriate for the program.
37. If the database is expected to give us an overall view of health and wellness in the United States, why will it include only underrepresented communities?

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The *All of Us* Research Program does not focus only on UBR communities, but the program and its engagement efforts are focused heavily on UBR groups. Many existing databases have significant numbers of members of majority populations. A core value of the *All of Us* Research Program is for its participants to reflect rich diversity of the United States. Hence, we are seeking engagement opportunities to help us engage underrepresented groups, especially those who are not well represented in health and medical research.

38. Would you please speak to the deliverables, including what types and how many are required?

All applicants are asked to address the criteria for the award and to include in their applications what they believe to be the best strategies to meet the stated goals.

39. It is significantly easier to engage underrepresented groups when you are a member of such a group. Will preference be given to entities whose PI is a member of an underrepresented group?

Preference will be given to ideas that will have the greatest impact on the program.

40. Is the 26-page limit for each category?

No, the 26-page limit is for the entire application. Details on this requirement are provided in the "Required Application Instructions" section on page three (3) of the funding opportunity.

41. The RFP asks for biosketches for key personnel, but the limit is three pages. Are you looking for briefer bio-blurbs than traditional NIH biosketches?

We are not seeking traditional NIH biosketches. Instead, we seek concise, program-specific relevant information on the background and expertise of the key team members involved in the application.

42. In the development of engagement materials and assets, are there any restrictions? Are we able to create innovative materials relevant to the communities being engaged?

We want applicants to propose innovative and creative engagement materials that resonate with the populations we are trying to reach, especially those that are UBR.

43. Is travel included in the \$8 million?

Yes, the \$8 million annual cap on direct costs must include the required travel costs described in the funding opportunity.

44. Will the award cover the entire United States?

The *All of Us* Research Program is a national program. The engagement assets that applicants plan to create should be replicable and scalable for use anywhere in the United States.

45. In the proposal, can we provide URLs to relevant materials we have produced previously to show the quality and relevance of our work?

URLs to relevant materials are not permitted in the application and will not be considered during the review.

46. Are there any other guidelines on the structure of the writing?

No, there are no other guidelines. Please refer to the language in the funding opportunity.

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47. Does this funding as a OT mechanism "count" in NIH ranking \$\$?
The OT mechanism is included in the NIH funding rankings that include **all** NIH funding support (including grants, contracts, and other). Various NIH programs that refer to the NIH ranking for determination of eligibility and funding levels do not always include OT. Please refer to the relevant program guidance for confirmation.
48. Do you have suggestions for formatting the science piece of the app?
No. Please refer to the language in the funding opportunity.
49. How is this tied to the Million Veteran Program?
While the VA is one of our partners and helping enroll veterans, some of whom may also be MVP participants, the MVP is a separate research effort.
50. If the awardee attracts additional demographics, may we adjust the scope to include their data?
This award is not limited to specific demographics. Programmatic priority will be given to applicants who have demonstrated experience and success working with and reaching into communities historically underrepresented in biomedical research as defined in the funding opportunity's Purpose section.
51. If answering both RFP's, should applicants provide redundant costs? For example, our PI's compensations would be entered in each proposal independently?
The Engagement and Retention Innovators award and the Communications and Marketing Partners award are two separate funding opportunities. Each funding opportunity will be reviewed separately. Please include a complete cost proposal that provides details of how you will use the funds requested in an application responsive to the Engagement and Retention Innovators funding opportunity. Applications that do not include all of the requested material will be considered non-responsive to the funding opportunity.
52. The 002 Campaign will generate marketing programs — this seems somewhat redundant... how will we integrate since the marketing partners are likely to define campaign messaging?
Impactful engagement is distinct from marketing and/or messaging. Impactful engagement means a bidirectional, co-equal relationship between the program and its participants. In terms of integration, the awardee must be innovative, collaborative, flexible, creative, responsive to many different stakeholders, and comfortable with being self-directed where appropriate.
53. May we use charts/graphs?
Charts/graphs may be utilized in the application submission. The total application submission must not exceed the stated page limits. Appendices are not permitted.
54. Are you seeking applicants that focus on a smaller target audience, e.g. as county or state area? Including territories, e.g. Puerto Rico?
Applicants that focus on a smaller target audience are acceptable, if these applicants are also innovative, collaborative, flexible, creative, responsive to many different stakeholders, and comfortable with being self-directed where appropriate. Applicants should also be able to create engagements that are scalable and can be used by the entire *All of Us* consortium with appropriate adjustments.

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55. Will you provide the names of the incumbents?
All of our current award partners are listed on our [website](#).
56. What is the basis for the evaluation criteria?
The evaluation criteria as stated in the funding opportunity are based on the priorities for this program.
57. Is the awardee covering the entire US?
While the awardee does not need to be an existing national organization, applicants should also be able to create engagements that are scalable and can be used by the entire *All of Us* consortium with appropriate adjustments.
58. Where do these engagements take place?
These engagements will take place in any location where our program partners might interact with participants.
59. Does it make any sense to submit an application for engagement in a part of the country where there is no nearby center to actually acquire samples, etc. from participants?
The Engagement and Retention Innovators award is focused on impactful engagement, not recruitment. The proximity of specific communities to clinics with the capacity to accept physical measurements and biospecimens should not impact an application.
60. Are evaluations that assess community response to and awareness of the program to date in order to determine the best localized engagements appropriate under this funding announcement?
Yes.
61. What would be the metrics of success once the award is rolled out?
Final metrics will be negotiated prior to award. In general, the applicant should outline their proposed evaluation plan.
62. What are current digital strategies in the All of Us program and how do you see the digital engagement strategies fitting with those?
The All of Us Program maintains an informational/marketing website (joinallofus.org) and digital assets used for marketing and engagement across multiple channels (including web and email). Current strategies are targeted at program needs across stages including education and awareness, recruitment and enrollment, and participant engagement and retention. Digital strategies are assessed and updated on an ongoing basis dependent on multiple factors including asset performance in campaigns and evolving programmatic needs over time.
63. Is there a preference for stand-alone engagement approaches vs approaches that integrate with the existing infrastructure? Do respondents need to address both to be competitive?
No preference. Respondents should address areas in which they have demonstrated expertise.
64. What counts as "success" in the targeted expertise areas?
Final success metrics will be negotiated prior to award.
65. Are you looking to fund piloting proposed strategies as part of this award?

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We are looking for innovative and creative engagement strategies.

66. An early slide in the webinar showed multiple partnering organizations across the country, is this list the same as the partners currently listed online?

Our current partnering organizations can be found on our [website](#).

67. We are considering developing a local strategy that can be deployed nationally and would like to ask if this would be an acceptable approach for this application.

Yes, this would be an acceptable approach for this application.

68. Are organizations (subs and prime) allowed to have a line for profit.

A line of profit may be requested for NIH review and consideration.

69. Are senior managers allowed to bill up to the max salary level on direct cost and also have income from G&A for their management responsibilities of the organization?

Salary support requested must be compliant with the [NIH Salary Cap](#).

70. Can you please confirm that letters of support are NOT to be included in the application?

The applicant has MANY community partners.

Appendices are not permitted for this funding opportunity. Letters of support may be included within the stated page limits.

71. Regarding the NOT-PM-19-003 notice: are Health Care Provider institutions currently funded by the All of Us Research Program eligible to apply to this notice? At the University of Chicago, we are very committed to engaging and retaining persons previously underrepresented in biomedical research, and we would be very interested in this funding opportunity.

Potential applicants that can address the needs listed in the funding opportunity should apply. The proposed activities in an application should be novel and not duplicative of existing activities supported through the All of Us Research Program or other NIH programs.

72. Can we include additional pages outside the technical page limit that would include citations? Perhaps in an appendix?

Additional pages and appendices will not be accepted. Please refer to the page limit requirements. Going beyond the stated page limits indicated will render the proposal ineligible.