Overview Information

Funding Opportunity Title	***All of Us* Research Program Genetic Counseling Resource (OT2)**
Funding Opportunity Number	OT-PM-19-001
Participating Organization	National Institutes of Health (NIH)
Components of Participating Organizations	This funding opportunity is part of the NIH *All of Us* Research Program. The funding opportunity will be administered by the National Center for Advancing Translational Sciences (NCATS) on behalf of the *All of Us* Research Program.
Opportunity Type	New
Related Notices	NOT-PM-19-001 – Notice Announcing Funding Opportunity Issued for the *All of Us* Research Program Genetic Counseling Resource (OT2) OT-PM-18-002 – Funding Announcement for *All of Us* Genome Centers (OT2)
Funding Opportunity Purpose	The purpose of this funding opportunity (FO) is to solicit applications for a Genetic Counseling Resource to support the *All of Us* Research Program and its participants. The *All of Us* Research Program seeks to create one of the world's largest and most comprehensive precision medicine research platforms. Its goal is to build a data resource containing multi-layered information on one million or more participants who reflect the rich diversity of the United States. In a new model for large-scale biomedical research programs, participants in *All of Us* are partners in the program and will have access to information collected about them, including genomic data. Genomic data can harbor important health information, such as indication of an individual's response to a medicine or specific measures of disease risk. Findings can also offer information relevant to family members, who may carry the same genomic variation, or inform family planning by revealing a risk of parents passing certain genetic disorders to their children. Due to the complexities surrounding the return of genomic results to participants, the *All of Us* Research Program has determined that a Genetic Counseling Resource is required to facilitate this return in a responsible fashion. The Genetic Counseling Resource awarded under this FO will be responsible for: 1) developing the capacity to provide genetic counseling call center services for participants (ultimately numbering > one million) in the *All of Us* Research Program and their health care providers, 2) delivering to participants clinical reports of findings of medically-actionable variants and providing initial genetic counseling and hand-off to medical care, 3) contributing to the development of genetic/genomic educational resources for the program, 4) contributing to protocol development for Institutional Review Board and/or for regulatory agency review, 5) developing innovative technologies and approaches for population-scale genetic counseling

	services, 6) establishing strong collaborative relationships with other awardees contributing to the *All of Us* genomics platform, and 7) contributing to strategic planning for the program as a member of the *All of Us* consortium.
Funding Instrument	The funding instrument is the Other Transaction (OT) award mechanism: an OT award is not a grant, cooperative agreement, or contract, and uses Other Transaction Authority.
Funds Available	The *All of Us* Research Program expects to adjust funds allocated for the Genetic Counseling Resource awards on an annual basis, dependent on volume of services, programmatic requirements, and availability of funds. Applicants should not exceed $2M in direct costs for year 1 of the OT2 award application. Budget proposals for each of years 2-5 should follow the Cost Proposal guidance provided in the Required Application Content section.
Anticipated Number of Awards	NIH intends to fund one to two awards in FY2019.

Key Dates

Award Project Period	The total project period is anticipated to be five (5) years.
Post Date	November 30, 2018
Application Due Date	February 1, 2019 (5:00 p.m. local time)
Scientific/Technical Review Date	Review will be conducted in March 2019.
Award Timeline	Award will be made upon selection and award negotiation. Earliest anticipated start date is April 15, 2019.

Application Instructions

Required Application Content	Applications must include sufficient detail to allow the NIH and reviewers to assess applicants' capabilities to successfully complete the award activities. All applicants must address and integrate all task areas. Eligible organizations may submit only one application. Applications must include the following with the total application package, not to exceed 30 pages: • Technical approach; not to exceed 15 pages. o Provision of electronic and tele-counseling services to participants and health care providers. o Establishment of a network of genetic counseling professionals for the *All of Us* Research Program. Applicants should comment on experience and capabilities of addressing cultural sensitivities such as those inherent in the program's diverse cohort.. o Approach to innovation for largescale counseling services. The *All of Us* Research Program anticipates achieving a scale of >200,000 participant enrollments per year, with the goal of reaching one million participants, each of whom will be offered the return of

genomic results. Substantial innovation may be necessary to achieve effective genetic counseling services at this scale. Applicants should clearly articulate solutions to the challenges in achieving scale effectively.
  - o Provision of educational materials.
  - o Data security and management (as described in Purpose and Objectives of the *All of Us* Research Program Genetic Counseling Resource section).
- Regulatory compliance; not to exceed 3 pages. Applicants must describe medical geneticist and genetic counselor licensure and compliance with state and federal regulations to allow services to be offered in all U.S. states and territories.
- Key personnel (applicants should provide brief bios of key personnel); section not to exceed 4 pages. The level of effort these individuals anticipate committing to this project, if awarded, must be identified. Minimum levels of effort (LoE) are given in parentheses below. Each application must identify the Program Director/Principal investigator (PD/PI LoE 25%) [or optionally, multiple PIs/PDs, LoE 20% each] and a Project Manager (LoE 80%). A list of other key investigators must be included. The individual with primary responsibility for regulatory compliance oversight should be identified. An overall leadership structure and management plan must be included in this section. If there are multiple PDs/PIs, a leadership plan that incorporates a conflict resolution strategy must be included.
- Corporate/organizational experience related to the funding opportunity; not to exceed 2 pages. Applicants should describe or refer to the institutional record of performing the specialized work required in this project.
- Cost proposal; not to exceed 6 pages. Applicants must provide a milestone-driven, cost-allocated plan. The table below describes the anticipated annual volume of genetic counseling (GC) case work for the return of monogenic disease variants and for inquiries to the Resource. These numbers are provided for guidance to applicants but may be adjusted during the award period. Applicants should describe proportions of call center volume that are expected to require or not require communication with a live, trained professional.

Budget Year	GC cases (annually)	Call Center Requirements (monthly contacts)
Yr 1	3,000	2,000
Yr2	4,000	3,000
Yr3	6,000	4,000
Yr4	6,000	>4,000
Yr5	6,000	>4,000

	Applicants should propose budgets necessary to achieve the scale described and should include hourly rates for professional services. A GC case is anticipated to require 2-3 hours, one for review and preparation, plus one to two for the counseling interaction. *All of Us* cannot provide extended services and therefore transition of a participant to appropriate health care services will be a core objective. Cost models can include elements of cost-sharing, fixed price, or adjustable (cost-reimbursable) agreements or a hybrid agreement. • Additional requirements, to be included within the above application segments: Applicants should comment on experience working with external partners. Collaborative work with other members of the *All of Us* Research Program consortium will be required of the successful applicant(s). Applicants must affirm agreement with *All of Us* Research Program principles regarding the privacy and trust of participants, specifically, the Precision Medicine Initiative Data Security Policy Principles and Framework and Privacy and Trust Principles. A one-page cover letter is not included in the 30-page limit. The cover letter must include the name and contact information for the authorizing organization representative and PD/PI(s). The letter must also include a statement and confirmation that the PD/PI(s) and authorizing organization representative have read and agreed to abide by the Other Transaction Award Policy Guide for the NIH Precision Medical Initiative Research Programs. Letters of support from partnering organizations/collaborators are also allowed and are not included in the page limit but are restricted to 12 letters in number. A literature reference list is allowed and is not included in the page limit. **Appendix – Genetics Educational Examples.** A single appendix, not to exceed 5 pages, is permitted to illustrate the content and client experience for reception of genetic results. This content may be in the form of hard copy materials sent to a client or screen shots of electronic presentation of materials.
Instructions for Application Submission	Applications must be submitted via the NIH eRA ASSIST System by February 1, 2019. To submit an application via ASSIST, the applicant organization must be registered in eRA Commons (see instructions). Organizations already registered in eRA Commons do not need to reregister. Once the organization is registered, the individual(s) with the role of Signing Official (SO) and Program Director/Principal Investigator (PD/PI) must be affiliated with the organization and have eRA Commons credentials to complete the submission process.

	Use OT-PM-19-002 in the field requesting Funding Opportunity Announcement. Here are Instructions for submitting via the NIH eRA ASSIST system. In the future, instructions will also be available in the ASSIST online help (look for the OTA section). Technical help is available at the eRA Service Desk
Eligibility Information	
Eligible Applicants	The following entities are eligible to apply as an applicant organization: Higher Education Institutions • Public/State Controlled Institutions of Higher Education • Private Institutions of Higher Education The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education: • Hispanic-serving Institutions • Historically Black Colleges and Universities (HBCUs) • Tribally Controlled Colleges and Universities (TCCUs) • Alaska Native and Native Hawaiian Serving Institutions • Asian American Native American Pacific Islander Serving Institutions (AANAPISIs) Nonprofits Other Than Institutions of Higher Education • Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education) • Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education) For-Profit Organizations • Small Businesses • For-Profit Organizations (Other than Small Businesses) Applicant organizations are encouraged to seek partnerships with all types of domestic organizations. Organizations with current awards from the *All of Us* Research Program are eligible for this opportunity.

Foreign Institutions	Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components are **not** allowed. Foreign components are defined as those responsible for performance of any significant element or segment of the project outside of the United States either by the award recipient or by an individual employed by a foreign organization whether or not OT2 award funds are expended.
Application Review	
Objective Review Process	Applications will be evaluated for responsiveness to the FO requirements by NIH staff. Criteria include completeness of technical and cost elements, ability to achieve throughput goals with available funds, and institution/team experience in genetic counseling services at large scale. Responsive applications will be evaluated for scientific and technical merit by an appropriate review group convened by the NIH. Reviewers will evaluate applications based on the following: • Technical approach • Plans and capabilities to achieve volume of services • PD/PI and key personnel experience • Cost proposal Applicants may receive a brief written summary of the review. Successful applicants will undergo a negotiation process for award determination.
Evaluation Process	In addition to technical and scientific merit, applications will be evaluated for programmatic priority. Programmatic priority will consider the applicant's: • Demonstrated expertise in offering genetic counseling services across multiple U.S. states and regions • Demonstrated expertise in delivering genetic counseling services through multiple means, including tele- and e-counseling, and a record of innovation in electronic delivery of counseling and genetic educational content • Demonstrated expertise in offering genetic counseling services in multiple languages including, at a minimum, English and Spanish • Expertise in offering genetic counseling services to people from diverse and disadvantaged communities • Ability to achieve cost efficiencies in the application

Questions Regarding this Funding Opportunity and Program and Agreements Officer Contact	**Informational Webinar:** Monday, December 10, 2018, 12:00 pm-1:00 pm EST To register for this webinar and receive instructions, email: PMICPFOAInquiries@mail.nih.gov. Questions may be submitted via email to Bradley Ozenberger, PhD, *All of Us* Research Program, for scientific/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:PMICPFOAInquiries@mail.nih.gov.
Authority	Other Transaction awards will be made pursuant to current authorizing legislation, including the 21st Century Cures Act as specified in Section 402(n) of the Public Health Service Act, 42 U.S.C. 282(n).
***All of Us* Research Program Other Transaction (OT) Policy Guide**	Other Transaction awards are subject to the requirements of the *Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative Research Programs*. Applicants must review this policy guide, available at : https://allofus.nih.gov/funding.

All of Us Research Program Genetic Counseling Resource

Background

The *All of Us* Research Program is an historic effort to gather data over many years from one million or more people living in the United States, with the ultimate goal of accelerating research and improving health. Unlike research studies that are focused on a specific disease or population, *All of Us* will serve as a national research resource to inform thousands of studies, covering a wide variety of health conditions. Researchers will use data from the program to learn more about how individual differences in lifestyle, environment, and biological makeup can influence health and disease. Participants may be able to learn more about their own health and contribute to an effort that may advance the health of generations to come.

The partnership between *All of Us* and the participants enrolled in the program manifests in numerous ways, from participant involvement in program governance to communication of research findings with participants and participant communities. A core value of the program is that "Participants have access to their information." Such information may include physical measurements, electronic health records obtained from health care providers, and results of assays conducted using biospecimens collected from the participant. This commitment to provide access to information includes the responsible return of genomic results. This FO describes the requirements for an *All of Us* Genetic Counseling Resource (GCR) to support the responsible return of genomic results to *All of Us* participants.

Considerations Toward a Comprehensive Genomics Strategy is a report convened by the *All of Us* Advisory Panel Genomics Working Group. Applicants may find this report useful as an additional source of background on the program's intentions. It describes deliberations towards the following goals for a return of genomic results pilot phase, which the genetic counseling resource will be an integral part of, including to: (1) test the generation, processing, analysis, interpretation, and sharing of genomic data in

All of Us at a scale sufficient to enable planning for a genomic strategy for the full cohort; (2) pilot the return of results of clinical utility to participants at a scale sufficient to inform the development and refinement of the return-of-results strategy and process; and (3) provide a genotype and phenotype resource that will add value above other existing genomic data sets and make this resource widely available to the research community in an efficient and non-burdensome manner. Although the report had a primary objective of considering the technical aspects of generating and analyzing one million genomes, the group did recognize the critical need for an *All of Us* partner to facilitate "return of results to participants, and a handoff to clinical care for participants with clinically actionable results." This FO describes the requirements for an *All of Us* Genetic Counseling Resource (GCR) to support this important objective for the program.

Genome Center Analyses

All of Us Genome Centers were awarded in September 2018 (see OT-PM-18-002). These Centers generate genotype and whole genome sequence data, analyze these data and call variants using state-of-the-science approaches. These data constitute a crucial element of the *All of Us* research platform (www.researchallofus.org). The Centers also analyze and interpret the variants for medical utility. Specifically, *All of Us* will provide to participants a genome report on pharmacogenomic variants and will alert any participant of a finding of a pathogenic variant in genes defined in the American College of Medical Genetics and Genomics (ACMG) Secondary Findings List, provided the participant has consented to receive such results. Each observation of a pathogenic variant in this set of genes will be validated by clinical assay and a clinical report will be generated for transmission to the *All of Us* GCR. Primary data files from genome analysis also will be made accessible to participants upon request.

These three categories of results (pharmacogenomics, pathogenic monogenic disease variants, and primary data file) are anticipated to constitute the first tier of genomic information to be offered to *All of Us* participants and to be included in considerations for the GCR. However, additional tiers of information are expected in the future. *All of Us* currently is evaluating the potential for return of non-clinical genomic information to participants. This may comprise non-clinical genetic traits as well as results of ancestry analysis. Applicants to this FO should anticipate services to support participants receiving such results within the first two years of the award. Applicants should anticipate further advances in later years of an award, with potential support at scale for return of such results as carrier status and polygenic risk scores.

Purpose and Objectives of the *All of Us* Research Program Genetic Counseling Resource

The NIH solicits proposals from US institutions (academic or private) or consortia of US organizations to serve as a GCR for the *All of Us* Research Program. Primary goals for the *All of Us* GCR are to: 1) provide tele-counseling and e-counseling services for *All of Us* participants and participants' health care providers, 2) deploy a network of genetic counselors to provide services to participants receiving medically-actionable genetic results, 3) contribute to *All of Us* consortium activities relating to the responsible return of genomic results, and 4) contribute to the advancement of technologies and approaches for population-scale genomic education and counseling for precision medicine delivery.

The specific research and support objectives for this FO are described below. All areas should be addressed in the Technical Approach section of the application.

Tele-Counseling and E-Counseling Services

All of Us Genome Centers will generate exceptionally large amounts of genomic data from the diverse cohort of participants represented in *All of Us*. These Centers will rapidly scale up high-density genotyping, up to 150,000 assays in year 1 of a GCR award and 200,000 or more in years 2-5. Simultaneously, the Genome Centers will be ramping up whole genome sequencing, ultimately

generating these data for one million *All of Us* participants. Genome Centers will conduct limited clinical interpretation of data to include pharmacogenomic markers and pathogenic variants in genes defined in the American College of Medical Genetics and Genomics (ACMG) Secondary Findings List. Participants will also be offered access to a personal genome data file without interpretation. *All of Us* expects to add more genome analysis result types as the program matures to enhance the value to participation in the program. These results likely will include ancestry, non-medical traits, carrier status, and polygenic risk scores. The GCR will be tasked with providing support to participants and their health care providers who may have questions about such results.

Applicants should describe approaches to applying technological solutions to counseling at high volume, potentially including computer-assisted counseling (e-counseling) as a supplement to tele-counseling services. These services must be capable of supporting the substantial volume anticipated by *All of Us* while also considering cultural sensitivities of the diverse communities represented in the *All of Us* Research Program. Genetic counseling support may be requested by participants and by their health care providers. Applicants should specify the types of services to be made available for each of these groups. As noted above, support resulting from providing a genome report to 150,000 participants is required in year 1 and will expand in later years. It is not feasible to predict *a priori* how many contacts may be made with the GCR. Applicants should budget for resources to support at least 2,000 contacts per month in year 1 of an award, 3,000 in year 2, and 4,000 or more each month in years 3-5. Actual demand on the GCR will determine the resource requirements in all years of the award.

Applicants should describe the rationale for allocation of resources for e-counseling versus tele-counseling services. To serve the scale and diversity of *All of Us* (with limited availability of genetic counselors) and to reduce costs, development of robust approaches for artificial intelligence (AI) or chat bot mediated counseling will be required. The successful applicant will have proven capabilities with such approaches and should describe both current methods and the development path toward increased capacity for *All of Us*. E-counseling is not a satisfactory solution for all inquiries, and an approach for live connection with a trained genetic counseling professional is required. The applicant should specify the diversity of and relevant resourcing for services like AI-directed electronic chat with a counselor and voice interactions.

All of Us participant enrollment and engagement is fully bilingual with participant interactions available in English and Spanish. Applicants must describe capabilities to support Spanish-speakers, as well as potential to support additional languages. The program anticipates increasing linguistic capabilities in the future and applicants should comment on experience working with translation services. In addition, experience in offering genetic counseling services to people from diverse and disadvantaged communities should be described.

Counselor Case Work

Return of a finding of a pathogenic variant in the list of genes defined by the ACMG for reportable secondary findings requires particular care in the communication to a participant. The *All of Us* Genome Centers will generate individual clinical reports describing such findings and transmit these reports to the GCR for assignment to a genetic counselor. The initiation of a case will include identification of the previously de-identified participant, examination of available medical records, and preparation for initiating contact with the affected participant. Applicants should describe procedures for creation of a genetic counseling case, starting from receipt of a clinical report and detailing a preferred approach to conducting review of records within the bounds of the *All of Us* program. Data from electronic health records for some participants, but not all, will be available to the genetic counselor (GC). Results of a survey instrument on family medical history may or may not be available.

Participants will consent, in general terms, to the return of genomic results prior to receipt of a genome report and prior to clinical validation of a pathogenic variant conferring disease risk. Participants then will have the option to receive or not to receive each report generated during the course of their participation in the program, including the option to receive a report of an actionable pathogenic variant from a GC. Following validation of a pathogenic variant at a Genome Center and assignment of the case to a GC, an important element of the GC encounter with the participant will be the conveyance of information that a finding is available and ascertainment whether the participant wishes to receive this finding. Note that *All of Us* has no disease emphasis and most participants receiving an incidental finding likely enrolled in the program believing themselves healthy. Applicants should describe their preferred approach to making initial contact with a participant including procedures for appointment scheduling, if necessary, and approaches to "pre-counseling" education. Applicants should describe methodologies for researching and improving the participant/counselor interaction, to include approaches to improve successful contact and engagement of affected participants.

All of Us has neither infrastructure nor funding to provide ongoing- support to affected participants. Genetic counseling will necessarily be brief, with the important objective of directing the participant to appropriate longer-term support. Applicants should describe the full extent of the genetic counseling case work flow, from medical history research prior to the counseling encounter through the counseling session and the recording of outcomes. Note should be made of estimated average GC time required for each case. The cost proposal should include the per case hourly effort and costs. The applicant should describe experience with directing clients to appropriate care, emphasizing experience with clients who do not have ready access to health care.

Educational Content
Applicants will contribute to development of *All of Us* educational materials relating to genetics/genomics and health. Applicants should describe capabilities in this area, regarding both general knowledge of genetics/genomics and specific genetic findings. Examples of the applicant's approach to client education and educational materials are encouraged, and an appendix is permitted to provide reviewers with this information. The appendix may not exceed 5 pages.

Data Security and Management
The awardee will work closely with the *All of Us* Data and Research Center and the *All of Us* Genome Centers.
Applicants should describe their organization's information technology (IT) platform and approach to data security. Technical details that will enable data exchange with the Data and Research Center (which uses a secure enclave on the Google Cloud Platform) should be provided. Awardees will be required to maintain standards and practices for data security to *All of Us* requirements.

Maintaining the trust of *All of Us* participants and ensuring the security of their data are essential elements of the program. Applicants should comment on policies and procedures to maintain compliance with the following *All of Us* Research Program principles:

- Precision Medicine Initiative: Data Security Policy Principles and Framework
- Precision Medicine Initiative: Privacy and Trust Principles

Technical Innovation for Precision Medicine
Successful awardees will have an opportunity to work at the forefront of precision medicine research and support the inclusion of genomic data into clinical decision making for the betterment of patient health and well-being. Applications should describe research approaches to providing genetic counseling

resources at a population scale. These approaches should include innovative means of offering direct counseling to patients as well as methods of assisting health care providers in the delivery of genetic findings. Applicants are directed to the sections below entitled **Inventions and Patents** and **Ownership of Data, Software, and Other Products** for more information on policies regarding invention rights in *All of Us*. Intellectual property developed as an awardee of the *All of Us* Research Program will be owned and controlled by the NIH.

Additional Elements

Professional Code and Regulatory Compliance
Applicants should provide a description of genetic counselor continuing education requirements and elaborate on communication and monitoring of ethics standards. *All of Us* enrolls participants in all U.S. states and populated territories. Applicants should describe capabilities to support the program with GCs licensure compliance in all U.S. jurisdictions which require GC licensure.

Other Transaction and Genetic Counseling Resource Awards

The Other Transaction award mechanism allows significant ongoing involvement from NIH staff and provides the NIH the flexibility to alter the course of the project in real time to better meet the program's overarching scientific goals and to explore with awardees additional innovative ways to improve the genomics platform. This may mean that awarded activity could be expanded, modified, and partnered –-or in some cases, not supported or discontinued – based on program needs, emerging methods or approaches, and availability of funds. Performance during the award period will be reviewed on a frequent and ongoing basis and milestone adjustments will be made as necessary.

Key Events	**Dates**	**Action needed by applicants**
Funding Opportunity Posted	November 30, 2018	
Applications Due	February 1, 2019 **Step 1 MUST be completed on time.**	**Refer to the Instructions for Application Submission section for details.** Submit electronically via ASSIST (https://public.era.nih.gov/assist), using Funding Opportunity Announcement number **OTA-19-002**. Applicants are encouraged to begin the eRA registration process early.
Review of applications completed	March, 2019	

Key Events	Dates	Action needed by applicants
DUNS and SAM number registration**	February 15, 2019	Potential award recipients must provide confirmation of DUNS and SAM number registration to PMICPFOAInquiries@mail.nih.gov
Estimated Earliest Award Date	April 15, 2019	

**DUNS and SAM number registration can take several weeks. Please see the registration link for helpful instructions. Awards require a DUNS and SAM registration. The registration link is specific to grants, however, the process for DUNS and SAM registration for this OT award is the same. Candidates should begin the registration process several weeks prior to this deadline to ensure completion in time to provide this information to NIH.

***All of Us* Research Program Organization and Governance Structure**

The *All of Us* Research Program functions as a Consortium, with all awardees considered members. Under the present structure, including committees, task forces, and boards are established by the *All of Us* Research Program to oversee the development and implementation of consortium activities. The governance structure may change periodically to meet the evolving needs of the program. Awardee personnel may hold specific roles in program governance structure based on their role in their institution's program activities. For example, the *All of Us* Research Program Steering Committee currently consists of the contact Program Directors/Principal Investigators (PDs/PIs) from all aspects of the awards. The *All of Us* Research Program consortium includes participant representatives in throughout its governance structure.

The *All of Us* Research Program has a single Institutional Review Board (IRB) that ensures prompt and thoughtful consideration of the evolving protocols and the central importance of participants as research partners in the *All of Us* Research Program. The single IRB includes representatives from the participant community. Each awardee will be required to either agree to an existing IRB reliance agreement with the program or establish a new IRB reliance agreement, depending on program requirements .

Budget

Funds requested for salary support for all personnel must comply with the NIH Salary Cap in effect at the time of award.

Applications will use a budget model separating tele-counseling/e-counseling services and case work for return of pathogenic monogenic disease risk results. Hourly rates for professional services should be indicated.

No separate equipment budget is allowed.

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.

The year 1 budget is limited to $2M direct costs. The budget for additional award years should be consistent with the volume of services as indicated in the Required Application Content section and should take into account increased efficiencies in the course of the program.

Inventions and Patents

To promote the broad sharing of information and inventions in the *All of Us* Research Program, awardee inventions will be governed by FAR clause 52.227-13, which provides title to the Government in any invention made under this award, subject to a revocable, nonexclusive, paid-up license in each patent application filed in any country on a subject invention and any resulting patent in which the Government obtains title. This is to assure that patents directed to inventions made under this award cannot be used to block access by the research public to this important resource and associated technology.

(1) The Awardee shall include the substance of this patent rights clause in all third-party agreements for experimental, developmental, or research work. This patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the third parties (subcontractor, sub-awardees, and vendors) have all rights and obligations of the Awardee in the clause. The Awardee shall not, as part of the consideration for awarding the third-party agreement, obtain rights in the third party's subject inventions.

(2) In the event of a refusal by a prospective third party to accept the clause, the Awardee—

a. Shall promptly submit a written notice to the *All of Us* Research Program Agreements Officer setting forth the third party's reasons for such refusal and other pertinent information that may expedite disposition of the matter; and

b. Shall not proceed with such third-party agreement without the written authorization of the *All of Us* Research Program Agreements Officer.

(3) In third party agreements at any tier, the agency, the third party, and the Awardee agree that the mutual obligations of the parties created by the patent rights clause constitute a contract between the third party and the agency with respect to those matters covered by this clause.

(4) The Awardee shall promptly notify the *All of Us* Research Program Agreements Officer in writing upon the award of any third party at any tier containing a patent rights clause by identifying the third party, the applicable patent rights clause, the work to be performed under the third-party agreements, and the dates of award and estimated completion. Upon request of the *All of Us* Research Program Agreements Officer, the Awardee shall furnish a copy of such third-party agreement, and, no more frequently than annually, a listing of the third-party activities that have been awarded.

Ownership of Data, Software, and Other Products

NIH will own all rights in data, software, and other products (collectively "Works") made or developed under this award, subject to a paid-up, nonexclusive, irrevocable worldwide license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the awardee. The parties further agree that these Works are "works made for hire" as defined by the Copyright Act.

Award recipients agree that no commercial intellectual property (*e.g.*, data, software, or other products), whether owned by the awardee or a third party except those specifically referenced in the application, will be utilized without express prior permission of NIH.

Data Policies

All data generated by the *All of Us* Research Program, including the Genetic Counseling Resource, are intended for use through the *All of Us* Data and Research Center. Awardees must restrict their use of the data only to activities stipulated and characterized in the program.

All activities between the prime awardee, any sub-awardees, or other third parties will be required to conform to the *All of Us* Research Program approved protocols.

Awardees, and some partnering organizations, will be required to execute an Interconnection Security Agreement with the DRC to ensure the secure transfer of data. In addition, awardees are subject to security breach reporting requirements involving *All of Us* data.

Material Transfer Agreement
All awardees and partnering organizations will be required to comply with the established material transfer agreement below.

Any and all Material delivered pursuant to the award is understood to be experimental in nature and may have hazardous properties. The recipients of funds under this award, and any sub-awardees, may not make any representations and extend no warranties of any kind, either expressed or implied, with regards to such Materials. Unless prohibited by law, neither the recipients of funds under this award, nor any of their respective officers, directors, employees or agents shall be liable to the *All of Us* Research Program Biobank, for any direct, indirect, or consequential loss or damages arising out of the transfer, use, storage, or disposal of any such Material.

Institutions who receive Data and/or Materials under these awards are required to use Data and/or Materials only as outlined in the *All of Us* Research Program protocols, in a manner that is consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the institution's NIH funding, if any. Failure to adhere with this criterion may result in enforcement activities, including termination of award.

Human Subjects Requirements
The institution and personnel involved in the conduct of the research are required to comply with 45 CFR Part 46 and establish a reliance agreement with the *All of Us* Research Program central IRB. The NIH will issue all awardees a Certificate of Confidentiality to protect against the compelled disclosure of *All of Us* genomic data records and to support and defend the authority of the Certificate against legal challenges, per this Notice.

Termination/Expiration Requirement
A fundamental objective of this Other Transaction award announcement is to ensure that all specimens and data remain available without interruption to the research public, even in the event that awardees withdraw, are terminated, or can otherwise no longer manage the project. Upon termination or expiration of this OT award, NIH may take exclusive ownership, custody, and control of the resources generated by the *All of Us* Research Program, including specimens, data, and software, at its reasonable discretion. For purposes of this solicitation, "exclusive custody and control" means that upon termination or expiration of this award, the departing awardee and its partners may not retain or disclose a copy of any data and may not use any specimen (or portions thereof), acquired or generated under the award.

If the NIH decides to terminate this award, the termination of the award will be considered a unilateral change and the recipient will not have the right to appeal. Although a decision is made to terminate an award, the recipient must continue to comply with the Record Retention and Access, and Final

Reporting requirements, and may need to sign a non-disclosure agreement to complete the termination process.