S A M P L E

[AWARD #]

OTHER TRANSACTIONS AGREEMENT

BETWEEN

RECIPIENT LEGAL (SAM.GOV) INSTITUTION NAME
Recipient Address

AND

NATIONAL INSTITUTES OF HEALTH (NIH)
OFFICE OF THE DIRECTOR
***ALL OF US* RESEARCH PROGRAM**
6710B Rockledge Drive, 4th Floor
Bethesda, MD 20817

CONCERNING

<INSERT RESEARCH AND DEVELOPMENT TITLE>

This Agreement is entered into between the National Institutes of Health (NIH), an agency of the United States of America, and RECIPIENT LEGAL (from SAM.gov) ENTITY NAME pursuant to and under United States Federal law, as applied by the federal courts in the District of Columbia.

FOR RECIPIENT INSTITUTION:

[RBO Name] Date
Recipient Business Official (RBO)

FOR NIH:

[OTAO Name] Date
Other Transactions Agreements Officer (OTAO)

ARTICLES

ATTACHMENTS

ARTICLE I: SCOPE OF THE AGREEMENT

A. Background

This Agreement supports the *All of Us* Research Program (*All of Us*).

All of Us is a historic effort to gather data from at least 1 million diverse people living in the United States and its territories, with the goal of accelerating health research and medical breakthroughs, and enabling individualized prevention, treatment, and care. The program has created the Researcher Workbench, a secure cloud-based 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.

The *All of Us* Researcher Workbench may create more opportunities to:

- Know the risk factors for certain diseases
- Figure out which treatments work best for people of different backgrounds
- Better understand health disparities and improve health equity
- Learn how technologies can help us take steps to be healthier

Knowledge gained from observational cohort studies has dramatically advanced the prevention and treatment of diseases. Many of these cohorts, however, are small, lack diversity, or do not provide comprehensive information about participants. The *All of Us* Research Program is enrolling a diverse group of people who may contribute a range of data. These data include information from health questionnaires, electronic health records (EHRs), physical measurements, the use of digital health technology, and the collection and analysis of biospecimens. The program aims to make research results accessible to participants, and it is developing new approaches to generate, access, and make data broadly available to registered researchers.

B. Definitions

In this Agreement, the following definitions apply:

Agreement: This Agreement, modifications to this Agreement, and any Attachments or other documents that are expressly incorporated in and made a part of the Agreement, including but not limited to, Attachments 1, 2, 3, 4 and 5. The official, legally binding document between the Government and the Recipient. This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a corporation, or other business organization.

Award: The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Data: Recorded information, regardless of form or method of recording, which includes but is not limited to, technical data, software, mask works, programs, firmware, technical data, images, figures, charts, forms, and copyrightable works. The term does not include financial, administrative, cost, pricing or management information, and does not include subject inventions.

Deliverables: Any tangible or intangible work product including Data, Inventions, Know-How, and Materials (including third party work product including Data, Inventions, Know-How, and Materials) provided by Recipient to the NIH as a result of the performance of work under the Statement of Objectives and Milestones (SOM).

Foreign Firm or Institution: A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions, including a firm or institution located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed Program Director/Principal Investigator (PD/PI).

Government: The United States of America, as represented by the Office of the Director (OD) / National Institutes of Health (NIH)/*All of Us* Research Program.

Government Purpose Rights: The rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

Invention: Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Know-How: All information including, but not limited to discoveries, formulas, processes, ideas, approaches, concepts, techniques, technical solutions, methods, procedures, specifications, and trade secrets.

Made: When used in relation to any invention and means the conception or first actual reduction to practice of such invention.

Materials: Tangible materials including, hardware, devices, apparatus, and machines.

Notice of Award (NoA): The system-generated document signed by an Other Transactions Agreements Officer that funds an Other Transaction (OT) award or modification, references Federal funding limits and obligations, and provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system. For this Agreement, the NoA is utilized as a funding obligation document only and is not incorporated into this Agreement.

Other Transactions (OT): OT awards are not grants, cooperative agreements, or procurement contracts. They provide considerable flexibility to the government to establish policies for the awards, so policies and terms for individual OT awards may vary between awards. Each award is therefore issued with a specific Agreement, which is negotiated with the Recipient and details specific terms and conditions for that award. Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts, conditions on activities and expenditure of funds in other statutory or regulatory requirements, including any revisions in effect as of the beginning date of the next funding segment. The terms and conditions of the resulting OT awards are intended to be compliant with governing statutes.

Other Transactions Agreements Officer (OTAO): Individual at NIH responsible for legally committing the government to an Other Transaction (OT) award and to the Agreement through which terms and conditions are established, and for the administrative and financial aspects of the award.

Other Transactions Agreements Specialist (OTAS): An NIH designee of the OTAO for administrative and financial aspects of the award.

Other Transactions Program Official (OTPO): The NIH official responsible for programmatic oversight and direction of the work performed under the Statement of Objectives and Milestones (SOM). Individual authorized to provide scientific, technical, and programmatic direction to the Recipient on behalf of the government.

Party: Includes the NIH, or the Recipient, or both.

Practical Application: To manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is capable of being utilized and that its benefits are, to the extent permitted by law or Federal regulations, available to the public on reasonable terms.

Principal Investigator/Program Director (PI/PD): Individual designated by the Recipient to have the appropriate level of authority and responsibility to direct the project or program supported by the Agreement.

Program: Research and development being conducted by the Recipient, as set forth in Article I, paragraph E.

Recipient: [Institution Legal Entity Name (from SAM.gov)], the entity responsible for performing the administrative and programmatic activities described in this Agreement.

Recipient Business Official (RBO): Individual responsible for the legal commitment by the Recipient and for the administrative and financial reporting compliance with terms and conditions of the Agreement. In signing this OT bilateral Agreement, the RBO certifies that the Recipient will comply with all applicable assurances and certifications referenced in the Agreement. This individual's signature further certifies that the Recipient will be accountable both for the appropriate use of funds awarded and for the performance of the OT supported project or activities. This individual is responsible for ensuring that the Recipient complies with applicable Federal laws and regulations, including required certifications and assurances, its application and terms and conditions of this Agreement. All official correspondence must be submitted by the RBO.

Subject Invention: Any invention conceived or first actually reduced to practice in the performance of work under this Agreement.

Technology: All Data, Know-How, and Materials developed under this Agreement, and Subject Inventions.

Unlimited Rights: The rights to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

C. Authorization

This Other Transactions award is made under the Other Transaction Authority (OTA) as authorized by section 402(n) of the Public Health Service Act as amended [42 U.S.C. 282(n)]. Unless otherwise stated in this Agreement, this Agreement is not governed by the Federal Acquisition Regulation (FAR), 2 CFR 200, the NIH Grants Policy Statement, or administrative regulations governing grants.

D. Scope

The Recipient shall perform a coordinated research and development project (hereafter referred to as "Project") designed to develop the *All of Us* Research Program. The research shall be carried out in accordance with the "Statement of Objectives and Milestones" (SOM) incorporated into this Agreement as Attachment 1.

The NIH will have continuous involvement with the Recipient in the administration of this Project. The NIH will obtain access to project results and certain rights in patents and data pursuant to the terms and conditions of this agreement. NIH and the Recipient are bound to each other by a duty of good faith in achieving the Program objectives.

Subject to the availability of funds, the Recipient shall be paid for meeting its objectives and milestones.

ARTICLE II: TERM

A. Term of this Agreement

The Agreement commences on Month XX, 202X and continues for the period through Month, XX, 202X or for other such period as mutually agreed to by the Parties in writing, subject to the availability of funds. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified herein, shall be given effect, notwithstanding this Article. If all funds are expended prior to the project end date, the Parties have no obligation to continue performance and may elect to end this Agreement at that point.

B. Termination Provisions

1. The NIH may terminate this Agreement in whole or in part by written notice to the Recipient, if the OTAO determines that a termination is in the Government's best interest, provided that such written notice is preceded by meeting consultation between the Parties.

2. The Recipient may terminate this Agreement by giving the OTAO ninety (90) calendar days written notification of its intent to do so, provided that such written notice is preceded by consultation between the Parties.

3. The NIH and the Recipient shall negotiate in good faith a reasonable and timely adjustment of all outstanding issues including amounts due between the Parties as a result of termination, which may include non-cancelable financial commitments. The Government has no obligation to pay the Recipient beyond the last completed and paid milestone if the Recipient decides to terminate.

4. Within 30 days of notice of termination, the Recipient shall develop a Termination Transition Plan to be approved by NIH, which must include the following terms:
   a. Information security, including confidentiality, integrity, and availability of Data and systems
   b. Data transfer process for NIH owned Data
   c. Relevant records and information to effect termination and Data transfer of NIH owned Data Property disposition or property transfers, if applicable
   d. Any other terms deemed necessary by NIH

5. The proceeds of any transfer or disposition of property shall be applied to reduce any payments to be made by the Government.

6. In the event that this Agreement is terminated, the NIH shall have paid-up rights in Data owned by NIH as described in Article VIII, Data Rights, Participant-Derived Resources, Deliverables.

7. Failure of the Parties to agree to a reasonable adjustment shall be resolved pursuant to Article VI, Disputes. The NIH has no obligation to pay the Recipient beyond the last completed and paid milestone if the Recipient fails to comply with the terms and conditions of this Agreement.

C. Enforcement, Termination

If Recipient has failed to materially comply with the terms and conditions of this Agreement, NIH may take one or more enforcement actions, which can include disallowing costs, withholding of further awards, or wholly or partly suspending the OT award, pending corrective action. NIH may also terminate the OT award with no obligation to pay the Recipient beyond the last completed and paid milestone.

NIH may suspend (rather than immediately terminate) the OT award and allow the Recipient an opportunity to take appropriate corrective action before NIH makes a termination decision; however, NIH may decide to terminate the award if the Recipient does not take appropriate corrective action during the period of suspension. NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An NIH *All of Us* OT award may also be terminated, partially or totally, by the Recipient. If the Recipient decides to terminate a portion of an OT award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the award was originally made. In any such case, NIH will advise the Recipient of the possibility of termination of the entire OT award and allow the Recipient to withdraw its termination request. If the Recipient does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award with no obligation to pay the Recipient beyond the last completed and paid milestone. The Recipient may terminate this Agreement by giving the NIH Other Transactions Agreements Officer (OTAO) ninety (90) calendar days written notification of its intent to do so, provided that such written notice is preceded by consultation between the Parties.

If the NIH decides to terminate an OT 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 requirements.

D. Flow Down / Lower Tier Agreements

1. Definitions

a. "Lower Tier Agreement" means a written agreement between the Recipient and a Sub-Recipient.

b. "Sub-Recipient" means any legal entity that, pursuant to a Lower Tier Agreement, uses Federal funds to carry out a purpose consistent with NIH's statutory authorities, has its performance measured in relation to whether the objectives of the NIH program were met, or has responsibility for programmatic decision making. A Sub- Recipient is distinguished from a contractor providing goods and services within normal business operations for the Recipient's own use or that are ancillary to the operation of the NIH program, provides similar goods or services to many different purchasers, and normally operates in a competitive environment. The Recipient is responsible for determining whether a legal entity is a Sub-Recipient on a case-by- case basis, consistent with any additional guidance supplied by the NIH to support these determinations.

2. Authorization

The Recipient is authorized to enter into Lower Tier Agreements with Sub-Recipients provided Recipient complies with Item 3. Authorization Process of this Section.

3. Authorization Process

a. Pursuant to Article III Paragraph A of this Agreement, either Party may recommend to the other the need for a Lower Tier Agreement. This recommendation should include a written justification describing the need for a Lower Tier Agreement and may also include, if feasible, the proposed scope of work, the identity of the suitably qualified Sub-Recipient(s), and the anticipated cost.

b. The Recipient may not communicate with any prospective Sub-Recipient with the intent of entering into a Lower Tier Agreement without receiving the prior written approval of the OTAO.

c. Lower Tier Agreements are subject to the review of the OTAO and may not be executed or modified by the Recipient until the Recipient has received the written approval of the OTAO.

4. Flow Down of Terms

Lower Tier Agreements must include the following Agreement terms, suitably modified to identify the Parties:

Paragraphs G, H, I, J, and L of Article V: Obligation and Payment

Article VI: Disputes

Article VII: Patent Rights

Article VIII: Data Rights, Participant-Derived Resources, Deliverables

Article IX: Data and Information Sharing

Article XI: Foreign Access to Technology

Article XIV: Applicable Statutes and Regulations

5. General

a. The Recipient shall give the OTAO immediate written notice of any action or suit filed and prompt notice of any claim made against the Recipient by any Sub-OT Recipient that, in the opinion of the Recipient, may result in litigation related in any way to this Agreement.

b. No funds awarded under this Agreement may be used by the Recipient to pay for costs associated with the management or administration of Lower Tier Agreements unless the Recipient has received the prior written approval of the OTAO.

c. Neither the approval nor the non-approval of a Lower Tier Agreement shall relieve the Recipient of responsibility to comply with the terms of this Agreement and perform work pursuant to the SOM.

E. Extending the Term

The Parties may extend, by mutual written agreement, the term of this Agreement if research opportunities or the goals or objectives of the project are within the scope set forth in Article I reasonably warrant. Any extension shall be formalized through revision of the Agreement by the OTAO and the Recipient Business Official (RBO) and shall be subject to the availability of funds.

F. No Cost Extension

For OT awards, any project period extension beyond the initial project period requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension.

G. Changing the Term

Changes to the terms and conditions are negotiated between the OTAO and the RBO.

H. Prior Approval

Any prior approval request (e.g., changes to key personnel/partners as noted on the award, changes in human and animal subjects requiring prior approval) must be submitted in writing to the assigned OTAO, OTAS, and OTPO no later than thirty (30) days before the proposed change. A request by a Sub-recipient will be addressed in writing to the prime Recipient. NIH prior written approval may be required before a Recipient makes certain modifications or undertakes activities.

All costs requested must be allocable, necessary, reasonable, and realistically reflect the approved project activities. Potential indicators of significant changes include, but are not limited to the following:

- Changes that would impact the timeline and/or scope of work to be completed
- Changes in the scope of work conducted by the award Recipient
- Changes in the approved facilities/administrative and/or indirect cost rate

Actions Requiring Prior Approval

- Deviation from the award terms and conditions including restriction removals
- Changes in key personnel
- Changes in key partnering organizations/Sub-recipients
- Changes that would impact the approved IRB
- Transfer of legal and administrative responsibility from one legal entity to another
- Additional time and/or funding

I. The System for Award Management (SAM)

All Recipients must register in the System for Award Management (SAM) (https://sam.gov) and maintain an active registration with current information at all times while it has an award with NIH. SAM is the primary registrant database for the federal government and is the repository into which an entity must provide information required for the conduct of business.

J. The Notice of Award (NoA)

NIH notifies the Recipient via e-mail when an award has been issued. In order to allow for the e-mail notification of the Notice of Award (NoA), the Recipient must register a valid e-mail address (in the NoA e-mail field) in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. It is the responsibility of the Recipient to maintain a current and accurate e-mail address for official award notices. Recipients that do not maintain a current NoA notification e-mail address will be responsible for accessing these notices via the eRA Commons.

ARTICLE III: MANAGEMENT OF THE PROJECT

The Recipient shall be responsible for the overall management of the project, and technical planning and execution shall remain with the Recipient. The NIH OTAO, in consultation with the NIH OTPO, shall provide recommendations for project developments and technical collaboration and be responsible for the review and verification of the completion of milestone objectives and deliverables.

A. Modifications

1. As a result of interactions with the Recipient or at any time during the term of the Agreement, progress or results may indicate that a change in the Statement of Objectives and Milestones (SOM) would be beneficial to program objectives. Recommendations to modify the SOM may be initiated by either Party. The initiating Party will document in writing and submit to the other Party its recommendations for modifying the SOM, including justifications to support the change. The NIH OTAO and the RBO shall approve any Agreement modification on a bilateral basis.

2. The NIH is not obligated to pay for additional or revised future work to be performed until the SOM is formally revised by the NIH OTAO and made part of this Agreement.

3. The NIH OTPO shall be responsible for the review and verification of any recommendations to revise or otherwise modify the SOM, prospective work, or other proposed changes to the terms and conditions of this Agreement.

4. The NIH OTAO will be responsible for documenting, communicating, and securing any necessary NIH approvals related to modifications to this Agreement.

B. Monitoring

The Recipient is responsible for managing the day-to-day operations of Agreement activities using their established controls and policies. The NIH OTPO will monitor and identify potential problems and areas where technical assistance might be necessary. This monitoring is accomplished through review of reports provided pursuant to the SOM.

C. Management Systems and Procedures

The Recipient must have in use clearly delineated roles and responsibilities for its organization's staff, both programmatic and administrative; written policies and procedures; training; management controls and other internal controls; performance assessment; administrative simplifications; and information sharing. The Recipient may use its existing systems to manage Agreement funds and activities, provided that policies and procedures are consistently applied across its business functions.

ARTICLE IV: AGREEMENT ADMINISTRATION

The NIH will actively engage with Recipients to achieve the *All of Us* Research Program's goals. Each Party may change its representatives named in this Article by written notification to the other Party. The NIH will affect the change as stated in this Agreement.

Unless otherwise provided in this Agreement, approvals are obtained, and changes may be made only by the NIH OTAO. Administrative and programmatic matters under this Agreement shall be referred to the following representatives of the Parties:

A. NIH Points of Contact

Other Transactions Agreements Officer (OTAO)
[Name]
[Contact Information]

Other Transactions Agreements Specialist (OTAS)
[Name]
[Contact Information]

Other Transactions Program Official (OTPO)
[Name]
[Contact Information]

B. Recipient Points of Contact

Recipient Business Official (RBO)
[Name]
[Title]
[Contact Information]

Principal Investigator (PI)/Program Director (PD)
[Name]
[Title]
[Contact Information]

All official communications must be sent from the Recipient Business Official (RBO), and at a minimum must include the OTAO, OTAS, OTPO and [INSERT AMB TEAM SPECIFIC EMAIL ADDRESS].

Each Party may change its representatives named in this Article by written notification to the other Party. The NIH will affect the change as stated in Article III, Paragraph A.

ARTICLE V: OBLIGATION AND PAYMENT

A. Obligation

The OT award provides funds for the budget period as appropriate for the negotiated and agreed upon work. Subsequent funding periods represent projections of future funding levels contingent on the availability of funds, achievement of agreed upon activities, and continued alignment with programmatic goals. Budget information, both obligated funds and funding projections, are detailed in the Statement of Budgetary Projections (SBP) (Attachment 2).

The NIH's liability to make payments to the Recipient is limited to only those funds obligated under the Agreement or by modification to the Agreement and is subject to availability of funds. NIH may obligate funds to the Agreement incrementally. If modification becomes necessary in performance of this Agreement, the NIH OTAO and the RBO shall execute a revised SOM.

B. Payment

The Payment Management System (PMS) is a centralized payment and cash management system, operated by the Department of Health and Human Services (HHS) Program Support Center (PSC). Agreement payments by the PMS may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis. Payments under this Agreement will be made upon completion of approved project milestones or as costs are incurred. Recipients must ensure PMS payments are drawn timely and that payments are no more than 60 calendar days in arrears. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal Government and disbursement to the Recipient.

Advances made by Recipients to third parties under the Agreement must conform to substantially the same standards of timing and amount that govern advances to the Recipient. Operational guidance for the Recipient is provided through training from the DHHS PSC. Inquiries regarding drawdown request, cash management rules should be directed to the HHS PSC (https://www.hhs.gov/about/agencies/asa/psc/index.html).

1. SMARTLINK II/ACH
   The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a Recipient's bank account and requires Recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

2. Cash Request
   Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance

or reimbursement basis. If the cash request is for an advance payment, the Recipient may request funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, the Recipient must submit the request through the OTAO early enough for it to be forwarded to PMS at least two weeks before the cash is needed. The PMS makes payment to the Recipient electronically through the ACH process upon receipt of the approved payment request.

C. Interest Earned on Advances

Recipients receiving advance payments must maintain those advanced funds in an interest-bearing account and promptly return any funds not spent within three (3) business days. Interest earned on federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, 11400 Rockville Pike Rockwall I, Suite 700, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the Recipient for administrative expenses.

D. Limitation of Funds

In no case shall the NIH's financial liability exceed the amount obligated under this Agreement.

E. Appropriation Legislative Mandates

This award must comply with NIH fiscal appropriation legislative mandates.

F. Close out of Fixed Year Appropriations Amounts

All Federal agencies are required by 31 U.S.C. 1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, Recipients must report total disbursements no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are canceled and returned to the Treasury.

G. Retention of Financial Records

The Recipient shall maintain adequate records to account for all funding under this Agreement.

1. The OTAO or designee shall have direct access to sufficient records and information of the Recipient, to ensure full accountability for all funding under this Agreement. Such audit, examination, or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party.

2. The Recipient's relevant financial records are subject to examination or audit on behalf of the NIH or by the NIH for a period not to exceed three (3) years. For OT awards, the 3-

year record retention period will be calculated from the date that the final Federal Financial Report (FFR) for the entire funding segment is submitted. If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. These record retention policies apply to both paper and electronic storage of applicable information, including electronic storage of faxes, copies of paper documents, images, and other electronic media.

H. Undisbursed Obligated Balances and Actual Expenditures

Using the principle of "first-in, first-out" undisbursed obligated funds carried over into a new budget period must be used before newly awarded funds.

I. Audit

For purposes of this Agreement, the Recipient is deemed subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F.

J. Financial Management System Standards

The Recipient must have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP) and accounting and internal control systems must provide for appropriate monitoring of award accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligations and expenditures of funds, and Recipient must notify the NIH OTAO when problems are identified. The Recipient's failure to establish adequate control systems constitutes a material breach of this Agreement and may result in the exercise of available enforcement remedies.

K. Procurement System Standards and Requirements

Recipients may acquire a variety of goods or services in connection with an OT award-supported project, ranging from those that are routinely purchased goods or services to those that involve substantive programmatic work. Recipients must acquire goods and services under OT awards in compliance with their established policies and procedures and for the negotiated purposes outlined in the SOM.

L. Cost Principles

In general, this Agreement is subject to reimbursement of actual, allowable costs incurred and must align with generally accepted and established federal cost principles for the entity receiving funding (academic, non-profit, for-profit, etc.). The cost principles are set forth in 2 CFR Part 200, Subpart E, 45 CFR Part 75, Subpart E, and Appendix IX (Hospital Cost Principles) to Part 200 and Part 45. Commercial organizations are subject to the cost principles located at 48 CFR Part 31.2 Federal Acquisition Regulation.

Recipients may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the Generally Accepted Accounting Principles (GAAP) standards for financial management systems.

M. Human Subjects Research

The Recipient cannot draw down funds from the payment system and no obligations may be made against Federal funds for research involving human subjects (as defined by 45 CFR part 46) https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html supported by this Agreement for any period not covered by both an Office for Human Research Protections (OHRP) https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html approved Federal Wide Assurance and, as required by 45 CFR Part 46 https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html, approval from an Institutional Review Board (IRB). This Agreement requires the institution to ensure that all personnel and partners who engage in human subjects research have completed education on the protection of human subjects.

Any individual involved in the design or conduct of the study must satisfy this requirement prior to participating in the project. The Recipient bears the ultimate responsibility for safeguarding the rights and welfare of human subjects, as stipulated in 45 CFR Part 46. Failure to comply will result in the immediate suspension and/or termination of this Agreement.

N. Animal Research

The Recipient cannot draw down funds from the payment system and no obligations may be made against Federal funds for research involving animals by any site engaged in such research for any period in which the site is not in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (https://olaw.nih.gov/policies-laws/phs-policy.htm). Failure to comply will result in the immediate suspension and/or termination of this Agreement.

O. Unallowable Costs

Direct charges for meals/food/beverages, pre-award costs, promotional items, entertainment, and alteration/construction costs are unallowable charges to this project, without the express written prior approval of the OTAO. Recipients shall provide the request in writing at least 30 calendar days in advance to the OTAO.

P. Other Support

Commitment overlap occurs when any project-supported personnel (including support staff and key personnel) have time commitments exceeding 100 percent, regardless of how the effort/salary is being supported or funded. Therefore, no individual may reflect over 100 percent in the total effort he/she spends on research and other organizational responsibilities. An investigator may be affiliated with several organizations; however, the combination of

appointments cannot exceed 100 percent. Reporting zero percent of effort is not acceptable. The award organization is responsible for ensuring no individual supported by this award exceeds 100 percent committed effort.

Q. Recovery of Funds
NIH may identify and administratively recover funds paid to a Recipient at any time during the life cycle of an OT award. Debts may result from cost disallowances, unobligated balances, unpaid share of any required matching or cost-sharing, funds in the account that exceed the final amount determined to be allowable, or other circumstances.

R. Debt Collection
The debt collection process is governed by the Federal Claims Collection Act, as amended (Public Law [P.L.] 89-508, 80 Stat. 308, July 19, 1966); the Federal Debt Collection Act of 1982 (P.L. 97-365, 96 Stat. 1749, October 25, 1982); the Debt Collection Improvement Act (P. L. 104-134, 110 Stat. 1321, April 26, 1996); and the Federal Claims Collection Standards (31 CFR Parts 900-904), which are implemented for DHHS in 45 CFR 30. NIH is required to collect debts due to the Federal Government and, except where prohibited by law, to charge interest on all delinquent debts owed to NIH by Recipients.

ARTICLE VI: DISPUTES

A. General
The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures
Any disagreement, claim or dispute between NIH and the Recipient concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this Article constitute the basis for relief under this Article.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement or misunderstanding by notifying the other Party (through the NIH OTAO or the RBO, as the case may be) in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought. Within ten (10) business days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the *All of Us* Director of Awards Management appointed by the NIH, and a senior executive

appointed by the Recipient. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The *All of Us* Director of Awards Management appointed by the NIH, and a senior executive appointed by the Recipient, shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

In the absence of a joint decision, the matter will be elevated to the *All of Us* Chief Financial and Management Officer for further review. The *All of Us* Chief Financial and Management Officer may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by the Recipient. Following the review, the *All of Us* Chief Financial and Management Officer or designee will resolve the issue(s) and notify the Parties in writing. Such resolution is not subject to further administrative review by the *All of Us* Chief Financial and Management Officer, whose decision to the extent permitted by law, shall be final and binding.

C. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of NIH funding disbursed as of the time the dispute arises. Subject to applicable law in no event shall either party be liable for claims for consequential, punitive, special or incidental damages, claims for lost profits, or other indirect damages.

ARTICLE VII: PATENT RIGHTS

A. Allocation of Principal Rights

Unless the Recipient notified NIH that the Recipient does not intend to retain title, the Recipient shall retain the entire right, title, and interest throughout the world to each Subject Invention consistent with the provisions of this Article and 35 U.S.C §§ 200-212 and associated regulations.

With respect to any Subject Invention in which the Recipient retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world.

With respect to any Data the Recipient will own the Data developed under this award, subject to the Government's royalty-free, nonexclusive, irrevocable right to use, disclose, reproduce, post, link to, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so anywhere in the world. In addition, Know-How developed under this Agreement will remain the property of the Recipient, who may freely use them for its own commercial purposes, subject to a nonexclusive, nontransferable, irrevocable, royalty-free, paid-up license to the Government to practice, or have practiced for or on its behalf, the Know-How throughout the world.

B. Invention Disclosure, Election of Title, and Filing of Patent Application

The Recipient shall disclose each Subject Invention to NIH within four (4) months after the inventor discloses it in writing to their company personnel responsible for patent matters. The disclosure to NIH shall be in the form of a written report and shall identify the Agreement and circumstances under which the Invention was made and the identity of the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Invention. The disclosure shall also identify any publication, sale, or public use of the invention and whether a manuscript describing the Invention has been submitted and/or accepted for publication at the time of disclosure.

If the Recipient determines that it does not intend to retain title to any such Invention, the Recipient shall notify NIH, in writing within six (6) months of disclosure. However, in any case where publication, sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by NIH to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

The Recipient shall file its initial patent application on a Subject Invention to which it elects to retain title within one (1) year after election of title or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use. The Recipient may elect to file patent applications in additional countries, including the European Patent Office and the Patent Cooperation Treaty, within either ten (10) months of the corresponding initial patent application or six (6) months from the date permission is granted by the Commissioner for Patents to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

The Recipient shall notify NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Requests for extension of the time for disclosure election, and filing under Article VII, may be granted at NIH's discretion after considering the circumstances of the Recipient and the overall effect of the extension.

The Recipient shall submit to NIH annual listings of Subject Inventions. At the completion of the Agreement, the Recipient shall submit a comprehensive listing of all subject inventions identified during the course of the Agreement and the current status of each.

C. Conditions When the NIH May Obtain Title

Upon NIH's written request, the Recipient shall convey title to any Subject Invention to NIH under any of the following conditions:

- If the Recipient fails to disclose or elects not to retain title to the Subject Invention within the times specified in this Article;

- In those countries in which the Recipient fails to file patent applications within the times specified in this Article; however, if the Recipient has filed a patent application in a country after the times specified in this Article, but prior to its receipt of the written request by NIH, the Recipient shall continue to retain title in that country; or

- In any country in which the Recipient decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

D. Minimum Rights to the Recipient and Protection of the Recipient's Right to File

The Recipient shall retain a nonexclusive, royalty-free, commercial license throughout the world in each Subject Invention to which the NIH obtains title, except if the Recipient fails to disclose the Subject Invention within the times specified in this Article. The Recipient's license extends to its domestic subsidiaries and affiliates, if any, and includes the right to grant licenses of the same scope to the extent that the Recipient was legally obligated to do so at the time the Agreement was awarded. Any extension of the Recipient's license to its subsidiaries and affiliates that are based outside the United States must comply with all export control laws and other federal laws that may apply. The license is transferable only with the approval of NIH, except when transferred to the successor of that part of the business to which the Subject Invention pertains. NIH approval for license transfer shall not be unreasonably withheld.

The Recipient's domestic license may be revoked or modified by NIH to the extent necessary to achieve expeditious practical application of the Subject Invention pursuant to an application for an exclusive license submitted consistent with appropriate provisions at 37 C.F.R. Part 404.

This license shall not be revoked in that field of use or the geographical areas in which the Recipient has achieved practical application and continues to make the benefits of the Subject Invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of NIH to the extent the Recipient, its licensees, or the subsidiaries or affiliates have failed to achieve practical application in that foreign country.

Before revocation or modification of the license, NIH shall furnish the Recipient a written notice of its intention to revoke or modify the license, and the Recipient shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

E. Action to Protect the NIH's Interest

The Recipient agrees to execute or to have executed and promptly deliver to NIH all instruments necessary to (i) establish or confirm the rights the NIH has throughout the world in those Subject Inventions to which the Recipient elects to retain title, and (ii) convey title to NIH when requested under this Article and to enable the NIH to obtain patent protection throughout the world in that Subject Invention.

The Recipient agrees to require by written agreement with its employees, other than clerical and non- technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Recipient each Subject Invention made under this Agreement in order that the Recipient can comply with the disclosure provisions of this Article. The Recipient shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to United States or foreign statutory bars.

The Recipient shall include, within the specification of any United States patent application and any patent issuing thereon covering a subject invention, the following statement: This invention was made with government support under Award Number: **OT2XXXXXXX awarded by the National Institutes of Health.** The Government has certain rights in the invention.

F. Reporting on Utilization of Subject Inventions

The Recipient agrees to submit, during and after the term of the Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Recipient or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Recipient. The Recipient also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with this Article and 35 U.S.C § 202. NIH agrees it will not disclose such information to persons outside the Government without permission of the Recipient, unless required by law. All required reporting shall be accomplished, to the extent possible, using the i-Edison reporting website: https://www.nist.gov/iedison. To the extent any such reporting cannot be carried out by use of i-Edison, reports and communications shall be submitted to the OTAO.

G. Preference for American Industry

Notwithstanding any other provision of this Article, the Recipient agrees that it shall not grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the subject invention shall be manufactured substantially in the United States. However, in individual cases, the requirements for such an agreement may be waived by NIH upon a

showing by the Recipient that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible.

H. March-in Rights

March-in Rights will follow the procedures set forth in 37 CFR 401.6.

The Recipient agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require the Recipient, an assignee, or exclusive licensee of a Subject

Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Recipient, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license itself if it determines that:

- Such action is necessary because the Recipient or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve practical application of the Subject Invention;

- Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Recipient, assignee, or their licensees;

- Such action is necessary to meet requirements for public use and such requirements are not reasonably satisfied by the Recipient, assignee, or licensees; or

- Such action is necessary because the agreement required by this Article has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such Agreement.

I. Background Inventions

Background Invention means any Invention in which the Recipient or sub-Recipients of any tier has retained title that (1) was not conceived or first actually reduced to practice in the performance of work under this Agreement and (2) was developed at private expense, either exclusively or partially. The Parties agree to the following:

1. With respect to any Background Invention incorporated into Deliverables or otherwise made available to the Government under this Agreement, the Government shall have a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for any Government purpose, and to authorize others to do so.

2. Incorporated into this Agreement as Attachment 4, the Recipient has disclosed in good faith a table of asserted Background Inventions that identifies for each Background Invention a minimum of the following:
    a. The US Patent or patent application covering the Background Invention; and
    b. The work products to be delivered under this Agreement that incorporate the Background Invention.
3. Any Invention arising under this Agreement or incorporated into work products delivered or otherwise made available to the Government under this Agreement shall be considered a Subject Invention if such Invention has not been asserted by the Recipient to be a Background Invention in Attachment 4.
4. In addition to the assertions made at the time of the execution of this Agreement, other asserted Background Inventions may be identified and added to Attachment 4 after award via mutual agreement of the Parties when based on new information or inadvertent omissions, unless the inadvertent omissions would have materially affected the NIH's decision to execute this Agreement.

ARTICLE VIII: DATA RIGHTS, PARTICIPANT-DERIVED RESOURCES, DELIVERABLES

The Recipient will own the Data and participant-derived resources acquired or generated under this award, including participant-derived Data, participant-derived biospecimens, and data generated from further analysis of participant-derived Scientific Data or biospecimens , subject to the Government's royalty-free, nonexclusive, irrevocable right to use, disclose, reproduce, post, link to, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so anywhere in the world.

At its reasonable discretion, NIH may take or transfer exclusive ownership, custody, and control of the participant-derived resources (including participant-derived Data, participant-derived biospecimens, and data generated from further analysis of participant-derived Data and participant-derived biospecimens) generated by the *All of Us* Research Program. For purposes of this agreement, "exclusive custody and control" means that upon such action by NIH, the Recipient and its partners/sub-Recipients may not retain or disclose a copy of any participant-derived resources and may not use any biospecimen (or portions thereof), acquired or generated under the award, unless otherwise directed by NIH.

The Government shall receive Unlimited Rights to deliverables (i.e. training modules, curriculum, recordings, teaching materials, other written products, video and images, methods, tools, etc.), computer software, and computer software documentation developed or delivered under this Agreement, or pertaining to any item, component, or process developed or delivered

under this Agreement, regardless of whether or not it is listed in the Statement of Objectives and Milestone in Attachment 1, except for any items previously developed at private expense that are to be furnished to the Government with restrictions as asserted in Attachment 4.

A. Allocation of Principal Rights

The Parties agree that in consideration for NIH funding, the Recipient intends to reduce to practical application items, components and processes developed under this Agreement.

The Recipient agrees that, in the event of a termination of the Agreement, the NIH may take exclusive ownership, custody, and control of the participant-derived resources generated by the *All of Us* Research Program as described in Data Rights. If NIH elects not to take exclusive ownership, custody, and control of participant-derived resources, and with respect to all other Data generated or developed under this Agreement, the NIH may, within three years after completion or termination of this Agreement, require delivery of Data or participant-derived resources and the Government shall have Unlimited Rights in such Data or participant-derived resources, unless otherwise stated in Attachment 4.

B. March-In Rights

In the event the NIH chooses to exercise its March-in Rights in a Subject Invention, the Recipient agrees, upon written request from the Government, to deliver at no additional cost to the NIH, all Data necessary to achieve practical application of a Subject Invention within sixty (60) calendar days from the date of the written request. The NIH shall retain Unlimited Rights to this delivered Data. To facilitate any potential deliveries, the Recipient agrees to retain and maintain in good condition until three years after completion or termination of this Agreement, all Data necessary to achieve practical application of any Subject Invention.

C. Marking of Data

Any Data delivered under this Agreement shall be marked with the following legend:

> *The Government may use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly this Data, in any manner and for any purpose, and to have or permit others to do so.*

The Recipient will mark any Limited or Restricted Rights Data delivered under this Agreement with appropriate Limited or Restricted Rights markings. Data Rights Assertions must be made and agreed to by the NIH for any data to be marked Limited/Restricted.

D. Background Data

Background Data means any Data, Technology, or Know-How in which the Recipient holds rights of ownership as recognized by U.S. law as an intellectual creation which (1) was not reduced to Practical Application under this Agreement and (2) was developed at private

expense, either exclusively or partially. In order to distinguish between Background Data and Data generated or developed under this Agreement, the Parties agree to the following:

1. With respect to any Background Data incorporated into work products delivered under this Agreement, the Government shall have a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for any Government purpose, and to authorize others to do so.
2. Incorporated into this Agreement as Attachment 4, the Recipient has identified and asserted in good faith a table of all Background Data to be furnished to the Government with restrictions on use, release, or disclosure. This table of asserted Background Data should include the following information for each item of Background Data:
    a. Background Data to be Furnished with Restrictions. The Recipient should identify the Background Data or enter “none” when all Background Data will be submitted without restrictions;
    b. Basis for Assertion. Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, the Recipient should enter the specific basis for asserting restrictions;
    c. Asserted Rights Category. Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in Small Business Innovative Research (SBIR) data generated under another contract, limited, restricted, or Government Purpose Rights under this or a prior contract, or specially negotiated licenses);
    d. Name of Person/Entity Asserting Restrictions. The Recipient should identify the corporation, individual, or other person, as appropriate.
    e. Deliverable(s) Affected. The Recipient should identify which deliverable(s) are affected.
3. The Government shall have Unlimited Rights in any Data, Technology, or Know-How arising under this Agreement or incorporated into work products delivered or otherwise made available to the Government under this Agreement unless the Recipient has identified and asserted the Data, Technology, or Know-How as Background Data in Attachment 4.
4. In addition to the assertions made at the time of the execution of this Agreement, other asserted Background Data may be identified and added to Attachment 4 after award via

mutual agreement of the Parties when based on new information or inadvertent omissions, unless the inadvertent omissions would have materially affected the NIH's decision to execute this Agreement.

ARTICLE IX: DATA AND INFORMATION SHARING

A. Public Release or Dissemination of Information

Recipients and their partners must have all public communications about the *All of Us* Research Program approved prior to release, in accordance with program guidance and standard operating procedures. Public communications include, but are not limited to, press announcements, website content, videos, social media posts, and print materials.

More information about the review processes for different types of communications is made available to Recipients through the onboarding process and in communications with their OTAS, OTPO, and the *All of Us* Division of Communications.

Questions about the public release of information may be directed to their OTAS, OTPO and aoucommunications@od.nih.gov.

B. Publications and Presentations

Publications derived from this research should acknowledge support by the NIH *All of Us* Research Program with reference to the award number [OT2 ODXXXX]. In addition, articles for publication or presentation must contain a statement on the title page worded substantially as follows:

> *This research was, in part, funded by the National Institutes of Health (NIH) All of Us Research Program. The views and conclusions contained in this document are those of the authors and should not be interpreted as representing the official policies, either expressed or implied, of the NIH.*

Recipients must fully comply with the NIH Public Access Policy, which ensures that the public has access to the published results of NIH-funded research at the NIH National Library of Medicine PubMed Central (PMC) (www.pubmedcentral.nih.gov). The NIH Public Access Policy is located at https://publicaccess.nih.gov/policy.htm. Furthermore, Recipients must comply with program policies germane to publications and presentations derived from this research, including but not limited to the *All of Us* Data and Statistics Dissemination Policy.

C. Prohibition from Confidential Information Release

The Recipient agrees to exclude any and all confidential information prior to public release of the material. The Parties agree that they shall take appropriate measures to protect Confidential Information received under this Agreement. Confidential Information shall mean information, any form, disclosed by one Party (Disclosing Party) to the other Party (Receiving

Party) and marked as confidential or proprietary at the time of disclosure. Receiving Party agrees not to disclose Confidential Information to anyone, other than its employees performing services under this Agreement, or to use Confidential Information for any purpose other than to carry out its role pursuant to this Agreement, except as required by law or a court of competent jurisdiction.

This restriction on disclosure and use of Confidential Information survives the Recipient's withdrawal or termination from this Agreement for five (5) years, unless required by law to be protected for a longer period. The previously stated obligations of confidentiality do not apply to any information that:

- becomes a matter of public knowledge by means other than a wrongful act, omission or fault of the Recipient Party, its employees, or agents;
- is rightfully received from a third party without restriction;
- is approved for release by the submitting Party; or
- is disclosed pursuant to a court order or as required by law.

D. NIH Genomic Data Sharing (GDS) Policy

The Recipient agrees to comply with the GDS Policy at https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html, as applicable. The NIH Genomic Data Sharing Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. For the purposes of this Policy, genomic data includes single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. For additional information, see: https://sharing.nih.gov/genomic-data-sharing-policy/about-genomic-data-sharing.

E. Data Management and Sharing (DMS) Policy

The Recipient agrees to comply with the Data Management and Sharing (DMS) Policy at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html, as applicable. The DMS Policy expects investigators and institutions to plan and budget for the managing and sharing of data, submit a DMS plan for review when applying for funding, including plans for sharing genomic data under the NIH Genomic Data Sharing Policy, as applicable, and comply with the approved DMS plan. For more information, visit https://sharing.nih.gov/data-management-and-sharing-policy.

F. *All of Us* Research Program's Data Sharing Requirements

Sharing research data supports the NIH mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health. NIH endorses

the sharing of research data to serve these and other important scientific goals and expects and supports the timely release and sharing of research data from NIH-supported studies for use by other researchers. In line with this ethos, all participant-derived Scientific Data (as defined in NOT-OD-21-013) produced by *All of Us* Research Program Recipients must be shared in accordance with the *All of Us* Research Program Core Protocol. A core value of *All of Us* is to make data collected from participants available to a broad array of researchers to accelerate research that may improve health, which is accomplished by making data available through the program's centrally managed data resource.

All data, including electronic health records (EHR) and participant-derived Scientific Data, generated and/or shared as part of the *All of Us* Research Program are intended for use through the *All of Us* Research Program data resource. Recipients must restrict their use of such data only to activities stipulated by the *All of Us* Research Program and characterized in the program protocol and Interconnection Security Agreement.

Recipients who receive Data and/or Materials under this award 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. For further questions about compliance, contact the *All of Us* Policy Office at aoupolicy@mail.nih.gov.

G. Underrepresented Groups

The *All of Us* Research Program encourages data sharing that supports historically underrepresented groups in Research and Development to the maximum extent possible. (https://grants.nih.gov/grants/glossary.htm#UnderrepresentedGroup)

ARTICLE X: DATA AND INFORMATION PRIVACY AND SECURITY

Recipients are required to adhere to the Precision Medicine Initiative Data Security Policy Framework which may be accessed at: https://allofus.nih.gov/protecting-data-and-privacy/precision-medicine-initiative-data-security-policy-principles-and-framework-overview/achieving-principles-through-precision-medicine-initiative-data-security-policy-framework/special-award-condition.

The National Institutes of Health (NIH) is an Operational Division (OpDiv) of the U.S. Department of Health and Human Services. Security controls are required by the Department to provide minimum levels of assurance for safeguarding OpDiv information. The NIH *All of Us* Research Program is a special federally funded Program that has selected National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Security and Privacy Controls for Information Systems and Organizations, as its security controls framework. Please note that NIST SP 800-53 is designed for safeguarding federal information and information systems;

however, the controls outlined in the framework provide adequate security that can be applied to Recipients as a method of meeting the Precision Medicine Initiative (PMI) Data Security Policy Principles and Framework. The Security standards identified or referenced within are subject to change at the sole discretion of the NIH *All of Us* Research Program Information Systems Security Officer.

The NIH *All of Us* Research Program may provide a list of NIST SP 800-53 exempt security controls as applicable. A separate control mapping will be provided as equivalent to lower risk profile systems that apply the NIST SP 800-171 controls framework for non-federal systems processing Controlled Unclassified Information.

As necessary, the *All of Us* Research Program's Security Program may require Recipients to apply specified ongoing system updates and/or mitigation measures; for example, when security updates and/or mitigation measures are required due to a newfound vulnerability, the *All of Us* Research Program's Security Program shall issue a notice requiring Recipients to update and/or mitigate its systems within the specified time-period that shall be provided in the notice.

Additional Conditions for Recipients with Significant Security Responsibilities

1) **Compliance with *All of Us* Research Program Security Authorization Process** — The NIH *All of Us* Research Program requires that the Recipient comply with the *All of Us* Research Program Security Authorization or Approval Process for *All of Us* Research Program systems under the direct management and operations of the Recipient. The NIH *All of Us* Research Program requires the Recipient to describe how it will design and implement technical and policy safeguards necessary to ensure data security, in accordance with an approved *All of Us* Research Program framework (e.g., NIST Special Publication 800-53).

   The NIH *All of Us* Research Program ISSO, in coordination with the OTPO, may request an annual independent review of security controls, in addition to continual review and testing, to ensure overall effectiveness against evolving threats and consistent implementation as a requirement of renewal of the approval or authorization. Risk assessments will use an approved *All of Us* Research Program framework (e.g., NIST SP 800-39, Managing Information Security Risk: Organization, Mission, and Information System View) depending on the risk profile and data sensitivity risk impacts of the system. Recipients are responsible for procurement of an independent reviewer to conduct the risk assessments.

   All major changes to an NIH *All of Us* Research Program system boundary as defined by the Federal Information Security Modernization Act of 2014 (FISMA) will be evaluated using a Security Impact Analysis within the *All of Us* Research Program Security Authorization Process to determine if a new or additional approval or authorization is required.

2) Risk Management — The NIH *All of Us* Research Program, through the program's ISSO, in coordination with the OTPO, may require additional security measures and defined parameters not included in NIST SP 800-53 to provide advanced cybersecurity measures following a risk-based approach. Any additional security measures and defined parameters will be communicated to the Recipient at a minimum of 6 months prior to implementation. The NIH *All of Us* Research Program and the Recipient shall establish data security implementation plans and timelines collaboratively. NIH *All of Us* Research Program will regularly monitor compliance with ongoing and new security requirements as specified by the NIH *All of Us* Research Program. The following terms apply:

a) Recipients are required to implement and maintain compliance with applicable NIH Manual Chapter Policies, NIH IT Security Handbook, NIH Data Sharing Policies, *All of Us* Research Program Policies, and *All of Us* Research Program Security Procedures and Memoranda;

b) Recipients shall make available upon request by the NIH *All of Us* Research Program's Security Program accurate security documentation and architecture diagrams;

c) Recipients shall maintain accurate security documentation and asset inventories;

d) Recipients shall implement risk-reducing measures and other NIH *All of Us* Research Program recommendations as requested;

e) Recipients shall maintain a record of completed trainings and signed user access agreements (Rules of Behavior);

f) Recipients shall provide security relevant information as requested by the *All of Us* Research Program ISSO, in coordination with the program's OTPO;

g) Recipients shall identify and uniquely call-out systems storing personally identifiable information within system security boundary diagrams, asset inventory tables, and ad hoc reports as requested by the program's ISSO, in coordination with the OTPO; and

h) Recipients shall encrypt all participant records that include personally identifiable information as defined by *NIST SP 800-122, Guide to Protecting the Confidentiality of Personally Identifiable Information (PII).*

i) In cases of deviations from the NIH *All of Us* Research Program's security and privacy policies, technology limitations, functional impacts to the *All of Us*, or conflicts in policy between the Recipient and the NIH, risk waivers shall be created;

j) All risk waivers shall be accurately documented with sound quality and will be submitted to the program's ISSO (in coordination with the OTPO) for approval by the *All of Us* Research Program Authorizing Official prior to implementation;

k) All risk waivers are maintained by *All of Us* Research Program ISSO and reviewed within twelve months of approval for consideration of waiver extension;

l) Recipients shall use an NIH *All of Us* Research Program-approved platform, site, or repository (i.e., DOJ Cyber Security Assessment and Management) to share documents as directed by the program's ISSO, in coordination with the OTPO.

3) Incident Response — The NIH *All of Us* Research Program requires all Recipients to maintain an active and evolving security program with incident response capabilities that meet NIH *All of Us* Research Program requirements. All Recipients will use the HHS Policy and Plan for Responding to a Breach as guide for implementing incident response capabilities. The following incident reporting requirements must be followed:

a) Recipients shall designate a dedicated incident response point of contact;

b) All perceived and potential security and privacy incidents must be reported to the OTAO, OTPO, and NIH *All of Us* Research Program ISSO within 1 hour of discovery;

c) During high impact incidents or as needed, Recipients shall provide necessary system-level access to third-parties, that include NIH employees, contractors and other incident responders/platform technology experts identified by the program's ISSO, in coordination with the OTPO;

d) During "major incidents" as defined by OMB M-22-05, the NIH *All of Us* Research Program reserves the right to retain third-party incident responders / platform technology experts (i.e., services provided by a vendor-partner contracted by the Continuous Diagnostics and Monitoring Program) identified by the *All of Us* Research Program's Information Systems Security Officer (ISSO);

e) All incidents will require full transcript of incident and timeline, response action report, and final report;

f) Notification of all types of incidents will be submitted via a process defined by the NIH *All of Us* Research Program's Security Program; all follow up communication and sharing information potentially containing with sensitive information will utilize NIH Secure Email and File Transfer (SEFT) or secure method of transfer approved by the NIH *All of Us* Research Program's ISSO, in coordination with the OTPO.

Additional data and information security requirements are included in Attachment 3.

NIH may take action, including reduction or reallocation of funds or termination of the award, for non-compliance with security requirements and milestones as agreed upon by both the NIH and the Recipient. Any disagreements or disputes regarding data security requirements specified by the *All of Us* Research Program, shall be resolved pursuant to Article VI, Disputes.

ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY

A. General

The Recipient will take no possession of any International Traffic in Arms Regulations (ITAR) controlled information or materials in performance of this agreement. At no time is any Recipient information technology product, as shipped from Recipient, subject to ITAR, under subchapter M of chapter I of title 22, Code of Federal Regulations, and no information technology products are being provided in performance of this agreement (i.e., no Recipient products are on the United States Munitions List).

B. Restrictions on Sale or Transfer to Foreign Firms or Institutions

In order to promote the national security interests of the United States and to effectuate the policies that underlie the export and ITAR regulations, the procedures stated below shall apply to any transfer of Technology under this Agreement. For purposes of this paragraph, a transfer includes a sale of the company, and sales or licensing of Technology.

Transfers do not include:

- sales of products or components, or
- licenses of software or documentation related to sales of products or components, or
- transfer to foreign subsidiaries of the Recipient for purposes related to this Agreement, or
- transfer which provides access to Technology to a Foreign Firm or Institution which is an approved source of supply or source for the performance of work under this Agreement provided that such transfer shall be limited to that necessary to allow the firm or institution to perform its approved role under this Agreement.

The Recipient shall provide timely notice to the NIH OTPO and OTAO of any proposed transfers from the Recipient of Technology developed under this Agreement to Foreign Firms or Institutions. If NIH determines that the transfer may have adverse consequences to the national security interests of the United States, the Recipient, its vendors, and NIH shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer, but which provide substantially equivalent benefits to the Recipient.

In any event, the Recipient shall provide written notice to the NIH OTAO and OTPO of any proposed transfer to a Foreign Firm or Institution at least sixty (60) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within thirty (30) calendar days of receipt of the Recipient's written notification, the NIH OTAO shall advise the Recipient whether it

consents to the proposed transfer. In cases where NIH does not concur or sixty (60) calendar days after receipt and NIH provides no decision, the Recipient may utilize the procedures under Article VI, Disputes. No transfer shall take place until Parties come to an agreement.

In the event a transfer of Technology to Foreign Firms or Institutions which is NOT approved by NIH takes place, the Recipient shall (a) refund to NIH funds paid for the development of the Technology and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, royalty-free, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the Recipient shall provide written confirmation of such licenses.

C. Prohibition on Expending Funding for Covered Telecommunications Equipment or Services

Other Transaction (OT) award Recipients and Sub-recipients are prohibited from expending OT funds to:

1. Procure or obtain;
2. Extend or renew an existing OT award; or
3. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    - For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
    - Telecommunications or video surveillance services provided by such entities or using such equipment.
    - Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country (i.e., the People’s Republic of China).

Withdrawing funds from the Payment Management System and/or executing any extensions of the Agreement, certifies the Recipient's compliance with this Article.

Should NIH determine non-compliance, NIH will take appropriate enforcement actions, which may include termination of award. The Recipient shall flow down the requirements of this Article to their sub-Recipients at all levels under this OT.

ARTICLE XII: ADDITIONAL ADMINISTRATIVE REQUIREMENTS

A. Organizational and Financial Conflicts of Interest (OCI/FCOI)

The Recipient must comply with the requirements of 42 CFR 50, Subpart F, Promoting Objectivity in Research (FCOI Regulation). The Recipient is required to identify and disclose all facts relevant to potential FCOI and OCIs involving sub-Recipients, consultants, etc. Under this section, the Recipient is responsible for providing this disclosure in writing to the OTAO and OTPO, as instances arise. The disclosure must include the PI/collaborators', and as applicable, proposed members' OCI/FCOI mitigation plan. The OCI/FCOI mitigation plan must include a description of the actions the Recipient has taken, or intends to take, to prevent the existence of conflicting roles that might bias the Recipient's judgment and to prevent the proposed collaborator/member from having an unfair competitive advantage.

NIH will evaluate OCI/FCOI mitigation plans to avoid, neutralize, or mitigate potential OCI/FCOI issues before award issuance and during the life of the award, as instances arise and the Recipient provides updated information, to determine whether it is in the NIH's interest to grant a waiver. NIH may require the Recipient to provide additional information to assist NIH in evaluating the OCI/FCOI mitigation plan. If NIH determines that the Recipient failed to fully disclose evaluating the OCI/FCOI mitigation plan, NIH may enforce corrective action, which may include suspension and/or termination as outlined in Article II.B. (Enforcement, Termination).

B. Closeout

The requirement for timely closeout is a Recipient responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the Recipient or NIH. The Statement of Objectives and Milestones (SOM), Attachment 1, will outline the specific timeline requirements for submission of all final reports (Federal Financial Report, Progress Report, and Invention Statement and Certification).

ARTICLE XIII: TITLE TO AND DISPOSITION OF PROPERTY

A. Title to Property

No significant items of property are expected to be acquired under this Agreement. Title to each item of property acquired under this Agreement with an acquisition value of $5,000 or less shall vest in the Recipient upon acquisition with no further obligation of the Parties unless otherwise determined by the OTAO. Should any item of property with an acquisition value

greater than $5,000 be required, the Recipient shall obtain prior written approval of the OTAO. Title to this property shall also vest in the Recipient upon acquisition. The Recipient shall be responsible for the maintenance, repair, protection, and preservation of all property at its own expense. The Recipient's deliverable shall not be classified as property. The Recipient shall obtain explicit written authorization from the OTAO for any transfer or disposition of all property.

B. Disposition of Property

At the completion of the term of this Agreement, items of property with an acquisition value greater than $5,000 shall be disposed of in the following manner:

- Purchased by the Recipient at an agreed-upon price, the price to represent fair market value, with the proceeds of the sale being returned to NIH; or
- Transferred to an NIH research facility with title and ownership being transferred to the NIH; or
- Donated to a mutually agreed upon university or technical learning center for research purposes; or
- Any other NIH-approved disposition procedure.

C. Property Management System Standards

The Recipient may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH OT award funds.

ARTICLE XIV: APPLICABLE STATUTES AND REGULATIONS

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its Recipients. The signature of the RBO on the application certifies that the organization complies, or intends to comply, with all laws, regulations, and NIH policies applicable to the Recipient and the performance of work outlined in the SOM. These include, but are not limited to, the following:

A. Anti-Sexual Harassment

NIH does not tolerate harassment of any kind, including sexual harassment, at research institutions that receive NIH funding, or anywhere NIH-funded activities are conducted. NIH expects recipient institutions to have policies and practices in place that foster a harassment-free environment. NIH requires that every organization receiving NIH funds has systems, policies, and procedures in place to manage research activities in accordance with our standards and requirements and complies with federal laws, regulations, and policies protecting the rights and safety of individuals working on NIH-funded projects. Recipients must notify NIH when individuals identified as Program Director/Principal Investigator (PD/PI) or other Senior/Key personnel are removed from their position or are otherwise disciplined by the

recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action.

B. Civil Rights

Recipients must comply with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex, and disability, and agree to comply with federal conscience laws, where applicable. Recipient must sign an HHS Assurance of Compliance (HHS 690) (https://www.hhs.gov/sites/default/files/form-hhs690.pdf), in which Recipient agrees, as a term and condition of receiving the award, to administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable.

C. Suspension and Debarment

This Agreement is subject to the HHS regulations at 2 CFR 376 (Nonprocurement Debarment and Suspension). The Recipient certifies that neither it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) are excluded or disqualified from participating in this Agreement.

The Recipient certifies that no individuals or entities on this Agreement are debarred or suspended from receiving Federal funds (2 CFR 180.995 and 2 CFR 376.995) https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.6_debarment_and_suspension.htm).

D. Certificate of Confidentiality

As a condition of this award, the Recipient is deemed issued a Certificate of Confidentiality, in accordance with 42 USC 241(d). The Certificate of Confidentiality (or Certificate) and its protections cover all identifiable, sensitive information (as defined by 42 USC 241(d)(4)) collected or generated during the conduct of the *All of Us* Research Program in perpetuity and extends to all such data held by sub-Recipients, subsidiaries, subcontractors, and vendors of or managed by the Recipient and to all copies of such data Recipient and its sub-Recipients, subsidiaries, subcontractors, and vendors are required to use all available legal means at their disposal to uphold the protections afforded by the Certificate and to fight unauthorized demands for *All of Us* data covered by the Certificate.

E. Dissemination of False or Deliberately Misleading Information

None of the funds made available pursuant to this Agreement may be used to disseminate information that is deliberately false or misleading.

F. Federal Information Security Modernization Act (FISMA)

If the Recipient's information systems, electronic or hard copy, contains Federal data, it must

be protected from unauthorized access consistent with the Federal Information Security Modernization Act (FISMA), 44 U.S.C. 3541 et seq, as amended, including by the Federal Information Security Modernization Act of 2014, P.L. 113-283.

The Parties also acknowledge that information security protocols and standards are likely to evolve over time. Therefore, the systems and processes made accessible to the NIH by the Recipient under this Agreement may need to be revisited and/or adapted to ensure the continued integrity, confidentiality, and security of data.

G. Fly America Act

Foreign air travel funded by this OT may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible, including where the U.S. has entered into an "open skies"" agreement with one or more foreign governments. For information about the Fly America Act, refer to the U.S. General Service Administration's web site at https://www.gsa.gov/policy-regulations/policy/travel-management-policy/fly-america-act.

The Recipient is required to follow the Federal Travel Regulation (https://www.gsa.gov/policy-regulations/regulations/federal-travel-regulation-ftr) to the maximum extent possible. Any deviation or waiver to the regulation must be pre-approved in writing by the OTAO. The Recipient is fully required to follow the Federal Travel Regulation possible unless a waiver is approved in writing.

H. Foreign Involvement

All OT awards that have foreign involvement shall use the Foreign Award and Component Tracking System (FACTS). For information about the Foreign Award and Component Tracking System, refer to https://era.nih.gov/about-era/nih-and-grantor/program/facts.htm.

I. Gun Control

NIH funds may not be used, in whole or in part, to advocate or promote gun control.

J. Human Embryo Research and Cloning Ban

NIH funds may not be used to support human embryo research.

K. Human Fetal Tissue Research

NIH Other Transactions Authorities may not be used to support Human fetal tissue research. Human fetal tissue (HFT) research is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions. This definition does not include established human fetal cell lines. For more information about this policy, refer to https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html.

L. Human Stem Cell Research

Under Executive Order 13505, NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells. NIH recipients may use hESCs that have been approved by NIH in accord with the NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and recipients must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/recipient must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used. For additional information on Human Stem Cell Research, refer to https://stemcells.nih.gov/.

M. Lobbying Prohibition

The Recipient agrees that:

1. No funds provided under this Agreement shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any state or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself.

2. No funds provided under this Agreement shall be used to pay the salary or expenses of the Recipient, or agent acting for Recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local or tribal government in policy making and administrative processes within the executive branch of that government.

3. The prohibitions in subsections (1) and (2) shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

N. National Environmental Policy Act

This OT award is subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 et seq.

O. Salary Limitation/Cap

None of the funds in this award shall be used to pay the salary of an individual at a rate more than the current salary cap in effect on the date the funding was obligated. See current and historical information on applicable salary cap levels for each fiscal year at the following URL: http://grants.nih.gov/grants/policy/salcap_summary.htm.

P. Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2019 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an institution that receives NIH support for recombinant or synthetic nucleic acid molecule research. For information about research involving recombinant or synthetic nucleic acid modules, refer to the NIH Office of Science Policy web site at https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/.

Q. Research Misconduct

Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies, for recipients of grants for biomedical or behavioral research, recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity and take all reasonable and practical steps to foster research integrity. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (https://ori.hhs.gov/).

R. Restriction on Abortion Funding

Funds provided under this Agreement shall not be spent for any abortion. None of the funds provided under this Agreement shall be expended for health benefits coverage that includes coverage of abortion. The term ''health benefits coverage'' means the package of services

covered by a managed care provider or organization pursuant to a contract or other arrangement.

S. Research Subjects Protections and Requirements

Activities under an Other Transaction shall abide by all applicable requirements for human subjects protections; clinical trials; and animal welfare. If the Other Transaction will involve Human Subjects research, Clinical Trials, and/or Animals in Research, the Other Transaction shall include terms that reflect the requirements of applicable laws, regulations, and NIH policy. For information about NIH policies and law for Animal Welfare, refer to the NIH Office of Laboratory Animal Welfare website at https://olaw.nih.gov/. For information about the NIH clinical trial requirements, refer to the NIH Office of Clinical Research website at https://grants.nih.gov/policy/clinical-trials.htm. For information about the NIH policies for Human Subjects Research, refer to the NIH Division of Human Subjects Research's website at https://grants.nih.gov/policy/humansubjects.htm, and refer to the website of the HHS Office for Human Subjects Protections for the Protection of Human Subjects regulations and regulatory guidance at https://www.hhs.gov/ohrp/regulations-and-policy.

T. Pro-Children Act of 1994

This OT is subject to the requirements of Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994.

U. Promotion or Legalization of Controlled Substances

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by Section 2020 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the recipient notifies the OTAO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

V. Restriction of Pornography on Computer Networks

No funds provided under this Agreement may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography. Nothing in this section shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

W. Restriction on Distribution of Sterile Needles

Funds provided under this Agreement may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drugs.

X. Select Agents

Domestic Recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with the Centers for Disease Control and Prevention (CDC) (or the United States Department of Agriculture (USDA), depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

Y. USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. Chapter 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. “Restricted persons,” as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent.

Z. Rehabilitation Act

The Recipient agrees to comply with Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93-112), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 84), to the end that, in accordance with Section 504 of that Act and the Regulation, no otherwise qualified individual with a disability in the United States shall, solely by reason of her or his disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity for which the Applicant receives Federal funding from the Department.

AA. Title IX of the Education Amendments of 1972

The Recipient agrees to comply with Title IX of the Education Amendments of 1972 (Pub. L. 92-318), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 86), to the end that, in accordance with Title IX and the Regulation, no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any education program or activity for which the Applicant receives Federal funding from the Department.

BB. Age Discrimination Act

The Recipient agrees to comply with the Age Discrimination Act of 1975 (Pub. L. 94-135), as amended, and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 C.F.R. Part 91), to the end that, in accordance with the Act and the Regulation, no person in the United States shall, on the basis of age, be denied the benefits of, be excluded from participation in, or be subjected to discrimination under any program or activity for which the Applicant receives Federal funding from the Department.

CC. Affordable Care Act

The Recipient agrees to comply with Section 1557 of the Affordable Care Act (Pub. L. 111-148), as amended, and all requirements imposed by or pursuant to the Regulation of the Department. of Health and Human Services (45 CFR Part 92), to the end that, in accordance with Section 1557 and the Regulation, no person in the United States shall, on the ground of race, color, national origin, sex, age, or disability be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity for which the Applicant receives Federal funding from the Department.

ARTICLE XV: ORDER OF PRECEDENCE

In the event of any inconsistency between the terms of this Agreement and language set forth in the Attachments, the inconsistency shall be resolved by giving precedence in the following order: (1) The Agreement, and then (2) all Attachments to the Agreement.

ARTICLE XVI: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations, and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of the Recipient and the NIH OTAO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.