Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative® Research Programs

U.S. Department of Health and Human Services

National Institutes of Health

11/18/15

Introduction

In his State of the Union Address on January 20, 2015, President Obama announced his intention to launch a Precision Medicine Initiative® (PMI) "to bring us closer to curing diseases like cancer and diabetes, and to give all of us access to the personalized information we need to keep ourselves and our families healthier." PMI will pioneer a new model of participant partnership in research that promises to accelerate biomedical discoveries and provide individuals, families, clinicians, and communities with new tools, knowledge, and therapies to select which preventions and treatments will work best for which people.

The National Institutes of Health (NIH) is responsible for the two research components of the President's Precision Medicine Initiative:

1. The development of a national research cohort—the PMI Cohort Program—of one million or more U.S. volunteers engaged as partners in a longitudinal, long-term effort to transform the understanding of factors contributing to individual health and disease. The PMI Cohort Program proposes a highly interactive participation model, which is untested for a project of this scale. Participants will be the primary source of research observations; providers of information about their health and experiences; contributors to research questions; mediators of access to their healthcare data; contributors to overall data quality control; donators of data from mobile and wearable devices; and recipients of their own as well as aggregate data and analysis results, according to their preferences.

   On September 17, 2015, the Precision Medicine Initiative Working Group of the Advisory Committee to the Director (ACD) presented a detailed design framework for building this national research participant group, which may be accessed at https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf. The framework was supported by the full ACD, and accepted by the NIH Director.

2. Efforts through the NIH's National Cancer Institute (NCI) to identify genomic drivers in cancer and apply that knowledge in the development of more effective approaches to cancer treatment. NCI will accelerate the design and testing of effective, tailored treatments for cancer by expanding genetically based clinical cancer trials, exploring fundamental aspects of cancer biology, and establishing a national "cancer knowledge network" that will generate and share new knowledge to fuel scientific discovery and guide treatment decisions. For more information, see http://www.cancer.gov/research/key-initiatives/precision-medicine.

This document describes flexible policies for implementing OT awards for the NIH PMI research programs. In addition to using grants and contracts, NIH will use Other Transaction Authority (OTA) to aggregate the necessary scientific, technological, and/or communications expertise for its PMI research program. OT awards will enable NIH to nimbly add or subtract specific expertise, tools, technologies, and approaches to the NIH PMI programs. A significantly different baseline of expertise is required to develop these programs, create infrastructure of this magnitude, and engage the U.S. population in novel interactive ways to build this research foundation for 21st century medicine.

Some components of the overall NIH PMI research programs will use the OTA described in NIH's annual appropriations (for 2015, the Consolidated and Further Continuing Appropriations Act of 2015 (P.L. 113-235)). Under OTA, NIH can make research awards that are not grants, contracts, or cooperative agreements. OTA has been used by the National Aeronautics and Space Administration (NASA), the Department of Defense (DOD), the Department of Energy (DOE), and certain components of the Department of Health and Human Services (DHHS), but implementation has been quite different.

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PART I: NIH PMI OTHER TRANSACTION AWARDS – GENERAL INFORMATION

1. Roles and Responsibilities

NIH, as a federal awarding agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its other transaction (OT) award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for awardee organizations.

The following subsections highlight the major functions and areas of responsibility of federal and awardee staff. NIH recognizes that additional staff members in a number of different organizations may be involved in OT-related activities; however, this section details only the major participants representing the Federal Government and the awardee.

1.1 NIH Staff

The roles and responsibilities of NIH staff are as follows:

- Agreement Officer (AO). The AO whose name appears on the notice of award (NoA) is the individual responsible for the business management and other non-programmatic aspects of the OT award. The AO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of award.

- Program/Project Manager (PM). The PM is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and OT awards. The PM and the AO work as a team on many of these activities. As the designated federal official for the review, the PM reviews applications for completeness and conformity to requirements, and ensures that adequate numbers of reviewers with appropriate expertise are available for application review.

1.2 Awardee Organization Staff

Overall responsibility for successfully implementing an NIH OT award is a shared responsibility of the awardee's program director/principal investigator (PD/PI), the authorized organizational representative (AOR), and the research/project administrator. As key members of the OT award team, they lead the scientific and administrative aspects of the OT award. While communications can be conducted among research/project administrators and other NIH PMI staff, NIH staff members conduct official business only with the designated PD/PI(s) and AORs. The roles and responsibilities of awardee participants are as follows:

- Authorized Organization Representative (AOR). The AOR is the designated representative of the awardee organization in matters related to the award and administration of its NIH other transactions, including those that require NIH approval. In signing an OT application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the OT application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the OT-supported project or activities resulting from the application. This individual also is responsible to NIH for ensuring that the organization complies with applicable federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. The NIH requires that the awardee organization designate such an official.

- Program Director/Principal Investigator (PD/PI). A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award.

- The PD/PI should work closely with designated officials within the awardee organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other federal and organizational requirements. NIH encourages awardee organizations to ensure that PD/PIs maintain contact with the NIH PM with respect to the scientific and technical aspects of the project and the AO concerning the business and administrative aspects of the award.

- Research/Project Administrator. The research/project administrator acts as a local agent of the AOR in providing day-to-day OT award-related support.

2. Applications Information and Processes

This section provides an overview of types of entities eligible to receive OT awards, funding opportunities, and the legal implications of applications.

2.1 Eligibility

NIH OT awards for the PMI may be awarded to organizations that are domestic, public, private, non-profit, or for-profit. Eligible organizations include governments, including federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, on rare occasions, individuals. Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI, or other staff or participants, will be specified in the funding opportunity, or other publicly available documents.

Individuals unaffiliated with an institution may receive OT awards. These awards will be made to outstanding applicants who have the ability to successfully complete work specified in an OT funding opportunity. The eligibility of these individuals to complete the project will be evaluated during the objective review process and by the AO and PM. Individual awardees will be considered the AOR and the PD/PI.

2.2 Funding Opportunity

A funding opportunity is a publicly available document in which a federal agency makes known its intentions to make awards (e.g., OT awards), usually as a result of competition for funds. Funding opportunities include information to allow prospective applicants to determine whether to apply.

Funding opportunities pertaining to OT awards for the NIH PMI will be published on the NIH PMI website (http://www.nih.gov/precisionmedicine/index.htm) and will be announced in the NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide/index.html). Such notices will direct interested parties to the funding opportunity on the NIH PMI website.

2.3 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt dates (deadlines) in order to be considered for award. The signature of an AOR on the application certifies that the applicant will comply with all applicable assurances and certifications referenced in the application. The applicant is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application. The AOR's signature further certifies that the applicant has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the OT award-supported project or activities resulting from the application.

2.4 Policies Affecting Applications

Application information to be submitted typically includes a technical approach for the project requested; individual, corporate, and/or organizational experience as it relates to the solicitation (referred to as "Past Performance"); brief biographical sketches of senior/key personnel; a cost/budget proposal; and any other information specified in the application instructions, in the announcement, and/or in program guidelines. Specific details on application content are addressed in application instructions and specific funding opportunities. Any significant change to information provided in the application post-submission must be reported immediately to the AO.

2.5 DUNS Number and SAM Registration Requirements

All applicants are encouraged to apply for a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and to register in the System for Award Management (SAM) at the time of application to ensure timely award processing.

All awardee organizations must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when accepting federal OT awards. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. If the organization does not have a DUNS number, the AOR should complete the US D&B D-U-N-S Number Request Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. If an OT award is issued, the awardee must notify potential third party vendors that they must provide their DUNS number to the awardee in order to receive a subaward under the OT award.

Additionally, all awardees must register in the System for Award Management (SAM) (formerly the Central Contractor Registry [CCR]) and maintain the registration with current information at all times during which it has an application under consideration for funding by 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 as an awardee.

3. The Objective Review Process

Annual appropriations (for 2015, Division G, Title II, Section 213 of the Consolidated and Further Continuing Appropriations Act of 2015 [P.L. 113-235]) allows the NIH Director to enter into transactions other than contracts, grants, or cooperative agreements to carry out Common Fund research. This authority additionally allows the NIH Director to use non-standard peer review procedures to obtain assessments of scientific and technical merit:

SEC. 213. (a) AUTHORITY.—Notwithstanding any other provision of law, the Director of NIH ("Director") may use funds available under section 402(b)(7) or 402(b)(12) of the Public Health Service (PHS) Act to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research identified pursuant to such section 402(b)(7) (pertaining to the Common Fund) or research and activities described in such section 402(b)(12). (b) PEER REVIEW.—In entering into transactions under subsection (a), the Director may utilize such peer review procedures (including consultation with appropriate scientific experts) as the Director determines to be appropriate to obtain assessments of scientific and technical merit. Such procedures shall apply to such transactions in lieu of the peer review and advisory council review procedures that would otherwise be required under sections 301(a)(3), 405(b)(1)(B), 405(b)(2), 406(a)(3)(A), 492, and 494 of the PHS Act.

Objective review is an assessment of scientific or technical merit of applications by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications of support they are reviewing. Objective review is essential to ensuring selection of applications that best meet the needs of the program consistent with established criteria and providing assurance to the public that the evaluation and selection process was rigorous and fair. To achieve this result, NIH strives to conduct reviews under the highest ethical standards. Any circumstance that might introduce any conflict of interest, or appearance thereof, prejudices, biases, or predispositions into the process must be disclosed and managed.

The review process and criteria will be specified in each funding opportunity. Only the review criteria described in the funding opportunity will be considered in the review process. An appropriate review group will evaluate all applications submitted in response to the funding opportunity.

PART II: TERMS AND CONDITIONS OF PMI OTHER TRANSACTION AWARDS

1. Overview of Terms and Conditions

Part II includes the terms and conditions of PMI OT awards and is incorporated by reference in all PMI OT awards. 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. Notice of requirements not specified in the *Other Transaction Award Policy Guide for the Precision Medicine Initiative* generally will be provided in the NoA, however, awards or a specified subset of awards, also may be subject to additional requirements, such as those included in executive orders and appropriations acts (including the other transaction legislation cited in the NoA), all terms and conditions cited in the NoA and its

attachments, conditions on activities and expenditure of funds in other statutory or regulatory requirements, and the *Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative*, including any revisions in effect as of the beginning date of the next budget period.

This *Other Transaction Award Policy Guide for the NIH Precision Medicine Initiative* is an aid to the interpretation of statutory requirements. These terms and conditions are intended to be compliant with governing statutes.

2. The Notice of Award

The NoA is the legal document issued to notify the awardee that an award has been made, subject to its terms and conditions, and that funds may be requested. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. If there is a change in the terms and conditions a revised NoA must be issued. NIH will not issue a revised NoA to reflect an awardee's post-award rebudgeting.

2.1 Notice of Award Notification

NIH will send the NoA by email to the awardee organization when an award has been issued. In order to allow for the email notification of the NoA, awardee organizations must include a valid email address in the application. It is the responsibility of the awardee organization to maintain a current and accurate email address for NoAs.

2.2 Funding

NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in increments called budget periods. The length of an initial project period (competitive segment) or of any subsequent competitive or non-competitive segments is determined by the NIH awarding official on the basis of:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project (for PMI the awarding IC is the Office of the Director), and
- NIH funding principles.

The total project period consists of the initial competitive segment, and any additional segments (competitive or non-competitive) as noted in the funding opportunity. A single award covering the entire period of support generally is used only if the total planned period of support will be less than 18 months.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal Government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Awardees are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period. A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future commitments. NIH may withhold support for failure to meet the terms and conditions of the award.

2.3 Budget

Each NoA sets forth the amount of funds awarded. The amount will be shown as a categorical (line item) budget. The awardee has certain rebudgeting flexibility within the overall amount awarded. The awardee may be required to provide matching funds under certain NIH programs or awards if specified in the funding opportunity.

3. Payment

The Payment Management System (PMS) is a centralized payment and cash management system, operated by the DHHS Program Support Center. OT award payments by 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, as specified in the NoA and as described in this section. Payments under PMI OT awards generally are made upon completion of approved

project milestones. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal Government and disbursement by an awardee.

Advances made by awardees to third party contractors under OT awards must conform to substantially the same standards of timing and amount that govern advances to the awardee.

Operational guidance for awardees is provided through training from the Program Support Center. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (FFR) SF 425 should be directed to the DHHS Program Support Center.

3.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to an awardee's bank account and requires awardees 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.

3.2 Cash Request

Awardees 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, as specified by the NIH awarding IC (for PMI the awarding IC is the Office of the Director). Cash requests are used when an awardee's cash management must be closely monitored or under programs where reimbursement financing is appropriate. An awardee also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the AO determines that an awardee is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports.

If the cash request is for an advance payment, the awardee 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, an awardee must submit the request through the AO early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the awardee electronically through the ACH process upon receipt of the approved payment request.

3.3 Interest Earned on Advances of PMI Other Transaction Award Funds

NIH awardees that receive advance payments must maintain those advances in an interest-bearing account. Awardees are expected to promptly return any funds not spent within three

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, Rockville, MD 20852. Interest amounts up to $500 per year may be retained by the awardee for administrative expenses.

3.4 Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the award. Using the principle of "first in-first out," unobligated funds carried over should be used before newly awarded funds.

4. Cost Considerations

Cost considerations are critical throughout the life cycle of an OT award. An applicant's budget request is reviewed using the governing cost principles and other requirements and policies applicable to the type of awardee as a guide. PMI OT awards will use the cost principles at 45 CFR Part 75, Subpart E as a guide for negotiating the award amount. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the awardee may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for awardees to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval.

During post-award administration, the AO monitors expenditures for conformance with cost policies. The AO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports.

4.1 The Cost Principles

In general, PMI OT awards provide for reimbursement of actual, allowable costs incurred and are subject to federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or facilities and administrative (F&A) costs, and set forth the allowability and allocability principles for selected items of cost. The cost principles are set forth in DHHS regulations at 45 CFR 75, Subpart E and Appendix IX (hospitals) to Part 75. Commercial organizations are subject to the cost principles located at 48 CFR 31.2 Federal Acquisition Regulation.

4.2 Direct Costs and Facilities and Administrative Costs

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree

of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the OT-award supported project or activity.

Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project or program. Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for the management and accounting of costs consistently and must not include costs associated with its F&A rate as direct costs. As a general policy NIH will reimburse F&A costs under OT awards using the applicants' federal negotiated indirect cost rate. Any applicant that has never received a negotiated indirect cost rate may propose a rate with a justification and NIH will determine the rate for the awards.

5. Activities Requiring Prior Approval

NIH prior written approval may be required before an awardee makes certain modifications or undertakes particular activities. The following section describes situations where an awardee may or may not have the authority to make modifications without NIH approval.

5.1 Acceptable Awardee Changes:

- Transfer of the Performance of Substantive Programmatic Work to a Third Party Contractor: Prior approval by the AO is not required to transfer the performance of already approved programmatic work unless the activity constitutes a change in scope.

- Awardee Rebudgeting Within Budget Categories: In general, NIH awardees are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the awardee's discretion as long as they are within the limits established by NIH.

5.2 Changes Requiring NIH Approval:

- Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period: The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the awardee has automatic carryover authority or if prior approval (from the Agreements Officer) is required to carryover unobligated balances from one budget period to any subsequent budget period. Awardees will be required to indicate, as part of the OT award's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected and the anticipated level. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance

is greater than 25 percent of the total approved budget, the awardee must provide an explanation and indicate plans for expenditure of those funds within the current budget year. The AO will review the circumstances resulting in the balance and may request a revised budget.

Awardees must report disbursements on the quarterly cash transaction report using the Federal Financial Report (FFR), FFR SF 425.

Note: Awardees should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the awardee and are considered to be obligations and, therefore, should not be reported as unobligated balances.

- No-cost Extensions: Any project period extension beyond the initial project period requires NIH prior approval from the AO. 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.

- Change in Scope: If authorized by the awardee organization, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the awardee must obtain prior approval from the NIH AO for a change in scope. Significant rebudgeting is a potential indicator of a change in scope.

- Change of Awardee Organization: NIH prior approval is required for the transfer of the legal and administrative responsibility for an OT-supported project or activity from one legal entity to another.

- Deviation from Award Terms and Conditions, including Restrictions in the NoA: NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in this Policy Guide.

5.3 Process for Requesting Prior Approval

All requests for NIH prior approval must provide evidence of the AOR's approval and be submitted by email to the AO no later than 30 days before the proposed change. A request by a third (3rd) party contractor for prior approval will be addressed in writing to the awardee. The awardee will promptly review such request and shall approve or disapprove the request in writing. An awardee will not approve any budget or project revision, which is inconsistent with the purpose or terms and conditions of the OT award to the awardee.

6. Availability of Research Results: Publications, Invention Rights, and Sharing Research Resources

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and awardee organizations must make the results and accomplishments of their activities available to the research community and to the public at large.

6.1 Rights in Data (Publication and Ownership)

- Ownership of Participant Data and Biospecimens*:* A fundamental objective of the Cohort Program is to ensure that all information obtained from the participant, including both data and biospecimens, remain available without interruption to the research public for many years to come, even in the event that awardees withdraw or are terminated or otherwise can no longer manage the resource, or when the associated scientific grants, discussed elsewhere in funding announcements are expired. NIH will own the biospecimens and data obtained from participants, and may take exclusive custody and control of these data and biospecimens at its reasonable discretion.

- Ownership and Rights to Materials and Resources*:* Except for participant data and biospecimens as specified above, awardees will own the rights to materials and resources resulting from an OT-supported project. FAR clause 52.227-14 (Rights in Data-General with no "alternate" and modified to provide the government with identical data and software licenses) will be incorporated into the funding agreement and the awardee will normally be provided with the agency's permission to assert copyright in data first produced under the award. The copyright will be subject to a paid-up, nonexclusive, irrevocable, worldwide license in any copyrighted data or software to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. Special terms and conditions of the award may indicate alternative rights, e.g., based on specific programmatic considerations as stated in the applicable funding opportunity. Therefore, except as otherwise expressly provided in the terms and conditions of the award, the awardee may assert copyright in any publications, data, software or other copyrightable works developed under a PMI OT award without NIH approval, subject to a paid-up, nonexclusive, irrevocable, worldwide license in any copyrighted data or software to reproduce, prepare derivative works, distributed copies to the public, and perform publicly and display publicly by or on behalf of the Government. For this purpose, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms,

diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

Additionally, the awardee and subcontractors at all tiers shall grant to the end-users and members of the public a paid-up, nonexclusive, irrevocable, worldwide license to use, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly any data in which the awardee asserts copyright including computer software in the Delivered Products when utilized in the PMI and its successor initiatives.

6.2 NIH Public Access Policy

Awardees will be expected to 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; http://www.pubmedcentral.nih.gov/). Awardees must submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.

6.3 Sharing Research Resources

NIH considers the sharing of research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community and the public. Program staff is responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources (64 FR 72090, December 23, 1999; http://grants.nih.gov/grants/intell-property_64FR72090.pdf) and Best Practices for the Licensing of Genomic Inventions (70 FR 18413, April 11, 2005). These policy documents will assist awardees in determining reasonable terms and conditions for disseminating and acquiring research tools.

6.3.1 Data Sharing Policy

- General Data Sharing*:* 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 final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. "Timely release and sharing" is defined as no later than the acceptance for publication of the main findings from the final data set.

- Human Subject Data Sharing*:* NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, and local, state and federal laws and regulations, including the HIPAA Privacy Rule. The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data-sharing is limited, applicants should explain such limitations in their data-sharing plans. Awardees must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to meet these data sharing expectations should promptly contact the AO to discuss the circumstances, obtain information that might enable them to share data, and reach an understanding in advance of an award.

6.3.2 Genomic Data Sharing (GDS) Policy

The NIH Genomic Data Sharing (GDS) 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.

All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to include a genomic data sharing plan (see http://gds.nih.gov/pdf/NIH_guidance_developing_GDS_plans.pdf for guidance on developing a genomic data sharing). For additional information, see: http://gds.nih.gov/. Questions about the GDS policy can be emailed to GDS@mail.nih.gov.

6.3.3 Inventions and Patents

In order to promote the broad sharing of information and inventions in the PMI, awardee inventions will be governed by FAR clause 52.227-13, which provides title to the Government in any invention made by the awardee, subject to a revocable, nonexclusive, paid-up license in

each patent application filed in any country on a subject invention and any resulting patent in which the government obtains title. This is to assure that patents directed to inventions made under this award cannot be used to block access by the research public to this important resource and associated technology.

6.3.4 Biospecimens and Reagents

A fundamental objective of the NIH PMI is to ensure that valuable biospecimens and other reagents and tangible resources made under it remain available without interruption to the research public for many years to come, even in the event that awardees withdraw or are terminated or otherwise can no longer manage the tangible resources, or when the associated scientific awards are expired. Accordingly, NIH will own the tangible resources generated by the PMI, including biospecimens and reagents, and may take exclusive custody and control of them at its reasonable discretion.

7. Management Systems and Procedures

Awardee organizations are expected to have in use clearly delineated roles and responsibilities for their 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.

Awardees may use their existing systems to manage NIH OT award funds and activities as long as policies and procedures are consistently applied across their business functions.

7.1 Financial Management System Standards

Awardees must have in place accounting and internal control systems that 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 obligation and expenditure of funds, and awardees must notify NIH when problems are identified. An awardee's failure to establish adequate control systems constitutes a material violation of the terms of the award.

7.2 Property Management System Standards

Generally, awardees may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH PMI OT award funds. Awardees are required to be prudent in the acquisition of property under an OT award-supported project. It is the awardee's responsibility to conduct a prior review of each proposed

property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization.

7.3 Procurement System Standards and Requirements

Awardees 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. Awardees must acquire goods and services under OT awards in compliance with the organizations established policies and procedures.

8. Monitoring

Awardees are responsible for managing the day-to-day operations of OT award-supported activities using their established controls and policies. However, to fulfill their role in regard to the stewardship of federal funds, the NIH PMI program team will monitor their OT awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence, audit reports, site visits and other information, which may be requested of the awardee.

Monitoring of a project or activity will continue for as long as NIH retains a financial interest in the project or activity as a result of property accountability, audit, and other requirements that may continue for a period of time after the OT award is administratively closed out and NIH is no longer providing active OT award support.

8.1 Reporting

NIH requires that OT award awardees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, conflict of interest reports, audit reports, reports to the appropriate payment points (in accordance with instructions received from the payment office), progress and financial status reports, and specialized programmatic reports. The contents and timelines for all required reports will be specified in the terms and conditions of the award.

The AO is the official recipient for required reports. All required reports must be submitted via email to the AO.

8.2 Progress Reports

Progress report requirements and processes will be determined at the time of award and will be included in the NoA.

8.3 Financial Reports

- Cash Transaction Reports*:* For NIH PMI OT awards, a Cash Transaction Report will be required on a quarterly basis. The SF-425 FFR has a dedicated section to report federal cash receipts and disbursements. For domestic awardees this information is submitted quarterly directly to the PMS using the web-based tool. Quarterly reports are due 30 days following the end of each calendar quarter. The reporting period for this report continues to be based on the calendar quarter. Questions concerning the requirements for this quarterly financial report should be directed to the PMS.

- Revised Expenditure Reports*:* NIH requires all financial expenditure reports to be submitted using the electronic Federal Financial Report FSR/FFR system located in eRA Commons. This includes the initial FFR and any FFR revisions being submitted or resubmitted to NIH. Revised or amended reports should be submitted in the same format as the original. When a revision results in a balance due to NIH, the awardee must submit a revised report as soon as the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. Revised expenditure reports representing additional expenditures by the awardee that were not reported to NIH within the 90-day time frame may be submitted electronically through the eFSR/FFR system to the AO with an explanation for the revision. If an adjustment is to be made, the NIH AO will advise the awardee of actions it will take to reflect the adjustment.

- Close out of Fixed Year Appropriations Accounts*:* Fixed year appropriation accounts have a five year availability span. Awardees must draw down all appropriated fiscal year award funds no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

8.4 Record Retention and Access

For OT awards, the 3-year record retention period will be calculated from the date the FFR for the entire competitive segment is submitted. Therefore, awardees must retain the records pertinent to the entire competitive segment for 3 years from the date the FFR is submitted to NIH. 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 document, images, and other electronic media. Institutions that rely on an electronic storage system must be able to assure such a system is stable, reliable, and maintains the integrity of the information. When storing

electronic images of paper documents, the system must also assure a full, complete, and accurate representation of the original, including all official approvals.

8.5 Audit

NIH funding awardees are subject to the audit requirements of OMB 2 CFR 200, Subpart F-Audit Requirements, as implemented by DHHS 45 CFR Subpart F. In general, 45 CFR 75, Subpart F-Audit Requirements requires a state government, local government, or non-profit organization (including institutions of higher education) that expends $750,000 or more per year under federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions in Subpart F.

For-profit organizations expending less than $750,000 a year are not required to have an annual audit for that year but must make their award-related records available to NIH or other designated officials for review or audit.

A for-profit organization is required to have a non-federal audit if, during its fiscal year, it expended a total of $750,000 or more in DHHS awards. For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The awardee either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the awardee receives awards under only one DHHS program, or (2) an audit that meets the requirements of 45 CFR 75, Subpart F—Audit Requirements.

9. Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support

If an awardee has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions, which 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 for cause.

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

An NIH PMI OT award also may be terminated, partially or totally, by the awardee. If the awardee decides to terminate a portion of a PMI 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 awardee of the possibility of termination of the entire OT award and allow the awardee to withdraw its termination request. If the awardee does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

10. Effect of Termination

If the NIH decides to terminate a PMI OT award, the termination of the award will be considered a unilateral change and the awardee will not have the right to appeal. Although a decision is made to terminate an award, the awardee must continue to comply with the Record Retention and Access requirements contained in Section 8.4.

11. Recovery of Funds

NIH may identify and administratively recover funds paid to an awardee 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 awardee's account that exceed the final amount determined to be allowable, or other circumstances.

12. 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 awardees.

13. Closeout

The requirement for timely closeout is generally an awardee responsibility. Closeout includes ensuring timely and accurate submission of all required reports and adjustments for amounts due to the awardee or NIH. Therefore, awardees must submit the last quarterly FFR, final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of OT award support. The reports become overdue the day after the 120 day period ends.

14. Public Policy Requirements and Objectives

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 awardees. The public policy requirements specified in this section set many of those standards. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions and this policy guide.

14.1 Debarment and Suspension

DHHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for DHHS' non-procurement programs and activities. NIH implements the DHHS Debarment and Suspension regulations as a term and condition of award. Accordingly, awardees of NIH OT awards are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction prior to entering into the covered transaction, i.e., prior to the drawdown of funds, which signals acceptance of the OT award. Awardees may decide the method and frequency by which this determination is made and may check excluded parties in SAM, although checking SAM is not required.

14.2 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal Government money 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. These circumstances are outlined below:

1. Airline "Open Skies" Agreement. A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. Government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued Guidance October 6, 2010. Pursuant to the amendment, federal contractors and awardees (not U.S. Government employees) need not be concerned about city-pair

contract fares. However, contractors and awardees must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the EU. For additional information, please see the text of the Amendment and GSA Bulletin FTR 11-02. For information on other "open skies" agreements in which the United States has entered, refer to GSA's website: http://www.gsa.gov/portal/content/103191.

2. Involuntary Rerouting. Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.

3. Travel To and From the U.S. Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

4. Travel Between Points Outside the U.S. Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

5. Short Distance Travel. For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

14.3 National Environmental Policy Act

All NIH OT awards, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires federal agencies to consider the reasonably foreseeable environmental consequences of all OT-supported activities. As part of NIH's implementation of this Act, awardees are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from OT-supported activities, or certify that no such impacts will arise upon receipt of an OT award. In addition, NIH has determined that most NIH OT awards are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a federal, state, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous waste, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

14.4 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH OT awards are subject to these requirements only if they

meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded healthcare, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH OT award should be directed to the AO.

14.5 Research Misconduct

Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions," specifies awardee responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the DHHS Office of Research Integrity (ORI), 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 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 (http://www.ori.dhhs.gov).

14.6 Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (November 2013 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 organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the NIH Guidelines is available at

http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

According to the NIH Guidelines, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified, but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The NIH Guidelines apply to both basic and clinical research studies. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH Guidelines.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. Two specific requirements of the NIH Guidelines are discussed below, but the awardee should carefully review the NIH Guidelines in their entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Recombinant or synthetic nucleic acid research involving select agents also is subject to pertinent Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture (USDA) regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.

14.7 Select Agents

Domestic awardees 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 CDC (or 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.

14.8 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.

14.9 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for the NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation.

14.10 Gun Control

The Consolidated and Further Continuing Appropriations Act, 2015, provides that NIH funds may not be used, in whole or in part, to advocate or promote gun control.

14.11 Lobbying Prohibition

(a) No part of any appropriation contained in the Consolidated and Further Continuing Appropriations Act, 2015, or transferred pursuant to section 4002 of Public Law 111-148 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.

(b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract awardee, or agent acting for such awardee, 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 policymaking and administrative processes within the executive branch of that government.

(c) The prohibitions in subsections (a) and (b) 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.

14.12 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, 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.

14.13 Exceptions to Restrictions on Abortions

(a) The limitations established in the preceding section shall not apply to an abortion—(1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a state, locality, entity, or private person of state, local, or private funds (other than a state's or locality's contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a state or locality to contract separately with such a provider for such coverage with state funds (other than a state's or locality's contribution of Medicaid matching funds).

(d) (1) None of the funds appropriated to NIH may be made available to a federal agency or program, or to a state or local government, if such agency, program, or government subjects any institutional or individual healthcare entity to discrimination on the basis that the healthcare entity does not provide, pay for, provide coverage of, or refer for abortions. (2) In this subsection, the term "healthcare entity" includes an individual physician or other healthcare professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of healthcare facility, organization, or plan.

14.14 ClinicalTrials.gov Requirement

Applicants and awardees should familiarize themselves with the requirements of Title VIII, Sec. 801 of Public Law 110-85 (also known as the U.S. Food and Drug Administration (FDA) Amendments Act of 2007 or FDAAA), with respect to registration and results reporting requirements that may apply to certain studies. In particular, awardees should be aware that if an applicable clinical trial is funded in whole or in part by an NIH OT award, any application or progress report shall include a certification that the Responsible Party has made all required

submissions to ClinicalTrials.gov. The NIH strongly encourages registration of all clinical trials, whether required by FDAAA or not. For additional information, see http://grants.nih.gov/clinicaltrials_fdaaa/index.htm and https://www.clinicaltrials.gov.

14.15 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.

For the purpose of the NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. Induced pluripotent stem cells are human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.

NIH awardees 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 awardees 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/awardee 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.

14.16 Human Embryo Research and Cloning Ban

NIH funds may not be used to support human embryo research. NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g[b]). The term "human embryo or embryos" includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization,

parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition to the statutory restrictions on human fetal research under subsection 498([b] of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using federal funds for cloning of human beings.

14.17 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable federal, state, and local laws as well as the following NIH guidance.

Guidance for awardees conducting research on human fetal tissue and other information on the governing federal statute is found in sections 498A and 498B of the PHS Act, 42 U.S.C. 298g-2.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the federal requirements, particularly section 498B. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with section 498B of the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

14.18 Human Subjects Protections

The DHHS regulations for the protection of human subjects, in 45 CFR 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the NIH or other DHHS components.

The DHHS regulations stipulate that the awardee organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported activities (46.101[a] and 46.103[a]). Awardee organization(s) "engaged" in

human subjects research must obtain a Federal-Wide Assurance (FWA) with the DHHS Office for Human Research Protections, and establish appropriate policies and procedures for the protection of human subjects.

14.19 Animal Welfare Requirements

The PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare at the time of award for all awardee organizations receiving PHS support for research or related activities using live vertebrate animals. Awardee organizations must establish appropriate policies and procedures to ensure the humane care and use of animals, and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training, and requires the awardee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495).

14.20 Promotion or Legalization of Controlled Substances

Awardees 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 202 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 awardee notifies the AO 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.

14.21 Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

14.22 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

14.23 Restriction of Pornography on Computer Networks

The Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) includes the following restriction:

(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) 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.

PART III: DEFINITIONS

Term	Definition
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-federal entity's regular accounting practices.
Award date	The date when the award is signed by the authorized official of the federal awarding agency.
Awarding IC	The NIH Institute or Center (IC) responsible for the award, administration, and monitoring of OT-supported activities. For PMI the awarding IC is the Office of the Director.
Awardee	An entity, usually but not limited to non-federal entities, that receives an award directly from a federal awarding agency to carry out an activity under a federal program. The term may also include an individual. The term awardee does not include subawardees, except as indicated below.

Term	Definition
Budget	The financial plan for the project or program that the federal awarding agency or pass-through entity approves during the award process, or in subsequent amendments to the award. It may include the federal and non-federal share or only the federal share, as determined by the federal awarding agency or pass-through entity. The approved budget specified in the notice of award (NoA) may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consist of both federal and non-federal shares are deemed to be borne by the awardee in the same proportion as the percentage of federal/non-federal participation in the overall budget.
Change of awardee organization	Transfer of the legal and administrative responsibility for an OT-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Closeout	The process by which the federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the award have been completed and the appropriate closeout actions have been taken.
Commercial organization	An organization, institution, corporation, or other legal entity, including, but not limited to, partnerships, sole proprietorships, and limited liability companies, that is organized or operated for the profit or benefit of its shareholders or other owners. The term includes small and large businesses and is used interchangeably with “for-profit organization.”
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.
Contract	A legal instrument by which a non-federal entity purchases property or services needed to carry out the project or program under an award. The term does not include a legal instrument, even if the non-federal entity considers it a contract, when the substance of the transaction meets the definition of an award or subaward. *See Subaward.*
Contractor	An entity that receives a contract. *See Contract*.
Disallowed costs	Those charges to an award that the federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable federal statutes, regulations, or the terms and conditions of the award.

Term	Definition
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-federal entity for financial statement purposes, or $5,000.
Expenditure report	The SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report);
Expenditures	Charges made by a non-federal entity to a project or program for which an award was received. (1) The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. (2) For reports prepared on a cash basis, expenditures are the sum of: (i) Cash disbursements for direct charges for property and services (ii) The amount of indirect expense charged (iii) The value of third-party in-kind contributions applied (iv) The amount of cash advance payments and payments made to subawardees. (3) For reports prepared on an accrual basis, expenditures are the sum of: (i) Cash disbursements for direct charges for property and services (ii) The amount of indirect expense incurred (iii) The value of third-party in-kind contributions applied (iv) The net increase or decrease in the amounts owed by the non-federal entity for: (A) Goods and other property received (B) Services performed by employees, contractors, subawardees, and other payees (C) Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.
Federal awarding agency	The federal agency that provides an award directly to another entity. *See also Awarding IC.*
Federal share	The portion of the total project costs that are paid by federal funds.
Funding Announcement/ Funding Opportunity	A funding announcement is a publicly available document in which a federal agency makes known its intentions to make awards (e.g., OT awards), usually as a result of competition for funds.

Term	Definition
Generally Accepted Accounting Principles (GAAP)	The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).
Generally Accepted Government Auditing Standards (GAGAS)	Generally Accepted Government Auditing Standards (GAGAS). also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.
Hospital	A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation).
Institution of Higher Education (IHE)	*IHE* is defined at 20 U.S.C. 1001.
Internal controls	A process, implemented by a non-federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) effectiveness and efficiency of operations (2) reliability of reporting for internal and external use (3) compliance with applicable laws and regulations.
Matching or cost sharing	The portion of project costs not paid by federal funds (unless otherwise authorized by federal statute). This may include the value of allowable third party in-kind contributions, as well as expenditures by the awardee. These costs are only required when identified in specific funding opportunities.
Non-federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out an award as an awardee or subawardee.

Term	Definition
Notice of Award (NoA)	The official, legally binding document, signed (or the electronic equivalent of signature) by an Agreement Officer that: (1) notifies the awardee of the OT award (2) contains or references all the terms and conditions of the OT award and federal funding limits and obligations (3) provides the documentary basis for recording the obligation of federal funds in the NIH accounting system.
Obligations	When used in connection with a non-federal entity's utilization of funds under an award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non-federal entity during the same or a future period.
Other Transaction (OT) Award	Refers to the authority provided to the Director, NIH, to enter into transactions other than contracts, grants or cooperative agreements to carry out research identified pursuant to section 402(b)(7) (pertaining to the Common Fund) or research and activities described in section 402(b)(12) of the Public Health Service Act.
Pass-through entity	A non-federal entity that provides a subaward to a subawardee to carry out part of a federal program.
Payment Management System	The DHHS centralized payment system operated by the Payment Management Service, Program Support Center. Most DHHS (and some other Federal Government agencies') awardees receive payments through this system.
Period of performance	The time during which the non-federal entity may incur new obligations to carry out the work authorized under the award. The federal awarding agency or pass-through entity must include start and end dates of the period of performance in the award.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.

Term	Definition
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public websites, and university listings. This type of information is considered to be public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.
Pre-award costs	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk. Under OT awards these costs are not allowable.
PMI Cohort Program	Research cohort of one million or more U.S. volunteers who will contribute their health data for a longitudinal study aimed to improve health outcomes, fuel the development of new treatments for diseases, and catalyze a new era of data-based and more precise preventive care and medical treatments.
Prior approval	Written approval by an authorized DHHS official, e.g., a designated Agreement Officer, evidencing prior consent before an awardee undertakes certain activities or incurs specific costs.
Program income	Gross income earned by the non-federal entity that is directly generated by a supported activity or earned as a result of the OT award during the period of performance. Program income includes but is not limited to income from fees for services performed, the use or rental of real or personal property acquired under an award, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and principal and interest on loans made with award funds. Interest earned on advances of federal funds is not program income. Except as otherwise provided in federal statutes, or the terms and conditions of the OT award, program income does not include rebates, credits, discounts, and interest earned on any of them.

Term	Definition
Project period	The total time for which federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal Government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions.
Property	Real property or personal property.
Protected Personally Identifiable Information (Protected PII)	An individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number; passport number; credit card numbers; clearances; bank numbers; biometrics; date and place of birth; mother's maiden name; criminal, medical, and financial records; and educational transcripts. This does not include PII that is required by law to be disclosed.
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
Research and Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by DHHS award awardees. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Special purpose equipment	Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers.
Subaward	An award provided by a pass-through entity to a subawardee for the subawardee to carry out part of an award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.

Term	Definition
Subawardee	A non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program; but does not include an individual that is a beneficiary of such program. A subawardee may also be an awardee of other awards directly from a federal awarding agency. The term includes consortium participants.
Supplies	All tangible personal property other than those described in the definition of "Equipment." A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-federal entity for financial statement purposes or $5,000, regardless of the length of its useful life.
Suspension of award activities	An action by NIH requiring the awardee to cease all activities on the award pending corrective action by the awardee. It is a separate action from suspension under DHHS regulations (2 CFR 376) implementing Executive Orders 12549 and 12689. *See Section 13.1 Debarment and Suspension and Section 8 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support.*
Termination	The ending of an award, in whole or in part at any time prior to the planned end of period of performance.
Third-party in-kind contributions	The value of non-cash contributions (i.e., property or services) that: (1) benefit a federally assisted project or program (2) are contributed by non-federal third parties, without charge, to a non-federal entity under a federal award.
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non-federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-federal entity for which expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under an award that the non-federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-federal entity's unliquidated obligations and expenditures of funds under the award from the cumulative amount of the funds that the federal awarding agency or pass-through entity authorized the non-federal entity to obligate.