NIH OTHER TRANSACTION AWARD POLICY GUIDE for HuBMAP

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Overview of the NIH Common Fund Human Biomolecular Atlas Program

The overall goal of the NIH Common Fund Human Biomolecular Atlas Program (HuBMAP) is to catalyze development of a framework for functional mapping of the human body with cellular resolution to enhance our understanding of organization-function by: (1) accelerating development of the next generation of tools and techniques for constructing high-resolution spatial tissue maps that quantify multiple types of biomolecules, (2) generating foundational 3D tissue maps using validated high-content, high-throughput imaging and omics assays, (3) establishing an open data platform that will develop novel approaches to integrating, visualizing and modelling imaging and omics data to build multi-dimensional maps, and making data rapidly findable, accessible, interoperable, and reusable by the global research community, (4) coordinating and collaborating with other funding agencies, programs, and the biomedical research community to build the architecture and tools for mapping the human body with cellular resolution, and (5) supporting projects that demonstrate the value of the resources developed by the program to study individual variation and tissue changes across the lifespan and the health-disease continuum.

HuBMAP will develop multi-dimensional maps of human tissues at the single cell level by integrating ideas and expertise from several disciplines, including anatomy, physiology, imaging, molecular biology, engineering, biotechnology, and chemistry. A significantly different baseline of knowledge is expected in various organs/organ systems and expertise gained on one organ could be flexibly combined with projects focused on less advanced areas to accelerate gains in knowledge across organs.

The HuBMAP Program uses the Other Transaction Authority described in the Consolidated Appropriations Act of 2018 (P.L. 115-141) to quickly modify/initiate projects as well as nimbly adapt the program focus to the rapidly-changing, high-risk neuromodulation landscape. Under Other Transaction Authority, NIH can make research awards that are not grants, contracts or cooperative agreements. In addition, HuBMAP program staff can add or subtract specific expertise, tools, technologies and translational approaches to advance funded projects. Other Transaction Authority has been used by NASA, DOD, DOE, and certain components of the HHS in the past, but implementation has been quite different. Because no discipline possesses all the expertise required to generate, visualize and share these multi-scale, multi-dimensional maps, the HUBMAP program staff will aggregate the necessary expertise by using OT authority to nimbly add or subtract specific expertise, tools, technologies, and approaches to the problem of mapping human tissues. This document describes flexible policies for implementing OT awards by the NIH HuBMAP Program.

PART I. 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 staffs. 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 participants are as follows:

- **Agreements Staff**
    - **Agreements Officer (AO).** The Agreements Officer (AO) whose name appears on the Notice of Award (NoA) is the Individual responsible for legally committing the government to an OT award, and for the administrative and financial aspects of the award. These activities include, but are not limited to, evaluating OT applications for administrative content and compliance with statutes and guidelines; negotiating OT awards; providing consultation and technical assistance to applicants and awardees, including interpretation of OT administration policies and provisions; and administering and closing out OT awards. The AO works closely with his or her counterparts in other NIH ICs and with the designated Project Manager. 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.
    - **Agreement Specialist (AS)**. The AO may choose to delegate limited administrative responsibilities to an Agreement Specialist (AS). The AS is assigned responsibility for the day-to-day communications and management of the OT award.
- **Program Staff**
    - **Program Manager (PM).** The Program Manager (PM) is responsible for overall coordination of the program and chairs the NIH Working Group. The PM provides overall direction for scientific and programmatic aspects for all awards in the program and may consult other NIH and non-NIH experts in making determinations. The PM's responsibilities include, but are not limited to, development of research programs to meet the IC's mission; oversight of the objective review; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the AO. The PM and the AO work as a team on many of these activities. The PM reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are

available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, and serves as the overall point of contact with applicants during the initial phase of the objective review process.

- **Program Officer (PO).** The Program Officer (PO) whose name appears in the Notice of Award serves as an agent of the PM during OT award negotiations, and in day-to-day scientific and technical discussions and management of the award. The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and OT awards. The PO provides advice to awardees, makes funding recommendations, oversees awardees progress, and facilitates scientific opportunities within the program. The PO is responsible for monitoring award performance, progress toward milestones, and adherence to timelines. The PO and the Agreements staff work as a team to enforce general statutory, regulatory, and policy requirements.
- **Subject Matter Expert (SME).** The Subject Matter Expert (SME) assists the PM and PO with post-award management by monitoring progress toward milestones and deliverables, adherence to timelines, and participates in the day-to-day scientific and technical discussions.

1.2. Awardee Organization Staff

Overall responsibility for successfully implementing an NIH OT award is a shared responsibility of the awardee Principal Investigator (PI) and the authorized organizational representative (AOR). As key members of the other transaction team, they respectively lead the scientific and administrative aspects of the OT award. While communications can be conducted with research administrators and other institutional staff, NIH staff members conduct official business only with the designated PI(s) and AOR(s). The roles and responsibilities of awardee participants are as follows:

- **Authorized Organizational Representative (AOR).** The AOR is the designated representative of the awardee organization in matters related to the award and administration of its NIH OT awards, including those that require NIH approval. This individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual further certifies that the awardee 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.
- **Principal Investigator (PI).** A 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 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 the PI(s) maintain contact with the NIH APM with respect to the scientific aspects of the project and the AO concerning the business and administrative aspects of the award.

PART II. APPLICATION INFORMATION AND PROCESSES

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

1. Funding/Negotiation Opportunities

A Funding/Negotiation Opportunity (F/NO) is a 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. F/NOs include information to allow prospective applicants to determine whether to apply.

F/NOs pertaining to OT awards for HuBMAP may be published on the following sites to enhance promotion of HuBMAP F/NOs even though the resulting awards are not grants, cooperative agreements, or contracts.

- HuBMAP website (https://commonfund.nih.gov/HuBMAP/funding)NIH Guide for Grants and Contracts (https://grants.nih.gov/funding/index.htm);
- Grants.gov (https://www.grants.gov/); or
- Federal Business Opportunities (https://www.fbo.gov/).

2. Eligibility

In general, criteria for applicant eligibility or requirements concerning the qualifications of the PI or other staff or participants will be specified in the Funding/Negotiation Opportunity (F/NO), program guidelines, or other publicly available documents. The F/NO will specify whether or not a domestic, public, private, non-profit, for-profit or foreign organization or individuals unaffiliated with an institution are eligible to apply for a particular OT initiative.

2.1. Legal implications of applications.

An applicant must be an eligible entity or individual and must submit a complete application in accordance with established receipt dates (deadline) 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.

2.2. Policies Affecting Applications

Specific details on application content are addressed in application instructions and specific F/NOs. Any significant change to the information provided in the application post-submission must be reported immediately to the AO.

PART III. REVIEW PROCESS

1. Objective Review

Objective review is an assessment of scientific and/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 F/NO. Only the review criteria described in the F/NO will be considered in the review process. All applications submitted in response to the F/NO will be evaluated by an appropriate review group.

PART IV. TERMS AND CONDITIONS OF HuBMAP OTHER TRANSACTION AWARDS

1. Overview of Terms and Conditions

This section includes the terms and conditions of HuBMAP OT awards and is incorporated by reference in all HuBMAP OT awards. These terms and conditions are not intended to be all-inclusive. Notice of requirements not specified in the NIH Other Transaction Award Policy Guide for HuBMAP generally will be provided in the Notice of Award (NoA), but awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

HuBMAP OT awards are subject to the terms and conditions incorporated either directly or by reference in the following:

- The other transaction legislation cited in the NoA.
- Conditions on activities and expenditure of funds in other statutory or regulatory requirements, such as those included in executive orders and appropriations acts. This also includes any recent legislation.
- The NIH Other Transaction Award Policy Guide for HuBMAP, including any revisions that take effect after the beginning date of the current funding segment.
- The HuBMAP Data Sharing Policy, including any revisions that take effect after the beginning date of the current funding segment.
- The NoA including all terms and conditions cited within the document and its attachments.

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. Thus, the Other Transaction Award Policy Guide for HuBMAP 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 (NoA)

The NoA is the legal document issued to notify the awardee that an award has been made, subject to its terms and conditions. The NoA is issued for the initial funding segment and each subsequent funding segment in the approved project period. A revised NoA may be issued during a funding segment to effect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award.

2.1. Notice of Award Notification

NIH notifies the awardee organization via E-mail 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

After award negotiation, projects are programmatically approved for support of the agreed upon project activities but may be funded in specified increments (e.g., ranging from 1 – 12 months). Award increments may be referred to as funding segments, award segments, or budget periods. The length of the approved project period (competitive segment) and award increment (competitive or non-competitive segments) is determined by NIH. The determination may be based on the following:

- Any statutory or regulatory requirements;
- The length of time necessary to complete the approved project activities;
- Programmatic determination of the frequency of review necessary relative to the risk of the activity; and
- NIH funding principles.

The NoA documents the approval of a project period that extends beyond the current award increment to express NIH intention to provide continued support for the project. Funding beyond the approved award increment is not guaranteed. Continued funding support is based on progress toward project activities, technical and scientific needs or direction, and availability of funds. The NoA does not guarantee that the project will be funded and creates no legal obligation to provide funding beyond the ending date of the approved award increment as shown in the NoA as the current budget period of support.

2.3. Budget and Costs

Each NoA sets forth the amount of funds awarded. The awardee has certain rebudgeting flexibility within the overall amount awarded. The awardee may be required to provide matching funds under certain HuBMAP initiatives or awards if specified in the F/NO.

2.3.1. Costs

The NoA will stipulate that federal funds and the OT awardee's cost sharing funds, if any, are to be used only for costs that a reasonable and prudent person would incur in carrying out the project.

3. Payments

The Payment Management System (PMS) is a centralized payment and cash management system, operated by the DHHS PSC, PMS. HHS OT award payments 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 HuBMAP other transaction awards generally are made as advance payments. HuBMAP other transaction award payments are made by PMS, operated by PSC, in accordance with Department of the Treasury requirements (31 CFR part 208). 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 consortium participants and 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 a training CD from the DHHS Program Support Center. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (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. 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 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.

4. Cost Consideration

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. HuBMAP OT awards will generally use the cost principles at 45 CFR Part 75, Subpart E and Appendix IX (hospitals), and 48 CFR 31.2 Federal Acquisition Regulation as a guide for negotiating the award amount. Any resulting award will include a budget that is consistent with these negotiations.

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, HuBMAP OT awards provide for reimbursement of actual, allowable costs incurred and are expected to generally align with accepted and established Federal cost principles for the awardee organization (e.g., academic, non-profit, for-profit, etc.). The applicable cost principles will be used as a guide for the cost accounting treatment of direct or facilities and administrative (F&A) costs, the allowability and allocability for selected items of cost, and the review and negotiation of OT awards.

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 or indirect 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. In general, NIH will reimburse F&A costs under OT awards using the applicant's federal negotiated indirect cost rate. Any applicant that has never received a negotiated indirect cost rate, may propose a rate as a percentage of modified total direct costs and NIH will determine the rate for the award. F&A costs on foreign awards will be reimbursed at a rate of eight (8) percent of total direct cost, less tuition and related fees, equipment, and subawards in excess of $25,000. NIH will not provide F&A reimbursement on awards to unaffiliated individuals.

4.2.1. Royalties and Licensing Fees from Copyrights, Inventions, and Patents

NIH awardees do not have to report program income resulting from royalties or licensing fees from sale of copyrighted material unless specific terms and conditions of the award provide otherwise. The NoA may include special terms and conditions if commercialization of an invention is an anticipated outcome of a research project.

5. Audit

NIH-funded 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.

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.

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.

Part V. ADMINISTRATIVE REQUIREMENTS

1. Changes in Project and Budget

In general, 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. In other cases, NIH prior written approval may be required before an awardee makes certain budget modifications or undertakes particular activities as outlined in the NoA. During a project period, NIH staff may propose changes in goals and milestones based on programmatic priorities. For future budget periods, goals and milestones may be revised or changed substantially and will be determined by mutual agreement between NIH staff and the awardees in advance of a new NoA.

1.1. Cost-Related Prior Approvals

All costs requested and expended for OT awards must be allocable, necessary, reasonable and realistically reflect the approved project activities. NIH prior written approval is required for significant changes to the awarded budget. Potential indicators of significant changes include, but are not limited to the following:

- Changes that would impact the timeline and/or project activities to be completed;

- Changes in the project activities conducted by an awardee and/or key partnering organization named on the NoA; or
- Changes in the approved facilities/administrative and/or indirect cost rate.

1.2. Unobligated Balance

There is no process for requesting the use of an unobligated balance (i.e. carryover). The anticipated funds remaining at the end of a reporting period, budget period and/or award segment will be reported in interim and/or annual progress reports. NIH Staff will review the funds remaining in coordination with the project activities and associated budget needs for the next award segment. NIH will determine how the remaining funds will be used and notify the award awardee accordingly via email or NoA.

1.3. Actions Requiring Prior Approval

The following actions will require NIH written prior approval:

- Deviation from the award terms and conditions including restriction removals;
- Changes that would possibly impact the timeline and/or scope of work to be completed;
- Changes in key personnel named in the NoA;
- Changes in key partnering organizations named in the NoA;
- Changes that would impact the approved IRB and/or IACUC protocol;
- Change of performance site;
- Transfer of legal and administrative responsibility from one legal entity to another; or
- Additional time and/or funding.

1.4. Requests for Prior Approval

All requests for prior approval must be made in writing (email submission is acceptable) by an AOR or provide evidence of the AOR's approval. The request must be sent to the named Agreement Officer, Award Project Manager, and Agreement Specialist (if applicable). The request should be made no less than thirty (30) days prior to the proposed date of change. NIH will review the request and provide a written response via email and/or revised NoA.

2. Management Systems and Procedures

Awardee organizations are expected to have an organizational culture that is committed to compliance by which they manage funds and activities, including a clear delineation of the roles and responsibilities of the 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 HuBMAP OT award funds and activities as long as they are consistently applied regardless of the source of funds.

2.1. Financial Management System Standards

The standards and requirements for a financial management system are essential to the OT relationship. NIH cannot support the research unless it has assurance that its funds will be used appropriately, adequate documentation of transactions will be maintained, and assets will be safeguarded.

Awardees must have in place accounting and internal control systems that provide for appropriate monitoring of OT 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 and may result in exercise of available enforcement remedies.

2.2. 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 HuBMAP 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.

2.3. Procurement System Standards and Requirements

Awardees may acquire a variety of goods or services in connection with a HuBMAP 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.

3. Monitoring

Awardees are responsible for managing the day-to-day operations of OT award-supported activities using their established controls and policies, as long as they are consistent with NIH requirements. However, to fulfill their role in regard to the stewardship of Federal funds, NIH 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 available, which may be requested of the awardee. The names and telephone numbers of the individuals responsible for monitoring the programmatic and business management aspects of a project or activity will be provided to the awardee at the time of award.

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.

3.1. Reporting

NIH requires that OT awardees periodically submit financial and progress reports. Other required reports may include annual invention utilization reports, lobbying disclosures, 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. Awardees also are expected to publish the results of research in peer-reviewed journals and to provide information to the public on the objectives, methodology, and findings of their NIH-supported research activities. The contents

and timelines for all required reports will be specified in the terms and conditions of the award. The APM, AO and AS are the official recipients for most required reports. All required reports must be submitted via email by the AOR to the APM, AO and AS.

Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions.

3.2. Progress Reports

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

3.3. Final Progress Reports

A final progress report is required for any HuBMAP OT award that is terminated and any award that will not be extended through award of a new award segment or budget period.

3.4. Financial Reports

The awardee shall maintain adequate records to account for all OT award funding. The NIH may require the awardee to submit the following expenditure data directly to the NIH:

- **Cash Transaction Reports** – For HuBMAP 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 directly to the AO and APM and/or using the electronic FSR/FFR system located in eRA Commons. 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 directly to the AO and APM or through the eFSR/FFR system with an explanation for the revision. The explanation should indicate why the revision is necessary and describe what action is being taken by the awardee to preclude similar situations in the future. 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.

3.5. Record Retention and Access

For awards under Other Transactions Authority, the 3-year retention period will be calculated from the date the annual progress report for the initial award segment is submitted. Therefore, awardees must retain the records pertinent to the entire initial award segment for 3 years from the date the annual progress report 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.

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 FFR, final financial report, 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.

3.6. Program Income

The amount of program income earned must be reported in the progress report.

Program income is gross income—earned by an awardee, a consortium participant, or a contractor under an OT award—that was directly generated by an OT-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.

4. 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 funding, or wholly or partly suspending the OT award, pending corrective action. NIH may also terminate the OT award for cause such as but not limited to (1) incompletion of negotiated milestones and/or (2) failure to adhere to the applicable HuBMAP Material Sharing Policy. NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

4.1. Termination

If the NIH decides to terminate an 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 3.5.

An OT award may be terminated, partially or totally, by the awardee by giving the NIH AO and PO ninety (90) days written notification of their intent to do so, provided that such written notice is preceded by consultation between the NIH and awardee. If the awardee decides to terminate a portion of an OT award, NIH may determine that the remaining portion of the award will not accomplish the purposes for which the OT award was originally issued. The NIH and the awardee should negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, which may include non-cancelable commitments. 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. The NIH has no obligation to pay the awardee beyond the last completed and paid milestone.

4.2. Suspension

NIH may suspend (rather than immediately terminate) an 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.

4.3. 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.

4.4. 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.

5. 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. PIs and awardee organizations must make the results and accomplishments of their activities

available to the research community and to the public at large and in accordance with the HuBMAP Material Sharing Policy.

5.1. Inventions and Patents

Depending on each HuBMAP initiative and as stated in the applicable F/NO, the award issued may adopt the prescriptions and requirements of the Bayh-Dole Act (http://grants.nih.gov/grants/bayh-dole.htm), as amended by the Technology Transfer Commercialization Act of 200 (P.L. 404) and 37 C.F.R. 401.14 in their entirety, portions thereof, or none at all. There may be circumstances where the scientific goals of the HuBMAP program require inventions made under a HuBMAP OT award to be managed by NIH in accordance with 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.

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212) and the related EO 12591 (April 10, 1987) provide incentives for the practical application of research supported through Federal grants, cooperative agreements, or contracts. Some of the adopted rights and obligations required by the Bayh-Dole statute and regulation for an awardee to retain intellectual property rights to inventions and provide the Federal Government with all of its rights include:

- Report all subject inventions to NIH and annually report an OT awardee's efforts to transfer the invention for the public's use.
- For all inventions that the funding awardee retains ownership, the funding awardee is obligated to file and prosecute all patent applications in a manner that protects the government's rights worldwide.
- Make reasonable efforts to and take effective steps to achieve practical application of an invention.
- Protect the Federal government's rights in all filed patent applications and issued patents by: (1) conveying to the government a confirmatory license that evidences the government's rights in the invention; and, (2) include a statement of the Federal government's rights in each patent application or issued patent.

For all prescriptions and requirements of the Bayh-Dole Act that may be adopted as specified in the F/NO and NoA, awardees should refer to 37 C.F.R. 401 (available at the NIH Interagency Edison site: http://grants.nih.gov/grants/intell-property.htm).

5.2. Rights in Data (Publication and Copyrighting)

In general, awardees own the rights in data resulting from an OT award-supported project. Special terms and conditions of the award may indicate alternative rights, e.g., based on specific programmatic considerations as stated in the applicable F/NO and NoA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under a HuBMAP OT award may be copyrighted without NIH approval. 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.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages awardees to arrange for publication of NIH-supported original research in primary scientific journals. Awardees also should assert copyright in scientific and technical articles based on data produced under the OT award where necessary to effect journal publication or inclusion in proceedings associated with professional activities. Journal or other copyright practices are acceptable unless the copyright policy prevents the awardee from making copies for its own use. All awardees must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money.

Each publication, press release, or other document about research supported by an NIH OT award must include:

- An acknowledgment of NIH OT award support such as:
  "Research reported in this [publication, release] was supported by the Office of the Director, National Institutes of Health under OT award number [specific NIH OT award number in this format: OT2GM012345]."
- A disclaimer that says: "The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

If the awardee plans to issue a press release about research supported by a HuBMAP OT award, it should notify the NIH AO, APM and AS in advance to allow for coordination. Publications resulting from work performed under a HuBMAP OT award-supported project must be included as part of the interim, annual or final progress report submitted to the NIH AO, APM and AS. When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report.

5.3. NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH-funded research at the NIH National Library of Medicine PubMed Central (NLM PMC), a free digital archive of full-text biomedical and life sciences journal literature (http://www.pubmedcentral.nih.gov/). Under the policy NIH-funded investigators must submit (or have submitted for them) to PMC (https://publicaccess.nih.gov/) 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. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the

article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy.

5.4. 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 are 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 Awardees 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.

5.4.1. Data Sharing Policy

General Data Sharing: Data sharing is essential for expedited translation of research results into knowledge, products, and procedures to 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.

5.4.2. 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 plan). For additional information, see: http://gds.nih.gov/. Questions about the GDS policy can be E-mailed to GDS@mail.nih.gov.

PART VI. Public Policy Requirements

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. The policies, certifications and assurances listed may or may not be applicable to the project, program, or type of applicant organization. This list is not intended to be comprehensive and other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the HuBMAP OT award. Details of these public policy requirements may be found on the HuBMAP NIH Policy & Compliance website at https://grants.nih.gov/policy/index.htm.

- Animal Welfare Requirements (P.L. 99-158, Sec. 495; PHS Policy on Humane Care and Use of Laboratory Animals and International Guiding Principles for Biomedical Research Involving Animals)
- ClinicalTrials.gov Requirement (42 U.S.C. 282j; 42 CFR Part 11, Section 801 also known as FDAAA 801; NIH Policy on Dissemination of NIH-Funded Clinical Trial Information)
- Debarment and Suspension (2 CFR 376 and 2 CFR 180)
- Dissemination of False or Deliberately Misleading Information (pursuant to P.L. 115-245, Section 515(b))

Federal Information Security Management Act (44 U.S.C. 3541)
Financial Conflict of Interest (42 CFR 50, Subpart F)

- Fly American Act (49 U.S.C. 40118 and http://www.gsa.gov/portal/content/103191);
- Gun Control (pursuant to P.L. 115-245, Section 210);
- Human Embryo Research and Cloning Ban (pursuant to P.L. 115-245, Section 508)
- Human Fetal Tissue Research (Sections 498A and 498B of the PHS Act, 42 U.S.C. 298g-1 and 298g-2);
- Human Subjects Protection (45 CFR 46)
- Human Stem Cell Research (pursuant to Executive Order 13505 and NIH Guidelines on Human Stem Cell Research)
- Lobbying Prohibition (pursuant to P.L. 115-245, Section 503 and https://grants.nih.gov/policy/lobbying_guidance.htm);

Metric System (EO 12770, July 25, 1991);

- National Environmental Policy Act (1969);
- Pro Children Act of 1994 (P.L. 103-227, Title X, Part C);
- Prohibition on Promotion or Legalization of Controlled Substances (pursuant to P.L. 115-245,

Section 509)

- Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines. November 2013 or latest revision and 42 CFR 73),
- Research Misconduct (Title 42 CFR 93, Subpart C);
- Restriction of Abortion Funding (pursuant to P.L. 115-245, Section 506);
    - Exceptions to Restrictions on Abortions (pursuant to P.L. 115-245, Section 507)
- Restriction on Distribution of Sterile Needles (pursuant to P.L. 115-245, Section 529)
- Restriction of Pornography on Computer Networks (pursuant to P.L. 115-245, Section 520)
- Salary Cap/Salary Limitation (pursuant to P.L. 115-245, Section 202);
- Select Agents and Toxins (42 CFR 73, Sections 3 and 4; 9 CFR 121; 7 CFR 331, Section 3);
- USA Patriot Act (P.L. 107-56);

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.
Advance payment	A payment that a Federal awarding agency or pass-through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.
Award	The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Award date	The date when the award is signed by the authorized official of the Federal awarding agency.
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.
Awarding IC	The NIH Institute or Center (IC) responsible for the award, administration, and monitoring of OT-supported activities.
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 NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists 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 award-supported project or activity from one legal entity to another before the completion date of the approved project period (award 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 additional award segments.
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.
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: A. Cash disbursements for direct charges for property and services;

	B. The amount of indirect expense charged; C. The value of third-party in-kind contributions applied; and D. The amount of cash advance payments and payments made to subawardees. (3) For reports prepared on an accrual basis, expenditures are the sum of: A. Cash disbursements for direct charges for property and services; B. The amount of indirect expense incurred; C. The value of third-party in-kind contributions applied; and D. The net increase or decrease in the amounts owed by the non-Federal entity for: (i) Goods and other property received; (ii) Services performed by employees, contractors, subawardees, and other payees; and 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 or Negotiation Opportunity	A funding or negotiation opportunity (F/NO) is a 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.
General purpose equipment	Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles.
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)	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).
Institutions of Higher Education (IHEs)	IHE is defined at 20 U.S.C. 1001.
Intangible property	Property having no physical existence, such as trademarks,

	copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).
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; and (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/negotiation opportunties.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education, or nonprofit organization that carries out an award as an awardee or subawardee.
Notice of Award	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; and, (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 signify 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.
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 an initial OT award segment or subsequent additional award segments is at the applicant's own risk. Cost shared funds incurred after the beginning of negotiations and prior to the effective date of the award may be considered pending review, acceptance and approval by NIH.
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.
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 award segment, any subsequent award 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 & Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by DHHS-funded 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.
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 "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. *See Equipment.*
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 Part VI – Debarment and Suspension and Section 4.2 Suspension.*
Termination	The ending of an award, in whole or in part at any time prior to the planned end of the period of performance. *See Section 4.1 Termination.*
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; and (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 an 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.