

***NIH Other Transaction
Award***

***Policy Guide for the NIH
Common Fund Human
Biomolecular Atlas
Program (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. 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 other transaction authority (OTA) to nimbly add or subtract specific expertise, tools, technologies, and approaches to the problem of mapping human tissues. 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.

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 (OTA) 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 other transaction-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 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 OTA agreement, and for the administrative and financial aspects of the award. These activities include, but are not limited to, evaluating other transaction applications for administrative content and compliance with statutes and guidelines; negotiating other transaction awards; providing consultation and technical assistance to applicants and awardees, including interpretation of other transaction administration policies and provisions; and administering and closing out other transaction 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.
- **Project Manager (PM).** The Project Manager (PM) is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and OTA awards. 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.
- **Agreements Specialist (AS).** The Agreements Specialist (AS) whose name appears on the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of OT awards.

1.2. Awardee Staff

Overall responsibility for successfully implementing an NIH other transaction award is a shared responsibility of the awardee program director/principal investigator(s) (PD/PI(s)), the Authorized

Organizational Representative (AOR), and the Research Administrator. As key members of the other transaction team, they respectively lead the scientific and administrative aspects of the OTA. While communications can be conducted with Research Administrators and other institutional 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 Authorized Organizational Representative (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. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar other transaction application. In signing an OTA, 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 other transaction application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the other transaction 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. For applications submitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the awardee organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this 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. When a PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the other transaction, if awarded, is usually made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization or individual being able to fulfill its responsibilities under the other transaction, if awarded. PD/PIs are members of the awardee team responsible for ensuring compliance with the financial and administrative aspects of the award. They 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 PD/PIs to maintain contact with the NIH PM with respect to the scientific aspects of the project and the AO concerning the business and administrative aspects of the award.
- **Research Administrator.** The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day other transaction-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

PART II. APPLICATION INFORMATION AND PROCESSES

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

1. Eligibility

In general, NIH other transactions may be awarded to organizations that are domestic, foreign, public, private, non-profit or for-profit. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in 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 Research Opportunity Announcement (FOA), program guidelines, or other publicly available documents. The FOA will specify whether or not a foreign organization is eligible to apply for a particular OTA program.

As indicated, individuals unaffiliated with an institution may receive other transaction awards. These awards will be made to promising applicants who have the ability to be productive, independent investigators in fields related to the HuBMAP mission. The eligibility of these individuals to complete the project will be evaluated during the objective review process and by the AO and PM.

2. Research Opportunity Announcements

A Research Opportunity Announcement (FOA) is a publicly available document in which a Federal agency makes known its intentions to make awards (e.g., other transactions), usually as a result of competition for funds. HuBMAP applications must be submitted in response to an FOA or in response to a specific request from HuBMAP staff. FOAs include information to allow prospective applicants to determine whether to apply.

FOAs pertaining to other transactions for HuBMAP are published on the HuBMAP website (<http://commonfund.nih.gov/HuBMAP/grants>), in the NIH Guide for Grants and Contracts (<http://grants.nih.gov/grants/guide/index.html>) and/or on Grants.gov under Find Grant Opportunities (http://www.grants.gov/applicants/find_grant_opportunities.jsp). Although these grants-related resources are being used for HuBMAP Other Transaction announcements, the awards are not grants or contracts.

3. Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. 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 other transaction-supported project or activities resulting from the application.

Applicants for and awardees of NIH OTA funds are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulation to OTA funds should be directed to the IRS. The applicant also is expected to be in

compliance with applicable State and local laws and ordinances.

3.1. Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the application instructions, in the announcement, and/or in program guidelines, if any. Specific details on application content are addressed in application instructions and specific FOAs Any significant change to the application post-submission must be reported immediately to the appropriate NIH official (AO).

3.2. 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 other transaction awards. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an 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. Note this is an organizational number. Individual PD/PIs do not need to register for a DUNS number unless they are unaffiliated and are applying as individuals.

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.

If an award is issued, the awardee must notify potential sub-awardees that they may not receive a subaward under the other transaction award unless they have provided their DUNS number to the awardee.

4. eRA Commons

eRA Commons is an online interface where other transaction applicants, awardees and Federal staff at NIH are able to conduct their research administration business electronically as well as access and share administrative information relating to research other transaction awards. While applicants use Grants.gov to find and apply for other transaction awards; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for many steps in the HUBMAP program's other transaction administration process. Following application submission, the eRA Commons becomes the primary site for accessing other transaction information such as IC assignments, review outcomes, Summary Statements, and NoAs. The eRA Commons also provides electronic business processes such as Internet Assisted Review (IAR), submission of prior approvals, and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the awardee organization.

In order to participate in the HUBMAP program, an organization and PD/PI(s) must complete a one-time registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in

the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

4.1. eRA Commons Registration for the Organization

Organizations may verify their current registration status by accessing the “List of Recipient Organizations Registered in eRA Commons” at https://era.nih.gov/reg_accounts/register_commons.cfm. This listing can be accessed without logging into the Commons.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the eRA Commons homepage at <https://commons.era.nih.gov/commons/> under the link “Recipient Organization Registration.”

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible. Note, acceptance of an organization’s registration in the Commons does not mean an organization is an acceptable awardee for a particular program. That assessment will be made by the NIH awarding component prior as part of the pre-award process.

4.2. eRA Commons Registration for the PD/PI

The individual designated as the PD/PI on the application must also be registered in the Commons. The PD/PI must hold a PD/PI eRA Commons role and be affiliated with the applicant organization. The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization. However, after the initial registration process is complete, it becomes the responsibility of the individual to maintain the information in his/her personal profile.

Designating the PD/PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., electronic submission status, review assignment, etc.). The PD/PI role within the eRA Commons is necessary to complete the other transaction application process, and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

Individual applicants not affiliated with an organization or who want to submit an application independently must complete all the required registrations as though they are an organization (<http://grants.nih.gov/grants/ElectronicReceipt/UnaffiliatedUserRegistration.pdf>). In eRA Commons, they will be registered as “independent scholars” and also be the Signing Official, with the same authority in eRA Commons that the AOR has in Grants.gov.

4.3. eRA Commons Registration for Other Individuals Participating in NIH Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral role who participates in a NIH-funded project for at least one-person month or more should also be registered in the eRA Commons

and should verify that all Personal Information located within the Personal Pro-file tab in the eRA Commons System is accurate. This is required regardless of whether salary is actually charged to the project. For graduate students supported on a particular other transaction award, this could include project roles of graduate research assistant or graduate student. For postdoctoral individuals supported on a particular other transaction award, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions. A Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

PART III. REVIEW PROCESS

1. Objective Review

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, i.e., reviewers who are the professional equals of the principal investigator (PI) or program/project director (PD) for the proposed project and who often are engaged or were previously engaged in comparable activities.

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 impartial and fair. To achieve this result, NIH strives to conduct reviews under the highest ethical standards. The review process should be viewed by practitioners, participants, and the public as credible and fair. Any circumstance that might introduce any conflict of interest, or appearance thereof, prejudices, biases, or predispositions into the process must be avoided.

The review process and criteria will be specified in each FOA. Only the review criteria described in the FOA will be considered in the review process. All applications submitted in response to the FOA will be evaluated by an appropriate review group.

Reviewers will individually provide an assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the review criteria. The HuBMAP PM will provide each invited applicant with the overall review outcome.

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 other transaction awards and is incorporated by reference in all HuBMAP other transaction awards. These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in federal statutes, regulations, executive orders, or appropriations acts.

HuBMAP other transaction awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The other transaction program legal authority and any program regulation cited in the Notice of Award (NoA).
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts. This also includes any recently enacted laws.
- The NIH Other Transaction Award Policy Guide for HuBMAP, including any revisions in effect as of the beginning date of the next budget period.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIH Other Transaction Award Policy Guide for the HuBMAP generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the AO may include terms or conditions necessary to address concerns about an applicant's management systems.

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 requirements of the NIH Other Transaction Award Policy Guide for HuBMAP apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the policy.

This NIH 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; however, in the case of a conflict, the statutes and regulations govern.

2. The Notice of Award (NoA)

The NoA is the legal document issued to notify the awardee that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. A revised NoA may be issued during a budget period to affect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect an awardee's post-award rebudgeting.

An awardee indicates acceptance of the associated terms and conditions of a HuBMAP other transaction award by drawing or requesting funds from the designated HHS payment system or office. If the awardee cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the Agreements Officer immediately upon receipt of the NoA. Once the award is accepted by the awardee, the contents of the NoA are binding on the awardee unless and until modified by a revised NoA signed by the Agreement Officer.

2.1. Notice of Award Notification

NIH notifies the awardee organization via E-mail when an award has been issued - i.e., on the award date. In order to allow for the E-mail notification of the NoA, awardee organizations must register a valid E-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique E-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the awardee organization to maintain a current and accurate E-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated E-mail notification process. Awardees

that do not maintain a current NoA notification E-mail address will be responsible for accessing NoAs via the eRA Commons.

2.2. Funding

NIH uses the project period system of funding. Under this system, projects are funded in increments called budget segment. The length of a budget segment is determined by the NIH on the basis of:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete remaining goals and milestones for the project,
- the awarding IC's programmatic determination of the desirable period for determining progress towards goals and milestones of the project, and
- NIH funding principles.

The initial NoA provides funds for the project during the first budget period. Budget periods are usually 4-12 months long; however, shorter or longer budget periods may be based on specific goals and milestones to be negotiated for individual awards. Future support is contingent on satisfactory progress, programmatic priorities, the availability of funds, and the continued best interests of the Federal government. NoAs create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

As a prerequisite to NIH approval and funding of each subsequent budget segment/period awardees are required to submit a progress report as specified in the NoA. A decision to fund the next budget segment/period will be formalized by the issuance of the NoA indicating the new budget segment/period and the amount of new funding. The goals and milestones for each budget/segment period will be determined in advance by mutual agreement between NIH staff and the awardees and detailed in the NoA. NIH may decide to withhold support for failure to meet the terms and conditions of the award.

2.3. Budget and Costs

Each NoA sets forth the amount of funds awarded. The amount will be shown as a categorical (line item) budget. The awardee may have rebudgeting flexibility as described in the NoA. The awardee may be required to provide matching funds if specified in the FOA.

2.3.1. Costs

The NoA will stipulate that federal funds and the OTA 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.

2.3.2. Cost Consideration

Cost considerations are critical throughout the life cycle of an OTA 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. 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 may provide some flexibility for awardees to deviate from the award budget, as described in the NoA. 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.

2.3.3. The Cost Principles

In general, HuBMAP other transaction awards provide for reimbursement of actual, allowable costs incurred and are subject to the 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 F&A costs, and set forth the allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization making the expenditure. For example, a for-profit organization collaborating with a university awardee would be subject to the cost principles for commercial organizations, while the university would be subject to the cost principles for Institutions of Higher Education (IHEs). 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.

2.3.4. 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 other transaction-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 other transaction awards using the applicants federal negotiated indirect cost rate. F&A costs on foreign awards will be reimbursed at a rate of eight (8) percent of total direct cost, less only equipment. NIH will not provide F&A reimbursement on awards to individuals.

2.3.5. Cost Sharing

Cost sharing may be required due to the likelihood of developing solutions with commercial applications, in which case proposers must identify a cost share percentage. The budget submission must clearly identify and justify the use of these resources. Any voluntary cost share must be supported by a letter of support from the providing organizations/individual. Cost-sharing presented as part of the funded application must be accounted for and reported along with required progress reports.

The non-federal amounts counted as provided, or to be provided, by a party to the OTA agreement (including any entity that participates in the performance of the agreement or a subordinate element of the party or entities) may not include costs that were incurred before the date on which the OTA agreement becomes effective. Costs that were incurred by a party, entity or subordinate element after the beginning of negotiations, but prior to the date the OTA agreement becomes effective may be counted for purposes of this subsection as being provided, or to be provided, by the party, entity or subordinate element to the OTA agreement if and to the extent that the Agreements Officer determines in writing that (i) the party, entity or subordinate element incurred the costs in anticipation of entering into the OTA agreement; and (ii) it was appropriate for the party, entity or subordinate element to incur the costs before the OTA agreement became effective in order to ensure the successful implementation of the OTA agreement.

2.3.6. 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.

3. Audit

NIH 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 HHS 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.

4. Payments

The Payment Management System (PMS) is a centralized payment and cash management system, operated by HHS PSC, PMS. HHS other transaction 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. Therefore, although the other transaction award may be financed by advance payments, the intent is that awardees draw funds on an as-needed basis—specifically, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in an awardee’s bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a awardee does not disburse Federal funds in this manner. The awardee is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next work day after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of funds and provide for use of the reimbursement method if cash management requirements are not met.

Advances made by awardees to consortium participants and contractors under other transaction 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 PSC. 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.

4.1. 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.

4.2. 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 awarding IC 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 from the awarding IC.

4.3. 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.

5. Property

Generally, awardees may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using HuBMAP other transaction award funds. Awardees are required to be prudent in the acquisition of property under an OTA-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.

PART V. ADMINISTRATIVE REQUIREMENTS

HuBMAP Other Transaction awards are not required to comply with the Federal Acquisition Regulation (FAR), its supplements, or laws that are limited in applicability to procurement contracts. Except for the

requirements identified within 45 CFR Part 75, Subparts E and F, HuBMAP Other Transaction awards are not subject to the Pre-award and Post award requirements contained within the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR Part 75), which are limited in applicability to grants, cooperative agreements, or other forms of Federal financial assistance, nor are HuBMAP Other Transaction awards subject to the NIH Grants Policy Statement.

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 Other Transaction awards must be allocable, necessary, reasonable and realistically reflect the approved scope of work. Prior written approval is required for significant changes to the awarded budget. Awardees are strongly encouraged to discuss changes in advance that would possibly impact the timeline and/or scope of work to be completed. Potential indicators of significant changes include, but are not limited to the following:

- Changes that would possibly impact the timeline and/or scope of work to be completed;
- Changes in the scope of work conducted by the award awardee and/or key partnering organization named on the Notice of Award;
- Equipment purchases greater than \$10,000 not included in the approved budget; or
- Changes in the approved facilities/administrative and/or indirect cost rate.

NOTE – 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 or award segment will be reported in interim and/or annual progress reports. NIH Staff will review the funds remaining in coordination with the scope of work 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 Notice of Award.

1.2. Actions Requiring NIH 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 Notice of Award;
- Changes in key partnering organizations named in the Notice of Award;
- 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.

1.3. Process for Requesting Prior Approval

All requests for NIH prior approval must be made in writing (including submission by E-mail) to the AO no later than 30 days before the proposed change, and signed by the AOR. If the request is E-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. A request by a sub-awardee 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 other transaction award to the awardee. The agreement officer and project manager will review requests and approve or disapprove the request in writing either via E-mail or revised Notice of Award, as appropriate.

2. Accounting and Management Systems

Awardee organizations are expected to have systems, policies, and procedures in place by which they manage funds and activities. Awardees may use their existing systems to manage NIH other transaction award funds and activities as long as they are consistently applied regardless of the source of funds.

NIH seeks to foster within awardee organizations an organizational culture that is committed to compliance, leading to both exemplary research and exemplary supporting systems and use of resources to underpin that research. Actions to achieve this result should include 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.

2.1. Financial Management System Standards

The standards and requirements for a financial management system are essential to the other transaction 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 other transaction accounts to ensure that obligations and expenditures are reasonable, allocable, and allowable. In addition, the systems must be able to identify large 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.

2.2. Procurement System Standards and Requirements

Awardees may acquire a variety of goods or services in connection with an OTA-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 other transaction awards in compliance with the organizations established policies and procedures.

2.3. Record Retention and Access

For awards under other transactions authority, the 3-year 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.

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 (FCTR portion), final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of other transaction award support. The reports become overdue the day after the 120-day period ends.

2.4. Program Income

Program income is gross income—earned by a awardee, a consortium participant, or a contractor under an OTA award—that was directly generated by the other transaction-supported activity or earned as a result of the award. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.) Unless otherwise specified in the terms and conditions of the award, NIH awardees are not accountable for program income accrued after the period of other transaction support.

NIH applies the additive alternative to all awardees, including for-profit entities, unless there is a concern with the awardee, or the program requires a different program income alternative.

2.5. Reporting Program Income

The amount of program income earned must be reported in the non-competing continuation progress report (RPPR). Income resulting from royalties or licensing fees is generally exempt from reporting as program income.

3. Termination

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

If a 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 other transaction award, pending corrective action. NIH may also terminate the award for convenience.

NIH generally will suspend (rather than immediately terminate) an OTA 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 an OTA award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

An OT award also may be terminated, partially or totally, by the 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 other transaction award was originally awarded. In any such case, NIH will advise the awardee of the possibility of termination of the entire other transaction 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.

3.2. Effect of 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 2.3.

3.3. 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.

3.4. 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.

4. Reporting, Administration, and Close Out

4.1. Monitoring

Awardees are responsible for managing the day-to-day operations of OT-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 awarding ICs monitor their other transaction awards to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the awardee, audit reports, site visits, and other information available to NIH. 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 other transaction award is administratively closed out and NIH is no longer providing active other transaction award support.

4.2. Reporting

NIH requires that 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), 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 AO is the official receipt point for most required reports. In addition, electronic submission through the eRA Commons is available for all closeout documents (final progress reports, final invention statements and certifications, and Final Federal Financial reports).

Awardees are allowed a specified period of time to submit required financial and final progress reports (within 120 calendar days of the end of HUBMAP other transaction award support). 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.

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

4.3. Final Progress Reports

A final progress report is required for any HuBMAP other transaction award that is terminated and any award that will not be extended through award of a new competitive segment.

4.4. Financial Reports

For HuBMAP other transaction awards, there is one type of financial report used. Cash transaction data is submitted on a quarterly basis directly to PMS. Expenditure data which is submitted directly to the NIH will not be required.

- **Cash Transaction Reports** - The 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 to the Project Manager and Agreement Specialist. This includes the initial FFR and any FFR revisions being submitted or resubmitted to NIH. In some cases, the awardee may have to revise or amend a previously submitted FFR. The revised report should be submitted in the same format as the original. When the revision results in a balance due to NIH, the awardee must submit a revised report whenever 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 to the Project Manager and Agreement Specialist with an explanation for the revision. The explanation also should indicate why the revision is necessary and describe what action is being taken by the awardee to preclude similar situations in the future. This should be done as promptly as possible, but no later than 1 year from the due date of the original report for FFRs and no later than 60 calendar days from the due date of the original report for final FFRs (i.e., 180 days from the project end date). If an adjustment is to be made, the NIH awarding IC 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.

- **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,” these funds, if approved, are expected to be used before newly awarded funds.

5. Intellectual Property Rights and Sharing Research Resources

5.1. Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides incentives for the practical application of research supported through Federal grants, cooperative agreements, or contracts. For some HUBMAP other transaction awards, all or some of the prescriptions and requirements of the Bayh-Dole Act (<http://grants.nih.gov/grants/bayh-dole.htm>) will be adopted, as specified in the FOA and NoA. There may be circumstances where the scientific goals of the HUBMAP program may require management of inventions made under a HUBMAP other transaction award to be managed consistent with NIH’s policies for the dissemination and use of information and technologies without the adoption of the prescriptions and requirements of the Bayh-Dole Act in their entirety or at all.

Some of the adopted rights and obligations required by the Bayh-Dole statute and regulation for an award 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 OTA award awardee of their 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 FOA 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. 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 are expected to make the results and accomplishments of their activities available to the research community and to the public at large. Depending on each HuBMAP program and as stated in the applicable FOA, the award issued may adopt the prescriptions and requirements of the Bayh-Dole Act (Act), 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.

5.3. Rights in Data (Publication and Copyrighting)

In general, awardees own the rights in data resulting from an OTA-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 FOA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under a HuBMAP other transaction 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 other transaction 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 other transaction award must include:

1. An acknowledgment of NIH other transaction award support such as:

“Research reported in this [publication, release] was supported by the NIH Common Fund of the National Institutes of Health under other transaction award number [specific NIH other transaction award number in this format: OT2GM012345].”

2. 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 other transaction award, it should notify the NIH funding component in advance to allow for coordination. Publications resulting from work performed under an NIH other transaction-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC. When publications are available electronically, the URL or the PMID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report.

5.4. 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 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 are required by Federal law to 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. The author's final peer-reviewed manuscript is defined as the final version accepted for journal

publication on or after 4/7/2008 and includes all modifications from the publishing objective 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.

Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance. This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH.

5.5. Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique 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. At the same time, NIH recognizes the rights of awardees and contractors to elect and retain title to subject inventions as may be set forth in the terms of the FOA. 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.

As specified in the HuBMAP FOA, the terms of HuBMAP other transaction awards may adopt the prescriptions and requirements of the Bayh-Dole Act to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery. In addition to sharing research resources with the research community, upon request of the NIH, the awardee also must provide a copy of documents or a sample of any material developed under an NIH other transaction award. The awardee may charge a nominal fee to cover shipping costs for providing this material.

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced Principles and Guidelines for Awardees of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

5.6. Data Sharing Policy

NIH believes that 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. NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, 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 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.

5.7. Sharing Model Organisms

All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible. Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. This expectation is for all applications where the development of model organisms is anticipated, regardless of funding amount.

For additional information on this policy, see the NIH Model Organism for Biomedical Research guidance.

5.8. 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 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 OTA awards, or specifically to a particular award depending on the terms of the OTA. Details of these public policy requirements may be found on the HuBMAP website at: <https://commonfund.nih.gov/hubmap/othertransactions>

- Animal Welfare Requirements (*PHS Policy on Humane Care and Use of Laboratory Animals*)
- ClinicalTrials.gov Requirements
- Comptroller General Access
- Debarment and Suspension
- Dissemination of False or Deliberately Misleading Information
- Federal Information Security Management Act
- Financial Conflict of Interest
- Fly America Act
- Gun Control
- Human Embryo Research and Cloning Ban
- Human Fetal Tissue Research
- Human Subjects Protections
- Human Stem Cell Research (NIH Guidelines)
- Lobbying Prohibition
- Metric System
- National Environmental Policy Act
- Pro-Children Act of 1994
- Prohibition on Promotion or Legalization of Controlled Substances
- Research Involving Recombinant or Synthetic Nucleic Acid Molecule
- Research on Transplantation of Human Fetal Tissue
- Restriction of Abortion Funding
- Restriction on Distribution of Sterile Needles
- Restriction of Pornography on Computer Networks
- Salary Cap/Salary Limitation
- Research Misconduct
- Select Agents
- Trafficking in Persons
- USA Patriot Act

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.
Additive alternative	A use of program income earned during or after the project period that permits income that is generated under an OTA award to be added to funds committed to the project by the Federal awarding agency and awardee and used to further eligible project or program objectives.
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.
Awarding IC	The NIH IC responsible for the award, administration, and monitoring of other transaction 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.
Capital assets	Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).

Capital expenditures	Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life.
Change of awardee organization	Transfer of the legal and administrative responsibility for an OTA-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 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.
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	(1) The SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report).

Expenditures	<p>Charges made by a non-Federal entity to a project or program for which an award was received.</p> <p>(1) The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied.</p> <p>(2) For reports prepared on a cash basis, expenditures are the sum of:</p> <ul style="list-style-type: none"> (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; and (iv) The amount of cash advance payments and payments made to sub-awardees. <p>(3) For reports prepared on an accrual basis, expenditures are the sum of:</p> <ul style="list-style-type: none"> (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; and (iv) The net increase or decrease in the amounts owed by the non-Federal entity for: <ul style="list-style-type: none"> (A) Goods and other property received; (B) Services performed by employees, contractors, sub-awardees, and other payees; and <p>Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.</p>
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.
Foreign components	The performance of any significant scientific element or segment of a project outside of the United States, either by the awardee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by awardee project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the awardee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.
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 FOA.
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 sub-awardee.
Notice of Award	The official, legally binding document, signed (or the electronic equivalent of signature) by an Agreement Officer that: <ul style="list-style-type: none"> (1) notifies the awardee of the other transaction award; (2) contains or references all the terms and conditions of the other transaction 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 a 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 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) of the Public Health Service Act. 42 U.S.C. 282(n).
Pass-through entity	A non-Federal entity that provides a subaward to a sub-awardee 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 Web sites, 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, E-mail 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 other transaction awards these costs are not allowable.
Prior approval	Written approval by an authorized DHHS official, e.g., a designated Agreement Officer, evidencing prior consent before a 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 other transaction 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 other transaction 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 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, educational transcripts. This does not include PII that is required by law to be disclosed.
Questioned cost	A cost that is questioned by the auditor because of an audit finding: <ul style="list-style-type: none"> (1) Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of an award, including for funds used to match Federal funds; (2) Where the costs, at the time of the audit, are not supported by adequate documentation; or (3) Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
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 sub-awardees, except as indicated below.
Research & 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 sub-awardee for the sub-awardee 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.
Sub-awardee	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 sub-awardee 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 Computing devices and 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 Section 2.1 Debarment and Suspension and Section 9 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; 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.