

Other Transaction Award Policy Guide

Cancer Grand Challenges Initiative

U.S. Department of Health and Human Services

National Institutes of Health

National Cancer Institute

INTRODUCTION

Cancer Grand Challenges is a global research initiative founded in 2020 by the two largest funders (the Funders) of cancer research in the world: Cancer Research UK (CRUK) and the National Cancer Institute (NCI) in the US. This partnership builds on the success of CRUK's Grand Challenge, launched in 2015 and currently supporting seven multidisciplinary teams across nine countries.

By daring global teams of multidisciplinary researchers to come together and think differently, Cancer Grand Challenges aims to find bold new solutions to challenges, some of which have confounded scientists for many years. The initiative sets ambitious challenges to inspire new thinking, providing diverse, global teams with up to GBP 20m over five years to unleash their scientific creativity. A guiding principle for setting a Grand Challenge is that it may be sufficiently difficult that success is not assured, but the possibility of success is so important that the attempt is worthy.

NCI, in consultation with NIH, has determined that the Other Transactions (OT) mechanism for making research awards was appropriate for advancing the CRUK-NCI partnership. Under OT authority, NCI can make research awards that are not grants, contracts, or cooperative agreements. OT authority enables NCI to establish a public-private partnership with CRUK for the joint research initiative.

NCI's use of Other Transactions (as authorized through Section 402(n) of the Public Health Service Act, and as by NIH approved in June, 2019 under Section 402(n)(2)(B)) allows the NCI-CRUK CGC collaboration to support world class international, multidisciplinary research teams focused on solving the most compelling problems that the cancer research community can identify. Each step in the CGC process – identifying the challenges, reviewing the scientific proposals, establishing the best interdisciplinary teams – has been designed to promote high impact cutting-edge research to foster scientific creativity and increase fundamental biological understanding.

This Policy Guide document contains information specific to NCI funding and supplements the Cancer Grand Challenges Award Management and Funding Policy Guide ([hyperlink forthcoming](#)). Collectively, this Policy Guide, the Award Management and Funding Policy Guide, and the Commercialization Policy are incorporated into the CGC Award Agreement.

TABLE OF CONTENTS

PART I: GENERAL INFORMATION	4
1. ROLES AND RESPONSIBILITIES	4
2. APPLICATION INFORMATION AND PROCESSES	5
3. THE OBJECTIVE REVIEW PROCESS	7
PART II: TERMS AND CONDITIONS OF THE NCI FUNDED CANCER GRAND CHALLENGES OTHER TRANSACTION AWARDS	7
1. OVERVIEW OF TERMS AND CONDITIONS	7
2. THE OTHER TRANSACTION AGREEMENT	8
3. THE NOTICE OF AWARD (NOA)	8
4. PAYMENT	10
5. COST CONSIDERATIONS	11
6. ACTIVITIES REQUIRING PRIOR APPROVAL	13
7. AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INVENTION RIGHTS, AND SHARING RESEARCH RESOURCES	13
8. MANAGEMENT SYSTEMS AND PROCEDURES	13
9. MONITORING	15
10. REMEDIES FOR NONCOMPLIANCE OR ENFORCEMENT ACTIONS: SUSPENSION, TERMINATION, AND WITHHOLDING OF SUPPORT	16
11. TERMINATION	17
12. RECOVERY OF FUNDS	17
13. DEBT COLLECTION	17
15. CLOSEOUT	18
16. LEGAL AND PUBLIC POLICY REQUIREMENTS AND OBJECTIVES	18
PART III: DEFINITIONS	25

PART I: GENERAL INFORMATION

1. Roles and Responsibilities

1.1 NIH Staff

The National Institutes of Health (NIH) is responsible to the Congress and to U.S. taxpayers for carrying out its mission in a manner that facilitates research and development in compliance with applicable laws and regulations. NIH seeks to ensure integrity and accountability in its Other Transactions and administration processes by relying on a system of checks and balances within and across staff teams.

The specific roles and responsibilities of NCI staff are described in the Award Management and Funding Policy Guide, Section 1.2.4 (hyperlink forthcoming)

1.2 Awardee Organization Staff

Overall responsibility for successfully implementing an NIH OT award is a shared responsibility of the awardee's program director/principal investigator (PD/PI), who leads the scientific aspects of the OT award, and the awardee's authorized organization representative (AOR) and research/project administrator, who lead the administrative aspects of the OT award. While communications can be conducted among research/project administrators and other NIH staff, NIH staff members conduct official business only with the designated PD/PI(s) and AORs.

Any institution receiving an NCI Notice of Award (NoA) must designate a program director/principal investigator (PD/PI). The PD/PI may also serve as a Team Lead or co-investigator on the CGC team. The roles and responsibilities of a program director/principal investigator (PD/PI), CGC Team Lead (TL), Co-Investigator (Co-I), and Authorized Organization Representative (AR) are described in the Cancer Grand Challenges Award Management and Funding Policy Guide Section 1.2.1 (hyperlink forthcoming) and Section 1.2.4 (hyperlink forthcoming)

2. Application Information and Processes

The solicitation and application process for Cancer Grand Challenges Award Teams is described in the Expression of Interest (EOI) Guidelines. The steps in this process are briefly described below:

a. PRE-SUBMISSION QUESTIONNAIRE

Once an applicant decides which of the Cancer Grand Challenges they will tackle, they submit a pre-submission questionnaire on the [CGC website](#). This questionnaire is used to check eligibility according to the criteria set out in the Expression of Interest (EOI) Guidelines.

b. EXPRESSION OF INTEREST

Once an application has been opened by the Cancer Grand Challenges office, the applicant team submits an EOI outlining the approach the team will take to address the challenge.

c. TEAMS SHORTLISTED TO SUBMIT FULL APPLICATIONS

The Cancer Grand Challenges Scientific Committee (CGCSC) reviews the EOIs and provides recommendations to CRUK on which applications are the most compelling. Thereafter, NCI and CRUK leaders meet to decide which teams should be shortlisted for submitting full applications. Each shortlisted team is awarded up to £30,000 seed-funding to get their teams off the ground and to help formulate their full application.

d. FULL APPLICATION AND INTERVIEW

Shortlisted teams submit a full application and attend an interview with the CGCSC.

e. CGC AWARD

The process for selecting winning teams is similar to the process for shortlisting teams. NCI and CRUK leaders meet to decide which teams should receive CGC Awards. Winning team members collectively enter into a Cancer Grand Challenges Award Agreement with one another, and with CRUK and the NCI. Each team member is issued their proportion of the award through a Grant Award Letter from Cancer Research UK and a Notice of Award from NCI.

2.1. *electronic Research Administration*

All applications to be considered for Other Transactions awards shall be submitted through NIH's electronic Research Administration (eRA), Application Submission System & Interface for Submission Tracking (ASSIST) module. When NCI and CRUK decide on which teams will receive CGC awards, the NCI Other Transaction Agreement Specialist will provide a link to a Research Opportunity Announcement to the CGC Teams selected for funding. Each Host Institution (as described in the Cancer Grand Challenges Award Management and Funding Guide) must reply to the announcement. NCI will evaluate the reply and engage with the Host Institution to negotiate an OT award.

2.2. *Legal Implications of Applications*

An applicant must be an eligible entity or individual and must submit a complete application to be considered for award. The signature of an AOR on the application certifies that the applicant will comply with all applicable assurances and certifications referenced in the application and in this Policy Guide. The applicant is responsible for verifying compliance 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 the applicant agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the OT award-supported project or activities resulting from the application.

2.3. *Policies Affecting Applications*

[Reserved for text to be added]

2.4. *DUNS Number and SAM Registration Requirements*

All awardee organizations must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier in order to accept a federal OT award. DUNS Number and System of Award Management (SAM) Registration are not required for application submission, however all applicants are encouraged to apply for a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number and to register in the SAM at the time of application to ensure timely award processing.

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

After the DUNS registration is complete, all awardees must register in the SAM. Applicants must ensure SAM is always updated with current information during which it has an application under consideration for funding by NIH. SAM is the primary registrant database for the Federal Government and is the repository into which an entity must provide information required for the conduct of business as an awardee.

3. The Objective Review Process

Objective review is an assessment of scientific and technical merit of applications by individuals with knowledge and expertise equivalent (peer) to that of the individuals whose applications of support they are reviewing. Objective review is essential to ensuring selection of applications that best meet the needs of the program, consistent with established criteria, and providing assurance to the public that the evaluation and selection process was rigorous and fair.

The review process for the Cancer Grant Challenges OT applications is described in (hyperlink forthcoming)

PART II: TERMS AND CONDITIONS OF THE NCI FUNDED CANCER GRAND CHALLENGES OTHER TRANSACTION AWARDS

1. Overview of Terms and Conditions

Part II includes the terms and conditions of OT awards and is incorporated by reference in all OT awards made under this program. Program and administrative policies and the terms and conditions of individual awards supplement, rather than substitute for, governing statutory and regulatory requirements. Notice of requirements not specified in this OTA Policy Guide or the CGC Award Agreement generally will be provided in the NoA; however, awards or a specified subset of awards also may be subject to additional requirements, including conditions imposed on activities and the expenditure of funds, such as those in –

- a. executive orders,
- b. appropriations acts, other statutes, regulations, and policies,
- c. terms and conditions in the NoA and its attachments,
- d. this OT Policy Guide, including any revisions to the Guide,
- e. the CGC Award Agreement (which incorporates the CGC Award Management and Funding Policy Guide, the Commercialization Policy, and this OT Policy Guide).

This OT Policy Guide also serves as an aid to interpreting statutory, regulatory, and policy requirements. The OT Policy Guide contains terms and conditions consistent with governing statutes, regulations, and policies.

2. The Other Transaction Agreement

The Cancer Grand Challenge Award Agreement (CGC Award Agreement) and the NoA are legally binding agreements between the U.S. Government and the recipient that includes an offer, acceptance, consideration, authority/capacity and lawful purpose. The CGC Award Agreement will serve as the legal document establishing the relationship between the NCI and the CGC Team and will include the terms and conditions that apply to each OT NoA.

The CGC Award Agreement and the NoA document the approval of a project period and expresses the NCI intention to provide continued support for the project. Projected levels of future funding support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal Government. The projected levels of future funding are not guaranteeing that the project will be funded and create no legal obligation to provide funding beyond the ending date of the current funding segment, as shown in the NoA.

CGC Teams are required to submit progress reports as a prerequisite to CRUK and NCI approval and funding of each subsequent funding segment within an approved project period. Submission of progress reports is described in the Award Management and Funding Policy Guide ([hyperlink forthcoming](#))

3. The Notice of Award (NoA)

For NCI funding, after the CGC Award Agreement has been signed, an initial NoA will be issued to each participating HI, usually covering the first 12 months of the award. NCI will notify the HI via e-mail when an award has been issued. NCI will thereafter issue subsequent NoAs, usually on an annual basis, subject to successful annual review (see section 2.2.1 of the Award Management and Funding Policy Guide).

If there is a change to the terms and conditions for an HI, NCI will issue a revised NoA. NCI reserves the right to act independently to modify the terms and conditions of award in the NoA or CGC Award Agreement as needed. If necessary, a change to the terms and conditions for each HI on a CGC Team may also require revisions to the CGC Award Agreement.

The NoA is the legal document issued to notify each host institution in the CGC team that an award has been made, subject to the terms and conditions in the CGC Award Agreement, and that funds may be requested. The NoA is issued for the initial funding segment and each subsequent funding segment in the approved project period. The NoA may reflect anticipated future-year commitments, but generally will not provide out-year funding commitments due to the nature of the OT program.

3.1. Notice of Award Notification

NCI will send the NoA by email to the host institution when it issues an award. To allow for the email notification of the NoA, awardee organizations must include a valid email address in the application. It is the responsibility of the awardee organization to maintain a current and accurate email address for NoAs.

3.2. Funding

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

- a. any statutory or regulatory requirements,
- b. the length of time requested by the applicant to complete the project,
- c. limitation on the length of the project period as recommended during objective review,
- d. programmatic determination of the frequency of competitive review desirable for managing the project and,
- e. NCI funding principles.

The total project period consists of the initial competitive segment, and any additional segments (competitive or non-competitive) as noted in the funding solicitation.

The initial NoA provides funds for the project during the first funding segment. Funding segments (also referred to as budget periods) for CGC OT awards will generally be 12 months; however, shorter or longer funding segments may be established for compelling programmatic or administrative reasons. A decision to fund the next funding segment will be formalized by the issuance of the NoA indicating the new funding segment/and the amount of new funding. The NoA may also reflect any remaining future time commitments. NCI may withhold future support if an awardee fails to meet the terms and conditions of the award.

3.3. Budget

Each NoA sets forth the amount of funds awarded. The awardee has certain rebudgeting flexibility within the overall amount awarded, as described in the Award Management and Funding Policy Guide ([hyperlink forthcoming](#))

4. Payment

The Payment Management System (PMS) is a centralized payment and cash management system, operated by the DHHS Program Support Center (PSC). OT award payments by PMS may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the OT Agreement and as described in this section. Payments under OTs generally are made as advance payments. NIH payments are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. The intent is that recipients draw funds on an as-needed basis, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in a recipient'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 recipient does not disburse Federal funds in this manner. The recipient 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 workday after they are received, and immediately returning all undisbursed Federal funds to PMS.

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

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

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. 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 Other Transactions Agreement Officer (OTAO) determines that an awardee is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports.

If the cash request is for an advance payment, the awardee may request funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, an awardee must submit the request through the AO early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the awardee electronically through the ACH process upon receipt of the approved payment request.

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.

4.4. Unobligated Balances and Actual Expenditures

Disposition of unobligated balances is determined in accordance with the terms and conditions of the CGC Award Agreement, the NoA, and the Award Management and Funding Policy Guide (hyperlink forthcoming). Using the accounting principle of “first in-first out,” unobligated funds carried over should be used before newly awarded funds. Unless otherwise specified, the anticipated funds remaining at the end of a reporting period or award segment will be reported in interim and/or annual progress reports, respectively. NIH staff will review the funds remaining in coordination with the project activities and associated budget under consideration for the next funded award segment, if applicable. NIH will determine how the remaining funds will be used and notify the award recipient accordingly via email or NoA.

5. Cost Considerations

Cost considerations are critical throughout the life cycle of an OT award.

An applicant’s budget request is reviewed using the governing cost principles and other requirements and policies applicable to the type of awardee as a guide. NIH OT awards will generally use the cost principles at 45 CFR Part 75, Subpart E, and Appendix IX (hospitals) to Part 75, and 48 CFR 31.2 Federal Acquisition Regulation as guides for negotiating the award amount. Any resulting award will include a budget that is consistent with these negotiations.

NIH anticipates that, because of the nature of research, the awardee may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for awardees to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval. Please see section 2.1.4 of the Award Management and Funding Policy Guide for additional information on budget transfers.

During post-award administration, the OTA and/or Other Transactions Agreements Specialist (OTAS) monitors expenditures for conformance with this OT Policy Guide, the CGC Award Agreement the CGC Award Management and Policy Guide and the NoA. The OTA and/or OTAS monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports.

5.1. The Cost Principles

In general, OT awards provide for reimbursement of actual, allowable costs incurred and for purposes of these OT awards, are expected to generally align with accepted and established federal cost principles for the entity receiving funding (academic, non-profit, for-profit, etc.). As noted above, the applicable cost principles will be used as a guide for reviewing and negotiating OT awards.

5.2. Direct Costs and Facilities and Administrative Costs

A direct cost is any cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the OT-award supported project or activity.

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

6. Activities Requiring Prior Approval

Requirements for prior approval are described in the Award Management and Funding Policy Guide at (hyperlink forthcoming)

6.1. Acceptable Award Changes

All costs requested and expended for OT awards must be allocable, necessary, reasonable, and realistically reflect the approved project activities. Prior written approval is required for significant changes to the awarded budget, as described in the Award Management and Funding Policy Guide (hyperlink forthcoming).

As described in the CGC Awards Management and Funding Policy Guide (hyperlink forthcoming), the NCI and CRUK each intend to provide 50% of the costs of each Cancer Grand Challenges team.

6.2. Process for Requesting Prior Approval

The process for requesting prior approval is described in the Award Management and Funding Policy Guide (hyperlink forthcoming)

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

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and awardee organizations must make the results and accomplishments of their activities available to the research community and to the public at large. Invention rights should be licensed and commercialized such that they are made as widely available as possible to the public, consistent with the CGC Commercialization Policy. Details on publication, commercialization, and sharing data and research resources appear in section 3.3 of the Award Management and Funding Policy Guide (hyperlink forthcoming).

Data Sharing and IP Requirements are described in the Award Management and Funding Policy Guide (hyperlink forthcoming)

8. Management Systems and Procedures

Awardee organizations are expected to have in use –

- a. clearly delineated roles and responsibilities for their organization's staff, both programmatic and administrative
- b. written policies and procedures

- c. training
- d. management controls and other internal controls
- e. performance assessment
- f. administrative simplifications, and
- g. information sharing.

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

8.1. Financial Management System Standards

Awardees must have in place accounting and internal control systems that provide for appropriate monitoring of award accounts to ensure that obligations and expenditures of federal funds are reasonable, allocable, and allowable. In addition, the systems must be able to identify unobligated balances, accelerated expenditures, inappropriate cost transfers, and other inappropriate obligation and expenditure of funds, and awardees must notify NIH when they identify or learn of financial management problems. An awardee's failure to establish adequate control systems constitutes a material violation of the terms of the award.

8.2. Property Management System Standards

Generally, awardees may use their own property management policies and procedures for property purchased, constructed, or fabricated as a direct cost using NIH OT award funds. Awardees are required to be prudent in the acquisition of property under an OT award- supported project. It is the awardee's responsibility to conduct a prior review of each proposed property acquisition to ensure that the property is needed and that the need cannot be met with property already in the possession of the organization.

8.3. Procurement System Standards and Requirements

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

9. Monitoring

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

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

9.1. Reporting

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

Submission of required reports is further described in the Award Management and Funding Policy Guide ([hyperlink forthcoming](#))

9.2. Progress Reports

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

9.3. Financial Reports

NCI will require a Final Financial Report, to be submitted via the Payment Management System. This includes the initial Final FFR and any Final FFR revisions being submitted or resubmitted to NIH. Revised or amended reports should be submitted in the same format as the original. When a revision results in a balance due to NIH, the awardee must submit a revised report as soon as the overcharge is discovered, no matter how long the lapse of time since the original due date of the report. Revised expenditure reports representing additional expenditures by the awardee that were not reported to NIH within 120 days may be submitted to the AO with an explanation for the revision. If an adjustment is to be made, the NIH AO will advise the

awardee of actions it will take to reflect the adjustment.

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

9.4. Record Retention and Access

Record Retention and Access Requirements are described in the Award Management and Funding Policy Guide (hyperlink forthcoming)

9.5 Audit

CGC awardees are deemed to be subject to the audit requirements of OMB 2 CFR 200, Subpart F- Audit Requirements. The Audit Requirements require 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 that are subject to the law to have a single or program-specific audit conducted for that year in accordance with the provisions in Subpart F.

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

A for-profit organization is required to have a non-federal audit if, during its fiscal year, it expended a total of \$750,000 or more in DHHS awards. For-profit organizations have two options regarding the type of audit that will satisfy the audit requirements. The awardee either may have (1) a financial-related audit (as defined in, and in accordance with, the Generally Accepted Government Auditing Standards (GAGAS), 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.

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

If an awardee has failed to materially comply with the terms and conditions of award, NIH may take one or more enforcement actions, which include disallowing costs, withholding of further awards, or wholly or partly suspending the OT award, pending corrective action. NIH may also terminate the OT award for cause.

NIH will usually suspend (rather than immediately terminate) an OT award and allow the awardee an opportunity to take appropriate corrective action before NIH makes a termination decision. However, NIH may decide to terminate the award if the awardee does not take appropriate corrective action during the period of suspension.

NIH may immediately terminate an OT award when necessary, such as to protect the public health and welfare from the effects of a serious deficiency.

11. 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 9.4, and any other terms and conditions of award that survive termination.

An NIH 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 award was originally made. In any such case, NIH will advise the awardee of the possibility of termination of the entire OT award and allow the awardee to withdraw its termination request. If the awardee does not withdraw its request for partial termination, NIH may initiate procedures to terminate the entire award for cause.

12. 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.

13. 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.

14. Disputes

The dispute resolution process is described in the Award Management and Funding Policy Guide (hyperlink forthcoming)

15. Closeout

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

16. Legal and Public Policy Requirements and Objectives

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its awardees. The legal and 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 laws, policies, certifications and assurances applicable to recipients of federal funds, including those referenced (and, in some cases, included) in the application instructions, this Policy Guide, and any other requirements incorporated by reference. This list is not intended to be comprehensive, other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms and conditions of the OT award. To the extent one or more of these laws or public policy requirements is amended following issuance of this Policy Guide, including during the term of the OT award, the law or public policy requirement as amended applies.

16.1. *Anti-Sexual Harassment*

NIH does not tolerate harassment of any kind, including sexual harassment, at research institutions that receive NIH funding, or anywhere NIH-funded activities are conducted. NIH expects recipient institutions to have policies and practices in place that foster a harassment-free environment. NIH requires that every organization receiving NIH funds has systems, policies, and procedures in place to manage research activities in accordance with our standards and requirements and that every organization comply with federal laws, regulations, and policies protecting the rights and safety of individuals working on NIH-funded projects. Information on this policy is located at <https://grants.nih.gov/grants/policy/harassment/policy-requirement.htm>.

16.2. *Debarment and Suspension*

DHHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for DHHS' non-procurement programs and activities. NIH implements the DHHS Debarment and Suspension regulations as a term and condition of award. Accordingly, a recipient of an NIH Other Transaction is required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in an OT prior to entering into the agreement. For more information about 2 CFR 180, refer to <https://www.ecfr.gov>.

16.3. Dissemination of Deliberately False or Misleading Information

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

16.4. Federal Information Security Management Act (FISMA)

All information systems, electronic or hard copy, which contain Federal data need to be protected from unauthorized access. When FISMA or FISMA-like security requirements are necessary, appropriate language pertaining to the access or use of personally identifiable information or PII will be included in the OT Agreement and/or the NoA.

16.5. Financial Conflict of Interest (FCOI)

The CGC Award Management and Funding Policy Guide includes a term in which the regulatory FCOI standards are deemed to apply to the recipient (e.g., recipient to submit their publicly accessible Financial Conflict of Interest policy to NIH via the eRA Commons Institution Profile (IPF) Module). The NIH is committed to preserving the public's trust that the research we support is conducted without bias and with the highest scientific and ethical standards. For information about the NIH FCOI policy that NCI will apply to OT awards, refer to <https://grants.nih.gov/grants/policy/coi/index.htm>.

16.6. Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible, including where the U.S. has entered into an "open skies" agreement with one or more foreign governments. For information about the Fly America Act, refer to the U.S. General Service Administration's web site at <https://www.gsa.gov/policy-regulations/policy/travel-management-policy/fly-america-act>.

16.7. Gun Control

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

16.8. Human Embryo Research and Cloning Ban

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

16.9. Human Fetal Tissue Research

NIH Other Transactions authority may not be used to support human fetal tissue research. Human fetal tissue (HFT) is defined as research involving the study, analysis, or use of primary HFT cells and derivatives, and human fetal primary cell cultures obtained from elective abortions. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State, and local laws as well as NIH guidance. For more information about this policy, refer to <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html>.

16.10. Human Stem Cell Research

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

16.11. Lobbying Prohibition

NIH appropriations have included restrictions on lobbying in past years. Applicable restrictions will be included as a term on the NoA.

16.12. National Environmental Policy Act

All NIH OT awards, whether or not they include construction or major Alteration and Renovation activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 *et seq.* For information about the National Environmental Policy Act, refer to EPA’s website at <https://www.epa.gov/nepa/what-national-environmental-policy-act>.

16.13 Data Sharing Requirement

Under NIH Sharing Policies, the results and accomplishments of the activities that NIH funds should be made available to the public. The [INSERT TITLE OF APPROPRIATE CGC DOCUMENT] includes terms that describe how the recipient will share data intended for disclosure, for public release, or dissemination of information. For additional information, refer to https://www.nlm.nih.gov/NIHBmic/nih_data_sharing_policies.html

16.14 NIH Salary Cap

The NIH Salary Cap is a legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts and other transactions. Individuals whose salaries are paid with NIH award funds may not be paid at a rate in excess of the salary cap prescribed by federal law. An organization may pay an individual beyond the cap with non-Federal funds. For information on current and historical salary cap rates, refer to https://grants.nih.gov/grants/policy/salcap_summary.htm

16.15 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children’s services are provided. NIH OT awards are subject to these requirements only if they meet the Act’s specified coverage. For more information about the Pro-Children Act of 1994, refer to <https://www.govinfo.gov/content/pkg/FR-1994-12-30/html/94-32136.htm>.

Promotion or Legalization of Controlled Substance

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812, except for normal and recognized executive-congressional communications. This limitation does not apply if the awardee notifies the OTA0 that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

16.13. Research on Animals Protections and Requirements

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

The PHS Policy incorporates the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training, and requires the awardee to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). For information about NIH policies and law for Animal Welfare refer to the NIH Office of Laboratory Animal Welfare website at <https://olaw.nih.gov>

16.14. Research on Human Subjects Protections and Requirements

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

The DHHS regulations stipulate that the awardee organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported activities (46.101[a] and 46.103[a]). Awardee organization(s) "engaged" in human subjects research must obtain a Federal-Wide Assurance (FWA) with the DHHS Office for Human Research Protections and establish appropriate policies and procedures for the protection of human subjects. For information about the NIH policies for Human Subjects Research, refer to the NIH

Division of Human Subjects Research Website at <https://grants.nih.gov/policy/humansubjects.html>

16.15. ClinicalTrials.gov Requirement

Applicants and awardees should familiarize themselves with the requirements of Title VIII, Sec. 801 of Public Law 110-85 (also known as the U.S. Food and Drug Administration (FDA) Amendments Act of 2007 or FDAAA), with respect to registration and results reporting requirements that may apply to certain studies. In particular, awardees should be aware that if an applicable clinical trial is funded in whole or in part by an NIH OT award, any application or progress report shall include a certification that the Responsible Party has made all required submissions to ClinicalTrials.gov. The NIH strongly encourages registration of all clinical trials, whether required by FDAAA or not. For additional information, see http://grants.nih.gov/clinicaltrials_fdaaa/index.htm and <https://www.clinicaltrials.gov>.

16.16. Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (April 2019 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the NIH Guidelines is available at <http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>.

16.17. Research Misconduct

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

16.18. Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term “health benefits coverage” means the package of services covered by a

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

16.19. Restriction on Distribution of Sterile Needles

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

16.20. Restriction of Pornography on Computer Networks

NIH appropriations historically have included a restriction regarding pornography on computer networks. For FY2021, the following restriction was included: (a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography; (b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

16.21. Select Agents

Domestic awardees who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR 73 and 9 CFR 121 and Section 3 of 7 CFR 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked. For more information about Select Agents, refer to <https://www.selectagents.gov/>.

16.22. USA Patriot Act

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

PART III: DEFINITIONS

Term	
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-federal entity's regular accounting practices.
Award date	The date when the award is signed by the authorized official of the federal awarding agency.
Awarding IC	The NIH Institute or Center (IC) responsible for the award, administration, and monitoring of OT-supported activities.
Awardee	The Host Institution named on a CRUK Grant Award Letter and/or NCI Notice of Award.
Budget	The financial plan for the project or program that the federal awarding agency or pass-through entity approves during the award process, or in subsequent amendments to the award. It may include the federal and non-federal share or only the federal share, as determined by the federal awarding agency or pass-through entity. The approved budget specified in the notice of award (NoA) may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consist of both federal and non-federal shares are deemed to be borne by the awardee in the same proportion as the percentage of federal/non-federal participation in the overall budget.
CGC Commercialization Policy	A document that establishes policies for commercializing Results from Cancer Grand Challenge Awards.

Transfer of the legal and administrative responsibility for an OT-supported

Change of awardee organization	project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Closeout	Closeout of an Other Transaction is a process that the NIH determines that all applicable administrative actions and all required elements have been completed by the recipient and the NIH.
Commercial organization	An organization, institution, corporation, or other legal entity, including, but not limited to, partnerships, sole proprietorships, and limited liability companies, that is organized or operated for the profit or benefit of its shareholders or other owners. The term includes small and large businesses and is used interchangeably with “for-profit organization.”
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.
Contract	A legal instrument by which a non-federal entity purchases property or services needed to carry out the project or program under an award. The term does not include a legal instrument, even if the non-federal entity considers it a contract, when the substance of the transaction meets the definition of an award or subaward. An OT award issued by NCI is not a Contract, as the term is defined in this paragraph. <i>See Subaward.</i>
Contractor	An entity that receives a contract. An entity that receives an OT award issued by NCI is not a Contractor. <i>See Contract.</i>
Disallowed costs	Those charges to an award that the federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable federal statutes, regulations, or the terms and conditions of the award.
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-federal entity for financial statement purposes, or \$5,000.
Expenditure report	The SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report).
Expenditures	Charges made by a non-federal entity to a project or program for which an award was received. <ul style="list-style-type: none">• The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied.

- For reports prepared on a cash basis, expenditures are the sum of:
 - Cash disbursements for direct charges for property and services
 - The amount of indirect expense charged
 - The value of third-party in-kind contributions applied
 - The amount of cash advance payments and payments made to subawardees.
- For reports prepared on an accrual basis, expenditures are the sum of:
 - Cash disbursements for direct charges for property and services
 - The amount of indirect expense incurred
 - The value of third-party in-kind contributions applied
 - The net increase or decrease in the amounts owed by the non- federal entity for:
 - Goods and other property received
 - Services performed by employees, contractors, subawardees, and other payees
 - Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.

Federal awarding agency The federal agency that provides an award directly to another entity. *See also Awarding IC.*

Federal share The portion of the total project costs that are paid by federal funds.

Funding Announcement/
Funding Solicitation A funding announcement is a publicly available document in which a federal agency makes known its intentions to make awards (e.g., OT awards), usually as a result of competition for funds.

Generally Accepted Accounting Principles (GAAP) The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).

Generally Accepted Government Auditing Standards (GAGAS) Generally Accepted Government Auditing Standards (GAGAS), also known as the Yellow Book, are the 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).

Host Institution The university, research institution, company or other entity at which specific Cancer Grand Challenges research will be carried out, as a result of funding issued to that entity in a CRUK Grant Award Letter and/or NCI Notice of Award

Institution of Higher Education (IHE) *IHE* is defined at 20 U.S.C. 1001.

Internal controls A process, implemented by a non-federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories:

- effectiveness and efficiency of operations
- reliability of reporting for internal and external use

Non-federal entity A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out an award as an awardee or subawardee.

Notice of Award (NoA)	<ul style="list-style-type: none">• The legal document electronically signed by an OTAO that includes the Federal funding limits and obligations. The NoA provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.• contains or references all the terms and conditions of the OT award and federal funding limits and obligations• 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 use of funds under an award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non-federal entity during the same or a future period.
Other Transaction (OT)	A special type of legal instrument other than contracts, grants or cooperative agreements. Generally, these awarding instruments are not subject to the FAR, nor grant regulations unless otherwise noted for certain provisions in the terms and conditions of the award, either explicitly or incorporated by reference to a policy guide. They are, however, subject to the OT authorities that govern the initiative and/or programs as well as applicable legislative mandates .
Other Transactions Agreement Officer (OTAO)	The NIH federal employee who is certified and responsible for legally committing funds on behalf of the Federal government to Other Transactions (OT). The OTAO is the only federal employee who has the signatory authority for OT.
Other Transactions Agreements Specialist	An NIH federal employee who serves as a delegate of the OTAO, assigned responsibility for the day-to-day administrative management of Other Transactions.
Pass-through entity	A non-federal entity that provides a subaward to a subawardee to carry out part of a federal program.
Payment Management System	The DHHS centralized payment system operated by the Payment Management Service, Program Support Center. Most DHHS (and some other Federal Government agencies') awardees receive payments through this system.

Period of performance	The time during which the non-federal entity may incur new obligations to carry out the work authorized under the award. The federal awarding agency or pass-through entity must include start and end dates of the period of performance in the award.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.
Personally Identifiable Information (PII)	<p>Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public websites, and university listings. This type of information is considered to be public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology.</p> <p>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.</p>
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. .
Prior approval	Written approval by an authorized DHHS official, e.g., a designated Agreement Officer, evidencing prior consent before an awardee undertakes certain activities or incurs specific costs.
Program income	Gross income earned by the non-federal entity that is directly generated by a supported activity or earned as a result of the OT award during the period of performance. Program income includes but is not limited to income from fees for services performed, the use or rental of real or personal property acquired under an award, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and principal and interest on loans made with award funds. Interest earned on advances of federal funds is not program income. Except as otherwise provided in federal statutes, or the terms and conditions of the OT award, program income does not include rebates, credits, discounts, and interest earned on any of them.

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

Subaward	An award provided by a pass-through entity to a subawardee for the subawardee to carry out part of an award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.
Subawardee	A non-federal entity that receives a subaward from a pass-through entity to carry out part of a federal program; but does not include an individual that is a beneficiary of such program. A subawardee may also be an awardee of other awards directly from a federal awarding agency. The term includes consortium participants.
Supplies	All tangible personal property other than those described in the definition of “Equipment.” A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-federal entity for financial statement purposes or \$5,000, regardless of the length of its useful life.
Suspension of award activities	An action by NIH requiring the awardee to cease all activities on the award pending corrective action by the awardee. It is a separate action from suspension under DHHS regulations (2 CFR 376) implementing Executive Orders 12549 and 12689. <i>See Section 16.2 Debarment and Suspension and Section 10 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support.</i>
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: <ul style="list-style-type: none">• benefit a federally assisted project or program• are contributed by non-federal third parties, without charge, to a non-federal entity under a federal award.
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non-federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-federal entity for which expenditure has not been recorded.

Unobligated balance The amount of funds authorized under an award that the non-federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-federal entity’s unliquidated obligations and expenditures of funds under the award from the cumulative amount of the funds that the federal awarding agency or pass-through entity authorized the non-federal entity to obligate.

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