

NIH Office of Acquisition Management and Policy Standard Operating Procedures for Other Transactions

I. PURPOSE

The intent of this document is to provide supplementary standard operating procedures for the NIH Other Transactions (OT) Policy Guide.

II. SCOPE

This SOP applies to Contracting Officers acting as Agreements Officers to award and administer OT transactions pursuant to the NIH OT Policy Guide. These individuals are hereafter referred to as Other Transaction Agreements Officers (OTAO).

III. OT AGREEMENT OFFICER WARRANT PROCEDURES

The NIH Office of Acquisition and Logistics Management (OALM) has authority to warrant OTAOs at NIH, and will take actions deemed necessary to ensure the integrity of the OTAO warrant system. Nominations for appointment of OTAOs shall be submitted to the NIH Acquisition Career Manager (ACM) for review and approval. The nomination package shall include the following:

- (1) A recommendation from the employee's immediate supervisor providing justification for the appointment as a NIH OT Agreements Officer, including a description of the employee's experience, education, and training; and,
- (2) Evidence of successful completion of the required training set forth in this policy.

A. WARRANT QUALIFICATION REQUIREMENTS

The Office of Acquisition and Logistics Management (OALM) will ensure that any delegation of the OT authority shall only be to warranted Contracting Officers possessing a Level III Federal Acquisition Certification in Contracting. These individuals must also possess a level of experience, responsibility, and business judgment that enables them to operate in this relatively unstructured business environment.

OTAOs must successfully complete the following courses, or an equivalent course, prior to appointment within the last five (5) years of submitting their request. (NIH OALM will determine course equivalency.)

- Other Transactions
- Appropriations Law
- Intellectual Property
- Acquisitions Law

B. SCOPE OF AUTHORITY

OTAOs may bind the government only to the extent of the authority delegated to them by their OT Agreements Officer warrant.

IV. OT AGREEMENT INTERNAL REVIEW LEVELS

In all cases, the OTAO must obtain review of the final OT agreement by the HHS Office of the General Counsel (OGC) and the NIH Office of Acquisition Management and Policy (OAMP) prior to executing the award.

The OTAO is encouraged to submit draft agreements and obtain assistance from OGC and OAMP during the pre-planning and negotiation stages of the OT program to facilitate the transfer of valuable advice about the structure and wording of the agreement.

V. MANDATORY JUSTIFICATION FOR USE OF AN OTA

The OTAO should determine whether an OTA would be more beneficial than other types of instruments. In conjunction with government program officials, the OTAO should answer the questions below, identify the ways the OTA can minimize barriers to nontraditional participation, and record those findings in the agreement file:

- Can a traditional government contract, grant, or cooperative agreement be used?
- What are the expected benefits of participation by prospective firms or consortia? Is a specific technology or research methodology availability that would be better, more readily available, or less expensive?
- Why would the prospective vendor(s) not participate if an instrument other than an OT was used?

A. LIMITATIONS ON COMPETITION

The award of an OT must be competitive to the maximum extent practicable. The procedures under the FAR-based Broad Agency Announcement (BAA) technique and the resulting technical merit selection process can be useful for this purpose. If it is not practicable to use competitive procedures, the OTAO must document the agreement file accordingly.

B. JUSTIFICATION FOR USE OF AUTHORITY FOR COMMON FUND, PRECISION MEDICINE INITIATIVE

Pursuant to the requirements of section 402(n) of the PHS Act, 42 U.S.C. 282(n), a proposal must be submitted to the Director of NIH for the use of this authority for a proposed Common Fund or Precision Medicine Initiative (a.k.a. All of Us) OT program before conducting or supporting the research, including

why the use of OT authority is essential to promoting the success of the project. Upon receiving approval, OT authority may be exercised under this authority, and an annual report must be submitted to the Director on the activities relating to research performed under the OT agreement.

VI. KEY PRINCIPLES FOR OT AGREEMENT NEGOTIATIONS

A. PAYMENT

The OTA must identify the payment method and tell the awardee how, when, and where to submit payment requests. The payment method must take into account sound cash management practices by avoiding unwarranted cash advances. The OTAO must determine that the amounts of the payable milestones are reasonable. In addition, the OTAO must provide good cash management monitoring (for a cost reimbursable OTA) and reasonable value for the completion of each observable technical event (for a fixed-price OTA).

For cost reimbursable OTA, the payment provision must require the return of interest if excess cash balances occur. For an OTA using the fixed price approach (i.e. milestone payment method or another negotiated payment schedule), the award document must include language notifying the awardee that the OTAO may adjust the amounts of milestone payments if project expenditures fall too far below the projections that were the basis for setting the amounts. Below are additional requirements:

- Financial management systems. A cost reimbursable OTA must specify the minimum standards for financial management systems.
- Allowable costs. A cost reimbursable OTA must specify the standards used to determine which costs may be charged to the project.
- Audits. A cost reimbursable OTA must include an audit provision.
- Purchasing system standards. If appropriate, the OTA should specify the standards for the purchasing system of the awardee.

1. JUSTIFICATION FOR COST-SHARING ARRANGEMENT

To the maximum extent practicable, program costs should be shared between the government and the nonfederal parties. However, no mandatory share ratio is established and cost sharing is not required, unless otherwise mandated by the statutory authority for the OT award at issue. Thus, unless otherwise required, the OTAO should use this flexibility when dealing with each awardee. The OTAO must determine that the cost sharing offered is reasonable.

B. AUDITS AND REPORTING

The OTA, or their appointed representative, must coordinate all audit requests and review audit reports, as necessary.

The awardee should be required to prepare and provide quarterly and final technical and business reports. The technical status reports detail technical progress to date and report on all problems, technical issues, major developments, and the status of external collaborations during the reporting period.

Business reports differ depending on the type of payable milestone used for the project:

- If the payments are cost reimbursable, the business report must provide summarized details of the cost status of the agreement, including the status of awardee's contributions. The report should include a quarterly accounting of current expenditures. Any major deviations, over plus or minus 10 percent, must be explained, and the proposed adjustment actions must be discussed.
- If the payments are fixed, the business report must provide estimated labor hours against planned labor hours. From this information, the status of work against the plan can be determined.

If utilizing the authority set forth in section 402(n) of the PHS Act, 42 U.S.C. 282(n), the OTA should observe the NIH Director's obligation to conduct an evaluation of activities and submit a report by September 30, 2020, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the results of such evaluation, as required under section 2036(b) of the 21st Century Cures Act, P.L. 114-255. Similarly, reporting requirements mandated for the use of any OT authority granted to NIH must be satisfied.

C. INTELLECTUAL PROPERTY (IP)

The goal of negotiating OTA IP provisions is to ensure that NIH acquires sufficient license rights in IP developed under the OTA which are necessary to further NIH's mission for now and the foreseeable future. Obtaining insufficient intellectual property rights could limit the government's ability to use them outside the initial scope of the project. Conversely, where the government overestimates the intellectual property rights it will need, the government's attempt to negotiate for unnecessary or unused rights may dissuade parties from entering into an agreement and increase the cost of the project. Bearing this in mind, the OTA staff should carefully assess the intellectual property needs of the government. The negotiation should focus on acquiring only those rights and deliverables necessary to satisfy the government's need.

IP rights should be negotiated on an agreement-by-agreement basis and with an eye toward future project developments. The OTA/O can take advantage of such flexibilities by adhering to the following fundamental principles:

- Integrate IP considerations fully into project strategies for biomedical research in order to protect core NIH interests. IP considerations have a critical impact on cost and affordability -- they should not be treated as a separate or distinct issue that can be negotiated apart from agreement performance requirements or price/cost factors. Therefore, when developing project strategies, the OTA/O should consider all types of potential future requirements.
- Respect and protect a company's IP, which is a valuable form of intangible property that may be critical to the company's financial strength. Innovation requires substantial financial investment and effort over a long period of time and uses scarce resources, i.e., personnel expertise and facilities. NIH should respect rights in IP resulting from research activities developed under the OT agreement, and limit its demands to IP rights to only those that are essential for carrying out NIH objectives. The unauthorized or inadvertent disclosure of IP can destroy its commercial value. Further, the inadvertent disclosure of an invention before a patent application is filed can render the invention unpatentable. This is equally true for both solicited and unsolicited proposals and other data delivered in confidence. As a result, most commercial businesses refuse to allow another party access to proprietary information unless adequate assurances are made that the IP will be handled and protected according to the best commercial standards. Therefore, NIH must use all available means to safeguard proprietary information, including employee training for the handling of restricted materials, technological access or copying protection, and physical access restrictions.
- Resolve issues prior to award by clearly identifying and distinguishing the IP deliverables from the license rights in those deliverables.

"IP deliverables" refers to the contractual obligation to deliver IP that has a predetermined content and format. NIH may own the delivered physical medium on which the IP resides, but generally it will not own the IP rights. License rights refer to NIH's ability to use, reproduce, modify, and release the delivered IP. These two concepts are integrally related, but are different and should be negotiated separately.

- Commercial or proprietary software and technical data not made under the award that will be delivered must be identified by the partner. To that end, FAR provision 52.227-14, which has language addressing this situation, can be modified to suit the circumstances and used in the OT agreement, if applicable.
- Seek creative solutions to IP issues by focusing on acquiring only those patent license rights, deliverables, and license rights necessary to accomplish the project strategy. If Agreement Officers choose to rely on FAR-based IP provisions, they must be mindful not to create inefficiencies that may

force parties to take unnecessarily restrictive positions on other important contract terms (e.g., price) to account for the imbalance.

- Program officials may also consider establishing performance-based requirements that enhance long-term competitive interests, in lieu of acquiring detailed design data and data rights.

2. REFERENCES

NIH Other Transactions Policy Guide