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Correspondence from: **Michelle Bulls (OER)**

Lead IC/OD Office: OER an OALM

Cleared by: OM, OGC (NIH) and General Law Division (HHS)

ES Remarks:

For your clearance, enclosed is the draft NIH-wide "Other Transactions" Policy Guide.

Dr. Tabak: OER has confirmed that OGC has cleared this document and there are no legal concerns.

Stamp Date to IMOD Above Stamp Date Returned from IMOD Above

PLEASE RETURN COMPLETED CORRESPONDENCE TO:
Contact: Michelle Whitfield, phone 301-402-0384 (Back-up: Greta Doswell)

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

"OTHER TRANSACTIONS" (OT)
POLICY GUIDE

May 22, 2017

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INTRODUCTION

"Other Transactions" (OT) refers to the authority to enter into transactions other than contracts, grants or cooperative agreements. When NIH, or a specific NIH Institute, Center or Office (ICO), has legal authority to award OT agreements (OTAs) and to design an OT award program, it must differentiate OTs from existing assistance/acquisition mechanisms. Requirements for awards issued under OT authorities are generally included in the authorizing language or budgetary appropriation for such awards.

While OTs come with fewer restrictions than other types of awards, they still must be awarded in a manner that ensures proper stewardship of Federal funds and comply with requirements applicable to all Federal funding (regardless of funding mechanism). For this reason, ICOs must be sure that their OT requirements are fully documented and consistently applied. They also must comply with the policy requirements discussed throughout this document, as appropriate.

OTs offer greater flexibility for NIH to develop programs that meet the rapidly advancing needs of biomedical research and may appeal to non-traditional partners that might not typically apply for grants, cooperative agreements, and contracts. ICOs are encouraged to think creatively when designing programs to take advantage of this flexibility.

I. GENERAL INFORMATION

A. LEGAL AUTHORITY FOR THE USE OF OTHER TRANSACTIONS

Before pursuing use of an OT funding instrument, it is important to determine whether specific legal authority exists to support use of OT for the designated purpose. Over the years, there have been several examples of specific OT authorities that exist, or have existed, for NIH or for specific ICOs in U.S. public law. It is important to note that authorities may expire, be revised, or be repealed, and must be accompanied by a Congressional appropriation of funding for that purpose. As a result, before developing a biomedical research program for which an OT may be used, consultation with the NIH Legal Advisor's Office (also known as the NIH Branch of the HHS Office of the General Counsel) and the applicable Office of Budget is strongly recommended to confirm that sufficient legal authorization and funding exists.

B. OTHER RELEVANT LEGAL AUTHORITIES

"Other Transactions" are not required to comply with the Federal Acquisition Regulation (FAR), its supplements, or laws that are limited in applicability to procurement contracts, such as the Truth in Negotiations Act, the Competition in Contracting Act, the Contract Disputes Act, and Cost Accounting Standards (CAS). Similarly, OTs are not subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (Uniform Regulations) (45 CFR Part 75), which are limited in applicability to grants, cooperative agreements, or other forms of Federal financial assistance, nor are OTs subject to the NIH Grants Policy Statement. Although these laws and regulations do not apply to OTs, 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. The statutes specified in this Policy Guide set many of those standards. This information is provided for guidance only and is not intended to be definitive; other laws may be determined to apply generally to all NIH OTs, or specifically to a particular award depending on the terms of the OT. Thus, it is essential that ICOs consult with the NIH Legal Advisor's office and other relevant offices to ensure the appropriate legal authorities have been addressed.

C. ROLES AND RESPONSIBILITIES

1. Agreements Officer. Individual responsible for legally committing the government to an OT agreement, and for the administrative and financial aspects of the award.

Agreements Officers must be either warranted contracting officers (at Level III) or grants management officers (at Level III or above) with a level of responsibility, formal training, business acumen, and judgment that enables them to operate in this relatively unstructured environment. Agreements Officers may bind the government only to the extent of the authority delegated to them by the Other Transaction Agreement warrant granted with concurrent approval by the NIH Office of Acquisition Management and Policy and the Office of Policy for Extramural Research Administration.

When negotiating financial and administrative requirements for OT awards, the Agreements

Officer should consider typical FAR procedures and clauses, principles from the Uniform Regulations, grants policies, commercial business practices, as well as other OT agreements; but ultimately is responsible for negotiating clauses and terms of award that appropriately reflect the risk to be undertaken by all parties on their particular project. If a policy or procedure, or a particular strategy or practice, is in the best interest of the government and is not specifically addressed in this Guide, nor prohibited by law or Executive Order, the government team should not assume it is prohibited. The Agreements Officer should take the lead in encouraging business process innovations and ensuring that business decisions are made on an informed basis, in good faith, and in the honest belief that actions are taken in the best interests of the government.

2. Staff Coordination. While Agreement Officers and Program/Project Managers are expected to work collaboratively on all aspects of an OTA award program, their roles may differ depending on the design of the OT program.

3. Training and Workforce Needs. To ensure the proper management of awards, NIH will develop appropriate training for OTA staff and conduct data-driven workforce assessments to identify the number, skills, location, and competencies of the OTA staff.

II. AGREEMENT PLANNING AND EXECUTION

A. AGREEMENT PLANNING

1. Appropriate Safeguards. OT authority provides flexibility to negotiate terms and conditions appropriate for the agreement. This includes assurances that the cost to the government is allocable, necessary, reasonable and realistically reflects the work that will be accomplished, the schedule and other requirements are enforceable, and the payment arrangements promote on-time performance. It is the responsibility of both the Agreements Officer and Program Manager to ensure the terms and conditions negotiated are appropriate for the particular project, and they should consider expected follow-on program needs.

There is a public expectation that Federal funding opportunities are made widely available to all parties and that open competition ensures only the most qualified applicants receive funding. Therefore, ICOs are encouraged to make OT funding opportunities known to a wide audience and to allow potential applicants to compete for funds to the maximum extent practicable. Examples of competitive announcements are in the forms of Funding Opportunity Announcements (FOAs), Broad Agency Announcements (BAAs) and Research Announcements (RAs). If competition is not practicable or appropriate for a given ICO or program, the Agreements Officer should document the file accordingly.

2. Peer Review. Current peer review regulations (42 CFR Part 52h) and the Public Health Service Act (as enacted in section 492 (42 U.S.C. 289a)) apply specifically to grants (and by definition, cooperative agreements), as well as contracts. While these authorities do not apply directly to OT awards, historically some NIH OT authorities have required some level of peer review to occur. Consultation with the NIH Legal Advisor's Office is recommended to determine whether and to what extent peer review requirements apply to a particular proposed OT program.

3. NIH Legal Advisor's Review. OTA staff should submit the agreement to the NIH Legal Advisor's office before execution to ensure compliance with applicable statutes, regulations, and policies. ICOs are also encouraged to discuss new solicitations and OTA policies with the NIH Legal Advisor's office, as appropriate.

4. Negotiated Agreement and Award. Prior to issuing an agreement, an ICO must document its rationale for using an OT, as opposed to a conventional funding instrument, and track circumstances throughout the life of the agreement to ensure the use of OT authority continues to be appropriate. Reasons to use OT authority may include, among others:

- Seeking participation by nontraditional research performers, such as:
    - Small businesses, patient advocacy organizations, educational institutions, pharmaceutical companies, foreign entities, or other organizations that are typically not inclined to work with the federal government;
    - Consortia comprised of the entities above who collaborate as peers with the government to manage the project and share its costs;
    - Non-profit entities that have an interest in the goals of the OT program; and

- Individuals.

- Requiring fluid implementation of a program - awards may need to begin quickly on a small scale, with additional funds added later if particular milestones are met, or awards may need to be downsized or discontinued.

- Nontraditional review and award management practices are needed because the science is expected to be highly evolving, with requirements for additional aims or expertise added to, or removed from, the project throughout the award period.

- The requirement for collaborative involvement by the government in the technical direction and oversight of the research, which can be akin to partnering. Examples of involvement can include participation in progress reviews and decisions on future efforts or direction. The government may also be a voting or non-voting member of the consortium.

Second, the ICO should document internal controls for assessing the risks associated with meeting the project objectives, including estimating the risk's significance, assessing the likelihood for the risk to occur, and deciding how to manage the risks and what specific actions to undertake. The documentation should address project-specific risks, such as fairness and reasonableness of cost estimates, but may also rely on broader risk management policies to inform overarching issues.

Third, the ICO's internal documentation should include a determination that the proposed awardee is a responsible party and is not on the excluded parties list in the System for Award Management (SAM), or otherwise prohibited from receiving federal appropriations.

Finally, the ICO's internal documentation must also address the reasonableness of the anticipated cost and applicable terms and conditions. This should include highlighting the key agreement clauses and explain why the proposed terms and conditions provide adequate safeguards to the government and are appropriate for the project.

ICOs should periodically review their internal processes to ensure that they include the defined elements identified within this section in their OTA files.

B. METRICS

Agreements Officers and Program Managers should establish and track any metrics that measure the value or benefits directly attributed to the use of the OT authority. Since OTs are too distinct from other funding approaches to perform a statistical comparison, traditional metrics, such as cost growth, schedule slips and performance shortfalls, are generally inappropriate. Therefore, such metrics must be specifically tailored to the objectives of the OT in question.

If OTA staff establish other metrics that could be used across the board to measure the value or benefits directly attributed to the use of the OT authority, they are encouraged to submit this information to the relevant policy offices in the NIH Office of the Director, such as the NIH

Office of Acquisition Management and Policy and the Office of Policy for Extramural Research Administration.

C. INTELLECTUAL PROPERTY

1. General. Agreements Officers can negotiate terms and conditions different from those typically used in other extramural funding instruments. However, in negotiating these clauses, the Agreements Officer must consider other laws that affect the government's use and handling of intellectual property, such as the Bayh-Dole Act (35 U.S.C. 200-212); the Trade Secrets Act (18 U.S.C. 1905); the Freedom of Information Act (5 U.S.C. 552); 10 U.S.C. 130; 28 U.S.C. 1498; 35 U.S.C. 205 and 207-209; and the Lanham Act, partially codified at 15 U.S.C. 1114 and 1122. Flexibility in the negotiation of IP rights is one of the rationales for using an OT.

1.1. Intellectual property (IP) collectively refers to rights governed by a variety of different laws, such as patent, copyright, trademark, data, and trade secret laws. Due to the complexity of intellectual property law and the critical role of intellectual property created under research projects, OTA staff should obtain the assistance of the NIH Legal Advisor's office, the appropriate technology transfer office representative, or the OPERA Division of Extramural Inventions and Technology Resources, as appropriate, as early as possible in the negotiation process.

1.2. OTA staff should assess the impact of intellectual property rights on the government's total life cycle cost of the research. Obtaining Insufficient intellectual property rights hinder the government's ability to adapt the developed research for use 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.

1.3. The negotiated intellectual property clauses should facilitate the agreement's strategy and balance the relative investments and risks borne by the parties. Due to the complex nature of intellectual property clauses, it may be advisable to incorporate the clauses in full text.

1.4. OTA staff should ensure that the disputes clause included in the agreement can accommodate specialized disputes arising under the intellectual property clauses, such as the exercise of intellectual property "march-in rights," reporting requirements, or the validation of restrictions on technical data, computer software or other rights provided to the Government.

1.5. OTA staff should consider how the intellectual property clauses applicable to the awardee flow down to others, including whether to allow others to submit any applicable intellectual property licenses directly to the government.

1.6. OTA staff should consider restricting awardees from licensing research developed under the Agreement to domestic or foreign firms under circumstances that would hinder potential domestic manufacture or use of the research. Such restrictions need to be consistent with NIH's public access and data policies or a waiver should be submitted. Consideration

should be given to whether a restriction facilitates the commercial development or research use of products or services that will benefit public health. If a restriction on future research by the Government, non-profits, or for-profits is necessary, a justification for such restrictions on future research should be developed by the ICO OTA staff and submitted to the OPERA Division of Extramural Inventions and Technology Resources. The Agreements Officer must also be aware that export restrictions prohibit awardees from disclosing or licensing certain research to foreign firms.

1.7. Additional Matters. OTA staff should consider including in the intellectual property clauses any additional rights available to the government in the case of inability or refusal of the private party or consortium to continue to perform the Agreement. It may also be appropriate to consider negotiating time periods after which the government will automatically obtain greater rights.

1.8. Enforcement and "March-in Rights." The Agreements Officer should consider negotiating enforcement rights similar to the "march-in rights" set forth in the Bayh-Dole Act (see 35 U.S.C. 203), or other remedies enforceable by the government should the awardee fail to comply with the use or restriction of the intellectual property rights in the OTA (e.g., fail to commercialize the results of the research, make the research results publicly available as required under the OTA, or make them available in the case of an exigent public health need).

D. AGREEMENT FUNDING

1. Funding Requirements. Federal funding requirements are applicable to OTs and are contained in agency fiscal regulations. No Agreements Officer or employee of the government may create or authorize an obligation in excess of the funds available, or in advance of appropriations (Anti-Deficiency Act, 31 U.S.C. 1341), unless otherwise authorized by law.

2. Funding Restrictions. Examples of laws not applicable to NIH OTs include the Buy American Act (41 U.S.C. 8303) and the Berry Amendment (10 U.S.C. 2533a). However, Agreements Officers should consult with legal counsel to determine the applicability of funding restrictions found in appropriations acts.

3. Limits on Government Liability. In accordance with appropriations law, when agreements provide for incremental funding or include cost-reimbursement characteristics, the Agreements Officer should include appropriate clauses that address the limits on government obligations.

E. FLOW DOWN

OTA staff should consider which of the OT clauses the awardee should be required to flow down to participants of the agreement. In making this decision, both the needs of the government (e.g., audits) and the protections (e.g., intellectual property) that should be afforded to all participants should be considered.

F. PRICE REASONABLENESS

The government must be able to determine that the amount of the agreement is fair and reasonable. The ICO may require the awardees to provide whatever data is needed to establish price reasonableness, including commercial pricing data, market data, parametric data, or cost information. However, OTA staff should attempt to establish price reasonableness through other means before requesting cost information. If cost information is needed to establish price reasonableness, the government should obtain the minimum cost information needed to determine that the amount of the agreement is fair and reasonable.

G. ALLOWABLE COSTS

1. General. This section applies only when the agreement uses amounts generated from the awardee's financial or cost records as the basis for payment (e.g., interim or actual cost reimbursement including payable milestones that provide for adjustment based on amounts generated from the awardee's financial or cost records).

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

3. Allowable Costs Requirements. In determining whether to include some or all of the allowable cost requirements contained in the Cost Principles (48 CFR Part 31) or Uniform Regulations (45 CFR Part 75), the Agreements Officer should consider the guidance contained in the section entitled "Accounting Systems."

4. Profit/Fee. Profit or fee may be permitted for awardees of OTs, but since most OTAs implement collaborative partnerships to advance research, it may not be considered appropriate for an OTA to be a profit or fee bearing instrument.

5. Travel, Transportation and Subsistence Expenses. Generally, an appropriation may not be used for travel, transportation, and subsistence expenses of non-federal individuals for a meeting unless specifically provided by law. 31 U.S.C. 1345. While procurement laws and the FAR, including the costs principles applicable under the FAR, do not apply to OT awards, the obligation of federal funds remains subject to federal appropriations laws. For guidance on when appropriated funds may be used to pay for such expenses, Agreement Officers should refer to applicable NIH policies (e.g. NIH Travel Policies and Procedures (Manual Chapter 1500)).

H. ACCOUNTING AND MANAGEMENT SYSTEMS

1. General. An important component of the use of OT agreements is the ability for awardees

to use appropriate accounting and management systems that may differ from those used for other award types. While not all agreements may require this option, the flexibility is available and the Agreements Officer should ensure it is addressed in the award document.

2. Applicability. This section applies only when the agreement uses amounts generated from the awardee's financial or cost records as the basis for payment (e.g., interim or actual cost reimbursement including payable milestones that provide for adjustment based on amounts generated from the awardee's financial or cost records). In these cases, the Agreements Officer should consider including a clause that requires the awardee to consider their accounting and management system capabilities when the awardee is expected to receive payments exceeding the Truth in Negotiations Act (TINA) threshold, as adjusted for inflation (41 U.S.C. 1908 and 41 U.S.C. 1502(b)(1)(B)), that will be based on amounts generated from their financial or cost records.

3. Financial System Capability. When structuring the agreement, the Agreements Officer must consider the capability of the awardee's accounting and management systems in accordance with Generally Accepted Accounting Principles (GAAP). Agreements should require that adequate records be maintained to account for federal funds received and cost-sharing, if any. The Agreements Officer should not enter into an agreement that provides for payment based on amounts generated from the awardee's financial or cost records if the awardee does not have an accounting and management system capable of identifying and accumulating the amounts/costs to individual agreements. Any system that segregates direct costs from indirect costs, identifies and accumulates direct costs by project and provides for an equitable and consistent allocation of indirect costs to intermediate and final cost objectives is acceptable.

3.1. When the awardee has a system capable of identifying the amounts/costs, the agreement should utilize the awardee's existing accounting and management system to the maximum extent practical. The agreement should include a clause that documents the basis for determining the interim or actual amounts/costs, i.e., what constitutes direct versus indirect costs and the basis for allocating indirect costs.

I. AUDIT.

1. General. Where appropriate, Agreements Officers should include audit access clauses in the agreement. In addition, Agreements Officers should require the awardee to insert an appropriate audit access clause in awards to key participants.

2. Frequency of Audits. Audits of agreements will normally be performed only when the OTA staff determine it is necessary to verify awardee compliance with the terms of the agreement.

2.1. Indirect Cost Rate Agreements. In the event a cost reimbursable payment schedule is utilized for the OTA, the NIH Division of Financial Advisory Services (DFAS) within OAMP, or the cognizant audit group, should be consulted to establish negotiated indirect cost rates.

3. Means of accomplishing any required audits. The provisions of the Single Audit Amendments Act of 1996 (31 U.S.C. 7501 *et seq.*) should be followed when the awardee is a state government, local government, or nonprofit organization whose federal procurement

contracts and financial assistance agreements are subject to that Act. The Single Audit Act is implemented by Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 200). The Single Audit Act is intended to minimize duplication of audit activity and provides for the use of independent public accountants, to conduct annual audits of state or local governments and educational or other nonprofit institutions.

4. Length and extent of access. Agreements should provide for the Agreements Officer's authorized representative to have direct access to sufficient records to ensure full accountability for all government funding or cost share under the agreement for a specified period of time after final payment, unless notified otherwise by the Agreements Officer.

J. COST SHARING

1. General. Cost sharing is an option as an administrative requirement, unless the authorizing legislation for the particular OT program specifies otherwise. If included, it shall be stated in the application instructions/guidance for each particular OT program. When the potential awardee willingly offers cost sharing, or when the government requires it for a specific project, the NIH Agreements Officer may include it in the negotiated agreement. The two types of cost sharing are "cash" – outlays of funds to support the total project, and "in-kind" – value of equipment, materials, or other property used in performance of the work. "In-kind" contributions and IP are calculated at reasonable fair market value and the burden of proof is with industry.

2. Restrictions.

2.1. Costs Incurred Before OT Agreement. The non-federal amounts counted as provided, or to be provided, by a party to the OT 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 OT 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 OT 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 OT 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 OT agreement; and (ii) it was appropriate for the party, entity or subordinate element to incur the costs before the OT agreement became effective in order to ensure the successful implementation of the OT agreement.

2.2. Other Constraints. The cost share cannot include foregone profit/fee, cost of money, or the cost of prior research.

3. Nature of cost-share. The Agreements Officer should understand and evaluate the nature of the cost share. Any part of the cost share that includes an amount for a fully depreciated asset should be limited to a reasonable usage charge. In determining the reasonable usage charge, the Agreements Officer should consider the original cost of the asset, total estimated remaining useful life at the time of negotiations, the effect of any increased maintenance charges or decreased efficiency due to age, and the amount of depreciation previously charged to

procurement contracts and subcontracts. In determining the amount of cost sharing, the agreement should not count, as part of the awardee's cost share, the cost of government-funded research, prior R&D, or indirect costs that are not allocable to the "other transaction."

4. Equity when sharing costs. OTAs that require cost sharing should generally provide for adjustment of government or private sector investment or some other remedy if the other party is not able to make its required investment. Such agreements should also address the procedures for verifying cost share contributions, the conditions that will trigger an adjustment and the procedures for making the adjustment.

K. PAYMENTS

1. General. There are three primary payable milestone options available for OTs: fixed, adjustable (cost reimbursable), and a hybrid approach that combines these two options. The agreement must identify clearly the basis and procedures for payment. Consider the following in drafting the agreement payment clauses:

- Are payments based on amounts generated from the awardee's financial or cost records? In determining whether the agreement should provide for reimbursement based on the awardee's financial or cost records, the Agreements Officer should consider the guidance contained in the section entitled "Accounting and Management Systems".

- Are the payment amounts subject to adjustment during the period of performance?

- If the payments can be adjusted, what is the basis and process for the adjustment?

- What are the conditions and procedures for final payment and agreement close-out?

- Is an interim or final audit of costs needed?

2. Payable Milestones. There is not one uniform clause or set of procedures for payable milestones. Payable milestone procedures vary, depending on the inherent nature of the agreement.

2.1. Fixed payable milestones. Agreements with fixed price characteristics may contain payable milestone clauses that do not provide for adjustment based on amounts generated from the awardee's financial or cost records. In these cases, this fact should be clear in the agreement and the negotiated payable milestone values should be commensurate with the estimated value of the milestone events.

2.2. Adjustable payable milestones. Alternatively, agreements may provide for payable milestones to be adjusted based on amounts generated from the awardee's financial or cost records. When this is the case, the agreement must address the procedures for adjusting the payable milestones, including consideration of the guidance contained in the section entitled "Accounting and Management Systems". Payable milestones should be adjusted as soon as it is reasonably evident that adjustment is required under the terms of the agreement.

3. Provisional Indirect Rates on Interim Payments. When the agreement provides for interim

reimbursement based on amounts generated from the awardee's financial or cost records, any indirect rates used for the purpose of that interim reimbursement should be no higher than the awardee's provisionally approved indirect rates, when such rates are available.

L. PROPERTY

The government is not required to take title to property (not including intellectual property) acquired or produced by a private party signatory to an OTA except property the agreement identifies as deliverable property. In deciding whether or not to take title to property under an OT, the government should consider whether known or future efforts may be fostered by government ownership of the property.

M. CHANGES

1. Method of change. The agreement should address how changes will be handled, including notification requirements. The Agreements Officer should consider whether the government should have the right to make a unilateral change to the agreement, or whether all changes should be bilateral. A process for managing unauthorized changes that have not been previously agreed to by the parties must also be established in the OT agreement.

2. Need for unilateral change. The government may need the right to make a unilateral change to the agreement to ensure that critical requirements are met, or to efficiently manage minor, administrative changes. The fact that unilateral changes may lead to disputes and claims, particularly in agreements with fixed-priced characteristics, should be considered.

3. Accounting Systems. In determining the method to be used to compute the amount of the equitable adjustment (monies due as a result of a change), the Agreements Officer should consider the guidance contained in the section entitled, Accounting and Management Systems.

N. PROTESTS AND DISPUTES

1. General. Agreements Officers should ensure each OT addresses the basis and procedures for resolving disputes. The Agreements Officer may negotiate disputes language that provides for final resolution to be made at a higher level, either jointly or by a Government official.

2. Disputes arising before the award is issued. The Government Accountability Office (GAO) protest rules do not apply to OTs. GAO's bid protest jurisdiction is limited to determining whether an agency has statutory authority to enter into an OTA and whether the OTA at issue falls within the agency's specified statutory authority. Solicitations and announcements that envision the use of an OT should stipulate the offerors'/ applicants' rights and procedures for filing a protest with the agency, using either the agency's established agency-level protest procedure or an OT-specific procedure. This stipulation could include a statement that there is no right of protest/appeal.

3. Disputes arising after the award is issued. Although OTs are not subject to the Contract Disputes Act (41 U.S.C. 7101-7109), an OT dispute can be the subject of an injunction action in the U.S. Court of Federal Claims. Agreements Officers should seek to reduce the risk of costly litigation by negotiating disputes clauses which maximize the use of Alternative Dispute Resolution when possible and appropriate.

Although OTs are not subject to GAO's bid protest jurisdiction, GAO may review the propriety of the agency's use of OT authority and challenge the decision not to use a traditional procurement instrument.

O. TERMINATION

1. Basis for termination. OTA staff should consider termination clauses (both for convenience and for cause) in light of the circumstances of the particular OT project. A unilateral government termination right is appropriate. In cases in which there is an apportionment of risk allocation and cost shares, it could be appropriate to allow an awardee termination right as well. Either party may terminate in this scenario per the terms of the agreement between the parties. Such a termination could occur in instances in which an awardee discovers that the expected commercial value of the research does not justify continued investment or the government fails to provide funding in accordance with the agreement. Termination clauses should identify the conditions that would permit terminations and include the procedures for deciding termination settlements.

2. Remedies. Agreements Officers should consider whether the government should be provided the opportunity to terminate the award, tailoring clauses to discourage defaults in line with the agreement's overall allocations of risk. When agreements provide the government the right to terminate or provide the awardee the right to terminate, the agreement should address what remedies are due to the government.

3. Accounting Systems. If termination settlement costs are expected to be the subject of negotiation based on amounts generated from the awardee's financial or cost records, then the Agreements Officer should consider the guidance contained in the sections entitled Allowable Costs, Accounting and Management Systems and Audit.

P. REPORTING, ADMINISTRATION, AND CLOSEOUT

1. Performance Reporting. The awardee is responsible for managing and monitoring each project and all participants. The solicitation and resulting agreement should identify the frequency and type of performance reports necessary to support effective management. Effective performance reporting addresses cost, schedule and technical/scientific progress, and may also include reporting of subject inventions. It discusses the progress achieved compared to the anticipated progress, as well as the budgeted and actual costs. It is vital that Agreements Officers receive all pertinent documentation to ensure the effective administration of the agreement.

1.1. Teaming Arrangements. If an awardee is teaming with other companies (e.g., consortium, joint venture) for the project, the Agreements Officer should consider if performance reporting on all team members would be appropriate.

1.2. Forms and Formats for Reporting. Any collection of information from ten or more people or organizations, including performance and financial reporting, must be approved by OMB before the collection can occur unless a statutory exemption is determined to apply. While

the Research Performance Progress Report (RPPR) has been approved for this use with OT agreements, OTA staff may utilize other forms or formats for reporting as long as they have received any necessary OMB approval for the requested reports.

2. Link to Payment. OTA staff, should consider whether reports required of the OT awardee are important enough to warrant establishment of line items or separate payable milestones, or if report requirements should be incorporated as a part of a larger line item or payable milestone.

3. Corrective action. It is the Agreements Officer's responsibility to ensure that all terms and conditions of the agreement are being satisfied. If the OT awardee has failed to comply with any term of the agreement, the Agreements Officer must take timely, appropriate action to remedy the situation.

4. Agreement Close-out. Standard close-out procedures used by the NIH acquisition and assistance communities may be utilized for OTAs and the requirements listed in the award document.

Q. Documentation of Standard Operating Procedures

1. Developing ICO-Specific OTA Policies. The requirements listed in this Policy Guide are not intended to address every issue OT programs will encounter. ICOs retain the authority to include additional requirements on OTA awardees and to provide further guidance on specific issues than what is provided in this Policy Guide. Where additional requirements are included in an ICO-specific OTA policy, the ICO should make clear to potential and current awardees that such additional requirements apply as part of the terms of award.

2. Documentation and Consistent Treatment. All ICO-specific policies and procedures must be fully documented and implemented consistently among all OTA awards issued by the ICO for a particular program, and must comply with the requirements of this Policy Guide.

APPENDIX 1

LAWS THAT MAY BE APPLICABLE TO "OTHER TRANSACTIONS"

For the purposes of identifying public policy requirements and appropriations laws that may be applicable to all NIH funding, this document highlights variouspublic policies and appropriations language that is applicable to NIH grants/cooperative agreements or other award types. However, please note that Other Transactions are not grants, cooperative agreements, nor contracts and therefore, the public policies that are outlined in this Appendix may not be applicable to Other Transactions unless the agency, in consultation, with the Office of General Counsel (OGC) states otherwise based on the specific OT program requirements and its applicable laws that govern the OT, which will vary depending on the nature of the OT program. Similarly, other laws may be determined to apply generally to all NIH OT awards, or specifically to a particular award depending on the terms of the OTA. In the interest of maintaining as much flexibility as feasible, programs may consult with OGC to discuss whether incorporation of the requirements outlined within this Appendix, or other requirements, are warranted under applicable program legislation.

Debarment and Suspension

HHS regulations published in 2 CFR 376 implement the government-wide debarment and suspension system guidance (2 CFR 180) for HHS' nonprocurement programs and activities. A "nonprocurement transaction" means any transaction, regardless of type (excluding procurement contracts), including but not limited to grants, cooperative agreements, scholarships, fellowships, and loans (2 CFR 180.970). NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, awardees of NIH OT awards are required to determine whether it or any of its principals (as defined in 2 CFR 180.995 and 2 CFR 376.995) is excluded or disqualified from participating in a covered transaction prior to entering into the covered transaction.

Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible. These circumstances are outlined below:

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

   The U.S.-EU Open Skies Agreement was amended effective June 24, 2010. GSA issued

Guidance October 6, 2010. Pursuant to the amendment, federal contractors and awardees (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and awardees must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

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

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

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

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

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

Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and awardee-prepared reports, publications, and OT award-related documents should be in metric.

National Environmental Policy Act

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

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

Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH OT awards are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient drug or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may

result in the imposition of a civil monetary penalty of up to $1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.
Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH OT award should be directed to the AO.

- **Research Misconduct**

  Title 42 CFR 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions" specifies awardee responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity, 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 HHS Office of Research Integrity (ORI) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities (http://www.ori.dhhs.gov).

- **Research Involving Recombinant or Synthetic Nucleic Acid Molecules**

  The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (November 2013 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research. A copy of the *NIH Guidelines* is available at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelinesOT Policy Guide Draft - 150930 NCO.doc.

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

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

pertinent CDC and USDA regulations, 42 CFR 73, Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121, Possession, Use, and Transfer of Biological Agents and Toxins.

- **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.

- **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.

- **Salary Cap/Salary Limitation**

  None of the funds appropriated in the governing appropriation Act for the NIH shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the NIH Office of Extramural Research Salary Cap Summary webpage.

- **Gun Control**

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

- **Lobbying Prohibition**

  NIH appropriations have in the past included restrictions similar to the following text from the 2016 appropriation:

(a) No part of any appropriation contained in the Consolidated Appropriations Act, 2016, or transferred pursuant to Section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself,

or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

(b) No part of any appropriation contained in this Act or transferred pursuant to Section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

(c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

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.

Exceptions to Restrictions on Abortions

(a) The limitations established in the preceding section shall not apply to an abortion— (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.
(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).
(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).
(d) (1) None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. (2) In this subsection, the term ‘‘health care entity’’ includes an individual physician or other health

care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

- **ClinicalTrials.gov Requirements**

  Applicants and awardees should familiarize themselves with the requirements regarding ClinicalTrials.gov, including the authorizing statute, as amended (42 U.S.C. 282(j)), the implementing regulations (42 CFR Part 11), and the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. 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. For additional information, see https://clinicaltrials.gov/.

- **Human Stem Cell Research**

  Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. NIH Guidelines on Human Stem Cell Research, effective July 7, 2009, implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

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

  NIH awardees may use hESCs that have been approved by NIH in accord with the NIH Guidelines and are posted on the NIH Human Embryonic Stem Cell Registry, or may establish eligibility of specific cell lines for NIH funding by submitting a Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890). Prior to the use of NIH funds, applicants and awardees must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/awardee must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

- **Human Embryo Research and Cloning Ban**

  NIH funds may not be used to support human embryo research. NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term “human

embryo or embryos" includes any organism not protected as a human subject under 45 CFR 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

- **Human Fetal Tissue Research**

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

  Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. 46.204 and 46.206 may be specifically relevant.

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

  Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

  When obtaining primary human fetal tissue for research purposes, NIH expects awardees of NIH OT awards to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

- **Research on Transplantation of Human Fetal Tissue**

  Sections 498A and 498B of the Public Health Service Act, 42 USC 289g-1 and 289g-2,

contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
    - for therapeutic transplantation research,
    - without any restriction regarding the identity of individuals who may receive the transplantation, and
    - without the donor knowing the identity of the recipient.
- The attending physician must sign a statement that he/she has:
    - obtained the tissue in accordance with the donor's signed statement and
    - fully disclosed to the donor his or her intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.
- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that he/she:
    - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
    - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
    - performed the abortion in accordance with applicable State and local laws.
- The PD/PI must sign a statement certifying that he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PD/PI must certify in writing that he/she has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the OT award, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the OT awardee. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm105857.htm.

- **Human Subjects Protections**

  The HHS 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 HHS components.

  The HHS regulations stipulate that the awardee organization(s), whether domestic or foreign, bears ultimate responsibility for safeguarding the rights and welfare of human subjects in HHS-supported activities (46.101(a) and 46.103(a)). Awardee organization(s) "engaged" in human subjects research must obtain a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP), and establish appropriate policies and procedures for the protection of human subjects.

- **Animal Welfare Requirements**

  The *PHS Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) 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 (IACUC) 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).

- **Promotion or Legalization of Controlled Substances**

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

therapeutic advantage.

- **Dissemination of False or Deliberately Misleading Information**

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

- **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.

- **Restriction of Pornography on Computer Networks**

  NIH appropriations since FY2014 have included the following restriction:

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

  b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities."

- **Trafficking in Persons, 22 US Code 7104**

  Agencies are authorized to terminate awards, without penalty, if the recipient or a subrecipient —

  1. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;
  2. Procures a commercial sex act during the period of time that the award is in effect; or
  3. Uses forced labor in the performance of the award or subawards under the award.

- **Federal Information Security Management Act**

  All information systems, electronic or hard copy, which contain Federal data need to be protected from unauthorized access.

- **Comptroller General Access**

  OT agreements that provide for total government payments in excess of $5,000,000 must include the following clause to provide for Comptroller General access to records.

"To the extent that the total Government payment under this Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any entity that participates in the performance of this Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any entity that has already entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that grants audit access by a Government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement."

APPENDIX 2

LAWS THAT MAY BE INAPPLICABLE TO "OTHER TRANSACTIONS"

This list of laws that apply to procurement contracts, but that are not necessarily applicable to OTs, is provided for guidance only and is not intended to be definitive. To the extent that a particular requirement is a funding or program requirement, or is not tied to the type of instrument used, it would generally apply to an OT, e.g., fiscal and property laws. Each law must be reviewed carefully to ensure it does or does not apply to a particular funding arrangement using an OT. This appendix may be updated periodically, as needed.[1]

1. Sections 202-204 of the Bayh-Dole Act, 35 U.S.C. 202-204 - Prescribes government's rights in patentable inventions made with government funds.

2. Competition in Contracting Act, Pub. L. No. 98-369 (1984), as amended, 10 U.S.C. 2304 and 41 U.S.C. 3301 - Promotes the use of competitive procurement procedures and prescribes uniform government-wide policies and procedures regarding contract formation, award, publication, and cost or pricing data.

3. Contract Disputes Act, Pub. L. No. 95-563 (1987), as amended, 41 U.S.C. 601 et seq. - Provides for the resolution of claims and disputes relating to government contracts.

4. Procurement Protest System, Subtitle D of Competition in Contracting Act, Pub. L. No. 98-369 (1984), 31 U.S.C. 3551 et seq. - Provides legal basis for procurement protests by interested parties to the Comptroller General.

5. 31 U.S.C. 1352. Limitation on the use of appropriated funds to influence certain Federal contracting and financial transactions - Prohibits use of funds to influence or attempt to influence government officials or members of Congress in connection with the award of contracts, grants, loans, or cooperative agreements.

6. Antikickback Act of 1986, 41 U.S.C. 51-58 - Prohibits kickbacks in connection with government contracts; provides civil and criminal penalties.

7. Procurement Integrity Provisions, section 27 of the Office of Federal Procurement Policy Act, 41 U.S.C. 423 - Imposes civil, criminal, and administrative sanctions against individuals who inappropriately disclose or obtain source selection information or contractor bid and proposal information.

8. Service Contract Act, 41 U.S.C. 351 et seq., Walsh Healey Act, 41 U.S.C. 35-45; Fair Labor Standards Act, 29 U.S.C. 201-219 - Provide protections for contractor employees by establishing minimum wage and benefit requirements.

9. Drug-Free Workplace Act of 1988, 41 U.S.C. 701-707 - Applies to contracts and grants.

[1] This list is derived from GAO-05-136, *Homeland Security: Further Action Needed to Promote Successful Use of Special DHS Acquisition Authority* (Dec. 2004), at p.6, Table 1.

10. Buy American Act, 41 U.S.C. 10a-d. Provides preferences for domestic end products in production.

APPENDIX 3

SAMPLE OT AGREEMENT TABLE OF CONTENT