NIH Policy Manual

6325-1 - Clearance of Foreign Contracts, Foreign Subcontracts, and Domestic Contracts or Subcontracts with a Foreign Component

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Approving Official(s): DDM

Release Date: 12/02/2014 ?

Transmittal Notice

1. **Explanation of Material Transmitted:** This Manual Chapter updates guidance regarding policies and procedures for obtaining a clearance prior to awarding a foreign contract, a foreign subcontract, or a domestic contract or subcontract with a foreign component. It also provides updated procedures for clearance of new work modifications to a foreign contract and modifications that extend a foreign contract for 12 months or more. The guidance in this policy applies to contracts and subcontracts for the acquisition of: (1) biomedical and behavioral Research and Development (R&D) and support of biomedical and behavioral R&D; and (2) human materials and/or biological materials. This Chapter provides consistency with current Department of Health and Human Services Acquisition Regulation (HHSAR) requirements and contains minor wording changes. It also revises Section F, Internal Controls, to conform to the latest NIH guidance.

   ***Note: The Foreign Tracking System (FTS), which was used to secure and track State Department clearances, has been retired. A new online system referred to as the Foreign Award and Component Tracking System (FACTS) has been established for tracking all NIH contracts that involve an international component, and when necessary, for requesting and documenting clearances from the Department of State.**

2. **Filing Instructions:**

   Remove: NIH Manual Chapter 6325-1, dated 02/05/2001.
   Insert: NIH Manual Chapter 6325-1, dated 12/02/2014.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.

- NIH Manual System: contact the Division of Management Support, OMA, on 301-496-2832, or enter this URL: http://oma.od.nih.gov/public/MS/manualchapters/Pages/default.aspx.

A. Purpose

This Manual Chapter updates guidance regarding policies and procedures for obtaining a clearance prior to awarding a foreign contract, a foreign subcontract, or a domestic contract or subcontract with a foreign component. It also provides updated procedures for clearance of new work modifications to a foreign contract and modifications that extend a foreign contract for 12 months or more. The guidance in this policy applies to contracts and subcontracts for the acquisition of: (1) biomedical and behavioral Research and Development (R&D) and support of biomedical and behavioral R&D; and (2) human materials and/or biological materials. This Chapter provides consistency with current Federal Acquisition Regulation (FAR) and the Fogarty International Center (FIC) requirements and contains minor wording changes. It also revises Section F, Internal Controls, to conform to the latest NIH guidance.

B. Background

FAR Part 25 and the FIC at the NIH, in concert with the Department of State, provide guidance on awarding foreign contracts, subcontracts, or domestic contracts/subcontracts with a foreign component, and obtaining the necessary clearances from the Department of State.

This Manual Chapter does not apply to actions awarded using the procedures prescribed in FAR Part 13, Simplified Acquisition Procedures.

For procedures pertaining to loan/donation and transportation of NIH property to foreign countries, refer to NIH Manual 26101-25-2, "Personal Property Management Guide," Appendix 8.

C. Policy

The U.S. Department of State (DOS) has authority under the Foreign Relations Authorization Act, to examine all international U.S. Government activities for its impact on national security and foreign policy. For the purpose of ensuring that activities supported outside the United States are consistent with the overall foreign policy objectives of the United States Government, the Department of State requires clearance of proposed R&D projects and projects in support of R&D conducted in a foreign country, and the proposed collection of human and other biological materials from sources in a foreign country. The Division of International Relations (DIR), FIC, must review and approve Institute/Center (IC) clearance documents prior to submission to the Department of State. To request DOS concurrence for international activities related to NIH contracts, FIC collects and forwards information to DOS regarding proposed NIH contracts to foreign institutions, and proposed NIH contracts that involve a foreign component, as defined in this chapter. FIC/DIR transmits DOS concurrence requests through FACTS to designated U.S. Embassy contacts identified by DOS.

A foreign contract may be awarded only after the NIH has documented clearance by the Department of State. Each RFP must indicate that this clearance is mandatory.

The Department of State clearance will be valid for the performance period of the foreign contract.

If, at any time during contract performance, a new work requirement is added, Department of State clearance must be obtained prior to the award of the requirement. In addition, Department of State clearance may be required prior to awarding a modification to extend a foreign contract for 12 months or more (see Section F.1.d, below).

D. References

1. FAR Part 25, Foreign Acquisition
2. HHSAR 370.3, Acquisitions Involving Human Subjects
3. HHSAR 370.4, Acquisition Involving the Use of Laboratory Animals
4. Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996
5. NIH Manual Chapter 1340-1, Permits for the Import, Transfer, or Export of Biological Materials
6. NIH Manual Chapter 1895, Coordination of International Activities
7. NIH Manual Chapter 6307-3, Special Clearance and Other Acquisition Procedures
8. NIH Manual Chapter 7410, Review And Documentation Of Protections For Human Subjects In Extramural Grant Applications And Research And Development Contract Proposals
9. NIH Manual Chapter 1743, Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule

E. Definitions

1. Foreign Contract: A contractual agreement between the NIH and any party organized and existing under the laws of other than the United States, its territories, or possessions. The term "foreign contract" refers to any foreign contract, foreign subcontract, or domestic contract or subcontract with a foreign component, awarded for the purpose of acquiring:

    a. biomedical or behavioral R&D, and projects in support of biomedical or behavioral R&D; or
    b. human products, such as blood products or biopsy material, or biological materials.

2. Foreign Subcontract: An identifiable subcontract awarded to a source in a foreign country as part of an NIH prime contract with a domestic or foreign organization.
3. Domestic Contract or Subcontract with a Foreign Component: An NIH contract or subcontract awarded to a domestic source, in which a part of the contract or subcontract

funds or effort is directed to a source in a foreign country

4. A foreign component is defined as:

   The performance of any significant scientific element or segment of a project outside of the United States, either by the contractor or by a subcontracted researcher employed by a foreign organization, whether or not contract funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the contract that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:

   - collaborations with investigators at a foreign site anticipated to result in co-authorship;
   - use of facilities or instrumentation at a foreign site; or
   - receipt of financial support or resources from a foreign entity.

   Foreign travel for consultation is not in itself considered a foreign component.

F. Procedures

1. General

   a. The contracting officer (CO) shall ensure that all necessary reviews and clearances pertinent to each acquisition subject to the requirements of this Manual Chapter have been obtained.
   b. The program office must review each proposed acquisition to ensure that:

      i. the proposed work is timely and essential to the achievement of the NIH/IC program objectives; and
      ii. the proposed work should be performed by a foreign contractor(s).

   c. Requests for Department of State clearance must be submitted at least 45 calendar days in advance of the effective date of the proposed award. However, for a new competitive award, the request should not be initiated until after source selection. In the case of a noncompetitive action, the request may be submitted for review and clearance concurrent with the routing of the Justification for Other than Full and Open Competition for review and approval.
   d. Proposed time extensions of one year or more must be entered into the Foreign Activities and Component Tracking System (FACTS). If the DIR/FIC determines that State Department clearance is required, the IC shall follow the procedures set forth in Section F.2, below.

2. Clearance Documents

a. For all actions requiring Department of State clearance, the CO must use the web-based Foreign Activities and Component Tracking System (FACTS) to submit summaries of proposed NIH-supported research. Staff will need a NIH Single-Sign-On (SSO) User Name and Password, or a Smart Card and Personal Identification Number (PIN) to access the FACTS.
b. NIH staff with access to the FACTS can enter clearance requests, check the status of a request, and review and track funds issued to foreign sites.
c. In order to access the FACTS, the CO must request appropriate user role from their IC's FACTS ERA coordinator. The CO will then go to https://public.era.nih.gov/facts and login using the NIH Single-Sign-On (SSO) User Name and Password, or the Smart Card and Personal Identification Number (PIN). Before entering information on the foreign site(s), the CO will be able to review FACTS User Guides that are available at the following ERA Intranet website: http://inside.era.nih.gov/FACTS/user_guide.cfm. The FACTS Institutes/Centers/Contracts User Guide gives step-by-step information on how to enter site information and submit for clearance.
d. Information that should be included in the clearance request entered into the FACTS includes, but may not be limited to:

    i. Collaborator Name
    ii. Foreign Institution Name
    iii. Foreign Institution Address
    iv. Estimated total cost, if any, of foreign component, at the Country-level
    v. a description, in lay terms, of the scope and objectives of the research to be performed in the foreign country, or a description of the materials to be acquired;
    vi. a statement justifying the need to acquire research services or supplies from a
    party in a foreign country, or an explanation of the need for an extension or expansion of the existing requirement;
    vii. if the project involves the use of human subjects, an explanation of how human subjects will be involved, and a statement indicating that the requirements of HHSAR 370.3 and NIH Manual Chapter 7410, will be followed. Where conflicts exist between HHSAR 370.3 and NIH Manual Chapter 7410, the guidance at the HHSAR will supersede the guidance in the NIH Manual Chapter;
    viii. if the project involves the use of animals, an explanation of how animals will be involved, and a statement indicating that the requirements of HHSAR 370.4 and the PHS Policy on the Human Care and Use of Laboratory Animals will be followed;

3. Except for Brazil, India and China, clearance requests for all non-prohibited countries, i.e., those approved by the U.S. Department of State and listed on the FACTS menu, will default to an "approved" status 14 calendar days from the date of FIC submission

to the relevant embassy queue. FIC is available to assist with clearances for Brazil, India and China, each of which requires review by the applicable foreign government and/or the appropriate U.S. official at Post. The POC can check the status of all clearances by searching FACTS to see the submission and approval dates.

4. Actions by the Fogarty International Center

    a. The DIR/FIC will review the clearance documents to determine the:

        i. adequacy of the documentation in satisfying the criteria set forth in F.1.b. above;
        ii. relationship of the project/activity to existing or proposed formal or informal inter-governmental arrangements on biomedical or other health-related research, and insofar as possible, the effect on the NIH's overall relationship with the biomedical community of the country concerned; and
        iii. adequacy of the documentation for the Department of State/Embassy review for determining conformance of the project with the foreign policy of the United States.

    b. If the above conditions are satisfactory, the DIR/FIC will forward the clearance request to the relevant embassy for approval via the FACTS. If there are questions, the DIR/FIC will contact the person listed as POC on the FACTS clearance request to obtain additional information before the request is forwarded.
    c. The DIR/FIC will be responsible for follow-up with the Department of State/Embassy to ensure prompt action.
    d. Additional Information

        Additional information about clearance procedures may be obtained from:

        Division of International Relations
        Fogarty International Center
        Building 31, Room B2C11 - MSC 2220
        Phone Number: 301-496-4784

G. Records Retention and Disposal

All records pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743,"Keeping and Destroying Records," Appendix 1, "NIH Records Control Schedules" (as amended). These records must be maintained in accordance with current NIH Records Management and Federal guidelines. Contact your IC Records Liaison or the NIH Records Officer for additional information.

H. Internal Controls

The purpose of this Manual Chapter is to provide updated guidance to contracting officers regarding the obtaining of clearances for foreign contracts, foreign subcontracts, and domestic contracts or subcontracts with a foreign component.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:** The Division of Acquisition Policy and Evaluation, Office of Acquisition Management and Policy, Office of Acquisition and Logistics Management, Office of Management, Office of the Director (DAPE/OAMP/OALM/OM/OD) is responsible for the method used to ensure that internal controls are implemented and working.
2. **Frequency of Reviews:** On-going
3. **Method of Review:** DAPE/OAMP/OALM will maintain appropriate oversight through reviews of the Offices of Acquisitions' (OAs) presolicitation and preaward contract files conducted by the NIH Board of Contract Awards (BOA). The NIH BOA reviews a percentage of contract actions from each OA. Issues identified by the Board are provided to the OA for corrective action. When repetitive issues are identified, these are brought to the attention of the Acquisition Management Committee, which is responsible for addressing and resolving common acquisition issues. In addition, the Head of the Contracting Activity (HCA) is routinely apprised of any difficulties in OA implementation of policy. Depending on the nature and extent of the problem, the HCA may recommend additional policy guidance or training of contract staff.
4. **Review Reports are sent to:** the appropriate Director, Office of Acquisition and Logistics Management (OALM), for either immediate corrective action or remedial action within 30 days.