

NIH POLICY MANUAL
6325-1 CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND
DOMESTIC CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT
Issuing Office: OA/OAMP/DAPE 301-496-6014
Release Date: 02/05/2001

1. **Explanation of Material Transmitted:** This Manual Chapter is being revised to (a) delete the NIH Form 1820 as an Appendix and add the URL for accessing this form; (b) change all references from OCM to OAMP; (c) change all references from PORA to HCA; and (d) make other minor editorial corrections.

2. **Filing Instructions:**

Remove: NIH Manual 6325-1, dated 04/14/00

Insert: NIH Manual 6325-1, dated 02/05/2001

PLEASE NOTE: For information on:

? content of this chapter, contact the Division of Acquisition Policy and Evaluation, OAMP, OA, on (301) 496-6014.

? NIH Manual System, contact the Division of Management Support, OMA, on (301) 496-2832.

? on-line information, use:

<http://www3.od.nih.gov/oma/manualchapters>

- A. Purpose
- B. References
- C. Definitions
- D. Policy
- E. Procedures
- F. Actions by Fogarty International Center
- G. Additional Information
- H. Records Retention and Disposal
- I. Management Controls

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

- A. PURPOSE: This chapter provides 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 covers procedures for clearance of new work modifications to a foreign contract and modifications that extend a foreign contract for 12 months or more. The requirements and procedures set forth in this policy apply 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 does not apply to actions awarded using the procedures prescribed in the Federal Acquisition Regulation (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." (See hard copy for Appendix VIII.)

B. REFERENCES:

1. Public Health Service Policy on Humane Care and Use of Laboratory Animals
2. NIH Manual 1340-1 - Permits for Import or Export of Biological Materials
3. NIH Manual 1895 - Coordination of International Activities
4. NIH Manual 26101-25-2, Personal Property Management Guide
5. NIH Manual 6307-3, Special Clearance and Other Acquisition Procedures
6. NIH Manual 6380-1 - Contracts Involving Human Subjects

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

7. NIH Manual 6380-2/4206 - Responsibility for Care and Use of Animals
8. Form NIH 1820, Notification of Proposal to Make an Award

C. DEFINITIONS

1. A foreign contract is 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 purposes 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. A foreign subcontract is 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. A domestic contract or subcontract with a foreign component is 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.

D. 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,

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

and the proposed collection of human and other biological materials from sources in a foreign country. The Division of International Relations (DIR), Fogarty International Center (FIC), will review and approve Institute/Center (IC) clearance documents prior to submission to the Department of State.

A foreign contract may be awarded only after obtaining approval of the Director, DIR/FIC, and clearance by the Department of State.

The DIR/FIC approval and the Department of State clearance will be valid for the performance period of the foreign contract.

If at any time during performance, a new work requirement is added, DIR/FIC approval and the Department of State clearance must be obtained prior to the award of the requirement. In addition, DIR/FIC review and, depending upon the circumstances of the particular case, Department of State clearance, may be required prior to issuing a modification to extend a foreign contract for 12 months or more (see E.1.d.).

E. PROCEDURES

1. General

- a. The contracting officer 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:
 - (1) the proposed work is timely and essential to the achievement of the NIH/IC program objectives; and
 - (2) the proposed work should be performed by the foreign contractor(s).

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

- c. Requests for DIR/FIC approval and the Department of State concurrence must be submitted at least 45 calendar days in advance of the effective date of the proposed award. However, for a new 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. The contracting officer must notify the DIR/FIC of proposed time extensions of one year or more. The DIR/FIC will request pertinent information from the IC, and promptly advise the contracting officer as to whether State Department clearance is required. If the DIR/FIC determines that State Department clearance is required, the IC shall follow the procedures set forth in E.2., below.

2. Clearance Documents

For all actions requiring DIR/FIC review and clearance from the State Department, the contracting officer will prepare and forward to the DIR/FIC (under cover of a Routing and Transmittal Slip) an original and one copy of:

- a. A completed Form NIH-1820, Notification of Proposal to Make an Award (Refer to URL: <http://forms.cit.nih.gov/adobe/misc/NH1820.PDF>.) Check the block, "New Foreign Clearance," for new actions. For all other actions, check the block "Renewal of Foreign Clearance." For competitive actions, include on the Form in section entitled, "Research Objectives," the legend "Source Selection Information-See FAR 3.104."

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

The items listed below in (1)-(6) should be included in the Research Objectives section of this form, continuing if necessary, on a separate page:

- (1) 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;
 - (2) 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;
 - (3) 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 the NIH Manual Chapter 6380-1 will be followed;
 - (4) if the project involves the use of animals, an explanation of how animals will be involved, and a statement indicating that the requirements of the NIH Manual Chapter 6380-2 and the PHS Policy on the Humane Care and Use of Laboratory Animals will be followed;
 - (5) evidence of permits for import or export of biological materials; and
 - (6) other pertinent information when known, e.g., use of consultants, subcontractors.
- b. Curricula vitae and pertinent bibliographies for each domestic and foreign principal investigator, and all other co-investigators proposed for the contract and/or subcontract.

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

F. ACTIONS BY THE FOGARTY INTERNATIONAL CENTER

1. The DIR/FIC will review the clearance documents to determine the:
 - a. adequacy of the documentation in satisfying the criteria set forth in E.1.b. above;
 - b. 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
 - c. adequacy of the documentation for the Department of State review for determining conformance of the project with the foreign policy of the United States.
2. If the above conditions are satisfactory, the DIR/FIC will forward the necessary documents to the Department of State for concurrence. If there are questions, the DIR/FIC will contact the contracting officer to obtain additional information.
3. The DIR/FIC will prepare a cable summarizing the proposed contract and will forward the cable and the completed Form NIH-1820 to the Department of State. The Department of State is responsible for transmitting the pertinent information to the relevant United States Embassy.

The DIR/FIC review normally requires seven working days. Embassy review and State Department clearance require approximately four weeks.

4. The DIR/FIC will be responsible for follow-up with the Department of State to ensure prompt action.

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

5. If there is no objection to a proposal to make an award, the DIR/FIC will forward the signed Form NIH 1820 to the contracting officer.

G. 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

Division of Acquisition Policy and Evaluation
Office of Acquisition Management and Policy
Building 6100, Room 6C01 - MSC 7540
Phone Number: 301-496-6014

H. RECORDS RETENTION AND DISPOSAL

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of the NIH Manual Chapter 1743, "Keeping and Destroying Records," Appendix 1, *NIH Records Control Schedule*, Item 2600-A-4, Routine Procurement Files.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. *These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.*

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

All e-mail messages are considered Government property, and if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of the Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to Congressional Oversight Committees, if requested, and are subject to the Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. MANAGEMENT CONTROLS

The purpose of this manual issuance is to provide procedures for obtaining FIC review and State Department clearance of foreign contract awards and certain types of modifications to those contracts.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter: The Division of Acquisition Policy and Evaluation (DAPE), Office of Acquisition Management and Policy (OAMP), is accountable for the method used to ensure that management controls are implemented and working.
2. Frequency of Reviews: Ongoing
3. Method of Review: DAPE/OAMP will maintain appropriate oversight through reviews of IC presolicitation and preaward contract files conducted by the NIH Board of Contract Awards. The NIH Board of Contract Awards reviews a percentage of contract actions from each IC. Issues identified by the Board are provided to the IC for corrective action. When repetitive issues are identified,

DATE: 02/05/2001

REPLACES: 04/14/2000

ISSUING OFFICE: OA/DAPE/OAMP (301-496-6014)

CLEARANCE OF FOREIGN CONTRACTS, FOREIGN SUBCONTRACTS, AND DOMESTIC
CONTRACTS OR SUBCONTRACTS WITH A FOREIGN COMPONENT

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 IC 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: The HCA is routinely notified of problems and takes necessary action to resolve them.