NIH Policy Manual

1895 - Coordination of International Activities

Issuing Office: FIC Phone: (301) 496-4784

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Transmittal Notice

1. **Explanation of Material Transmitted:** This revision includes updates the policy and procedural responsibilities whereby the John E. Fogarty International Center (FIC), coordinates and facilitates international activities on behalf of the National Institutes of Health (NIH) in cooperation with other Institutes, Centers, and Offices (ICOs).

2. Filing Instructions:

Remove: NIH Policy Manual, Chapter 1895, dated 08/19/1983

Insert: NIH Policy Manual, Chapter 1895, dated 02/27/2024

PLEASE NOTE: For information on:

- Content of this chapter, contact the Division of International Relations Point of Contact in the issuing office listed above.
- NIH Policy Manual, contact the Division of Compliance Management, (OMA) on 301-496-4606, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx.

A. Purpose

This chapter explains the policies and procedural responsibilities whereby the John E. Fogarty International Center (FIC), through its Division of International Relations coordinates international activities on behalf of the NIH in cooperation with NIH Institutes, Centers and Offices (ICOs).

B. Scope

FIC covers key NIH-wide responsibilities, namely liaison for and coordination of NIH-wide international activities usually focused on low-and middle-income countries.

Within FIC, the Division of International Relations (DIR) serves as a central international relations office at NIH for all global regions and for activities outlined in this chapter, and

maintains an overview of key international engagements at NIH. These functions are conducted in close collaboration with the NIH ICOs. While DIR is a component of the FIC, its role is focused primarily on NIH-wide international coordination and facilitation, which includes activities conducted by the FIC as one of the NIH ICOs.

The policies and procedures in this chapter primarily apply to relevant multi-ICO international activities supported and conducted by the ICOs, including the NIH Office of the Director. Unless specifically requested otherwise by any ICO, FIC is responsible for international interactions, processes that include HHS/OGA and/or Department of State that pertain to NIH at-large or NIH-wide programs and that are not the sole responsibility of a specific ICO. FIC serves as an initial point of contact to provide an operational overview of NIH and how NIH engages internationally to determine specific interests of international organizations so that more detailed discussions can be scheduled with relevant ICOs which will then be engaged based on their mission/priorities.

C. Statutory Authority

The mission of FIC is set out in the Public Health Service Act, Section 482, 42 U.S.C. §287b:

- Facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally.
- Provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences.
- Provide post-doctorate (sic) fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries.
- Coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and
- Receive foreign visitors to the National Institutes of Health.

D. Policy

FIC, through DIR, provides coordination and liaison for NIH international relevant requests and inquiries that pertain to more than one ICO or require a response by NIH as an agency of the U.S. Government, and also engages with individual ICOs if requested. Serving as the central NIH point of contact for international engagement requires FIC to have a frequent connection with, request input from, and share information with the various NIH ICOs. This allows FIC to facilitate communication across NIH. FIC specifically provides expertise and guidance for international research policy questions and international arrangements, creates platforms for discussion, coordinates and facilitates multi-ICO or NIH-wide visits by foreign delegations and organizations, and coordinates substantive ICO input on relevant U.S. Government interagency, international, and multilateral arrangements. Further, FIC serves as the principal NIH liaison with U.S. Government agencies engaged in international health research, foreign embassies in the United States, U.S. Embassies in foreign countries, and

scientists, institutions, and funding organizations around the world.

E. Roles and Responsibilities

1. John E. Fogarty International Center (FIC) – Division of International Relations

a. International Cooperation and Engagement

FIC reviews NIH international bilateral and/or multilateral collaborative program agreements, recommends policies, represents NIH in discussions about processes and procedures for review of all international agreements with HHS and Department of State, and recommends approaches and content of international arrangements.

FIC facilitates NIH ICO participation in Joint Committee Meetings with a focus on health research that is part of U.S. Science and Technology Agreements with a foreign country and represents, where appropriate, the NIH organization.

FIC provides summaries of the status of NIH international activities in response to requests for information to the relevant NIH Offices of the Director. FIC also provides summaries, drawn from public databases, to ICO Directors, staff of the Department of Health and Human Services (DHHS), other Federal agencies, and foreign delegations and Embassy staff through appropriate channels. FIC may produce NIH internal reports on NIH international activities and NIH's international scientific footprint, which will be shared with the ICOs and the NIH Office of the Director, as appropriate.

FIC also serves as an information resource to the Director, NIH, and the ICOs on the organization, funding, research trends, and capabilities of foreign countries and their major biomedical research and funding institutions with which the NIH shares or may share collaborative research interests.

b. Coordination of NIH International Activities

FIC serves as the principal multi-ICO point of contact with the Office of Global Affairs (OGA), Office of the Secretary, DHHS; other Public Health Service (PHS) and Federal agency international offices; the Department of State; U.S. missions abroad; foreign missions in the United States; foreign government agencies and officials; and international organizations, and, when delegated, represents NIH on relevant international topics with the White House Office of Science & Technology Policy (OSTP), National Security Council and other White House convened working groups.

FIC may participate with ICO international representatives at meetings involving the international interests of NIH or it may, on request, represent individual ICOs at such meetings.

FIC coordinates responses from ICOs to the OGA for annual multilateral events, such as the WHO Executive Board and the World Health Assembly. FIC provides feedback to NIH ICOs regarding relevant international policy changes and outcomes.

c. Provision of Liaison with ICO International Representatives

FIC will share relevant information with ICO international representatives, discuss perspectives and plans regarding international activities and request input into issues that affect the conduct of NIH international activities and the implementation of related policies, procedures and programs.

FIC also shares pertinent scientific and technical information with the larger NIH community interested or engaged in international research through appropriate interest groups.

d. Negotiation and Clearance of International Arrangements and Commitments

FIC provides policy guidance to the ICOs in the negotiation of arrangements for cooperation with foreign institutions, organizations and agencies, or multinational organizations.

FIC develops and routes all arrangements on behalf of NIH, when they include multiple ICOs, or when requested by a specific ICO, for required review and clearances through OGA and the Department of State.

For binding arrangements that include multiple ICOs, for binding arrangements that are on behalf of NIH, or when individual ICOs request FIC assistance for binding agreements, FIC applies, through OGA, to the Department of State for Circular 175 (C-175) authority to negotiate an agreement that is covered under the Department of State's C-175 authority.

FIC will consult with the ICOs concerning international matters that may involve the use or commitment of ICO resources or that may be within the area of interest or responsibility of an ICO. FIC does not make commitments for resources or funds on behalf of an ICO.

e. Department of State Review of Foreign Grants and Contracts

On behalf of the Director of NIH, FIC is responsible for requesting and documenting, as appropriate, clearances from the Department of State through the Foreign Award and Component Tracking System (FACTS) for all NIH grants and contracts that involve a foreign component. Foreign components are defined in the NIH Grants Policy Statement Chapter 16.2 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components. ICO procedures for implementing this requirement are outlined in NIH Manual Chapter 6325-1 and Chapter 6307-3.

FIC serves as the principal point of contact for the Department of State staff at U.S. Embassies abroad for issues arising from FACTS related State Department Clearance requests.

f. Coordination of NIH Responses to Inquiries on International Matters

FIC coordinates NIH positioning and responses to urgent global issues and inquiries about international matters. These inquiries may be directed to the NIH from the OGA, other Federal agencies, the Congress (in coordination with the NIH Office of Legislative Policy and Analysis), the media (in coordination with relevant NIH OD or ICO communications office), the public, multinational organizations, or foreign entities.

FIC advises and consults with the ICOs concerning any inquiries or requests concerning international matters that involve or affect the NIH as a whole. FIC provides relevant ICOs with NIH summary responses to inquiries concerning international matters, where appropriate.

g. Serving as the Focal Point for Coordination of Foreign Visitors to the NIH -

FIC advises the Director, NIH, and the ICOs of pending visits to the NIH by high-level foreign visitors and delegations and arranges appropriate programs for these visitors.

h. Coordination of Relevant Bilateral Scientific Programs -

FIC may facilitate the establishment and execution of individual intramural bilateral formal training and exchange programs, as well as relevant extramural co-funding programs that involve more than one NIH ICO. As requested, FIC will serve as Secretariats and principal NIH points of contact for the foreign partnering organization.

2. NIH Institutes, Centers, and Offices (ICOs)

a. Participation in NIH International Activities

The ICOs are to inform FIC of invitations to, or plans by staff to participate in: (1) meetings that are called by the OGA, other PHS and Federal international offices, the Department of State, U.S. missions abroad, foreign missions in the U.S., foreign government agencies and officials, and international organizations; and (2) meetings that may have a bearing on international activities by other NIH ICOs or NIH as an organization, the DHHS, or the Federal Government.

The ICOs are to inform FIC of significant plans, decisions, communications, contacts, or events with foreign governments or governmental organizations that may have an impact on the NIH or U.S. relations with foreign organizations and countries. Such events include the initiation or cancellation of bilateral or multilateral international programs, conferences, receptions and exchanges of important individuals or delegations. This ensures that FIC can advise the ICOs on similar discussions or interactions taking place at NIH to assure cohesive approaches or collaborative opportunities with other ICOs.

b. Provision of Liaison with ICO International Representatives -

ICOs will designate appropriate staff as their international representatives who will serve as FIC's contact person for action requests on an ongoing basis.

c. Negotiation and Clearance of International Arrangements and Commitments

The ICOs notify FIC of any executed bilateral or multilateral arrangements between the ICO and foreign organizations and whether these arrangements have been reported to HHS/OGA. ICO notification excludes arrangements such as Material Transfer Agreements or other technical and working-level documents.

d. Coordination of NIH Responses to Inquiries on International Matters -

The ICOs are to advise and consult with FIC concerning any inquiries or requests concerning international matters that involve or affect the NIH as a whole or multiple ICOs. This is to ensure that where requested, a comprehensive and representative NIH perspective is provided.

e. ICO Foreign Visitors to the NIH -

The ICOs are to advise FIC of requests or plans for visits by high-level representatives of foreign governments or agencies.

F. References

- 1. 22 U.S.C. 2102; 42 U.S.C. 242; 42 U.S.C. 241(a)(4) (PHS Act, Section 301(a)(4)).
- 2. PHS Act Section 482, 42 U.S.C. 287b
- 3. <u>Public Law 95-426</u>, "Title V; Science, Technology and American Diplomacy" (Foreign Relations Authorization Act, FY 1979).
- 4. 22 C.F.R. Part 181.
- 5. Federal Register, March 16, 1968 (33 FR 4641, Part 4), Statement of Organization and Functions of the Fogarty International Center.
- 6. Federal Register, June 22, 2011 (76 FR 36539), "Statement of Organization, Functions, and Delegations of Authority" Office of the Secretary, HHS.
- 7. Federal Register, July 13, 1981 (46 FR 35917), "Coordination and Reporting International Agreements," Office of the Secretary, Department of State.
- 8. Federal Register, September 8, 2006 (71 FR 53007), "Publication, Coordination and Reporting of International Agreements, Amendments" Office of the Secretary, Department of State.
- 9. <u>Department of State, Foreign Affairs Manual 11 FAM 721, "Circular 175 Procedure"</u> updated May 26, 2006.
- 10. <u>NIH Manual Chapter 54104</u>, NIH Grants Involving Foreign Institutions and International Organizations.
- 11. <u>NIH Manual Chapter 6325-1</u>, Clearance of Foreign Contracts, Foreign Subcontracts, and Domestic Contracts or Subcontracts with a Foreign Component.
- 12. NIH Manual Chapter 6307-3, Special Clearance and Other Acquisition Procedures.

- 13. NIH Manual Chapter 1743, Managing Federal Records.
- 14. NIH FACTS Overview
- 15. <u>NIH Grants Policy Statement, Chapter 16</u>: Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components