NIH Policy Manual

2300-308-4 - NIH On-Site Research Collaborator Policy

Issuing Office: OD/OIR **Phone:** (301) 496-1921

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Transmittal Notice

1. **Explanation of Material Transmitted:** This new issuance communicates the policy and provisions for on-site Research Collaborators (RCs) (clinical and non-clinical) at the NIH Intramural Research Program (IRP) and establishes the conditions under which a Research Collaborator may utilize NIH facilities.
2. **Filing Instructions:**
   Insert: NIH Manual 2300-308-4, dated 05/21/2013.

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Management Support, OMA on 301-496-2832, or enter this URL: https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx.

A. Purpose and Definition

This chapter communicates the policy and provisions for on-site Research Collaborators (RCs) (clinical and non-clinical) at the NIH Intramural Research Program (IRP) and establishes the conditions under which a Research Collaborator may utilize NIH facilities.

On-Site Research Collaborators (RCs) include but are not limited to scientists, engineers, physicians and other scientific or health care providers who are engaged in research collaborations with the NIH intramural research program (IRP) staff and are authorized by NIH to engage in scientific studies and investigations with IRP staff using NIH facilities. RCs further collaborative research projects with NIH by interacting with IRP investigators and utilizing equipment and other resources located within NIH IRP facilities that are otherwise unavailable to or not easily accessible by them. There are two kinds of RCs: (1) those who provide no direct services to NIH; and (2) those who, as appointees or detailees under the Intergovernmental Personnel Act (IPAs), provide some services to NIH and function, in part, under the supervision and control of the NIH. Specific permissible activities of a RC will vary, depending upon the mechanism used to bring the person to the NIH and specific program needs. RC agreements must be documented in writing and all RCs must sign a "Research Collaborator Agreement" (see Appendixes 1-3).

RCs cannot be financially compensated by the IRP for their collaborative efforts, but they may be recipients of extramural NIH grants and fellowships, and they may receive funds from commercial collaborators (for instance, as part of a Cooperative Research and Development Agreement) or other sources outside of NIH. RCs who are on IPA agreements may receive funding from the IRP consistent with NIH policy for IPAs, found at NIH Manual 2300-334-1 Assignments Under the Intergovernmental Personnel Act (IPA),

B. Legal Authority

Section 301(a)(2) of the Public Health Service Act authorizes the Secretary to "...make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study." Under section 402 of the Public Health Service Act, the NIH Director may establish and implement general policies for the operation of NIH programs and activities. 45 CFR Part 9, "Use of DHHS Research Facilities by Academic Scientists, Engineers, and Students," and DHHS General Administration Manual Chapter 13-10, state DHHS policy on making Department facilities available to the scientific community. Public Health Service General Administration Manual, PHS 13-10, "Use of Research Facilities by Academic Scientists, Engineers, and Qualified Students", states PHS policy and procedures pertaining to the use of research facilities.

C. Approval Authority

IC Scientific Director (or designee; but may not re-delegate authority)

D. Eligibility Requirements

NIH research facilities are available to non-NIH employees, such as NIH grantees or other researchers who have funding from non-IRP sources, **and** who are engaged in a documented research collaboration with the NIH IRP. A **documented research collaboration** is defined as a collaboration where the scope and goals of the research project are described in writing and approved by the Scientific Director or higher authority for an NIH Institute or Center (IC). Examples of such documentation include but are not limited to: a Cooperative Research and Development Agreement (CRADA), a Memorandum of Understanding (MOU), an Interagency Agreement (IAA), a Clinical Trial Agreement or approved clinical research protocol or other written research agreements, provided that such agreement(s) contain the required elements set forth in this chapter.
The following individuals are not eligible to be RCs:

- Scientists at NIH for the purpose of informal observation or discussions unrelated to an established research collaboration;
- Scientists at NIH for less than 1 week;
- Individuals under 18 years of age;
- Individuals who are not covered by a documented research collaboration with NIH IRP staff; and

- Individuals who are covered by one of the following NIH programs or appointment mechanisms:
    - IRTA (NIH Manual 2300-320-7);
    - Visiting Fellows (NIH Manual 2300-320-3);
    - Special Volunteers (NIH MAnual 2300-308-1);
    - Guest Researchers (NIH MAnual 2300-308-1); and
    - Contractors.

E. Policy Requirements

FOR ALL RCs

1. **Citizenship.** RCs are not required to be U.S. citizens or U.S. permanent residents. However, non-immigrant foreign nationals (i.e., non-US citizens or permanent residents) must be cleared by the Division of International Services (DIS), Office of Research Services (ORS), NIH, in order to permit them to collaborate in research in NIH facilities. Such clearance is required before the on-site research collaboration may commence. (See also Section M on Visas).
2. **Employing Organization/NIH Agreement.** The documented research collaboration agreement must include reference to a RC and delineate the roles and responsibilities of a RC in the research collaboration. The NIH IC and the RC's employing institution must execute a written agreement documenting the research collaboration and referencing the details of the on-site collaboration arrangement. For RCs who are not IPAs, the employing institution does not relinquish supervision or control over the RC's activities while the RC is at NIH.
3. **Investigative Requirements.** The same tests of character, reputation, and fitness applicable to regular Federal employees should be considered when accepting RCs.
4. **Medical Requirements.** RCs must meet Medical Requirements in accordance with NIH Manual 2300-339-2, Medical Qualifications Determinations.
5. **Health Insurance.** RCs, save certain IPA appointees, are not eligible for health insurance coverage under the Federal Employees Health Benefits Program. Those who do not have adequate health insurance must obtain immediate coverage that is substantially equivalent to the Federal Employees Health Benefits Plan and show proof of coverage prior to beginning an assignment. NIH may not purchase health insurance for RCs. RCs who fail to obtain adequate health insurance coverage will be denied the use of NIH facilities. Furthermore, those sponsored as J-1 Exchange Visitors who willfully fail to obtain and maintain the minimum health insurance coverage (for themselves and any J-2 dependents) required by the United States Department of State (DOS) will be deemed in violation of J-1 regulations and may be terminated by DIS, ORS as a participant in the exchange visitor program.
   RCs are not covered by the Federal Employees Compensation Act and are responsible for assuring they have coverage for work-associated injuries or illnesses.
6. **Conflict of Interest Review.** At the discretion of the NIH IRP collaborator or SD, proposed RC collaboration agreements should be reviewed by the IC Deputy Ethics

Counselor for potential COI before they are executed. Agreements like CRADAs, which have established COI review processes, may not need such additional review. All RCs who are NIH grantees are required to be in compliance with the recently issued NIH Financial Conflict of Interest regulation applicable to investigators and their institutions (see:http://grants.nih.gov/grants/policy/coi/coi_faqs.htm). RCs who are detailed or appointed under the IPA are subject to Federal statutes and regulations on conflict of interest and ethical conduct. RCs who are IPA appointees are also subject to the HHS NIH-specific ethical conduct requirements.

7. **Documentation Requirements.** All documents specifying the terms, conditions, and limitations of a RC's status, together with the Research Collaborator Agreement document (i.e., Appendix 1- Research Collaborator Agreement for use with non-CRADA research collaboration, Appendix 2 – Research Collaborator Agreement for use with a CRADA, or Appendix 3 – Research Collaborator Agreement for use with "Opportunities for Collaborative Research and the NIH Clinical Center UO1.") should be filed and maintained in accordance with established IC policy.

   Non-immigrant foreign national RCs must be cleared by the DIS, ORS, before the assignment may commence. In addition to the above required documentation, ICs must also submit a request to the DIS for clearance. Document requirements can be located on the DIS web site (http://dis.ors.od.nih.gov/forms/01_forms.html). The IC must submit a request to the DIS in accordance with the DIS processing times (http://dis.ors.od.nih.gov/advisories/techadvis_no01.html).

ADDITIONAL REQUIREMENTS FOR CLINICAL RCs

1. **Patient Contact.** Consistent with applicable PHS policy, RCs who will engage in direct patient care activities in NIH IRP facilities must have and maintain current valid professional licensure; have their professional credentials reviewed; and obtain clinical privileges consistent with requirements specified by the Clinical Center or responsible IC. Any patient contact by a non-immigrant foreign national RC must be consistent with visa provisions and authorized by the DIS, ORS (see also Section M on Visas).
2. **Medical Executive Committee Review (MEC).** RCs who may be providing clinical care to patients in NIH facilities should have their clinical credentials approved by the MEC or other credentialing entity recognized by the Deputy Director for Intramural Research. In addition, any patient contact by a non-immigrant foreign national RC must be consistent with visa provisions and authorized by the DIS, ORS. (See also Section M on Visas).
3. **Proof of Malpractice Coverage.** RCs engaged in patient contact in NIH facilities (except RCs who are IPAs) must provide proof of malpractice coverage in the amount of $1 million per occurrence and $3 million in the aggregate.
4. **Serving as a Principal Investigator (PI) on a clinical protocol at NIH.** While most RCs will not be PIs on intramural clinical protocols, RCs who wish to serve as PIs on clinical protocols conducted in NIH IRP facilities must be brought in under an IPA agreement.

F. Responsibilities

1. Deputy Director for Intramural Research (DDIR) / Office of Intramural Research (OIR), OD:

    a. Communicates this policy to the Intramural Research Program (IRP) at each Institute/Center.
    b. Makes exceptions to this policy when legally permissible.
    c. Provides additional guidance as needed to IRPs regarding implementation of this policy.
    d. Monitors appropriate use of this policy across IRPs.

2. IC Scientific Director (SD):

    a. Assures the faithful implementation of this policy by reviewing all research collaborations in which an on-site RC will participate.
    b. Reviews and approves the appropriate "Research Collaborator Agreement" pertinent to the type of RC (Appendixes 1-3).
    c. Maintains a record of all research collaborations involving on-site RCs and the "Research Collaborator Agreement" signed by all parties (Appendixes 1-3), as well as any exceptions granted by the DDIR/OIR.

3. On-site Research Collaborator (RC):

    a. Co-writes the proposed on-site research collaboration with an IRP principal investigator for review / approval by the IC SD.
    b. Abides by all conditions stipulated in the appropriate "Research Collaborator Agreement" (Appendixes 1-3) and by all instructions on the use of NIH facilities.
    c. Clinical RCs abide by policy on use of certain Clinical Center facilities (NIH Manual 1366).

G. Exceptions

Exceptions to this policy require the approval of the Deputy Director for Intramural Research (DDIR), NIH, or the DDIR's designee.

H. Tort Claims/Malpractice Coverage

Researcher Collaborators are not eligible for coverage under the Federal Torts Claim Act in the event of a tort/malpractice claim unless they are on an IPA agreement. As noted above, RCs engaged in patient contact in NIH facilities (except RCs who are IPAs) must provide proof of malpractice coverage in the amount of at least $1 million per occurrence and $3 million in the aggregate.

I. Publications

Publications resulting from research conducted by RCs in NIH IRP facilities must acknowledge the collaborating IC and the NIH and be cleared in advance in accordance with NIH Manual 1183. They are subject to the most current NIH IRP policies for review and distribution, including the NIH public access policy.

J. Inventions

Patent rights provisions for three distinct RC situations are set forth in Appendices 1-3. Please refer to those first. In general, and in accordance with United States Health and Human Services Technology Transfer Manual General Procedures Chapter 203 approved September 23, 2013, patent rights for inventions developed in NIH facilities are NIH property unless NIH waives its rights by approval from the DDIR. Contact the appropriate HHS Technology Transfer Office https://www.ott.nih.gov/tdcs who will forward the request for review by other entities, as needed.

K. Length of Assignment

The length of the Research Collaborator assignment and renewal terms will be set according to the needs of the research collaboration and must be stated in the documented research agreement. Length of assignment for RCs who are on IPA agreements are limited by NIH policy for IPAs, found at NIH Manual 2300-334-1 Assignments Under the Intergovernmental Personnel Act (IPA).

L. Termination

An RC's on-site appointment will terminate at the conclusion of the research collaboration, and may be terminated at any prior time by either party to the agreement, unless a different termination clause is provided in the applicable documentation of the research collaboration. The NIH may terminate a RC's on-site appointment for cause, e.g., to protect patient safety or following reports of violations of the IRP Human Research Protection Policies. Except in emergency circumstances, ICs must notify the DIS, ORS of non-immigrant foreign national RC assignment termination at least 30 days prior to the projected end date.

M. Extension

An RC may extend his/her visit at NIH with the approval of the proper NIH IC officials as noted in Section C. In addition, if the RC is a foreign non-immigrant, he/she must remain in a valid visa status with clearance by the DIS, ORS.

N. Visas

Non-immigrant foreign national RCs must have appropriate visas that support their activities at NIH. Supporting documentation for these individuals must be sent to the DIS, ORS. The candidate RC must be cleared by the DIS, ORS, in order to permit their assignment at the NIH. Such clearance is required before the assignment may commence. Clearance must also be sought for any renewal of the RC appointment.

The full document requirements can be located on the DIS web site (http://dis.ors.od.nih.gov/forms/01_forms.html). Requests for all foreign non-immigrant foreign RCs should be sent to the DIS in accordance with their processing times (http://dis.ors.od.nih.gov/advisories/techadvis_no01.html).

In some instances, a non-immigrant foreign RC may come to NIH as a Temporary Visitor for Business in either B-1 or WB status (Visa waiver for Visitor for Business, intended for stays of 90 days or less for individuals from certain countries), provided he/she will receive no salary or other remuneration from a U.S. source. The B-2 (Temporary Visitor for Pleasure) or WT status (Visa Waiver for Visitor for Pleasure, for stays of 90 days or less for individuals from certain countries) is intended for tourism purposes and is not allowed for RC assignments. For further guidance, refer to the DIS Technical Advisory No. 5 (http://dis.ors.od.nih.gov/advisories/technicaladvisory05.pdf).

Non-immigrant foreign RCs must be physically located at NIH IRP research facilities and not in contract facilities or at local universities.

Any patient contact by a non-immigrant foreign RC must be consistent with visa provisions and authorized by the DIS, ORS (refer to the DIS Technical Advisory No. 4 for a summary).

The DIS, ORS must be notified and concur with extended absences in order to avoid violation of immigration rules and regulations.

Non-immigrant foreign RCs must receive approval from the DIS, ORS, before any outside activity may commence.

For further information or guidance on immigration-related issues, contact the DIS, ORS

O. Available Resources

1. **For their own injuries**, RCs may use Occupational Medical Service facilities for emergencies or other authorized treatment and NIH supplies and research services.
2. **Training or travel** for RCs who are not IPAs, including travel and training pertinent to the collaboration, may not be paid by IRP funds.
3. **Parking, ID Cards and NED designation**. RCs may obtain parking permits and identification cards (ID) in the same manner as NIH employees (see NIH Manual 1410, "Parking"). Their NED designation is Collaborator (clinical) or Collaborator (non-clinical).

Complete HHS-745 “HHS ID Badge Request” (http://intranet.hhs.gov/forms/hhs_forms/hhs-745.pdf).

4. **Access to NIH servers, desktops, and laptops** requires PIV smartcard approval (see NIH Manual 2811).

P. Awards and Recognition

RCs will not be eligible for any form of award or recognition.

Q. Forms

DIS form requirements for non-immigrant foreign RCs can be located on the DIS web site (http://dis.ors.od.nih.gov/forms/01_forms.html).

R. Internal Controls

The purpose of this chapter is to provide guidelines on the use of the NIH On-Site Research Collaborator appointments. It establishes the conditions under which a Research Collaborator may use NIH facilities during the course of a research collaboration and defines responsibilities of the various parties involved. This issuance is intended to be used in conjunction with NIH and also Government-wide policies and regulations.

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter.** Through this issuance, the Office of Intramural Research, Office of the Director, NIH, is accountable for the method used to ensure that internal controls are implemented and working.
2. **Frequency of Review.** Review of the internal controls will be required every three years, after the annual OIR Management Controls Survey detects which ICs may have higher vulnerability.
3. **Method of Review.** Internal Control Review will be conducted through the annual OIR Management Controls Survey which includes all ICs using this program to determine their compliance with the policies and procedures.
4. **Review Reports are sent to:** Deputy Director for Intramural Research and the Deputy Director for Management, NIH.

S. 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 NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule".

NIH e-mail 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 Liaison for additional

information.

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 Inspector General may request access to or copies of e-mail messages. E-mail messages must also be provided to Congressional oversight committees, if requested, and are subject to Freedom of Information Act requests. Back-up files are subject to the same requests as the original messages.

Appendix 1

- NIH Research Collaborator (RC) Agreement for Use with (print name of research collaboration document and attach it) - WORD Document
- NIH Research Collaborator (RC) Agreement for Use with (print name of research collaboration document and attach it) - PDF Document

Appendix 2

- NIH Research Collaborator (RC) Agreement for Use with IC CRADA # _____ - WORD Document
- NIH Research Collaborator (RC) Agreement for Use with IC CRADA # _____ - PDF Document

Appendix 3

- NIH Research Collaborator (RC) Agreement for “Opportunities for Collaborative Research at the NIH Clinical Center U01” - WORD Document
- NIH Research Collaborator (RC) Agreement for “Opportunities for Collaborative Research at the NIH Clinical Center U01” - PDF Document

Appendix 3A

Intellectual Property Policy Waiver Request for U01 grant "Opportunities for Collaborative Research at the NIH Clinical Center" - PDF Document