

### § 46.503

the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

### § 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

### § 46.504 How must an IRB be registered?

Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

### 45 CFR Subtitle A (10-1-10 Edition)

### § 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

### PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

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AUTHORITY: 75 Stat. 527 (22 U.S.C. 2451 et seq.); 84 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9900, Mar. 16, 1984, unless otherwise noted.

### § 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the Department of State to recommend to the Attorney General waiver of the two-year foreign residence requirement for Exchange Visitors under the Mutual

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Educational and Cultural Exchange Program. HHS eligibility requirement criteria for waivers are in addition to and independent of the existing waiver and visa criteria established by the Immigration and Naturalization Service (INS), the Department of State, and the Department of Labor. The waiver regulations described in this part do not relieve alien physicians seeking a waiver of the 2-year foreign residence requirement from complying with the terms and conditions imposed on their admission to the United States.

[67 FR 77695, Dec. 19, 2002]

### § 50.2 Exchange Visitor Waiver Review Board.

(a) *Establishment.* The Exchange Visitor Waiver Review Board is established to carry out the Department's responsibilities under the Exchange Visitor Program.

(b) *Functions.* The Exchange Visitor Waiver Review Board is responsible for making thorough and equitable evaluations of applications submitted by institutions, acting on behalf of Exchange Visitors, to HHS for a favorable recommendation to the Department of State that the two-year foreign residence requirement for Exchange Visitors under the Exchange Visitor Program be waived.

(c) *Membership.* The Exchange Visitor Waiver Review Board consists of no fewer than three members and two alternates, of whom no fewer than three will consider any particular application. The Director of the Office of Global Health Affairs, Office of the Secretary, is an ex officio member of the Board and serves as its Chairman. The Director may designate a staff member of the Office of the Secretary to serve as member and Chairman of the Board in the Director's absence. The Assistant Secretary for Health appoints two regularly assigned members and two alternates to consider applications concerning health, biomedical research, and related fields. The Chairman may request the heads of operating divisions of the Department to appoint additional members to consider applications in other fields of interest to the Department. The Board may obtain expert advisory opinions from other sources. The Board may es-

tablish a workgroup from the operating divisions of the Department to consider applications for waivers based on the need for the delivery of health care services to underserved populations.

[49 FR 9900, Mar. 16, 1984, as amended at 67 FR 77695, Dec. 19, 2002]

### § 50.3 Policy.

(a) *Policy for waivers.* The Department of Health and Human Services endorses the philosophy that Exchange Visitors are committed to return home for at least two years after completing their program. This requirement was imposed to prevent the Program from becoming a stepping stone to immigration and to ensure that Exchange Visitors make available to their home countries their new knowledge and skills obtained in the United States. The Department will request waivers for the delivery of health care service to carry out the Department's mission to increase access to care for the nation's most medically underserved individuals. However, in keeping with the philosophy of the Program, the Exchange Visitor Waiver Review Board may determine the appropriate numbers and geographic areas for waivers for the delivery of health care service.

(b) *Criteria for waivers.* The Exchange Visitor Waiver Review Board carefully applies stringent and restrictive criteria to its consideration of requests that it support waivers for Exchange Visitors. Each application is evaluated individually based on the facts available.

(c) *Waiver for members of Exchange Visitor's family.* Where a decision is made to request a waiver for an Exchange Visitor, a waiver will also be requested for the spouse and children, if any, if they have J-2 visa status. When both members of a married couple are Exchange Visitors in their own right (*i.e.*, each has J-1 visa status), separate applications must be submitted for each of them.

[67 FR 77696, Dec. 19, 2002]

### § 50.4 Waivers for research.

In determining whether to request a waiver for an Exchange Visitor engaged in the conduct of research, the