

who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under § 46.406 or § 46.407 only if such research is:

- (1) Related to their status as wards; or
- (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

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

Sec.

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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 United States Information Agency to recommend to the Attorney General waiver of the two-year foreign residence requirement for exchange visitors under the Mutual Educational and Cultural Exchange Program.

§ 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 the Department of HHS for a favorable recommendation to the United States Information Agency that the two-year foreign residence requirement for exchange visitors under the Exchanges 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 shall consider any particular application. The Director of the Office of International 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

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in the Director's absence. Two regularly assigned members and two alternates are appointed by the Assistant Secretary of Health 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 (e.g. human services, social security). The Board may obtain expert advisory opinions from other sources.

(d) *Eligibility.* The Board will review applications submitted by private or non-federal institutions, organizations or agencies or by a component agency of HHS. The Board will not consider applications submitted by exchange visitors or, unless under extenuating and exceptional circumstances, other U.S. Government Agencies.

§ 50.3 Policy.

(a) *Criteria and information pertaining to waivers.* The Department of Health and Human Services endorses the philosophy of the Exchange Visitor Program 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 insure that exchange visitors make their new knowledge and skills available to their home countries. Accordingly, the Board carefully applies stringent and restrictive criteria to its consideration of requests that it support waivers for exchange visitors. Each application is evaluated individually on the basis of the facts available.

In determining whether to recommend an exemption for an exchange visitor from his/her obligation to the Exchange Visitor Program, the Board considers the following key factors:

(1) The program or activity at the applicant institution or organization in which the exchange visitor is employed must be of high priority and of national or international significance in an area of interest to the Department. The Board will not request a waiver when the application demonstrates that the exchange visitor is needed merely to provide services for a limited

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geographical area and/or to alleviate a local community or institutional manpower shortage, however serious.

(2) The exchange visitor must be needed as an integral part of the program or activity, or of an essential component thereof, so that loss of his/her services would necessitate discontinuance of the program, or a major phase of it. *Specific evidence* must be provided as to how the loss or unavailability of the individual's services would adversely affect the initiation, continuance, completion, or success of the program or activity. The applicant organization/institution must clearly demonstrate that a suitable replacement for the exchange visitor cannot be found through recruitment or any other means. The Board will not request a waiver when the principal problem appears to be one of administrative, budgetary, or program inconvenience to the institution or other employer.

(3) The exchange visitor must possess outstanding qualifications, training and experience well beyond the usually expected accomplishments at the graduate, postgraduate, and residency levels, and must clearly demonstrate the capability to make original and significant contributions to the program. The Board will not request a waiver simply because an individual has specialized training or experience or is occupying a senior staff position in a university, hospital, or other institution.

(b) *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.

§ 50.4 Procedures for submission of application to HHS.

(a) The applicant institution (educational institution, hospital, laboratory, corporation, etc.) should send a completed application (HHS Form 426; O.M.B. No. 0990-0001) to the Executive Secretary, Exchange Visitor Waiver Review Board, Room 655-G, Humphrey