the Administrator will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing human research, covered by subparts A through L of this part, conducted under the review of the IRB. EPA will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the FEDERAL REGISTER.

(d) EPA may refuse to consider in support of a regulatory decision the data from human research, covered by subparts A through L of this part, that was reviewed by an IRB or conducted at an institution during the period of disqualification, unless the IRB or the parent institution is reinstated as provided in §26.1505, or unless such research is deemed scientifically sound and crucial to the protection of public health, under the procedure defined in §26.1706.

§26.1504 Public disclosure of information regarding revocation.

A determination that EPA has disqualified an institution from studies subject to this part and the administrative record regarding that determination are disclosable to the public under 40 CFR part 2.

§26.1505 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated to conduct studies subject to this part if the Administrator determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB has taken or plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under §26.1502(c).

§26.1506 Debarment.

If EPA determines that an institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of this part, EPA may recommend that institution or investigator be declared ineligible to participate in EPA-supported research (debarment). Debarment will be initiated in accordance with procedures specified at 2 CFR part 1532.

[71 FR 6168, Feb. 6, 2006, as amended at 72 FR 2427, Jan. 19, 2007]

§26.1507 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other statutorily authorized proceedings or actions. EPA may, at any time, on its own initiative or through the Department of Justice, institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The Agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

Subpart P—Review of Proposed and Completed Human Research

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§26.1601 EPA review of proposed human research.

(a) EPA shall review all protocols submitted under §26.1125 in a timely manner. With respect to any research or any class of research, the Administrator may recommend additional conditions which, in the judgment of the Administrator, are necessary for the protection of human subjects.

(b) In reviewing proposals covered by this subpart, the Administrator may take into account factors such as whether the applicant has been subject to a termination or suspension under §26.123(a) or §26.1123 and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Administrator, materially failed to

discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

(c) When research covered by subpart K takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in subpart K. (An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration of Helsinki, issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.) In these circumstances, if the Administrator determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in subpart K, the Administrator may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in subpart K.

(d) Following initial evaluation of the protocol by Agency staff, EPA shall submit the protocol and all supporting materials, together with the staff evaluation, to the Human Studies Review Board.

(e) EPA shall notify the submitter of the proposal of the results of the EPA and Human Studies Review Board reviews.

§ 26.1602 EPA review of completed human research.

(a) When considering data under FIFRA or FFDCA from research involving intentional exposure of humans, EPA shall review the material submitted under § 26.1303 and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

(1) The data are derived from research initiated after April 7, 2006, or

(2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

(c) In its discretion, EPA may submit data from research not covered by paragraph (b) of this section to the Human Studies Review Board for their review.

(d) EPA shall notify the submitter of the research of the results of the EPA and Human Studies Review Board reviews.

§ 26.1603 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) *Membership.* The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) *Responsibilities.* The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

Subpart Q—Ethical Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1701 To what does this subpart apply?

This subpart applies to EPA's decisions whether to rely in its actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) on scientifically valid and relevant data from research involving intentional exposure of human subjects.