

§ 26.1507

§ 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 Med-

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ical 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.