§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults initiated after April 7, 2006.

(a) This section applies to research subject to this subpart, that:

(1) Was initiated after April 7, 2006.

(2) Was subject, at the time it was conducted, either to subparts A through L of this part, or to the codification of the Common Rule by another Federal department or agency.

(b) Except as provided in §26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) All applicable provisions of subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency; or

(2) If the research was conducted outside the United States, with procedures at least as protective of subjects as those in subparts A through L of this part, or the codification of the Common Rule by another Federal department or agency.

(c) Except as provided in §26.1706, EPA must not rely on data from any research subject to this section unless EPA determines that the research was conducted in substantial compliance with either:

(1) A proposal that was found to be acceptable under §26.1603(c), and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent. If EPA discovers that the submitter of the proposal materially misrepresented or knowingly omitted information that would have altered the outcome of EPA’s evaluation of the proposal under §26.1603(c), EPA must not rely on that data.

(2) A proposal that would have been found to be acceptable under §26.1603(c), if it had been subject to review under that section, and no amendments to or deviations from that proposal placed participants at increased risk of harm (based on knowledge available at the time the study was conducted) or impaired their informed consent.

(d) The prohibition in this section is in addition to the prohibitions in §26.1703.

[78 FR 10545, Feb. 14, 2013]

§ 26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA has published a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10546, Feb. 14, 2013]