activity has/have, in the judgment of
the Administrator, materially failed to
discharge responsibility for the protec-
tion of the rights and welfare of human
subjects (whether or not the research
was subject to Federal regulation).

(f) When research covered by subpart
K takes place in foreign countries, pro-
cedures normally followed in the for-
eign countries to protect human sub-
jects may differ from those set forth in
subpart K. (An example is a foreign in-
stitution which complies with guide-
lines consistent with the World Med-
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 de-
termines that the procedures pre-
scribed by the institution afford pro-
tections that are at least equivalent to
those provided in subpart K, the Ad-
ministrator may approve the substi-
tution of the foreign procedures in lieu
of the procedural requirements pro-
vided in subpart K.

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

(h) EPA must provide the submitter
of the proposal copies of the EPA and
Human Studies Review Board reviews.

§ 26.1604 EPA review of completed
human research.

(a) When considering, under any reg-
ulatory statute it administers, data
from completed research involving in-
tentional exposure of humans to a pes-
ticide, EPA must thoroughly review
the material submitted under § 26.1303,
if any, and other available, relevant in-
formation and document its conclu-
sions regarding the scientific and eth-
cical 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 re-
search initiated after April 7, 2006, or
(2) The data are derived from re-
search 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 re-
views.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78
FR 10544, Feb. 14, 2013 and amended at 78 FR
10545, Feb. 14, 2013]

§ 26.1605 Operation of the Human
Studies Review Board.

EPA shall establish and operate a
Human Studies Review Board as fol-
lows:

(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 appro-
priate for the scientific and ethical re-
view of human research, including re-
search ethics, biostatistics, and human
toxicology.

(b) Responsibilities. The Human Stud-
ies Review Board shall comment on the
scientific and ethical aspects of re-
search proposals and reports of com-
pleted 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.

[71 FR 6168, Feb. 6, 2006. Redesignated at 78
FR 10544, Feb. 14, 2013]

§ 26.1606 Human Studies Review
Board review of proposed human
research.

In commenting on proposals for new
research submitted to it by EPA, the
Human Studies Review Board must
consider the scientific merits and eth-
cical aspects of the proposed research,
including all elements required in
§26.1603(b) and (c) and any additional