§ 26.1301

shall a person conduct or support re-

search covered by §26.1201 that involves

intentional exposure of any human

subject who is a pregnant woman (and

therefore her fetus), a nursing woman,
or a child.

[71 FR 36175, June 23, 2006]

Subpart M—Requirements for Sub-
mision of Information on the
Ethical Conduct of Com-
pleted Human Research

Source: 71 FR 6168, Feb. 6, 2006, unless oth-
erwise noted.

§ 26.1301 To what does this subpart
apply?

This subpart applies to any person
who submits a report containing the
results of any human research if:
(a) The report is submitted after
April 7, 2006, and
(b) The report is submitted for con-
sideration in connection with any ac-
tion that may be performed by EPA
under the Federal Insecticide, Fun-
gicide, and Rodenticide Act (7 U.S.C.
136 et seq.) or section 408 of the Federal
Food, Drug, and Cosmetic Act (21

§ 26.1302 Definitions.

The definitions in §26.102 shall apply
to this subpart as well.

§ 26.1303 Submission of information
pertaining to ethical conduct of
completed human research.

Any person who submits to EPA data
derived from human research covered
by this subpart shall provide at the
time of submission information con-
cerning the ethical conduct of such re-
search. To the extent available to the
submitter and not previously provided
to EPA, such information should in-
clude:
(a) Copies of all of the records rel-

vant to the research specified by
§26.1115(a) to be prepared and main-
tained by an IRB.
(b) Copies of all of the records rel-

vant to the information identified in
§26.1125(a) through (f).
(c) Copies of sample records used to
document informed consent as speci-

fied by §26.1117, but not identifying any
subjects of the research.
(d) If any of the information listed in
paragraphs (a) through (c) of this sec-
tion is not provided, the person shall
describe the efforts made to obtain the
information.

Subpart N [Reserved]

Subpart O—Administrative Actions
for Noncompliance

Source: 71 FR 6168, Feb. 6, 2006, unless oth-
erwise noted.

§ 26.1501 To what does this subpart
apply?

This subpart applies to any human
research subject to subparts A through
L of this part. References to State or
local laws in this subpart are intended
to include the laws of federally recog-
nized American Indian and Alaska Na-
tive Tribal Governments.

§ 26.1502 Lesser administrative ac-
tions.

(a) If apparent noncompliance with
the applicable regulations in subparts
A through L of this part concerning the
operation of an IRB is observed by an
officer or employee of EPA or of any
State duly designated by the Adminis-
trator during an inspection. EPA may
send a letter describing the noncompli-
ance to the IRB and to the parent in-
stitution. The agency will require that
the IRB or the parent institution re-
spond to this letter within a reasonable
time period specified by EPA and de-
scribe the corrective actions that will
be taken by the IRB, the institution, or
both to achieve compliance with these
regulations.
(b) On the basis of the IRB’s or the
institutions’s response, EPA may sched-
ule a reinspection to confirm the ade-
quacy of corrective actions. In addi-
tion, until the IRB or the parent insti-
tution takes appropriate corrective ac-
tion, the Agency may:
(1) Withhold approval of new studies
subject to the requirements of this part
that are conducted at the institution
or reviewed by the IRB;
(2) Direct that no new subjects be
added to ongoing studies subject to
this part;