§ 50.205 Consent form requirements.

(a) Required consent form. The consent form appended to this subpart or another consent form approved by the Secretary must be used.

(b) Required signatures. The consent form must be signed and dated by:

(1) The individual to be sterilized; and
(2) The interpreter, if one is provided; and
(3) The person who obtains the consent; and
(4) The physician who will perform the sterilization procedure.

(c) Required certifications. (1) The person obtaining the consent must certify by signing the consent form that:

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,
(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and
(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify by signing the consent form, that:

(i) Shortly before the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,
(ii) He or she explained orally the requirements for informed consent as set forth on the consent form, and
(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(3) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally, read the consent form and explained its contents and to the best of the interpreter’s knowledge and belief, the individual to be sterilized understood what the interpreter told him or her.

§ 50.206 Sterilization of a mentally incompetent individual or of an institutionalized individual.

Programs or projects to which this subpart applies shall not perform or arrange for the performance of a sterilization of any mentally incompetent individual or institutionalized individual.

§ 50.207 Sterilization by hysterectomy.

(a) Programs or projects to which this subpart applies shall not perform or arrange for the performance of any
§ 50.208 Program or project requirements.

(a) A program or project must, with respect to any sterilization procedure
or hysterectomy it performs or arranges, meet all requirements of this
subpart.

(b) The program or project shall maintain sufficient records and docu-
mentation to assure compliance with these regulations, and must retain
such data for at least 3 years.

(c) The program or project shall submit other reports as required and when
requested by the Secretary.

§ 50.209 Use of Federal financial assistance.

(a) Federal financial assistance administered by the Public Health Serv-
ice may not be used for expenditures for sterilization procedures unless the
consent form appended to this section or another form approved by the Sec-
retary is used.

(b) A program or project shall not use Federal financial assistance for any
sterilization or hysterectomy without first receiving documentation showing
that the requirements of this subpart have been met. Documentation in-
cludes consent forms, and as applicable, either acknowledgments of receipt
of hysterectomy information or certifi-
cation of an exception for
hysterectomies.


The Secretary will request public
comment on the operation of the provi-
sions of this subpart not later than 3
years after their effective date.

APPENDIX TO SUBPART B OF PART 50—
REQUIRED CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME
NOT TO BE STERILIZED WILL NOT RE-
SULT IN THE WITHDRAWAL OR WITH-
HOLDING OF ANY BENEFITS PROVIDED
BY PROGRAMS OR PROJECTS RECEIVING
FEDERAL FUNDS.

CONSENT TO STERILIZATION

I have asked for and received information
about sterilization from (doctor or clinic). When I first asked for the in-
formation, I was told that the decision to be
sterilized is completely up to me. I was told
that I could decide not to be sterilized. If I
decide not to be sterilized, my decision will
not affect my right to future care or treat-
ment. I will not lose any help or benefits

[43 FR 52165, Nov. 8, 1978, as amended at 47
FR 33701, Aug. 4, 1982]