§ 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sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,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) Shorty 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the performance of the sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized,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.

§ 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
hysterectomy solely for the purpose of rendering an individual permanently incapable of reproducing or where, if there is more than one purpose to the procedure, the hysterectomy would not be performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) Except as provided in paragraph (c) of this section, programs or projects to which this subpart applies may perform or arrange for the performance of a hysterectomy not covered by paragraph (a) of this section only if:

(1) The person who secures the authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make her permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(c)(1) A program or project is not required to follow the procedures of paragraph (b) of this section if either of the following circumstances exists:

(i) The individual is already sterile at the time of the hysterectomy.

(ii) The individual requires a hysterectomy because of a life-threatening emergency in which the physician determines that prior acknowledgment is not possible.

(2) If the procedures of paragraph (b) of this section are not followed because one or more of the circumstances of paragraph (c)(1) exist, the physician who performs the hysterectomy must certify in writing:

(i) That the woman was already sterile, stating the cause of that sterility; or

(ii) That the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

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

§ 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 documentation 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 Service may not be used for expenditures for sterilization procedures unless the consent form appended to this section or another form approved by the Secretary 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 includes consent forms, and as applicable, either acknowledgments of receipt of hysterectomy information or certification of an exception for hysterectomies.

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


The Secretary will request public comment on the operation of the provisions 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 result in the withdrawal or withholding 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 information, 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 treatment. I will not lose any help or benefits