

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]

#### **§ 50.210 Review of regulation.**

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

from programs receiving Federal funds, such as A.F.D.C. or medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a \_\_\_\_\_. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on \_\_\_\_ (day), \_\_\_\_ (month), \_\_\_\_ (year).

I, \_\_\_\_\_, hereby consent of my own free will to be sterilized by \_\_\_\_\_ by a method called \_\_\_\_\_. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form.

Signature \_\_\_\_\_

Date: \_\_\_\_\_

(Month, day, year)

You are requested to supply the following information, but it is not required:

Ethnicity and Race Designation

Ethnicity:

- Hispanic or Latino
 Not Hispanic or Latino

Race (mark one or more):

- American Indian or Alaska Native
 Asian
 Black or African American
 Native Hawaiian or Other Pacific Islander
 White

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in \_\_\_\_\_ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation.

Interpreter \_\_\_\_\_

Date \_\_\_\_\_

STATE OF PERSON OBTAINING CONSENT

Before \_\_\_\_\_ (name of individual), signed the consent form, I explained to him/her the nature of the sterilization operation \_\_\_\_\_, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure.

Signature of person obtaining consent \_\_\_\_\_

Date \_\_\_\_\_

Facility \_\_\_\_\_

Address \_\_\_\_\_

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon \_\_\_\_\_ (name of individual to be sterilized), on \_\_\_\_\_ (date of sterilization), \_\_\_\_\_ (operation), I explained to him/her the nature of the sterilization operation \_\_\_\_\_ (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(Instructions for use of alternative final paragraphs: Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested):

Premature delivery  
Individual's expected date of delivery: \_\_\_\_\_  
 Emergency abdominal surgery:  
(Describe circumstances): \_\_\_\_\_  
Physician \_\_\_\_\_  
Date \_\_\_\_\_

#### Paperwork Reduction Act Statement

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays the currently valid OMB control number. Public reporting burden for this collection of information will vary; however, we estimate an average of one hour per response, including for reviewing instructions, gathering and maintaining the necessary data, and disclosing the information. Send any comment regarding the burden estimate or any other aspect of this collection of information to the OS Reports Clearance Officer, ASBTF/Budget Room 503 HHH Building, 200 Independence Avenue, SW., Washington, DC 20201.

Respondents should be informed that the collection of information requested on this form is authorized by 42 CFR part 50, subpart B, relating to the sterilization of persons in federally assisted public health programs. The purpose of requesting this information is to ensure that individuals requesting sterilization receive information regarding the risks, benefits and consequences, and to assure the voluntary and informed consent of all persons undergoing sterilization procedures in federally assisted public health programs. Although not required, respondents are requested to supply information on their race and ethnicity. Failure to provide the other information requested on this consent form, and to sign this consent form, may re-

sult in an inability to receive sterilization procedures funded through federally assisted public health programs.

All information as to personal facts and circumstances obtained through this form will be held confidential, and not disclosed without the individual's consent, pursuant to any applicable confidentiality regulations.

[43 FR 52165, Nov. 8, 1978, as amended at 58 FR 33343, June 17, 1993; 68 FR 12308, Mar. 14, 2003]

### Subpart C—Abortions and Related Medical Services in Federally Assisted Programs of the Public Health Service

AUTHORITY: Sec. 118, Pub. L. 96-86, Oct. 12, 1979, unless otherwise noted.

SOURCE: 43 FR 4570, Feb. 2, 1978, unless otherwise noted.

#### § 50.301 Applicability.

The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, appropriated to the Department of Health and Human Services and administered by the Public Health Service.

#### § 50.302 Definitions.

As used in this subpart: (a) *Law enforcement agency* means an agency, or any part thereof, charged under applicable law with enforcement of the general penal statutes of the United States, or of any State or local jurisdiction.

(b) *Medical procedures performed upon a victim of rape or incest* means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

(c) *Physician* means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she practices.

(d) *Public health service* means: (1) An agency of the United States or of a State or local government, that provides health or medical services; and

(2) A *rural health clinic*, as defined under section 1(d)(aa)(2) of Pub. L. 95-