from Nard
for Dr F

DR. HENRY W. FOSTER JR. -- QUESTIONS AND ANSWERS
FEBRUARY 10, 1995

Q. What did you mean when you said that you abhor abortion?

A. Whether or not to have an abortion is a complex and difficult decision. My goal as a physician has always been to ensure that none of my patients ever has to face that decision. That's why I've focused my efforts on preventing unplanned pregnancy. Our nation's goal must be to make abortion less necessary.

But when a woman feels she must choose abortion, it is my responsibility as her physician to provide her access to safe medical procedures.

Q. Why have you equivocated and changed your response to the number of abortions you have performed?

A. The number has no place in this debate. Most ob/gyns have performed abortions, which is a legal medical procedure. But I have always worked to help my patients avoid unplanned pregnancy and abortion. It was a mistake for me to have given an estimate in response to that question, but it was not an attempt to deceive.

notification

Q. Do you support restrictions on abortion like parental consent and notice?

A. As Surgeon General, I will not be involved in these matters. I do believe that parents should be involved when their teenage daughter faces a crisis pregnancy. In fact, most young women do tell a parent. But family communication can't be mandated by law.

parents involved not politicians

The American Medical Association concluded in a study that these laws increase the risks associated with abortion because they delay the procedure. They also lead some teens to resort to unsafe and illegal abortions.

Q. Do you favor mandatory waiting periods?

A. It's my experience as a physician that by the time a woman chooses to have an abortion, she has already reflected on the moral, ethical and religious questions involved in that decision. Waiting periods only serve to delay the procedure. The American Medical Association has said that delaying abortion increases the health risks to women.

Q. Do you favor distribution of condoms?

A. First and foremost, I believe in teaching our youngsters to abstain from sex. But since many teens are sexually active, I believe that they should have access to condoms to protect themselves from sexually transmitted diseases and lessen the likelihood they will of unplanned pregnancy and abortion.

Q. Do you favor abortions for sex selection?

A. Although very few women ever make the abortion decision for this reason, I am strongly opposed to abortion for sex selection.

Q. Do you support making the abortion pill available to American women?

A. When a woman faces a crisis pregnancy, she must have access to all medically safe options, including medical abortion. RU-486 also holds promises for treating diseases like breast and other cancers, Cushing's Syndrome and endometriosis. If the FDA certifies its safety and scientific merit, it should be available to American women.

DRAFT D for Dr F

TOUGH Q & A

February 14, 1995

Q: What is your position on the federal funding of abortions?

A: My understanding is that, under the Clinton Administraion, the Hyde Amendment was changed to allow the Medicaid program to pay for abortions for poor women in the case of rape or incest or danger to the life of the mother. I support that [and would not want to see these protections taken away.] [NEED TO PASSS BY N-A MIN / GALSTON]

Q: Do you support restrictions on abortion like parental consent and notification?

A: As Surgeon General, I will not be involved in these matters. I do believe that parents should be involved when their teenage daughter faces a crisis pregnancy and will do everything I can to encourage that. In fact, it has been my experience that most young women do tell a parent. But family communications can't be mandated by law. I want parents involved, not politicians. That's why the program I founded -- "I Have A Future" -- involves parents in the lives and aspirations of their teenage children.

And as I've said, I believe abortion should be safe, legal, and rare. The American Medical Association concluded in a study that these laws increase the risks associated with abortion because they delay the procedure. They also lead some teens to resort to unsafe and illegal abortions.

ADMINISTRATION POSITION: [??] The President's position has always been that this decision is best left to the states and communities. He supported a parental notification law as Governor of Arkansas that encouraged teenagers to talk with their parents but allowed them to apply to the court in ___ [certain? abusive?] situations.

Q: Do you favor mandatory waiting periods?

A: It has been my experience from 38 years as a physician that by the time a woman chooses to have an abortion, she has already reflected on the moral, ethical, and religious questions involved in that decision. Waiting periods only serve to delay the procedure, which the American Medical Association says increases the health risks to women.

ADMINISTRATION POSITION: ??

Q: Do you favor distribution of condoms?

A: First and foremost, I believe in teaching our young men and women to abstain from sex. My "I Have A Future" program promotes abstinence as the best way to prevent unwanted pregnancy. In fact, one of the reasons I established this program was because I saw that most efforts to control teen pregnancy focused only on distributing condoms, rather than empowering teenagers to take charge of their lives and consciously make other choices.

At the same time, we have to recognize that we will never be completely successful and that too many teenagers, despite our best efforts, will choose to be sexually active. We should provide access to condoms so that those teenagers can protect themselves from sexually transmitted diseases and lessen the likelihood that they will have an unplanned pregnancy -- and an abortion.

[Should we add?] As I've stressed, first and foremost, I want abortions to be rare and am committed to ensuring that young people don't have to face the choice of having abortions.

ADMINISTRATION POSITION: President Clinton said upon Dr. Foster's nomination that this issue should be decided locally, in consultation with families, schools, and communities. *"There is no national policy on that, and there will not be."*

Q: Dr. Foster, what is your position on needle exchange programs?

A: I do not support federal funds being used for needle exchange programs. I have see no compelling evidence that these programs both stop the spread of the AIDS virus and curb the abuse of drugs.

ADMINISTRATION POSITION: Phil Lee position from story

Questions

Who are you?

Why do you want to be surgeon general?

Why did President Clinton nominate you?

Abortion numbers questions? Why should we trust you?

Mismanagement? Meharry accreditation?

If abhor abortion, why perform?

Parental consent & notification?

24 hour waiting period?

Tuskegee syphilis study

Were you at that meeting?

How many abortions at Tuskegee?

Accomplishments of Surgeon General?

Shouldn't the President just choose someone uncontroversial?

Why should you be confirmed?

How do you define abortion?

John Thorpe
This is helpful.
Please call me to
discuss anything
else you need.
Also to talk
event.
— Meg

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET

ROUTE SLIP

TO: Meeghan Prunty

Take Necessary Action	____
Approval or Signature	____
Comment	____
Prepare Reply	____
Discuss With Me	____
For Your Information	____
See Remarks Below	____

FROM: Nancy-Ann Min DATE: FEB 16 1995

REMARKS:

From Nancy-Ann
Min

OFFICE OF MANAGEMENT AND BUDGET

Legislative Reference Division
Labor-Welfare-Personnel Branch

Telecopier Transmittal Sheet

SPECIAL

FROM: Bob Pellicci -- 395-4871

DATE: 2-16-95 **TIME:** 3:45

Pages sent (including transmittal sheet): 15

COMMENTS: From Shalala's confirmation hearing -- responses on RU 486, Norplant, Abortion policy, the Gag rule etc. Hope this is helpful. This document is from May 1993.

TO: Nancy-Ann

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

Child Care

QUESTION #1

In 1990, Congress passed the Child Care and Development Block Grant which included funding of certificates to low income parents which could be used for a variety of child care, including religious child care. Knowing how important you believe tolerance to be, I trust that you have no intention of altering federal regulations to prohibit parents from using child care certificates in religious day care programs. Is that a safe assumption? Will your office continue to support use of child care certificates for these programs? How will your office encourage States to comply with the law and final regulations?

ANSWER

- Parents who wish to choose a sectarian (religious) provider may do so through a child care certificate. The availability of certificates is mandated in the Block Grant statute and reinforced in the regulations. Parents are informed of the option to request a certificate through consumer education and at the time they apply for child care assistance. Consumer education is also mandated by the statute and regulation.

- We have reviewed each grantee's plan to ensure that certificates are available to parents when Block Grant services are offered and that certificates may be used with sectarian providers. We also verified that all grantees required to offer certificates by the October 1992 statutory deadline were, in fact, offering certificates. Note that some "small" Tribes are exempted from the requirement to offer certificates. Presently, we are reviewing how each grantee is implementing the certificate feature of the program.

- This fiscal year we also began general program reviews. These reviews are intended to cover each State, territory, and non-exempt Tribal grantee program at least every two years.

- Additionally, we are conducting a series of technical assistance symposia across the country for all grantees. These symposia provide a forum for exchanging information about the promising practices of different grantees on many aspects of the program, including their certificates. Finally, our regional offices are in frequent contact with grantees to assist them with meeting the statutory and regulatory requirements of the program.

QUESTION #2

Ms. Shalala, among the areas overseen by the Department of Health and Human Services are a number of programs that are intended to provide direct benefits to children, including Title X, Head Start, Federal aid to State and local programs to combat child abuse and neglect and so forth.

Up here, we've been debating issues relating to children and government for some time, whether it's the child care issue or parental leave or whatever it might be, and one argument we frequently hear is that if government is to be active on behalf of children, it ought to do so in a way that is respectful of the role of parents. We are warned against programs that would treat children as a separate client group for government services, bypassing parents, and making parents merely sticks of furniture in a child's life; useful, but replaceable.

When you become responsible for policy-making in these areas, what concept of the role of parents will you be guided by?

ANSWER:

- I believe that Federal programs serving children should respect, encourage and assist parents in carrying out their roles as the principal educators and nurturers of their children.

- Federal, State, and local programs should seek to empower parents to enhance their own family unit and to help it become a stronger part of the community as a whole. Programs should work with parents to assist them in identifying family needs, establishing goals for themselves and their children and in helping to shape the programs intended to serve them.

- A useful model for this type of parent involvement is the Head Start program. Head Start encourages parents to become involved in all aspects of local program operation and decision-making and also helps them in their own individual efforts to care for their children within the context of the home and larger community.

Family Planning

QUESTION #1

It was recently announced that Baltimore City Schools are expected to be the first in the nation to offer Norplant, a surgically implanted contraceptive, to teenage girls. The drug is expected to be offered to students at Laurence Paquin Middle and High School, and will eventually be expanded to the six high schools that have school-based health clinics on campus.

Do you support the distribution of Norplant to this population?

ANSWER

- I am not aware of any Federal restrictions on the provision of Norplant through the schools, nor would I support such restrictions at the national level. Norplant, a new implantable hormonal, long-term contraceptive, has been approved by the Food and Drug Administration (FDA) as safe for use as a contraceptive method in the United States. Local community groups, including the Baltimore City schools, may provide voluntary contraceptive services to sexually active individuals in compliance with any relevant Federal, State or local requirements, including informed consent requirements.

QUESTION #2

Given the drug's short history, do you believe these minor girls should have to obtain parental consent before implanted with Norplant?

ANSWER

- Norplant has been approved by the FDA as a safe, reversible family planning method that can be reversed through a simple, outpatient procedure, to remove the implant. As with all other contraceptive services provided to adolescents through the Title X national family planning program, Norplant is available to adolescents who request such services on a confidential basis. I would certainly urge parents to become involved with their children's decisions whenever practicable.

QUESTION #3

If you do not support parental consent before Norplant is distributed to minor girls, do you at least support parental notification before this new drug is distributed?

ANSWER

- There are no Federal laws that require parental consent or notification for the provision of contraceptive services to minors. I would not recommend that Norplant be singled out for such a requirement.

QUESTION #4

Would you support using federal funds for this type of distribution?

ANSWER

- Funding for the provision of Norplant is currently available through various Federal programs including Medicaid and the Title X national family planning program. Programs are specifically required to provide all family planning services to adolescents in a confidential manner, and parental consent or notification requirements for the provision of such services are prohibited.

QUESTION #5

What if any restrictions would you place before federal funds could be used to distribute Norplant to minors?

ANSWER

(see above response)

QUESTION #6

Section 1008 of the Public Health Service Act implementing the Title X Family Planning Act provides that: "None of the funds appropriated under this Title shall be used in programs where abortion is a method of family planning."

How do you interpret this section of the law, which has not been altered since 1970?

ANSWER

- The previous Administration's interpretation of this section of the statute lead to the so-called "gag rule", which has been the focus of much litigation and controversy, and which we believe the rule inappropriately restricted grantees. I therefore suspended the so-called "gag rule" and proposed that the program return to the compliance standards operative prior to the issuance of the "gag rule" in 1988. The Department is currently reviewing comments received in response to its

February, 1993 Federal Register notice and working on the development of a new rule in accordance with the notice and comment provisions of the Administrative Procedure Act. As the Department's February, 1993 interim rule notes, the original interpretation of section 1008 (from the programs inception in 1970 up until the 1988 "gag rule") did not include a prohibition on non-directive counseling on abortion.

QUESTION #7

Do you support regulations known as the "Gag Rule" which aim to separate abortion related activities from federally supported family planning activities? If not, do you support any limitations on the ability of clinics receiving federal funds to counsel and refer women for abortion in federally funded Title X clinics?

ANSWER

- See above response. The Department has published in the Federal Register -- (1) a notice of proposed rulemaking (NPRM) proposing to return the program to the abortion policies and interpretations that were in effect prior to February 1988 and (2) an interim final rule suspending the "gag rule" and reinstating the pre-1988 policies pending the issuance of a final rule.

- The Department has proposed that the compliance standards operative prior to 1988 be reinstated, including those set out in the Family Planning Program Guidelines that require that in the event of an unplanned pregnancy, that non-directive counseling be provided to a client at her request, on all options relating to her pregnancy, including abortion, and to refer her for abortion, if that is the option she selects.

QUESTION #8

Do you view the federal family planning program as preventive in nature?

ANSWER

The Department believes that the Federal family planning program is intended to provide a broad range of acceptable and effective medically approved family planning methods and services to persons desiring such services. The Department view is that these services must be provided in a manner that does not subject individuals to coercion, deception or withholding of complete and accurate medical information about their health condition and legal options.

QUESTION #9

Do you think it is important to separate abortion activities from legitimate family planning or preventive activities? How do you propose to separate abortion activities from legitimate family planning activities?

ANSWER

- As the Department stated in the February, 1993 interim rule, we believe the 1988 "gag rule" would have required many grantees to make extensive, expensive and unnecessary alterations in their physical facilities and organizational structures. Consistent with the longstanding Departmental interpretation and administration of the statute, we have proposed that Title X projects not be permitted to promote or encourage abortion as a method of family planning, and that they be required to maintain a separation (that is more than a mere exercise in bookkeeping) of their project activities from any activities that promote or encourage abortion as a method of family planning. The Department will consider this issue further when promulgating a new final rule in light of the comments receive to its February 1993 interim final rule.

QUESTION #10

Should Title X clinics be permitted to perform abortions on the same site as the federally funded Title X clinic?

ANSWER

(see above response)

QUESTION #11

Should personnel whose salaries are supported by federal funding be permitted to work in abortion related activities at the same site?

ANSWER

(see above response)

QUESTION #12

Since its involvement in funding contraceptives and family planning, the Federal government has invested over $2 billion to curb teenage pregnancy. Yet the rate of teenage pregnancy and sexually transmitted diseases afflicting teenagers continues to grow. Many experts feel it is time for us to admit this approach has not yielded the returns we had hoped, and to recognize that

we have focused on the symptom of teen pregnancy rather than the root, which is teen sexual activity.

What if anything will you direct the Department of Health and Human Services to do to curb the rate of teen sexual activity?

ANSWER

- Adolescent pregnancy prevention is a priority within the Department in order to provide national leadership in developing a credible, reliable response to the problem. Toward this end, I have asked several experts in the Department to begin to design a strategy on teenage pregnancy in order to develop a strong adolescent pregnancy initiative.

QUESTION #13

What role, should abstinence education play in this effort?

ANSWER

- Abstinence is a legitimate public health approach to preventing early adolescent sexual activity and the transmission of sexually transmitted diseases, including HIV infection. <u>However</u>, a broader, more comprehensive range of public health and social service approaches is needed to target these dual problems.

Drug Approval

QUESTION #1

During the last 15 years, a lot of attention has been focused on making the drug approval process at FDA function fairly and efficiently. Although some problems remain, great progress has been made in eliminating needless delay.

Not so, however, in the Center for Food Safety and Nutrition. Of four major direct food additive petitions filed in the 1980's, only one has been approved. That one required six years of review. The remaining three have now been pending at least seven years.

According to some, this leisurely pace of review seriously discouraged innovation, and denies the American public useful new products, which accolade (sic) contribute to its health. Can we have your assurance that the Department, working through FDA, will focus on the food additive approval process, and make sure the CFSAN has the resources, the discipline, and the appropriate procedures in place to assure reviews of food additives in a fair and timely manner?

ANSWER:

- Proper and timely action on food additive petitions is an important issue. CFSAN's food and color additive petition review process was subject to an assessment of risk review in the last fiscal year and is scheduled for a more rigorous evaluation of management controls in FY 1994. In addition, the Office of Inspector General is developing a survey concerning internal controls in all of FDA's premarket review processes. These oversight steps should identify any problems that exist, and we will take prompt action to correct problems and improve the process wherever possible.

QUESTION #2

What are your views on the drug approval process put forward by the FDA and former Vice President Quayle's Competitiveness Council? These proposals have received a great deal of support in the AIDS and orphan drug community. Do you anticipate changes in any of these proposals? If so, which ones?

ANSWER

- Many of the changes in the drug approval process, such as accelerating drug approvals, were well underway before they were recommended by the Competitiveness Council. Many other Council recommendations fall under the category of good management practices; and again, FDA continues to make

improvements in many of these same areas. Expanding the role of institutional review boards (IRBs) and contracting out the review of drug applications are two recommendations of the Council. These have proceeded more slowly because FDA believes that industry support is necessary if these recommendations are to work. We believe that these two mechanisms should be limited to application supplements for additional indications and other areas of the drug application that are unlikely to entail major public health risks.

Substance Abuse

QUESTION #1

One area where I tend to agree with President [-Elect] Clinton is in the need to get government and business working together to build and enhance American jobs. And one area where the Department of Health and Human Services could do a better job is in prevention of high risk behaviors among youth, including substance abuse. I'm aware that the alcohol beverage industry has been supporting effective prevention programs for over a decade. Can we count on you to lead your Department to work with the industry on education and prevention programs that have been demonstrated to be effective?

ANSWER

- Yes, I plan to continue to work with industry on education and prevention programs. In the past, we have jointly worked with the National Commission on Drunk Driving and participate in the Drunk and Drugged Driving Awareness Month, which the industry supported. The industry has also carried out other programs to raise public awareness about the negative consequences of drinking and driving. However, there is still a lot to be done. It is my hope that industry would be willing to join in cooperative efforts to address such critical problems as underage drinking, and the risks to women of childbearing age of having offspring with fetal alcohol syndrome and fetal alcohol effects.

Fetal Tissue

QUESTION #1

Do you support using funds for the purpose of supporting research using fetal tissue obtained from induced abortions?

ANSWER

- Yes, I support Federal funding of human fetal tissue transplantation research using fetal tissue obtained from induced abortion. Consistent with the President's directive of January 22, the National Institutes of Health (NIH) will fund meritorious proposals for such research.

QUESTION #2

Would you consider first directing NIH to study, through the use of a tissue bank, alternative sources as those obtained from ectopic pregnancies and miscarriages?

ANSWER

- We are currently evaluating whether to fund assessment and epidemiological studies of tissues from ectopic pregnancies and spontaneous abortions. These studies have the potential of providing information that may be useful in determining whether this tissue is suitable for transplantation purposes. In addition, such studies could provide epidemiological information about early pregnancy loss. Consistent with the decision of the President, we will, however, be proceeding to make decisions on funding meritorious research using tissue from other sources.

Abortion

QUESTION #1

What is your position on abortion?

ANSWER

- The Administration's objective is to make abortion safe, legal, and rare.

QUESTION #2

Do you believe a woman should have a right to an abortion, for any or no reason, throughout the entire duration of pregnancy?

ANSWER

- The application of the right to privacy in this context has been articulated by the Supreme Court in Roe v. Wade.

QUESTION #3

Do you support reasonable restrictions on abortion such as parental consent for minors? What about parental notification?

ANSWER

- The Administration opposes any Federal attempts to limit access to abortion through mandatory waiting periods or parental or spousal consent requirements. The Administration does not oppose State efforts to require some form of adult counseling or consultation for underage girls who choose to have an abortion -- as long as workable and effective bypass provisions are attached to such laws.

QUESTION #4

What is your position on the Freedom of Choice Act?

ANSWER

- The Administration supports a freedom of choice act that codifies the tenets of the Roe v. Wade.

QUESTION #5

Do you support the "Hyde" amendment which prohibits the expenditure of federal funds for abortion except in those cases where the mother's life would be endangered if the fetus was carried to term?

ANSWER

- The Administration's FY 1994 budget request does not include the so-called "Hyde Amendment", an annual HHS appropriations rider which has limited the use of federal funds for abortion since the mid-70's.

QUESTION #6

What is your position on RU-486?

ANSWER

- The President directed the Department to review the scientific basis for the import ban on RU-486 and to pursue initiatives that promote the testing, licensing, and manufacturing of RU-486 in the U.S. Roussel-Uclaf, the French manufacturer of RU-486, has agreed to license the drug to an American organization, the Population Council, to begin the process of clinical trials in the U.S.

DeLuca Case

QUESTION #1

What role did you play in the DeLuca case involving two professors at the University of Wisconsin who were under investigation for fraud?

ANSWER

- I appointed the chair of the inquiry committee that took a preliminary look to determine if an investigation was warranted. I was not personally involved in the inquiry or the subsequent investigation. Upon completion of the investigation committee's work, I reviewed the report and accepted the recommendation of the committee.

QUESTION #2

What steps are you now willing to take to ensure that the documents requested by Department of Health and Human Services are released?

ANSWER

- After an administrative review of this case by officials of the Office of Research Integrity (ORI), this case was closed during the previous Administration. No further action is anticipated.

What Dr. Foster Really Did In Tuskegee

- Once again, the nomination of Dr. Henry Foster, a good, decent, dedicated physician to be the Surgeon-General of the United States, has entered the land of political distortion.

- The attack on Dr. Foster by right-wing critics like Gary Bauer for alleged insensitivity to poor, rural blacks in Tuskegee, Alabama is nothing short of grotesque.

- These critics would have us believe that Dr. Foster knowingly cooperated with the most notorious, racially insensitive experiment ever undertaken by the federal government. What the federal government's white medical establishment did in 1932 was design a study to deliberately withhold treatment of syphilis from poor black men in Tuskegee without their knowledge so the doctors could observe the long-term effects of the disease. And even after penicillin became widely available in the late 1940s, these federal doctors continued to withhold treatment.

- To accuse Dr. Foster of complicity in this affair is not only slanderous, it is nonsensical in light of who Dr. Foster was and what he was doing in Tuskegee.

- Unlike the medical establishment working in the offices of Washington and Atlanta far from the rural poor upon whom they were experimenting, Dr. Foster dedicated the first nine years of his career to serving those people hands on, teaching them about preventive medicine, caring for them.

- After graduating as the only African-American in his medical school class at the University of Arkansas and serving as a medical officer in the Air Force, he came to Tuskegee in 1964 as the lone obstetrician-gynecologist at the John A. Andrew Memorial Hospital. His caseload ran into the hundreds.

- The population was 87% black. The median income was $2,500. Many families went without electricity, or phones, or even running water. And the local hospital served only white people -- because this was still the Jim Crowe South.

- As a story in the Los Angeles Times said, "Among the poor, the uneducated and the sick living on the red clay soil of east-central Alabama, among the women who didn't know or couldn't afford to call a doctor, Foster was the best they had."

- He is recalled by the people of Tuskegee as the town's "baby doctor" who delivered countless babies for the poor. A man who saved the life of the mayor's infant son. A man who talked a scared, 20-year old student out of an abortion, to see that student's daughter grow up to be the valedictorian of her high school. A man who devoted his young life to helping his own people.

- That's what Henry Foster did in Tuskegee. Latter-day critics who dare, for cheap political gain, to try to paint him as complicit in a federal government study that turned the people he tried to help into guinea pigs should be ashamed.

Office for Protection from Research Risks

National Institutes of Health
Suite 3B01
6100 Executive Boulevard
Rockville, MD 20892-7507

Date: FEB 10 1995

To: KAREN GUSS

FAX: 202-456-7431
Phone: _____

From: Gary B. Ellis

FAX: 301-402-2071
Phone: 301-496-7005

Comments:

AS REQUESTED

Document consists of 18 pages, including cover sheet.

OPRR Reports

NIH PHS HHS

PROTECTION OF HUMAN SUBJECTS

TITLE 45
CODE OF FEDERAL REGULATIONS
PART 46

REVISED JUNE 18, 1991

REPRINTED MARCH 15, 1994

THE PUBLIC HEALTH SERVICE ACT
AS AMENDED BY THE HEALTH RESEARCH EXTENSION ACT OF 1985
PUBLIC LAW 99-158
NOVEMBER 20, 1985

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 491. (a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

"(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

"(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this Act. The process shall include procedures for the receiving of reports of such information from recipients of funds under this Act and taking appropriate action with respect to such violations.

"FETAL RESEARCH

"SEC. 498. (a) The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

"(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

"(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

"(b) In administering the regulations for the protection of human research subjects which—

"(1) apply to research conducted or supported by the Secretary;

"(2) involve living human fetuses in utero; and

"(3) are published in Section 46.208 of Part 46 of Title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in Section 46.102(g) of such Part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

NOTE: Section 46.102(g) becomes Section 46.102(i) in Title 45 CFR Part 46 as revised on June 18, 1991.

THE CODE OF FEDERAL REGULATIONS, TITLE 45 CFR PART 46, IMPLEMENTS THESE AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

CODE OF FEDERAL REGULATIONS

TITLE 45

PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS

PART 46—PROTECTION OF HUMAN SUBJECTS

Revised June 18, 1991

(Effective August 19, 1991)

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

Sec.

46.101 To what does this policy apply?

46.102 Definitions.

46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

46.104–46.106 [Reserved]

46.107 IRB membership.

46.108 IRB functions and operations.

46.109 IRB review of research.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

46.111 Criteria for IRB approval of research.

46.112 Review by institution.

46.113 Suspension or termination of IRB approval of research.

46.114 Cooperative research.

46.115 IRB records.

46.116 General requirements for informed consent.

46.117 Documentation of informed consent.

46.118 Applications and proposals lacking definite plans for involvement of human subjects.

46.119 Research undertaken without the intention of involving human subjects.

46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

46.121 [Reserved]

46.122 Use of Federal funds.

46.123 Early termination of research support: Evaluation of applications and proposals.

46.124 Conditions.

Subpart B—Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Sec.

46.201 Applicability.

46.202 Purpose.

46.203 Definitions.

46.204 Ethical Advisory Boards.

46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

46.206 General limitations.

46.207 Activities directed toward pregnant women as subjects.

46.208 Activities directed toward fetuses *in utero* as subjects.

46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects.

46.210 Activities involving the dead fetus, fetal material, or the placenta.

46.211 Modification or waiver of specific requirements.

Subpart C—Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Sec.

46.301 Applicability.

46.302 Purpose.

46.303 Definitions.

46.304 Composition of Institutional Review Boards where prisoners are involved.

46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

46.306 Permitted research involving prisoners.

Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research

Sec.

46.401 To what do these regulations apply?

46.402 Definitions.

46.403 IRB duties.

46.404 Research not involving greater than minimal risk.

46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

46.408 Requirements for permission by parents or guardians and for assent by children.

46.409 Wards.

Authority: 5 U.S.C. 301; Sec. 474(a), 88 Stat. 352 (42 U.S.C 2891-3(a)).

Note: As revised, Subpart A of the DHHS regulations incorporates the Common Rule (Federal Policy) for the Protection of Human Subjects (56 FR 28003). Subpart D of the HHS regulations has been amended at Section 46.401(b) to reference the revised Subpart A.

The Common Rule (Federal Policy) is also codified at

7 CFR Part 1c Department of Agriculture

10 CFR Part 745 Department of Energy

14 CFR Part 1230 National Aeronautics and Space Administration

15 CFR Part 27 Department of Commerce

16 CFR Part 1028 Consumer Product Safety Commission

22 CFR Part 225 International Development Cooperation Agency, Agency for International Development

24 CFR Part 60 Department of Housing and Urban Development

28 CFR Part 46 Department of Justice

32 CFR Part 219 Department of Defense

34 CFR Part 97 Department of Education

38 CFR Part 16 Department of Veterans Affairs

40 CFR Part 26 Environmental Protection Agency

45 CFR Part 690 National Science Foundation

49 CFR Part 11 Department of Transportation

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects)

Source: 56 FR 28003, June 18, 1991.

§ 46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each Department or Agency head may adopt such procedural modifications as may be appropriate from an administrative

standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal Department or Agency, whether or not it is regulated as defined in § 46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal Department or Agency but is subject to regulation as defined in § 46.102(e) must be reviewed and approved, in compliance with § 46.101, § 46.102, and § 46.107 through § 46.117 of this policy, by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or Agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or Agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Department or Agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) 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 a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

(i) Unless otherwise required by law, Department or Agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the Department or Agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services (DHHS), and shall also publish them in the **Federal Register** or in such other manner as provided in Department or Agency procedures.[1]

[1] Institutions with DHHS-approved assurances on file will abide by provisions

Continued

§ 46.102 Definitions.

(a) *Department or Agency head* means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or Agency (including Federal, State, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a Federal Department or Agency solely as part of the Department's or Agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an Institutional Review Board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a Federal Department or Agency shall provide written assurance satisfactory to the Department or Agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual Department or Agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, National Institutes Health, DHHS, and approved for Federalwide use by that office. When the existence of an DHHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to Department and Agency heads shall also be made to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Department or Agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to Department- or Agency-supported or regulated research and need not be

---

of Title 45 CFR Part 46 Subparts A–D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

applicable to any research exempted or waived under § 46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Department or Agency head, unless in accord with § 46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

(d) The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under § 46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § 46.103 of this policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by § 46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Department or Agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§§ 46.104—46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one

member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § 46.103(b)(4) and to the extent required by § 46.103(b)(5).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the **Federal Register**. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or

economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.
(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of

records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) the research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Department or Agency.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the Department or Agency, and final approval given to the proposed change by the Department or Agency.

§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The Department or Agency head will evaluate all applications and proposals involving human subjects submitted to the Department or Agency through such officers and employees of the Department or Agency and such experts and consultants as the Department or Agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the Department or Agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 [Reserved]

§ 46.122 Use of Federal funds.

Federal funds administered by a Department or Agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The Department or Agency head may require that Department or Agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Department or Agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the Department or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the Department or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to Federal regulation).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Department or Agency head may impose additional conditions prior to or at the time of approval when in the judgment of the Department or Agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Source: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978; 43 FR 51559, November 3, 1978.

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (DHHS) to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of

implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the **Federal Register** guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these Board(s) shall be so selected that the Board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

Nullified June 10, 1993 (Public Law 103-43)

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) determine that all aspects of the activity meet the requirements of this subpart;

(2) determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) appropriate studies on animals and nonpregnant individuals have been completed;

(2) except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) individuals engaged in the activity will have no part in: (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

Source: 40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975.

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses *in utero* as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses *ex utero*, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this subpart unless:

(1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) vital functions of the fetus will not be artificially maintained,

(2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the **Federal Register**.

Subpart C—Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov. 16, 1978.

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and

any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "DHHS" means the Department of Health and Human Services.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) in the judgment of the Secretary the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of his intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the **Federal Register**, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or

supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983; 56 FR 28032, June 18, 1991.

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at § 46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at § 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

DHHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) the risk represents a minor increase over minimal risk;

(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

DHHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent

disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405. Where research is covered by § 46.406 and § 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under § 46.406 or § 46.407 only if such research is:

(1) related to their status as wards; or

(2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

Research activities involving no more than minimal risk *and* in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in § 46.110 of 45 CFR Part 46.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Source: 46 FR 8392; January 26, 1981.

February 9, 1995

To: John Podesta

From: Beth Nolan, Marvin Krislov

Re: Dr. Foster

We are leaving this for you to review. Please accept this in the spirit of the best we could do given the deadline. We know how much that excuse is worth.

There are two sets: (1) plain-language charges and responses, and (2) charges and responses with more detailed cites to articles, etc. HHS did (1) and we did (2), though we talked to each other and shared ideas. We can combine if you wish, or keep both sets for different purposes.

The most important thing is that Dr. Foster agree that his views (in both charges and responses) are not misrepresented.

It's 5 am, and we're going home. We will try to be back around 8, but feel free to start without us. Really.

Set #1

ABORTION AS CONTRACEPTION

Charge:

Dr. Foster advocates abortion as a method of contraception.

Response:

Dr. Foster recognizes that abortion can be used as a method of contraception, but believes that it should not be used that way. Dr. Foster believes in preventing abortions by preventing unplanned pregnancies. He has created innovative programs to fight unwanted teen pregnancy through education and building young women's self-esteem. However, Dr. Foster does believe that safe and legal abortion must be available.

Charge:

But Dr. Foster has specifically listed abortion as a method of contraception in his writings.

Response:

Dr. Foster has acknowledged that abortion is available as a method of contraception, but this does not mean that he advocates its use as a form of contraception. To the contrary, he has stated in his writings his preference that abortion be used for contraceptive purposes only when other methods of contraception fail.

Dr. Foster advocates abortion on demand.

Response:

Dr. Foster does not advocate abortion; he believes it should be available as an option. He believes that unwanted pregnancy should be avoided so that the use of abortion is rare.

Charge:

Dr. Foster believes in abortion as a method of contraception, but not abstinence.

Response:

Dr. Foster believes that abstinence is the best way of preventing pregnancy. This is apparent in his work with innovative programs to help teens avoid pregnancy through education and development of self-esteem.

Charge:

Dr. Foster has written that in counselling for abortion, "the overall objective is to decrease the patient's fears and anxieties."

Response:

Dr. Foster is a strong proponent of counselling to help women make their own decisions about abortion. Dr. Foster does not encourage his patients to undergo abortions.

Charge:

Dr. Foster advocates the development of in-home abortion to make it more available as a contraceptive.

Response:

Dr. Foster has researched non-surgical abortion methods using medications administered in hospitals, not in home settings. Although Dr. Foster believes abortions should be performed only as a last resort, he believes that they should be done in the safest manner possible. Therefore, he supports research into safer methods.

Charge:

Dr. Foster advocates abortion on demand for all nine months of pregnancy.

Response:

Dr. Foster does not advocate abortion but believes they should be available as a last resort. Dr. Foster believes in preventing abortions by preventing unplanned pregnancies. Abortions in the third trimester are generally illegal, and Dr. Foster would oppose such abortions.

SOCIAL ENGINEERING

Charge:

Dr. Foster advocates abortion for any fetus that shows any abnormality.

Response:

Dr. Foster does not advocate abortion in any case. He believes that prospective parents are entitled to as much information as is available regarding the health of the fetus. He believes that abortion should be available as an option but has worked to minimize the use of that option by developing treatments for fetuses with health problems.

Charge:

Throughout his practice, Dr. Foster has coerced women to get abortions.

Response:

Dr. Foster does not coerce his patients to have abortions, nor does he encourage them to have abortions. He is a strong proponent of counselling to help women make their own decisions about abortion.

Charge:

Dr. Foster advocates genetic testing with an eye toward encouraging abortion.

Response:

Dr. Foster believes that prospective parents are entitled to as much information as is available regarding the health of the fetus. He believes that abortion should be available as an option but has worked to minimize the use of that option by developing treatments for fetuses with health problems.

HYSTERECTOMIES

Charge:

In an article, Dr. Foster states that he has performed hysterectomies on mentally retarded women for hygienic purposes.

Response:

The article was written over 20 years ago, and relies upon medical theory from that time, which has since changed significantly. Dr. Foster has always advocated informed consent.

Charge:

Dr. Foster has justified a hysterectomy on the basis that the woman had a "dismal social history," i.e., was unmarried, had four children, was unemployed, and received no welfare assistance. ["Meigs' Syndrome Complicated by Pregnancy," 1972]

Response:

Dr. Foster has acknowledged that that article contains a value judgment that he shouldn't have made at the time and would not make today. He believes that the decision about whether to undergo sterilization should be made by the patient after receiving thorough and accurate information. In this particular case, the pelvic organs were removed because of the presence of a tumor with a high probability of malignancy.

Set #2

ABORTION FOR CONTRACEPTIVE PURPOSES

Charge:

Dr. Foster advocates the use of abortion as a means of contraception. He has specifically referred to abortion as "a contraceptive measure." (Contraceptives in Sickle Cell Disease, Southern Medical Journal, 1981)

Response:

- Dr. Foster does not equate abortion and contraception. In his writings and speeches, Dr. Foster has used the words abortion and contraception to denote two very different concepts. Dr. Foster has never advocated that abortion be used in place of contraceptives.

used as

- Although Dr. Foster acknowledged in his 1981 article that abortion is a type of contraceptive, he did not advocate the use of abortion as a contraceptive measure.

- Dr. Foster has not promoted the use of abortion solely for contraceptive purposes. In discussing its use as a contraceptive measure for women with sickle cell anemia, he stated that "clearly this would not be ideal."

patient / woman

- Instead, Dr. Foster has stated his preference that, even when the health of the mother is at issue, abortion should be used ~~for contraceptive purposes~~ only when other methods of contraception fail.

- Dr. Foster has not advocated the use of abortion. He specifically stated that the risks associated with abortion were too great, and his ultimate recommendation in the article was that barrier methods of contraception combined with timing should be used by women with sickle cell disease.

Charge:

Dr. Foster is cavalier and indifferent to the use of abortion.

Response:

safe, legal and

way to prevent unwanted pregnancy

- Dr. Foster believes that abstinence is the best ~~contraceptive~~, and that abortion should be rare. ~~(Nightline, Feb. 8, 1995)~~

(A) Dedicated his 30 yrs of practice

- Dr. Foster has expressed his concern about reliance on abortions rather than on birth control measures. (Family Planning and the Black Community, 1975). Dr. Foster has focused much of his energy on promoting family planning in order to prevent unwanted pregnancies and abortions.

Charge:

Dr. Foster has promoted in-home abortions to make them more available as contraceptives. (Upjohn Study, 1985)

Response:

- Although Dr. Foster believes abortions should be performed only as a last resort, he believes that they should be done in the safest manner possible. Therefore, he supports research into safer methods.

- As Chairman of the Obstetrics Department at Meharry Medical College, Dr. Foster was the principal investigator for an FDA-approved clinical trial to test the efficacy and safety of an abortifacient suppository administered during early pregnancy. The trial was a research project conducted in an academic setting and all medical procedures were conducted in the hospital. All patients were volunteers who gave informed written consent.

Charge:

Dr. Foster's treatment of abortion as a contraceptive measure is evidence of the liberal mind set that promotes sexual promiscuity among young people and does not require them to take responsibility for their actions.

Response:

- Dr. Foster has devoted much of his life and career to the community, establishing such programs as "I Have A Future" (IHAF), which seeks to provide positive alternatives to teenage pregnancy. Through IHAF, Dr. Foster has helped build the self-esteem of young men and women by providing education and job opportunities.

- Dr. Foster anchored the IHAF program in the neighborhoods where the young participants were living to ensure that their parents were involved with their choices. One critical aspect of the program is parental involvement.

STERILIZATION

Charge:

Dr. Foster advocates hysterectomies as a means of sterilization. He has performed hysterectomies to sterilize severely retarded individuals.

> "Recently, I have begun to use hysterectomy in patients with severe mental retardation. Hysterectomy can be done either for sterilization or to eliminate the menses, which is of significant hygienic benefit to those severely handicapped individuals." (Removal of the Normal Uterus, Southern Medical Journal, 1976).

Response:

- Dr. Foster stressed in this article that "obstetricians and gynecologists must guard vigilantly against the injudicious and indiscriminate removal of the normal uterus."

- Nonetheless, he recognized that hysterectomy might be appropriate for some severely retarded women. Medical theory has changed in the intervening decades, and Dr. Foster no longer believes that hysterectomy is appropriate solely for sterilization of a mentally retarded woman, although medical reasons might justify such a procedure.

- Dr. Foster has always advocated informed consent by the woman or her legal guardian.

Charge:

Dr. Foster has routinely encouraged sterilization of patients with sickle cell disease after they have been able to deliver a child. (Clinical Management: Sickle Cell State and Pregnancy, Urban Health, 1977).

Response:

- Dr. Foster actively opposed routine sterilization of sickle-cell-disease patients. He encouraged counseling, screening, and patient management to enable women with sickle cell disease to have healthy children.

Charge:

Dr. Foster has justified a hysterectomy on the basis that the woman had a "dismal social history," i.e., was unmarried, had four children, was unemployed, and received no welfare assistance (Meigs' Syndrome Complicated by Pregnancy, Journal of the National Medical Association, 1972).

Response:

• The procedure was medically necessary to remove a tumor with a high probability of malignancy. Dr. Foster noted in the article, however, that the woman's situation made the medically necessary removal of her reproductive organs "a bit less difficult." This insensitive comment reflected a value judgment Dr. Foster believes he should not have made then, and he would not make today.

Charge:

Dr. Foster's work and writings show a cavalier attitude toward sterilization. For example, he stated in 1972 that the number of tubal sterilizations -- 193 -- performed in one calendar year in a rural county with a small population was "low and in need of improving." (A Rural Hospital and Family Planning, 1972).

Response:

• Dr. Foster is not at all cavalier about sterilization. In a textbook on Ambulatory Gynecologic Surgery, he wrote: "As with abortion, the psychosocial dynamics associated with sterilization are profound and require special counseling. Sterilization should be offered only to mature women with no further desire of pregnancy."

• Dr. Foster has consistently advocated only voluntary, informed family planning. Moreover, he views family planning as only part of an overall strategy to improve health care, including reduction in infant mortality. He has stressed his opposition to "coercive sterilization" (same 1972 source).

• Dr. Foster has eloquently stated on numerous occasions that he, the father of two children and the grandfather of __, considers the creation of a human being one of the greatest joys anybody can have.

SOCIAL/GENETIC ENGINEERING

Charge:

Dr. Foster has promoted radical social engineering by encouraging amniocentesis and eventual abortions where there are any indications of genetic defects. In numerous articles, he has advocated monitoring pregnancies through amniocentesis so that patients can choose abortions. Additionally, he has encouraged patients to choose abortions where the woman was sick or where the child might have a genetic defect.

> "The couple must be provided with genetic counseling and offered antenatal diagnosis, with the option of pregnancy termination." Thalassemia, Hematologic Problems in Pregnancy, 1987);
>
> "It should be recommended that subsequent pregnancies be monitored by amniocentesis in such cases [couples with recurrent miscarriages] so that abortion can be made available for genetically abnormal fetuses when found." (Reproductive Performance in Women with Sex Chromosome Mosaicism, Obstetrics and Gynecology, 1980).
>
> "The presence of hemoglobin SS, SC, or sickle thalassemia, which constitute sickle-cell disease, should not be the sole justification for either abortion or sterilization. The procedures should be done on the basis of medical indications or patient desire, or both." (Transfusion Therapy in Pregnant Patients with Sickle Cell Disease, Annals of Internal Medicine, 1979);

Response:

- Dr. Foster has not and does not advocate aborting fetuses where there is a potential for genetic defects.

- Dr. Foster recognizes that his responsibility as a treating physician and health care academic is to inform patients and practitioners of medical options as those patients make difficult, often painful decisions regarding pregnancy and childbirth.

- Over the course of his career, Dr. Foster has devoted himself to preventing unwanted pregnancies and to improving the health of pregnant women and their fetuses, particularly in the case of sickle cell disease.

- Dr. Foster is dedicated to informing patients so they can make voluntary, educated choices about their medical options. For his valuable work in promoting greater knowledge on the part of patients he has received national recognition.

- Dr. Foster recommends antenatal diagnosis and genetic counseling for pregnant patients who are at risk for certain genetically transmitted traits, such as sickle cell disease. He has written that "proper counseling for pregnant patients is essential to provide education, reassurance, and optimal medical outcome." (Sickle Cell Disease in Pregnancy, Obstetrics and Gynecology Annual, 1982).