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The Honorable James G. Abourezk
United States Senate

Dear Senator Abourezk:

In our March 15, 1976, letter report (HRD-76-108) we responded to your April 30, 1975, and subsequent requests for information concerning activities of the Indian Health Service.

After our March letter report, we obtained a copy of the draft Urban Associates report and sent it to you. As discussed with your office, an analysis of the Urban Associates report and a review of the Indian Health Service's research, development, and training programs will be included in our continuing reviews of the Indian Health Service. As Chairman of the Subcommittee on Indian Affairs, Senate Committee on Interior and Insular Affairs, you will be provided copies of our future reports.

This letter presents our findings on the remaining topics on which you requested information:

--Medical research involving American Indian subjects.

--Research on the control of trachoma.

--Permanent sterilization of Indians at Indian Health Service facilities and contract facilities.

We discussed the results of our review with officials of the Indian Health Service, Department of Health, Education, and Welfare (HEW). Their comments have been recognized in preparing this report. They did not review the report nor provide written comments on its contents. However, during a briefing on August 3, 1976, with Indian Health Service officials and also in their letter of August 11, 1976, they agreed with our observations and recommendations. Our observations are summarized below; more detailed information is contained in the enclosure.

MEDICAL RESEARCH INVOLVING
INDIAN SUBJECTS

We obtained information on (1) selected medical research projects involving Indians for fiscal years 1972-75, (2) the adequacy of informed consent on certain projects involving Indians in fiscal years 1974 and 1975, and (3) the extent drug companies funded research projects involving Indians.

Informed consent, according to HEW regulations which the Indian Health Service follows, is required whenever an individual is considered to be "at risk." HEW's basic elements of informed consent are:

--A fair explanation of the procedures to be followed, including an identification of those which are experimental.

--A description of the attendant discomforts and risks.

--A description of expected benefits.

--A disclosure of appropriate alternative procedures that would be advantageous for the subject.

--An offer to answer any inquiries concerning the procedures.

--An instruction that the subject is free to withdraw consent and discontinue participation in the project or activity at any time.

We reviewed 56 proposals for research projects and, of the 36 projects entailing a service or treatment to Indians, we concluded that none appeared to expose participants to serious risks. However, Indian Health Service procedures for approving and monitoring research projects need strengthening. Officials said that they are revising research requirements and procedures to deal with the weaknesses we found. Our review of patient consent forms at selected projects did not indicate any significant inadequacies. Drug company involvement in Indian health research was minimal. (See pp. 1-10, enc. I.)

TRACHOMA RESEARCH
INVOLVING INDIAN SUBJECTS

Based on information furnished by your office, including a March 28, 1975, letter from the Children's Defense Fund, we concentrated on the following three areas:

--Whether Indian children are being used as subjects in trachoma experiments.

--If Indian children are being used in such experiments, whether informed parental consent has been obtained.

--Whether Indian patients with trachoma are subject to unnecessary risks because of the drugs used to treat the disease.

The Proctor Foundation for Research in Ophthalmology, University of California, conducted trachoma research. The research involved Indian children in three boarding schools and was conducted during school years 1967-68 through 1972-73. Proctor terminated its participation in the Indian Health Service's trachoma control and surveillance program in September 1974. The Children's Defense Fund allegation that for most of the research period there was no informed parental consent appears correct.

Parental consent forms were obtained during the last year of the research. However, parental consent was not obtained earlier because Proctor believed it was not necessary "since the Indian Health Service acts as legal guardian for the children while they attend the boarding schools * * *" and because "* * * only accepted freely available drugs in standard doses are employed."

We believe that the drugs used by the Indian Health Service to treat trachoma did not subject the Indians to any unnecessary risk. (See pp. 10-16, enc. I.)

STERILIZATION OF INDIANS

Indian Health Service records show that 3,406 sterilization procedures were performed on female Indians in the Aberdeen, Albuquerque, Oklahoma City, and Phoenix areas during fiscal years 1973-76. Data for fiscal year 1976 is for a 12-month period ending June 30, 1976.

Of the 3,406 procedures performed, 3,001 involved women of child-bearing age (ages 15-44) and 1,024 were performed at Indian Health Service contract facilities. (See enc. II.)

HEW responded to an order of the U.S. district court for the District of Columbia by issuing regulations on April 18, 1974, which (1) continued a July 1973 moratorium on sterilizing persons who were under 21 years of age or mentally incompetent, (2) specified the informed consent procedures for persons legally capable of consenting to sterilization, and (3) omitted the requirement "that individuals seeking sterilization be orally informed at the outset that no Federal benefits can be withdrawn because of failure to accept sterilization."

Even though the number of persons under 21 years of age sterilized has decreased considerably since the regulations were issued, the Indian Health Service identified 13 moratorium violations between April 30, 1974, and March 30, 1976. The violations occurred apparently because (1) some Indian Health Service physicians did not completely understand the regulations and (2) contract physicians were not required to adhere to the regulations. (See pp. 18-20, enc. I.)

For the sterilization procedures we reviewed in detail, we found consent forms in the medical files. However, as of September 1975, the Aberdeen, Albuquerque, Oklahoma City, and Phoenix areas were generally not in compliance with the Indian Health Service regulations. Several different consent forms were used. The most widely used form did not (1) indicate that the basic elements of informed consent had been presented orally to the patient, (2) contain written summaries of the oral presentation, and (3) contain a statement at the top of the form notifying subjects of their right to withdraw consent. One consent form document did meet the Indian Health Service requirements, but when used was filled out incorrectly.

As agreed with your office, we did not interview patients to determine if they were adequately informed before consenting to sterilization procedures. We believe such an effort would not be productive because recently published research noted a high level of inaccuracy in the recollection of patients 4 to 6 months after giving informed consent. (See p. 8, enc. I.)

RECOMMENDATIONS

We recommend that the Secretary of HEW direct the Indian Health Service to

--expedite its efforts to have a standard consent form which provides for full disclosure of the information required by the regulations (enc. IV shows a form that could serve as a guide to counsel patients and which details all the basic elements of informed consent),

--provide training to their physicians and administrators so that they fully understand the requirements concerning (a) sterilization of persons under 21 and persons who are mentally incompetent and (b) obtaining informed consent,

--include in the contracts with non-Indian Health Service physicians and facilities, provisions to insure that contractors comply with HEW sterilization regulations,

--continue to monitor compliance with the moratorium on sterilization of persons under 21 years of age, and

--develop monitoring procedures to assure compliance with the regulations by contract physicians and facilities.

We also recommend that the Secretary of HEW direct that HEW sterilization regulations be amended to (1) conform with the ruling of the U.S. district court order that a patient, regardless of the consent form document used, be informed orally that no Federal benefits can be withdrawn or withheld if they decide not to be sterilized and (2) require that the signature of the person obtaining a patient's consent appear on the consent form.

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As agreed during a December 1, 1975, meeting with your office, we are sending a copy of this report to Senator Edward Kennedy.

B-164031(5)

This report contains recommendations to the Secretary of Health, Education, and Welfare. As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report. We will be in touch with your office in the near future to arrange for release of the report so the requirements of section 236 can be set in motion.

Sincerely yours,

Comptroller General
of the United States

Enclosures - 4 -

SUMMARY OF INFORMATION OBTAINED

MEDICAL RESEARCH INVOLVING INDIAN SUBJECTS

The Indian Health Service (IHS) has a policy of promoting, whenever feasible, research projects and activities concerning American Indian health, provided that:

--The projects are directed toward improving the health of Indians.

--Projects have the approval of, and are understood by, the tribal groups involved.

IHS identified 56 projects, excluding trachoma experiments, involving Indian participation during fiscal years 1972-75. Most projects were conducted in the Phoenix and Navajo areas, where committees have been established to review proposed research projects and professional papers submitted for publication.

After reviewing each of the protocols and contacting the Phoenix and Navajo area research and publications committees and, in most instances, the project researcher, we categorized the 56 projects as follows:

Number of projects	Category
7	Project was approved but never started.
13	Project did not entail a service to or treatment of Indian subjects. (Usually involved research of medical records.)
12	Project involved a medical practice, procedure, or drug dosage considered usual and customary.
24	Project involved a medical practice, procedure, or drug dosage, which was not considered usual or customary.

We reviewed and compared the 24 projects involving a medical practice, procedure, and/or drug dosage, which was not considered usual or customary. We selected five projects involving Indians in fiscal years 1974 and 1975, based on one or more of the following criteria:

--The risk to the patient appeared higher. None of the projects, however, was considered to involve serious risk to the patient.

--The potential benefit appeared more significant.

--The reason for selecting Indian subjects was not apparent.

Description of the five projects

Information obtained from the five project protocols and the principal researchers, and our comments concerning the significance of the project and potential hazards, are presented below.

Evaluation of prediabetics in the Pima Indians

The project was conducted in 1974, by the National Institute of Arthritis, Metabolism and Digestive Disease at the Phoenix Indian Medical Center and funded by the National Institutes of Health. Seventy-one Indians were paid to participate in the project.

The project attempted to determine the state of certain small blood vessels of Pima Indians who are considered potential diabetics. Previous evidence indicates that changes occur in certain blood vessels before a person becomes a diabetic. Identification of such changes could detect prediabetics.

The Pima Indians are a logical group for the study because of the high prevalence of the disease among members. They are a relatively stable population, a factor advantageous for long-term followup.

The study involved (1) taking several blood samples using an intravenous catheter, (2) administering two doses of cortisone, and (3) performing a needle muscle biopsy.

Discomfort to the patient may result from the indwelling venous catheter (2-5 hours each day) and the muscle biopsy. In either procedure, hematoma (a tumor or swelling containing blood) could occur. The National Institute of Arthritis, Metabolism and Digestive Disease reports that in another study over 1,500 muscle biopsies were performed by the same method and hematomas occurred in 3 cases. One case healed in several days, two required a week to resolve, and none

required further therapy. Infections may also result from the above procedures. There is also potential danger resulting from too large a dosage of cortisone.

The principal researcher said that there were no cases of hematomas, infections, or identified errors in administering cortisone during the project.

Low density lipoprotein metabolism in southwestern Indians

This project, conducted in 1975, was also funded by the National Institutes of Health and performed by the National Institute of Arthritis, Metabolism and Digestive Disease at the Phoenix Indian Medical Center. Twenty-two individuals were paid to participate in the project--12 were Indians and 10 were Caucasians.

This study deals with cardiovascular diseases. Southwestern Indians are logical choices for such a project because they are less prone to atherosclerotic cardiovascular disease than non-Indians. Positive results could lead to a reexamination of current diets and drug therapy designed to lower serum cholestrol values to prevent coronary artery disease. The study also proposes to explore more fully the cause for the increased incidence of cholesterol gallstones in the American Indian.

The project involves removing 150cc of blood from the patient. The blood is then centrifuged. The patient is later given blood proteins and a radioactive element intravenously. Blood and urine samples are collected and tested daily for 2 weeks.

Reinjecting the patient's blood could produce an allergic reaction. The patient also receives potassium iodide which sometimes causes gastro-intestinal upset and a skin rash. The principal researcher said that these reactions are rare and were not experienced by the participants in this project.

The pharmacist as a provider of primary medical care--IHS hospitals

This project was funded by the National Center for Health Services Research and Development and conducted by IHS at the Phoenix Indian Medical Center and Sacaton Indian Hospital. There were 504 Indian participants in the project; none were paid.

The project is unusual because the pharmacist is not generally thought of as a primary provider of direct patient care. The program intends to evaluate the pharmacist's ability to help a physician manage certain specified acute and chronic conditions.

There is no apparent reason for using Indians as subjects because the project objectives could be achieved just as well outside of IHS. The chairman of the Phoenix area research and publication committee said, this project was more of a training program than a research project. We did note in the project's proposal that the stated objectives included continuing and expanding the pharmacist's ongoing role at the Phoenix Indian Medical Center.

The following safeguards against potential risks were approved by the Phoenix area research and publications committee:

--Each individual will be given a choice of being seen by a pharmacist-practitioner or a physician.

--Every patient must give informed consent.

--Each pharmacist-practitioner will wear a name tag indicating his profession. He will also identify himself verbally to each patient.

--The pharmacist-practitioners will all be given 50 hours of didactic training by a physician, followed by 3 to 4 months on-the-job training until proficiency is assured in specific, defined tasks.

--Prompt (within 24 hours) physician review of each patient consultation performed by the pharmacist-practitioner. The physician will determine whether the consultation and remedial actions were appropriate.

The acting chief pharmacist of the Phoenix IHS area, who is also a pharmacist-practitioner, said that the safeguards were met. However, informed consent was not documented, as required by HEW research guidelines. The acting chief pharmacist said that he was unaware of the need to document patient consent. He said that patient consent was received orally by either the hospital's nurse receptionist or the pharmacist-practitioner.

The chairman of the research committee said informed consent was not documented because of the committee's lack of specific instructions on how the project was to comply

with HEW standards. (See p. 6.) The chairman thought that the research committee unofficially relied on assurances of the director of a similar physician extender program being conducted by IHS that oral consent without documentation was acceptable.

The acting chief pharmacist also said that during the program's training phase, a qualified physician did review the pharmacist-practitioner's work concurrently with the patient's visit. However, since the completion of the training phase in April 1975, there has not been a continuing review of the pharmacist-practitioner's work at the Phoenix Indian Medical Center by a qualified physician. We brought this to the Phoenix Indian Medical Center director's attention in May 1976. He said that immediate steps are being taken to assign the four pharmacist-practitioners at Phoenix Indian Medical Center to a qualified physician. The physician will be responsible for periodically monitoring the pharmacist-practitioner's work.

White Mountain Apache pediatric pulmonary disease study

The project which was funded by IHS, was conducted at Whiteriver Indian Hospital by Project Apache, a maternal and child health program conducted by the Samaritan Health Services, Inc. Ninety-four Indian children participated in the project; none were paid.

The purpose of this study is to determine the underlying factors contributing to the high incidence of respiratory disease in Apache Indian children. This illness is the leading cause of death among infants and the second most common diagnosis of children admitted to the IHS Hospital, Whiteriver, Arizona. Death caused by respiratory disease is more common among Apache Indians than non-Indians.

Among the tests to be performed on some children were (1) a laryngoscopy (a procedure using an instrument for examing the interior of the larynx) which might be hazardous and (2) aspiration of stomach contents. The latter requires intubation (swallowing a tube), a difficult and uncomfortable procedure for a child. All children were given blood tests, which can be painful. The principal researcher told us there were no unusual problems during this study.

Epidemiologic surveillance and vaccine trial of pneumococcal pneumonia in Navajo Indians

This project was performed at Gallup Indian Medical Center by IHS and the University of New Mexico from fiscal years 1972-75. Funding was provided by IHS, the National Institutes of Health, and Eli Lilly Company. None of the participants were paid.

The project protocol identifies pneumococcal pneumonia as a major cause of death on the Navajo reservation. To determine if this mortality rate could be reduced, IHS had planned to test a vaccine on at least 3,000 persons. The possible reactions to the vaccine are redness, swelling, tenderness, and pain at site of injection. A local infection could also develop, as well as a general reaction, including fever and a general malaise.

The vaccine was first tested on 27 individuals, including 6 Indians. The principal researcher said that, except for local infections, the above reactions occurred in most subjects and caused some loss of time from their jobs. The principal researcher said that the reaction rate among the pilot group was too high to risk any more immunizations. The vaccine trial was discontinued.

Receipt of informed consent on selected projects

According to HEW criteria, informed consent is required whenever an individual is considered to be "at risk." The determination of when an Indian subject is "at risk" is determined by the IHS research and publication committee during review of the research protocol.

HEW's basic elements of informed consent are:

--A fair explanation of the procedures to be followed, including an identification of those which are experimental.

--A description of the attendent discomforts and risks.

--A description of the benefits to be expected.

--A disclosure of appropriate alternative procedures that would be advantageous for the subject.

—An offer to answer any inquiries concerning the procedures.

—An instruction that the subject is free to withdraw his consent and discontinue participation in the project or activity at any time.

Informed consent, which must be documented, can be obtained by any of the following methods:

—The written consent which includes an explanation of the basic elements of informed consent. The form is to be signed by the subject or his authorized representative.

—The written consent which indicates that the basic elements of informed consent were orally presented to the subject or his authorized representative. If this approach is used, written summaries of what the patient would be told are to be approved in advance by the research committee. The consent form is to be signed by the patient or his authorized representative, and by a witness to the oral presentation and to the subject's signature. The written summary is to be signed by the person obtaining consent and by the witness.

—Informed consent can be a modification of the above two procedures. Modifications are to be approved by the research committee and recorded in the meeting's minutes. The minutes must be signed by the committee chairman.

For three of the five projects we selected, we examined the medical files of the Indians involved for written informed consent. We did not verify the receipt of informed consent for the other two projects because one involved only six Indian hospital employees and the other project, concerning pharmacist-practitioners, obtained oral, not written, consent. The results of our verification follow.

Project name	Number of participants	Number of consent forms verified	Difference
Evaluation of Prediabetics in the Pima Indians	71	65	a/6
Low Density Lipoprotein Metabolism in Southwestern Indians	12	11	a/1
White Mountain Apache Pediatric Pulmonary Disease Study	94	90	b/4

a/At the time of our verification, the medical file was either missing from the files or the participant's file number was incorrect. The project's researcher later said that the discrepancies had been corrected and all consent forms had been located.

b/Consent forms were missing from patient medical files and could not be located.

Of the three projects, the consent form used on the White Mountain Apache study was the only one that generally lacked full written disclosure of each of the basic elements of informed consent. However, the principal investigator said that the child's parent or legal guardian was fully informed when they signed the consent form.

A review of the research committee files failed to disclose the receipt and approval of written summaries, as required by HEW guidelines, of what the patient (in this case the child's parent or legal guardian) would be told.

We did not interview patients to determine if they were adequately informed of the risks, discomforts, and benefits of the project. We believe that such an effort would not be productive because (1) no serious hazard existed for the patients and (2) recently published research noted a high level of inaccuracy in the recollection of patients 4 to 6 months after giving informed consent.

The Medical Tribune and Medical News issue dated February 25, 1976, reported that several New York doctors tape recorded all informed consent conversations held with cardiac surgical patients at Montefiore Hospital and Medical Center during 1975. The team then randomly interviewed 20 patients

4 to 6 months postoperatively to determine how much the patients remembered. The interview included a discussion of the risks and benefits. On the average, the patients recalled less that one-third of the surgeon's discussion. Even with prompting, the average overall recall was only about 42 percent.

Extent of drug company participation in research projects involving Indian subjects

From the 56 projects identified by IHS, we identified 4 projects in which various drug companies provided free drugs for testing Indian subjects. The drugs were pneumococcal vaccine, vitamin C, iron tablets, tylenol, and darvon. Two of the projects also were funded, in part, by drug companies. In our opinion, the four projects did not demonstrate extensive involvement by drug companies in IHS-approved research nor did they involve significant risk to Indian participants.

Epidemiologic surveillance and vaccine trial of pneumococcal pneumonia in Navajo Indians

IHS' principal investigator said that Eli Lilly Company had developed a pneumococcal vaccine in conjunction with the National Institutes of Health. In 1974 when the vaccine was ready for testing on Indian subjects, Eli Lilly paid IHS $26,688 and the University of New Mexico $51,582. The vaccine and placebo were provided free. As discussed on page 6, a major reason for terminating the project was the adverse reactions experienced by the individuals in the pilot study group.

According to IHS' principal investigator, Eli Lilly has decided to discontinue manufacturing all vaccines. As a result, all funding and other forms of participation by the drug company in this vaccine research project were discontinued.

Evaluation of ascorbic acid prophylaxis

IHS and the University of Pittsburgh conducted a project at the Navajo reservation Toyei and Greasewood boarding schools to test whether daily doses of vitamin C can prevent respiratory and certain nonrespiratory diseases. Over 1,500 students were involved in the 1973-74 project.

IHS' principal investigator said that the Hoffman LaRoche Company supplied the vitamin C and granted the University of Pittsburgh about $10,000 to participate in the study.

The published results from the 1973 study indicated that those students receiving vitamin C had fewer days of morbidity from respiratory illness than those not receiving vitamin C. The principal investigator, no longer with IHS, said that the 1974 results have not been published.

Hemotologic standards and extent of iron deficiency in Navajo children ages 6-12

This project, conducted by IHS in 1972, entailed giving iron tablets to about 300 children at the Crystal, Hunters Point, and Lower Greasewood boarding schools on the Navajo reservation. Baun Laboratories donated the tablets.

The project's purpose was to determine the optimum ratio of red blood cells to the volume of whole blood (hematocrits) and iron in red blood cells (hemoglobins) for the high altitude present on the Navajo reservation. Iron deficiency in children of the 6 to 12 age group was also determined.

The principal researcher, no longer with IHS, said that the data still needs to be analyzed. He said, however, about 2 percent of the children had iron deficiency anemia and were treated immediately.

A comparison of the analygesic effectiveness and safety of tylenol

The purpose of this project, performed by IHS in fiscal years 1974 and 1975 on 225 patients at the Gallup Indian Medical Center, was to compare the effectiveness and safety of acetaminphen (tylenol) versus propoxphene hydrochloride-APC combination (darvon).

Patients suffering from moderate-to-severe pain related to surgery were randomly given either tylenol, darvon, or a placebo. The drugs and the placebo were donated by McNeil Laboratories, Inc.

The published results showed that tylenol was safer and more effective than darvon.

TRACHOMA

Based on information furnished by your office, including

a March 28, 1975, letter from the Children's Defense Fund, we concentrated on the following areas:

--Whether Indian children are being used as subjects in trachoma experiments.

--If Indian children are being used in such experiments, whether informed parental consent has been obtained.

--Whether Indian patients with trachoma are subject to unnecessary risks because of the drugs used to treat the disease.

Trachoma has been a problem of the American Indians since the early explorers. It is a viral disease that causes a chronic contagious inflammation of the membrane surrounding the inside of the eyelids and the eyes.

According to IHS, the maximum incidence of active trachoma usually occurs among Indian children about 8 years old. The disease generally results from poor personal hygiene, attributable mostly to the lack of an adequate water supply. The disease is most common in desert populations where the economic level is low, and health, education, and personal hygiene are deficient.

In the 1930s, following the discovery of sulfonamide therapy for trachoma, a massive effort was undertaken to treat the disease among American Indians. Based on the number of Indians examined and the positive cases identified, the incidence rate subsequently dropped from 20 to 5 percent.

However, the trachoma program was stopped during World War II because of the physician and nurse shortage, and it was not reestablished. Trachoma disease rates subsequently increased. This resulted in congressional appropriations, starting in fiscal year 1967, for another trachoma program. From fiscal year 1967-75, IHS' reported yearly funding for trachoma control ranged from $283,000 to $340,900.

The IHS Phoenix Area Trachoma Control Office reported that a comprehensive trachoma control program was instituted in August 1966. In this area the trachoma rate decreased from 13.8 percent to 3.1 percent between fiscal years 1967 and 1975, respectively. The reduction was attributed to the trachoma treatment program and to improved conditions in sanitation and home environment. The contribution of each factor is not known.

Involvement of Indian children

The Proctor Foundation for Research in Opthalmology, University of California, San Francisco, performed trachoma research using Indian children from school years 1967-68 through 1972-73. The purpose was to determine the best method of treating active trachoma, including a comparison of oral triple sulfa, tetracycline, and a placebo on Indian children with active trachoma. The IHS senior clinician in opthalmology said that the studies usually lasted 4 to 5 months and the children who received the placebo were given standard treatment by the end of the study. Because the disease was mild, the delay in treatment was not considered harmful. The table below identifies the Indian school, period of testing, and drugs tested by Proctor.

School	School year 1967-68	1968-69	1969-70	1970-71	1971-72	1972-73
Stewart: (Carson City, Nev.)						
oral triple sulfa	X					
placebo	X	X				
tetracycline		X				
Intermountain: (Brigham City, Utah)						
tetracycline		X	X			
doxycycline (note a)			X	X		
placebo		X		X		
Tuba City, Ariz.:						
doxycycline					X	X
placebo					X	X

a/Doxycycline, a derivative of tetracycline is administered only once daily. Tetracycline must be given several times a day.

Since school year 1972-73, Proctor has done some followup on earlier research studies. The followup, according to the IHS senior clinician in opthamology, was limited to examining some patients involved in the earlier studies.

On July 14, 1975, Proctor reported that it had abandoned research on American Indians as of September 1974. Following a meeting with the Children's Defense Fund, Proctor prepared the following statement which states why it abandoned the research.

> "I brought out clearly that we were aware how easily a case could be construed that we were using 'defenseless minority children' to study an immunological problem, without direct and immediate therapeutic impact, and not presenting a major health problem among

> American Indians in 1974-75. This was a political issue, not a scientific or medical one. We were not willing to invite 'trial by publicity' (which has been common in recent years), and, therefore, we had abandoned experimentation on American Indian children as of September 1974. We realized fully that such withdrawal on our part would mean a possible reduction in ophthalmological surveillance and care for these children."

A 1975 report by the Phoenix IHS area attributes the phasing out of research to the small number of active trachoma cases at any given location. The report states that there are not enough cases to draw a valid conclusion. The report also indicates that "previous drug studies have given us the tools to comfortably treat trachoma to the point where mass research is no longer possible." The IHS senior clinician in opthamology said, however, that additional research is needed to determine why certain individuals are being reinfected with the disease. Proctor, before discontinuing trachoma research using Indian subjects, was planning to do research on the causes of the reinfection. This would have involved a relatively small number of individuals.

Receipt of informed parental consent

Since Proctor has discontinued trachoma research, the matter of obtaining informed parental consent is no longer a current issue. Informed consent problems that may have existed were highlighted in the Children's Defense Fund materials supplied to us by your office. The Defense Fund's allegation that, for most of the research period, there was no informed parental consent appears correct. The school year 1972-73 was the first time that Proctor Foundation received informed consent forms from parents of children involved in trachoma research. During school year 1971-72, Proctor and IHS decided to obtain individual informed consent. Since the school year was already underway, they believed that it would confuse the parents if they began seeking informed consent at that time. Research approvals, however, were received from the area research and publication committee, tribal advisory board, school board, school principal, and service unit director. Some approvals appear to be in response to an October 8, 1971, letter from the Director, IHS, to Proctor which stated

> "It is the policy of the Indian Health Service that written consent of the tribal group involved must be obtain prior to approval of

a research project. In addition, as you know, research proposals must be reviewed by both the Area and Headquarters Research Committees."

Correspondence between Proctor's principal investigator and the University of California committee on research indicates the lack of receipt of individual informed consent was based upon the premise that the work they were performing was on behalf of IHS. Further, Proctor believed that because IHS was acting as legal guardian for the children while they attended the boarding schools, and only commonly prescribed drugs in standard doses were used, specific consent was not required.

Safety of drugs used to treat trachoma

One principal allegation of the Children's Defense Fund centered around the safety of the drugs used to treat trachoma. The Fund alleged "The natural course of trachoma in this country usually ends with complete recovery." Our review showed that IHS was not subjecting Indians to unnecessary risks by treating trachoma.

IHS reports that the present-day trachoma among American Indians is mild compared to the classical form found in the North African countries. Even though the remission rate is high and visual complications are rare, IHS' senior clinician in opthalmology said that untreated trachoma could, in some cases, result in blindness or other serious eye problems. Hence, he believes, and we agree, that if treatment was ended, blindness or serious vision problems could result. In his opinion, continued treatment of trachoma has reduced the incidence of the disease as well as its chances of spreading. Based on the results of reexaminations 3 to 4 months after the initial treatment, IHS reported a success rate from 70 to 80 percent. Subsequent treatments usually result in a continuing higher overall success rate.

The Proctor drug research which showed that tetracycline was safer than, and as effective as, triple sulfa, caused IHS, beginning in 1972, to use oral tetracycline to treat trachoma for individuals 8 years and older.

According to the IHS senior clinician in ophthalmology, triple sulfa is still used on children under 8 years of age, because tetracycline, if used in this age group, could result in stained teeth and affect the development and fusion of bone joints.

ENCLOSURE I

Tetracycline is approved by the Federal Drug Administration and is considered the drug of choice for treating trachoma by "The Medical Letter on Drugs and Therapeutics," a nonprofit publication. "The Physicians' Desk Reference" also identifies tetracycline as a treatment for trachoma as well as other disorders.

The use of tetracycline and triple sulfa for treating trachoma usually results in temporary clinical improvement, but may not eliminate the infectious disease.

IHS Phoenix area guidelines identify several specific situations, depending on an individual's health, when neither drug would be used. For example, some individuals would not receive either drug it they were pregnant or had a liver or kidney impairment.

The guidelines also identify the following reactions and side effects that can occur when tetracycline or triple sulfa is used to treat trachoma.

Tetracycline	Triple sulfa
anorexia (loss of appetite)	fever of unknown origin
vomiting	vomiting
pruriticani (itching in anal region)	headache
photosensitivity (light hurts eyes)	abdominal distress
nausea	nausea
diarrhea (many watery bowel movements)	urticaria (hives)
rash	rash
	hematuria (blood in urine)
	mucous membrance ulceration (a sore/blister on lips or inside mouth)
	swelling of lips

If there is to be a reaction or a side effect, the above symptoms generally occur 7-14 days after the administration of tetracycline and 7-10 days after the administration of triple sulfa. The guidelines provide for followup by the treatment nurse. In the case of sulfa treatment, the patient is to be seen twice a week. Tetracycline patients are to be seen twice the first week and once a week for the following 2 weeks.

The Phoenix area annual reports for trachoma and eye care identified the following number of drug reactions for fiscal years 1967-75. The reported number of treatment cases are those where the records were sufficiently complete to make the following drug sensitivity assessment.

Fiscal year	Total treated	Mild reactions from treatment (note a)	Specific reactions from treatment (note b)	Percent of specific reactions
1967	6,594	144	69	1.05
1968	6,531	150	99	1.52
1969	3,847	141	48	1.25
1970	4,294	160	52	1.21
1971	3,602	114	75	2.08
1972	2,092	(unknown)	c/19	.91
1973	1,485	17	8	.54
1974	1,779	42	20	1.12
1975	1,012	44	10	.99

a/Nonspecific reactions--fever, headache, nausea.

b/Specific reactions were skin reactions, skin reactions and temperature, Stevens Johnson reaction, mucous membrane blister, swollen lips, or treatment discontinued because of topical irritation.

c/The drop is primarily attributed to the substitution of oral tetracycline for triple sulfa.

AREA RESEARCH AND PUBLICATIONS COMMITTEES

We reviewed the procedures followed by the Phoenix and Navajo area research and publication committees in their review of proposed research projects. We believe these procedures need strengthening.

A prime function of both committees is to review all proposed research projects involving Indian subjects within their respective areas and to approve or reject each project. Once a project is approved, however, the committee's involvement appears limited. For example, neither the Phoenix nor Navajo research committees have a formal process for following up on approved research projects. As a result, there is no assurance that researchers are conducting the project by the protocol approved by the research committee.

ENCLOSURE I

IHS guidelines provide that the researchers submit annual progress reports. However, the files for 38 research reports in the Phoenix and Navajo areas showed that for 16 of these projects periodic reports were not on file. Also, the formats used by various researchers varied greatly.

We believe IHS guidelines should be strengthened to provide for better overall monitoring of all research activities. Specific improvements should include (1) periodic monitoring of each researcher's activities to insure full compliance with the approved protocol and (2) identifying the type of information the committee desires on progress reports. We also believe IHS should assure itself that the researchers submit progress reports in a timely manner.

We also noted that the Phoenix area research committee, in many cases, is approving research projects contingent upon the researcher obtaining tribal and/or other approvals. However, no documentation was contained in the research committee files showing that tribal approvals were obtained. We believe the committee should withhold final approval until the researcher provides evidence of tribal and other necessary approvals.

Agency comments

During a briefing on August 3, 1976, with IHS officials and also in an IHS letter of August 11, 1976, IHS agreed with our observations and recommendations and said it has been aware of deficiencies in such procedures for several years. In 1969 and again in the early 1970s IHS drafted new guidelines to deal with these deficiencies. However, as the issuances neared completion, more controversy and discussion on human experimentation and protection of human subjects surfaced at the national level, with the promise of definitive HEW guidelines and regulations.

Most of the HEW guidelines and regulations were finalized by late 1975. At that time IHS revised its research manual and sent the revisions to its field personnel and Indian groups for review and comment. Several comments and recommendations have been received and will be incorporated.

Also, recently the Public Health Service and the Health Services Administration have prepared separate draft policy and procedural guidelines dealing with this subject. Before issuing a final manual chapter, IHS wishes to make certain the chapter will be consistent with such guidelines. Hopefully this process will be completed in the near future and the IHS research policy and procedures will be issued.

IHS believes the draft manual addresses the major deficiencies we noted. Specifically, it believes that the proposed policy and procedures will:

"(1) Provide specific guidelines for the authorities, responsibilities and functions of Area and Headquarters Research Review Committees, including membership, ongoing monitoring requirements, formal review procedures, cataloging, reporting, etc.

(2) Provide specific guidelines for information required and reporting frequency for ongoing projects.

(3) Provide for a central repository of all proposed, ongoing and recently completed projects along with appropriate required reports and activity status.

(4) Mandate that Tribal approval be obtained before favorable action by any IHS research committee.

(5) Provide a management structure that will assure proper review, monitoring and evaluation of all research activities."

PERMANENT STERILIZATION OF INDIANS

Voluntary or nontherapeutic sterilizaton is defined in the HEW regulations as "any procedure or operation, the purpose of which is to render an individual permanently incapable of reproducing." Sterilizations to treat an existing illness or injury are classified as therapeutic sterilizations.

IHS records identify the number of surgical procedures resulting in sterilization. For fiscal years 1973-76 (number of contract cases for fiscal year 1976 is only 10 months) the records of the Aberdeen, Albuquerque, Oklahoma City, and Phoenix IHS areas showed 3,406 female sterilization procedures. This includes 3,001 women of child bearing age (ages 15-44). Of the 3,406, 30-percent (1,024) were performed by doctors and facilities under contract to IHS. (See enc. III.) For the same period, 142 male sterilization procedures were reported. IHS' information system does not classify these sterilizations as voluntary and therapeutic.

To assess IHS compliance with HEW regulations concerning voluntary sterilizations, we requested its records and data for female sterilizations in the Aberdeen, Albuquerque,

Oklahoma City, and Phoenix areas performed between April 1 and September 30, 1975. As of August 1976, however, IHS was unable to supply us with complete and statistically reliable data on (1) whether the sterilizations were voluntary or therapeutic and (2) the ages of the patients.

We found no evidence of IHS sterilizing Indians without a patient consent form on file, although we did find several weaknesses in complying with HEW's sterilization regulations. The primary weaknesses related to (1) sterilization of persons under 21 years of age, (2) inadequately documenting what the Indian subjects were told before signing the consent form (largely attributable to the use of consent forms that failed to meet HEW standards), (3) lack of widespread physician understanding of the regulations, and (4) the lack of definitive requirements for informed consent when sterilizations are performed by contract doctors at contract facilities.

HEW sterilization regulations

In response to a March 15, 1974, order of the U.S. district court for the District of Columbia, HEW published in the Federal Register on April 18, 1974, revised regulations concerning human sterilizations (42 C.F.R 50.201-50.204). The regulations prohibit using Federal funds for the voluntary sterilization of anyone under the age of 21 or legally incapable of consenting to the sterilization (declared mentally incompetent under State laws). The regulations also state that individuals wanting to be sterilized must first give their consent after they have been provided the six basic elements of informed consent. (See p. 6.) For sterilizations, the explanation of these basic elements must also include other appropriate family planning methods and the effect of the proposed sterilization including the irreversibility of the procedure. Also, the individual has to be informed that he or she is free to withdraw consent at any time.

Informed consent must be evidenced by a document which is either (1) a written consent document detailing all the basic elements of informed consent or (2) a short form written consent document indicating that the basic elements of informed consent have been presented orally to the patient, and a summary of the oral presentation. Both forms must contain the following statement at the top: "Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects." The short form document must be signed by the patient and an auditor-witness to the oral presentation,

and the written summary must be signed by the person obtaining the consent and the auitor-witness.

For voluntary sterilizations, HEW regulations also provide for a waiting period of at least 72 hours after the patient's consent.

With one exception, HEW's regulations complied with the court order. The exception was the court's requirement "that individuals seeking sterilization be orally informed at the outset that no Federal benefits can be withdrawn because of failure to accept sterilization." The HEW regulations allow this information to be presented in writing when the detailed written consent document is used. To comply with the court order, the regulations should specifically provide that the required printed statement be read to the patient. The statement should also be signed by a witness as evidence that it was presented orally.

Sterilization of mentally incompetent persons and persons under the age of 21

The HEW policy and guidelines prohibiting Federal financial participation in sterilizing the mentally incompetent or persons under 21 years of age was initially announced on July 23, 1973, by the Secretary of HEW. On August 2, 1973, the IHS Director sent the following telegram to all area directors:

> "* * * there is, effective immediately, a temporary halt in the IHS sterilization procedures performed on an individual who is under the age of 21 or who is legally incapable of consenting to sterilization. This policy does not apply when the operation is performed for the surgical treatment of specific pathology of the reproductive organs * * *."

The moratorium was reconfirmed by an October 16, 1973, memorandum to the area directors and in an April 29, 1974, telegram in which the area directors were informed they would be provided a copy of April 18, 1974, HEW sterilization regulations. On August 12, 1974, IHS headquarters sent another memorandum to its physicians, with a copy to all area directors emphasizing the importance of the HEW's sterilization regulations. A copy of the HEW regulations and a copy of the Director's telegram was attached to the memorandum.

ENCLOSURE I

To further clarify the HEW sterilization policy, the Director notified area and service unit personnel, in a memorandum dated December 15, 1975, that a sterilization of individuals under 21 years of age or mentally incompetent is permissible only when "the procedure is carried out for 'medical reasons' unrelated to the primary intent to sterilize the individual. Examples could include cancer of the pelvic organs and uncontrolled uterine hemorrhage."

IHS began monitoring the HEW sterilization regulations in September 1974 by preparing a special periodic computer printout identifying selected information on all sterilization cases, including the patient's age. Beginning in November 1974 area directors were requested to furnish headquarters pertinent information on each sterilization performed on persons under 21 years of age. In subsequent requests, the area directors were specifically requested to provide information on (1) the medical reason for performing the sterilization, (2) if not for medical reasons, the reason for performing the procedure and the reason why HEW sterilization regulations were not followed, and (3) the action taken to insure their compliance with the HEW sterilization regulations.

IHS identified and categorized 36 moratorium violations occuring between July 1, 1973, and March 30, 1976. Twenty-three of the 36 violations occurred after the moratorium but before April 29, 1974, when area directors were informed of the HEW regulations. As shown in the following table, 13 violations occurred between April 30, 1974, and March 30, 1976.

Justification provided by IHS	Before April 30, 1974	After April 30, 1974	Total
Thought permissible prior to 4-29-74 communication	15	-	15
Confusion in interpreting policy	-	1	1
Performed for legitimate serious medical reasons but with the intent to sterilize	5	7	12
Administrative error authorizing payment to contract facility (note a)	1	4	5
Within few weeks of 21st birthday	1	1	2
Unknown	1	-	1
Total	23	13	36

a/Does not include two cases in which an administrative error was made but cases were performed for medical reasons with the intent to sterilize.

Of the 36 violations, 16 were performed at contract facilities and 20 at IHS direct care facilities.

The Deputy Director of Program Operations reports that before the HEW regulations were issued on April 18, 1974, and the IHS directive on April 29, 1974, most IHS areas

> "were under the impression that they could either perform sterilization on minors or mental incompetents with proper (72 hour) informed consent and/or that they could employ the age of majority of the respective state in which the procedure was performed (18 years in most cases)."

He further states that, except for one case, all patients were 18 or older.

Twelve of the 36 violations were categorized by IHS as being performed for legitimate medical reasons, but with the intent to sterilize. The IHS Deputy Director of Program Operations told us the violations were primarily caused by physicians who did not understand that there were unacceptable medical reasons for performing sterilizations or physicians who were unaware of the prohibition of sterilizing persons under 21 years of age. He believed that the December 15, 1975, memorandum from the IHS Director, clarifying sterilization procedures on persons under 21 years of age, should help to reduce the number of sterilizations that should not have been performed.

IHS administrative clerks inadvertently authorized payment for five cases at contract facilities.

The Deputy Director of Program Operations could not explain the two violations which occurred on individuals within a few weeks of their 21st birthday.

In the four IHS area we reviewed, three persons under 21 years of age were sterilized from April 1 to September 30, 1975. One case involved a 19-year old woman in the Albuquerque area on May 20, 1975. Area officials advised IHS headquarters that the procedure was inadvertently authorized. The other two cases involved women, both age 20, in the Oklahoma City area. The procedures were performed on August 26 and September 11, 1975. In both cases it was reported that the physician did not understand how the HEW sterilization policy was to be interpreted.

The Deputy Director of Program Operations said tnat IHS does not maintain a routine surveillance to assure against sterilizing mentally incompetent persons. He said this responsibility is left to the person obtaining the guardian's consent. He added, and we agree, that sterilization of a mentally incompetent person generally occurs between puberty and 21 years of age. Therefore, with headquarters monitoring sterilization procedures for persons under 21 years of age, surveillance over the sterilization of mentally incompetent persons is also maintained. He also said it would be impractical to establish a separate management reporting of sterilizations involving mentally incompetent persons, because it is highly unlikely a physician would ever report such a case knowing there was a moratorium against this type of sterilization.

Weaknesses in the informed consent procedures followed by direct facilities

We reviewed the consent forms for 113 voluntary sterilizations which were performed in the Aberdeen, Oklahoma City, and Phoenix IHS areas between April 1 and September 30, 1975. In no case did the documented consents, which IHS provided us, fully comply with HEW regulations.

In the 113 cases, 3 different versions of the short consent form were used. A combination of more than one of these forms was occasionally used.

--HSA-83 Consent for Sterilization Procedures

--HSM-83 Consent for Sterilization Procedures

--Standard Form 522 Request for Administration of Anesthesia and for Performance of Operations and Other Procedures

The most commonly used form was HSM-83 (91 of 113 cases); a form designated for medically required, rather than voluntary, sterilization. This form and the standard form 522, which was designed for all types of surgery, did not comply with HEW informed consent regulations because they (1) failed to indicate that the basic elements of informed consent had been presented orally to the patient, (2) were not supplemented as short form documents by written summaries of what the patient was orally presented, and (3) failed to contain the required printed statement advising individuals of their rights in case they decide not to be sterilized.

Consent form HSA-83, used in 12 of the 113 cases, appears to comply with the regulations as they pertain to a short-form consent document. However, the written summary of the oral presentation was either not prepared or contained insufficient detail to determine whether all the elements of informed consent were covered.

On March 21, 1975, IHS Headquarters sent the HSA-83 form to its area directors for comments on its content, clarity, and suitability. The most frequent comment was directed at omitting the written summary, because it was too time consuming to prepare. As of June 7, 1976, IHS reported that it still had not given its area offices any specifc instructions to use the form, because a new form was being considered.

We reviewed the proposed form and, in our opinion, it does not comply with HEW regulations. The form does not contain full written disclosure of all the basic elements of informed consent nor, if used as a short-form document, does it provide for a narrative summary of the oral presentation given the patient.

We believe that using the narrative summary with the short-form consent document allows too much latitude as to what is an adequate written summary of the oral presentation. This discretion could foster the type of abuse the court intended to prevent. We, therefore, believe that the short-form consent document should not be used, and a written consent form detailing all the basic elements of informed consent should be developed and used. Consideration, however, should be given to the effects that elimination of the short-form document would have on those persons who are completely or functionally illiterate. In those instances, we believe that the individual obtaining the consent should read the document to the patient in the presence of a witness, with the witness' signature attesting to the reading.

We also found 13 cases where the time lapse between the date the patient signed the consent form and date of the sterilization procedure was less than the required 72 hours.

We did not interview sterilized patients to determine if they were adequately informed about the risks, discomforts, and irreversibility of the procedure because, as noted on page 8, we believe that such an effort would not have been productive.

With the assistance of a physician, we reviewed 54 therapeutic sterilizations performed at Phoenix Indian Medical Center from April 1 through September 30, 1975, to evaluate

the medical justification for the sterilizations. In 19 cases, questions arose which could not be resolved from the records. These questions were discussed with the Center's chief of obstetrics and gynecology. Even though some questions remained after these discussions, we believe that the number of cases questioned and the number of questions which could not be resolved would be similar to what one would expect to find in a non-Indian Health Service hospital of comparable size.

Also, as a result of our review at Phoenix Indian Medical Center, the service unit director said that he and his assistant chief will periodically review consent forms for compliance with HEW regulations. If the review discloses continuing noncompliance, he plans to institute a policy involving a review of the completed consent forms before the surgical procedure is performed.

The deficiencies we found appear to be attributable primarily to (1) the failure of IHS area offices to adhere to the HEW sterilization regulations provided by headquarters and (2) the lack of specific direction by headquarters to the area offices. Since the issuance of the regulations on April 18, 1974, IHS headquarters has not (1) officially adopted a consent form for its area offices to use in complying with HEW standards, (2) revised its manual to reflect current HEW sterilization regulations, or (3) provided area offices with specific guidance for implementing the regulations.

Headquarter officials attribute their delay in implementing the April 18, 1974, regulations to HEW's inability to develop specific sterilization guidelines and a standardized consent form for all its agencies to use.

Weaknesses in the sterilization consent form used by IHS contract facilities

Because no IHS facilities in the Albuquerque area perform sterilizations, we reviewed sample copies of the consent forms used by six contract care facilities in this area. Three of the six facilities used consent forms that did not meet HEW standards.

The consent forms mainly failed to provide full disclosure or space for additional comments on what the patient was told about the basic elements of informed consent. The forms also failed to include the required statement "Your decision at any time not to be sterilized will not result in

the withdrawal or withholding of any benefits provided by programs or projects."

IHS officials in the Albuquerque and Aberdeen areas said that they do not monitor the adequacy of informed consent received by contract care doctors or facilities. They also said that the contracts they have with doctors and facilities do not stipulate that HEW regulations for sterilization procedures are to be followed. We believe that IHS has a responsibility for assuring that contract doctors and facilities adhere to the HEW sterilization regulations. In this regard, we noted that section 50.201 of the regulations provide that:

> "The provisions of this subpart are applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service." (Emphasis added.)

RECOMMENDATIONS

We recommend that the Secretary of HEW direct IHS to (1) expedite its efforts to have a standard consent form which provides for full disclosure of the information required by the regulations (enc. IV shows a form that could serve as a guide to counsel patients and which details all the basic elements of informed consent), (2) provide training to their physicians and administrators so that they fully understand the requirements concerning (a) sterilization of persons under 21 and persons who are mentally incompetent and (b) obtaining informed consent, (3) include in the contracts with non-IHS physicians and facilities, provisions to insure that contractors comply with HEW sterilization regulations, (4) continue to monitor compliance with the moritorium on sterilization of persons under 21 years of age, and (5) develop monitoring procedures to assure compliance with the regulations by contract physicians and facilities.

We also recommend that the Secretary of HEW direct that HEW sterilization regulations be amended to (1) conform with the ruling of the U.S. district court order that a patient, regardless of the consent form document used, be informed orally that no Federal benefits can be withdrawn or withheld if they decide not to be sterilized and (2) require that the signature of the person obtaining a patient's consent appear on the consent form.

ENCLOSURE II

IHS REPORTED FEMALE STERILIZATION PROCEDURES

FOR FOUR AREAS DURING FISCAL YEARS 1973-76

Area	1973 Number of women (all ages) (note a)	1973 Performed at: IHS facilities (note b)	1973 Performed at: Contract facilities (note b)	1974 Number of women (all ages) (note a)	1974 Performed at: IHS facilities (note b)	1974 Performed at: Contract facilities (note b)	1975 Number of women (all ages) (note a)	1975 Performed at: IHS facilities (note b)	1975 Performed at: Contract facilities (note b)	1976 Number of women (all ages) (note a)	1976 Performed at: IHS facilities (note b)	1976 Performed at: Contract facilities (notes b and c)
Aberdeen (note d)	34,297	79	134	34,775	65	143	36,803	55	125	37,361	56	103
Albuquerque	17,828	-	60	18,217	-	68	18,618	-	65	19,016	-	29
Oklahoma City	54,933	326	34	56,688	389	36	58,530	393	50	60,291	394	27
Phoenix	26,088	121	41	26,607	163	40	27,098	180	33	27,617	119	34
Total	133,146	588	269	136,287	597	289	141,049	628	273	144,285	569	193

a/IHS estimate of women of all ages residing in the IHS area.

b/Includes hysterectomies and tubal ligations.

c/Numbers are for the first 10 months of FY 1976.

d/Includes the Zemidgi Program Office.

ENCLOSURE II

ENCLOSURE III

IHS REPORTED FEMALE STERILIZATION PROCEDURES PERFORMED ON WOMEN OF CHILD-BEARING AGE FOR FOUR AREAS DURING FISCAL YEARS 1973-76

Areas	1973		1974		1975		1976	
	Number of women (age 15-44) (note a)	Number of procedures (note b)	Number of women (age 15-44) (note a)	Number of procedures (note b)	Number of women (age 15-44) (note a)	Number of procedures (note b)	Number of women (age 15-44) (note a)	Number of procedures (notes b and c)
Aberdeen (note d)	12,608	193	12,784	162	13,529	151	13,690	132
Albuquerque	7,150	54	7,310	65	7,471	54	7,630	24
Oklahoma City	20,556	330	21,212	388	21,901	390	22,561	374
Phoenix	10,398	199	10,604	176	10,800	186	11,007	123
Total	50,712	776	51,910	791	53,701	781	54,888	653

a/IHS estimate of women 15 through 44 years of age.

b/Includes hysterectomies and tubal ligations.

c/Numbers include all of the direct cases but only 10 months of the contract cases.

d/Includes the Bemidgi Program Office.

ENCLOSURE III

ENCLOSURE IV

ENCLOSURE IV

[illegible] HEALTH AND SOCIAL SERVICES DEPARTMENT
VOLUNTARY STERILIZATION
PATIENT CONSENT FORM

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS.

A non-therapeutic sterilization may not be performed until at least 72 hours have elapsed after the execution of the consent document.

I, _____ have been counseled by

_____, of _____

_____, on the below mentioned items in regard to my request for a voluntary sterilization:

I. PROCEDURES FOR VASECTOMY

I understand that sterilization for men is the surgical procedure called the vasectomy. In a vasectomy a doctor cuts and ties off the vas tube so that the sperm, produced by the testicle, cannot mix with the semen. What the doctor does is very simple. Usually it is done in his office and only takes about a half hour and he usually uses a local anestnesia. The vasectomy is a permanent method of contraception. A doctor will not usually perform a vasectomy unless he is sure that the man who wants it understands that it is permanent.

There are some temporary inconveniences following vasectomy, normal routine may have to be limited in the following 2-3 days and an additional contraception is necessary for the next 3 months, or until the physician is able to determine that there are no sperm present in the ejaculate. Sexual relations are usually not hampered.

Also, with the male vasectomy, as with any other surgical procedure, there are potential-side effects. Any time one makes an incision in the human body, there is a possibility of immediate or delayed bleeding and/or infection. With vasectomy, these side effects are very rare and much less frequent than similar side effects of the sterilization procedure for women. From the physiological point of view, there is no difference in the sexual relationship of a man and a woman before and after vasectomy has been performed. Sexual excitement, sexual intercourse, and orgasm remain totally unaffected. The nature of the ejaculate is thinner and less opaque. The amount is fractionally reduced.

II. PROCEDURE FOR TUBAL LIGATION

I understand this operation is performed to block the path of the reproductive cells so they cannot reach the uterus where fertilization occurs.

Addressograph or I.D.

This operation does not affect either menstrual periods or the age at which change of life occurs The ovaries and uterus are unchanged by the operation, the ovary continues to release an egg each month and tying the tubes merely prevent the egg from being fertilized by the sperm. Production of female hormones by the ovaries that determine feminity is not interrupted by

ST-007 (PLOIII)

ENCLOSURE IV

II. PROCEDURE FOR TUBAL LIGATION (CONTD)

cutting and tying the tubes. As with male vasectomy, no reduction of sex drive or function occurs. Also as with the male vasectomy and with any other surgical procedure, there are potential side effects. Any time one makes an incision in the human body, there is a possibility of immediate or delayed bleeding and/or infection.

A. TUBAL LAPAROSCOPY

The physician makes two small incisions about a half inch long in the abdomen. Through one incision is inserted a laparoscope, an instrument that combines a high intensity light and magnifying lenses. Carbon dioxide gas is then pumped in to distend the abdomen, thus allowing the physician to see the Fallopian tubes more clearly. A second instrument, combining a tiny forcep and a cauterizing device, is inserted into the other incision. Grasping the Fallopian tube with the forceps, the physician fuses the tube shut with a brief burst of electricity. This procedure is done on both tubes. Laparoscopy is ordinarily performed under general anesthesia. In many cases the woman is able to leave the hospital the same day, although an overnight stay may be necessary. As with any surgical procedure, there are some potential side effects; however, with this operation, they are minimal. Recovery only takes a few days with some slight discomfort in the abdominal area.

B. ABDOMINAL TUBAL LIGATION

The physician makes an incision just above the pubic hair line about 4-5 inches long. The physician will expose the Fallopian tubes and cut a small piece out of both tubes, tying and cauterizing the ends of the tubes. The abdominal tubal ligation is usually performed under general anesthesia and frequently in conjunction with other abdominal surgery. The woman usually remains in the hospital for 2-3 days. The abdominal muscles will feel sore, and it may take a few days to walk easily. Normal activity may be resumed after 10 days, or whenever the physician advises.

C. VAGINAL TUBAL LIGATION

This procedure is performed through an incision about one inch long in the vaginal wall. The patient is in the same position as when having a pap smear, and generally has had a general or spinal anesthetic.

The physician inserts an instrument called culdoscope through the incision to locate the tubes. The culdoscope has a tiny forcep attachment and cauterizing device which cuts and cauterizes both Fallopian tubes. After he has cut and cauterized the tubes, the physician closes the incision with suture which dissolve in about 10 days. The procedure usually lasts about a half hour, but the woman usually remains in the hospital overnight. This procedure has a slightly higher risk of infection, and the patient may feel discomfort in the lower abdomen for a few days. After 5 days she may resume normal activities, but the physician should be consulted as to when she may resume intercourse. Tampons should not be used for at least 4 weeks after surgery.

ENCLOSURE IV

ENCLOSURE IV

III. I UNDERSTAND THAT THE INTENT OF THIS PROCEDURE is to make me sterile and unable to have additional children. I have been informed that this procedure is non-reversible and that it must be considered as such prior to my consent. I am aware that on occasion some people have psychological depression after tubal ligation or vasectomy. It was pointed out that the intense counseling performed prior to surgery is an effort to minimize this depression. I understand that this procedure will in no way interfere with my normal sex habits after recovery and may decrease sexual tensions caused by the fear of unplanned pregnancy.

IV. METHODS OF FAMILY PLANNING

During the counseling session(s) prior to my surgery I have been instructed in other methods of family planning:

1. PILLS: I was told how the pill works and that the effective rate was the highest available among non-surgical methods. I was informed that many pills were available, some more acceptable than others depending upon the needs of the individual.

2. IUD: The intrauterine device was explained and demonstrated including appropriate effective rates and the fact that this method requires no daily pills or other function to be remembered daily. The discomforts which sometimes accompany insertion were explained as were the numerous types of IUD's.

3. DIAPHRAGM: This method was explained to me starting with the method of measurement. I was instructed on how to insert the device properly and the absolute requirement to use proper lubricants. I was informed that the diaphragm must be used each time intercourse occurs.

4. CONDOM: Condoms were explained as an effective method, especially when used in conjunction with spermacidal foam. I was told that when used according to directions, these two methods in combination should be considered as effective as the birth control pill with fewer side effects. I was also informed that some pregnancies occur when only one of these methods is used, and that an interruption in the lovemaking process is necessary to insure proper contraceptive protection which some individuals deem undesirable.

5. FOAM: Foam and other chemical spermacides such as jellies and creams were explained as an effective method, especially when used with a condom. I was told that when used according to directions, these two methods in combination should be considered as effective as the birth control pill with fewer side effects. I was also told that pregnancies may result when foam, cream or jelly is used by itself. I understand that to use foam there may be an interruption in the lovemaking process which some people find undesirable.

6. NATURAL: Natural family planning was explained as a method involving selective abstinence. I was told that only on certain days could I get pregnant and was told how to predict when these days were. I was informed that this was a highly participatory method and cooperation (from sex partner) was an absolute necessity before any contraceptive protection was available.

ENCLOSURE Iv

ENCLOSURE IV

IV. METHODS OF FAMILY PLANNING (CONTD)

7. STERILIZATION: This surgical procedure was explained to me as a method to make my body incapable of becoming pregnant/or making a woman pregnant. I was informed that some individuals accidentally become pregnant/impregnate after this procedure because the canal which is cut during the operation grows back. I was told that this is rare. I was also informed that some individuals have periods of depression following this procedure. I am fully aware that I may, at any time before surgery, retract my consent to have this procedure performed. I am also aware that my decision will not in any way affect any other benefits or privileges which are available to me or my family from this or any other organization.

I have received counseling as described above and have been given an opportunity to ask additional questions about any and all methods, procedures, risks, benefits, or other concerns which I may have.

I understand that there must be a 72 hour waiting period between the time I receive counseling and sign this consent form, and the time my sterilization surgery is actually performed.

I now hereby voluntarily consent to a _____ surgical sterilization procedure.

_____
(SIGNATURE OF PATIENT)

_____
(SIGNATURE OF PERSON OBTAINING THE CONSENT)

_____
(SIGNATURE OF SPOUSE) - (IF MARRIED)

_____ _____
(TIME) (DATE)

I, _____, was designated by _____ as her/his auditor-witness, and was present when she/he received her/his counseling and information on sterilization surgery and birth control methods. Everything described by this consent form was discussed and there were opportunities for additional questions.

_____
(Signature of auditor-witness designated by patient)

_____ _____
(Time) (Date)