

though project descriptions are general and couched in scientific terms, it appears that some projects are being conducted under grant from HEW that involve direct electrical stimulation of the brain in an effort to discover and neutralize neurological sources of violence. Although such experiments are not classified as psychosurgery under the classic definition, the effect of the practice is the same: in both instances, the brain itself is manipulated in order to identify and control conscious functions. For example, in one such electrical stimulation project funded by the Center for the Study of Crime and Delinquency conducted at the Patuxent Institution in Maryland:

One specific hypothesis to be tested is that chloralose activation of the EEG (electroencephalogram) will correlate positively with epileptoid impulsivity. Data will be collected in such manner as to determine the reliability of psychiatric, psychometric, and EEG measures of epileptoid and hysteroid impulsivity, and to allow later quantitative computer analysis of both psychologic and electroencephalographic data. Finally, the clinical usefulness of the anticonvulsant primidone (Mysoline) will be tested in a double-blind study, and the results compared with those of a previous study in which diphenylhydantoin was used with a similar group at the same institution.²⁶

Through various other sub-agencies, HEW funds a number of programs designed to modify various forms of behavior. One such program that until recently received substantial funding from the Department is "The Seed," a Florida-based drug treatment program that uses intensive peer-group pressure to reform both known and suspected drug abusers. The Seed is a private organization, and the program is admittedly highly coercive. Though the program claims a substantial cure rate, the types of therapy employed have attracted much controversy and publicity.²⁷ Most "seedlings," as subjects are called, are committed to the program either by their parents, their schools, or the courts. Because the program produces pronounced changes in the general attitudes and behavior of former drug users, it receives considerable approval from various elements of the community. For example, in a testimonial letter from the Nova University Institute of Human Development, the associate director stated:

I am happy to have the opportunity to write a letter in support of the activities of the Seed with young people who are experimenting with, using, and abusing dangerous drug substances.

I have referred a number of my patients to the Seed with dramatic results, not only in terms of getting off the use of drugs but also in terms of positive attitude changes. The attitude changes have made possible family and school adjustments which were completely rejected prior to the experience at the Seed.²⁸

Once in the program, participants are subjected to a regimen which several individuals have referred to as brain-washing. Seedlings are required to dress, act, and think in more socially acceptable manners. Once out of the program, graduates are encouraged to observe fellow Seedlings, and to report any vacillation from accepted modes of behavior. In a statement critical of the program, a guidance counselor from a South Florida high school described Seedlings when they return to school after participation in the program:

²⁶ *Id.*

²⁷ See "Two Views of the Seed: For and Against," from *The St. Petersburg Times*, September 16, 1973, p. D-1, printed in the Appendix as Item I.C.2.d.

²⁸ Included in Excerpts from Grant Request by the Seed to the Department of Health, Education and Welfare, June 20, 1972, printed in the Appendix as Item I.C.2.a.

When they return, they are "straight," namely, quiet, well-dressed, short hair, and not under the influence of drugs compared to their previous appearance of [being] stoned most of the time. However, they seem to be living in a robot-like atmosphere, they won't speak to anyone outside of their own group. They sit in a class together, and the classes become divided of Seedlings opposing non-Seedlings. . . .

Seedlings seem to have an informing system on each other and on others that is similar to Nazi Germany. They run in to use the telephone daily, to report against each other to the Seed and it seems that an accused Seedling has no chance to defend himself because if enough persons accuse him of something, he is presumed guilty. The Seedlings also make numerous false accusations about drug behavior concerning non-Seedlings.³⁰

Following an inquiry to the Department of Health, Education, and Welfare concerning funding for the program, the subcommittee received a number of letters from members of the community in praise of the Seed. The majority of the letters in support of the Seed repeatedly referred to the remarkable and positive changes that have occurred in the individuals referred to the program. One such writer, describing the Seed as a "fantastically successful youth drug program" stated:

I am writing as a Seed parent—our 15 year old daughter has just completed the program—who has been involved with the Seed for eight months. My wife and I both feel that it is the most wonderful and worthwhile endeavor that we have ever had the privilege of being a part of. . . . The Seed has a cure rate of approximately 90% which I believe is by far the best of any drug program in the country. The children in this program basically learn to live the Golden Rule. They also learn what is good and bad for themselves and to work hard in school or in whatever job they may have. Senator, as a parent of a Seedling and as an employer of five others, I can vouch that the Seed is a tremendous force for good in our community.³⁰

Because of the controversy raised and because of growing pressure from various groups who question the techniques upon which the Seed is based, early in 1974 the Seed decided to forego Federal funding.³¹

The exact extent of involvement by the Department of Health, Education, and Welfare in behavioral research and behavior modification programs has not yet been ascertained. In an effort to compile comprehensive information on the department's activities in this area an inquiry was directed to the department on February 22, 1974.³² Because of the vast number of such projects, an agency-by-agency canvass took a great deal of time.

The Department first provided information concerning only the Public Health Service, one of the major organizations within HEW. In listing some forty-five Public Health Service research projects that dealt in some manner with the modification or control of behavior, the Department noted:

The projects included in the enclosed listing fall within the defined area of behavioral modification, i.e. the systematic application of psychological and social principles to bring about desired changes in or to prevent development of certain "problematic" behaviors and responses. Among the many types of projects included in our response are those designed to teach narcotic addicts

³⁰ Excerpts from "The Study of the Advisability of the 'Seed' in Dade County," Comprehensive Health Planning Council of South Florida, printed in the Appendix as Item I.C.2.b.

³¹ Letter received by the Subcommittee on Constitutional Rights, in subcommittee files.

³² Letter from Art Barker, President of "The Seed," Department of Health, Education and Welfare, February 19, 1974, printed in the Appendix as Item I.C.2.c.

³³ Letter from Chairman Sam J. Ervin, Jr., to Secretary Caspar Weinberger, February 22, 1974, printed in the Appendix as Item I.A.21.

or alcoholics to develop self-control over their drug-taking behavior; to alter behavior of persons with serious psychiatric or behavioral problems such as chronic schizophrenia, autism, or learning disabilities; and develop methods for training persons responsible for children, such as parents, teachers or child welfare workers, to use behavioral principles in fostering child development and preventing or dealing with problem behaviors.³³

The projects listed in this phase of the canvass appear to deal primarily with the less direct forms of behavior modification such as token economies and other forms of positive reinforcement. A number of the project descriptions, however, also relate to the pre-determination and prediction of behavior. For example, in one of these programs:

Children with cross-gender (sex role) problems are being studied to improve the understanding and treatment of sexual deviation in its nascent stages. The subjects, boys five to eight years of age who have exhibited various signs of a cross gender problem. (cross-dressing, playing with girl's toys, feminine mannerisms), participate in a variety of studies. The investigator is attempting to develop reliable and objective data on the behavior of these children in the home and in the clinic. Based upon this data, treatment is developed for helping children to adopt normal gender behavior. This treatment is based on principles of "behavior contingency management," in which subjects are given token rewards for displaying behavior appropriate to their gender. The investigator is also trying to identify the environmental conditions under which sex role problems are likely to occur. Long-term studies attempt to follow the subjects over crucial development years into adulthood.³⁴

Finally, on July 25, 1974, the department reported the results of "a canvass of non-health-related agencies of the Department" and "identified ten projects" related to behavior modification. "One project is supported by the National Institute of Education (NIE), one by the Office of Child Development (OCD), and eight by the Social and Rehabilitation Service (SRS)."³⁵

In addition, "all programs under the responsibility of the Office of Education and the National Institute of Education (NIE) have been reviewed, and biomedical and behavioral research designed to alter the behavior of human subjects is not being supported."³⁶ One NIE project funding educational systems "which serve to remediate the [disadvantaged] child or correct deficiencies in the educational environment" was considered a possible exception.³⁷

The length of time and apparent difficulties involved in preparing a response to the subcommittee's February 22, 1974, inquiry may itself indicate that the Department is ill-equipped to provide the kind of monitoring and review that is essential in research situations that raise serious questions of individual privacy, freedom and self-determination. Quite clearly, the first step toward devising and then applying adequate standards for HEW-sponsored programs is for the department to have complete knowledge of the programs it is actually funding.

³³ Letter from Acting Secretary Frank Carlucci to Chairman Sam J. Ervin, Jr., May 10, 1974, printed in the Appendix as Item I.A.22.

³⁴ Abstracts of Project Descriptions of HEW-Funded Behavior-Related Research projects," received May 10, 1974, and July 25, 1974, printed in the Appendix as Item I.C.1.

³⁵ Letter from Acting Secretary Frank Carlucci to Chairman Sam J. Ervin, Jr., July 25, 1974, printed in the Appendix as Item I.A.26.

³⁶ *Id.*

³⁷ Abstracts of Project Descriptions of HEW-Funded Behavior-Related Research Projects, *supra*.

THE DEPARTMENT OF JUSTICE

The Department of Justice participates in a wide variety of controversial behavior-related projects primarily through the Bureau of Prisons and the Law Enforcement Assistance Administration, under guidelines and procedures which are ineffective at best. By comparison with the Department of Health, Education, and Welfare, which has devoted some energy to the resolution of the ethical and constitutional issues involved in behavior modification and behavioral research, the Department of Justice has made virtually no effort either to provide the necessary monitoring of research projects or to resolve important questions relating to individual liberties. This conclusion is inescapable in view of the policy innovations made in response to legal challenges and other objections to Department programs.

Bureau of Prisons

The Bureau of Prisons' involvement in behavior modification and behavioral research was of special interest to the staff both because of the nature of the projects it conducts and because of the special problems raised when behavior modification techniques are applied in a coercive environment. Recent court cases have raised serious questions concerning informed consent in a coercive environment, the rights to minimum standards of treatment, and the constitutional prohibition of cruel and unusual punishment, all in addition to the more fundamental questions of individual rights to privacy and freedom of thought. Two projects conducted by the Bureau were of special concern to the subcommittee: Project START (an acronym for Special Treatment and Rehabilitative Training), and the Federal Center for Correctional Research presently under construction at Butner, North Carolina (originally named the "Center for Behavioral Research").

Project START was a prototype behavior modification program conducted at the Federal Medical Center for Prisoners at Springfield, Missouri. Its goal was to rehabilitate unmanageable prisoners. Roughly fifteen prisoners were required to participate in the program involuntarily; no attempt was made to obtain the consent of the prisoners involved. In fact, because the program was designed to rehabilitate incorrigible offenders, volunteers were precluded from participation on the grounds that willingness to participate would lessen the effectiveness of the program on the individual. In a Bureau of Prisons operations memorandum, START was described as follows:

In an attempt to develop behavioral and attitudinal changes in offenders who have not adjusted satisfactorily to institutional settings, the Bureau has recently initiated a Special Treatment and Rehabilitative Training (START) Program at Springfield. The program is designed to provide care, custody, and correction of the long-term adult offender in a setting separated from his home institution.³³

³³ Project START Operations Memorandum, October 25, 1972, printed in Appendix as Item 11.B.2.a.

In the operations memorandum, selection criteria for the START program were outlined in detail. Each participant:

- (a) Will have shown repeated inability to adjust to regular institutional programs—not just minor offenses.
- (b) Will be transferred from the sending institution's segregation unit.
- (c) Generally, will have a minimum of two years remaining on his sentence.
- (d) Will not be overtly psychotic (overtly psychotic inmates are at appropriate referrals from the regular medical center psychiatric program).
- (e) Will have had experience in an adult penitentiary.
- (f) Will not be a continuous escape risk and in terms of personality characteristics, shall be aggressive, manipulative, resistive to authority, etc.³⁰

Project START was based on classical concepts of behavior modification involving the use of both positive and negative reinforcement as a means of altering behavior. Once in the program, an inmate would be placed in a solitary cell and allowed out of the cell only twice a week for showers and only once for exercise. After twenty days of what was determined to be good behavior, a prisoner would be graduated to the next level where his privileges would increase, i.e., he would be allowed out of his cell for one and one-half hours a day. The object of the program was the effective use of basic privileges as incentives for acceptable behavior. Privileges were accorded on the basis on accumulated "good days." "Good days" were earned, depending upon the level in the program, on the basis of compliance with twelve "good day" criteria which included "neat and clean personal appearance," "shower and shave according to guidelines on designated days," "follow[ing] directions and instructions in a willing manner without bickering," and "communicat[ing] with others in a reasonable tone of voice without belittling, agitating or using abusive language."⁴⁰

Because an inmate's movement to a higher level depended upon value judgments by individual guards, various inequities appeared. Moreover, the coercive nature of the program, the fact that it used basic privileges as incentives, and numerous allegations of abuse of prisoners by prison guards, attracted a great deal of controversy to Project START. In one case brought by the National Prison Project of the American Civil Liberties Union on behalf of several of the participants in the program, START was described in plaintiff's Post-Trial Memorandum of Law as "humiliating" and "unlawful." One incident was described in the memorandum as follows:

* * * the managerial staff, in response to petitioners' complaints, stripped petitioners of their clothing and shackled them to their beds for one day. Neither petitioner ever received a disciplinary report or charge, in spite of the shackling and in spite of their placement in a specially constructed strip cell whose lighting, heat and ventilation and bedding were markedly inferior to the already inadequate solitary cell furnishings within Unit 10-D."

Following several adverse court rulings and while other cases were pending, the Bureau of Prisons quietly cancelled the program in February 1974.

³⁰ *Id.*

⁴⁰ START Revised Program Description, November 1973, printed in the Appendix as Item 11.B.2.d.

⁴¹ Post-Trial Memorandum of Law, at 4, *Sanchez v. Glaccone*, Nos. 20182-4, 2001-4 (D.W.Mo., filed April 25, 1973). See also *Glaccone v. Richardson*, *supra*, printed in the Appendix as Item 11.B.4.

The Center for Correctional Research at Butner, North Carolina, has also generated considerable public interest partly as a result of the controversy surrounding Project START. In an effort to find out more about the proposed facility, the subcommittee addressed a series of inquiries to Norman Carlson, director of the Bureau, and to Dr. Martin Groder, the psychiatrist named to head the Butner facility. These inquiries were addressed primarily to issues concerning the Center for Correctional Research, but the subcommittee was also concerned about other Bureau of Prisons research programs and about agency mechanisms for the protection of human subjects.⁴²

Due to the controversy surrounding Project START as well as the atmosphere of secrecy surrounding the Butner project, subcommittee mail from ordinary citizens and federal prisoners alike indicated that the specter had been raised of an isolated enclave in which various forms of radical experimentation would be conducted using prisoners as subjects. In response to its various inquiries, the subcommittee has received repeated assurances that no psychosurgery, no chemotherapy, and no aversive conditioning of any kind will be tested or used at the Butner facility. The subcommittee has also been assured that a mental health facility to be located in the same compound at Butner will be separate and distinct from the Center for Correctional Research. According to Dr. Groder, all participants in the Center for Correctional Research will be volunteers, as the project depends upon willing cooperation for its success.

However, a number of important questions concerning the Center remain to be considered. For example, serious questions of voluntariness in a prison setting have been raised in recent court cases, as discussed above. Further, detailed ethical guidelines and a workable, effective review structure have not yet been developed for the Center. Chairman Ervin stated in a recent letter to Dr. Groder that such mechanisms are essential to the constitutional operation of the program.⁴³

Although the precise design of specific programs to be developed and tested at Butner has not yet been determined, it appears that several treatment modalities involving various forms of indirect behavior therapy are to be tested. In a meeting with the subcommittee staff on January 25, 1974, Dr. Groder described the plans for the Butner facility as really two separate institutions in a single location. A separate section will be devoted to the treatment of acutely psychotic prisoners; a second section will be used to conduct an experimental program that will seek to evaluate several experimental approaches to corrections. The experimental program will be a "multiple integrated treatment approach," which Dr. Groder described as an attempt to structure the environment of prisoners in such a way as to include all those supporting services that have been demonstrated to have a positive effect on the prisoner's chances of succeeding in the outside world.

⁴² See Bureau of Prisons' Policy Statement on Research, October 31, 1967, printed in the Appendix as Item II.B.1.

⁴³ Letter from Chairman Sam J. Ervin, Jr., to Martin Groder, April 19, 1974, printed in the Appendix as Item II.A.11.

Dr. Groder enumerated four experimental programs to be tested at Butner: (1) "Asklepion," a self-help transactional analysis program Dr. Groder himself developed at the Marion Federal Penitentiary; (2) a "Human Resources Development Program" developed by Dr. R. R. Carkhuff and based on the theory that physical, social, and intellectual fitness are all interrelated; (3) "Psychodrama," a program that employs the use of role-playing as a means of reducing anxiety and rebuilding personality; (4) a program as yet to be determined, possibly one based on the "rational emotive therapy" approach of Dr. Albert Ellis. Dr. Groder was emphatic that all of the participants in the program will be volunteers. The nature of the research design, according to Dr. Groder, requires that the participants be motivated to cooperate with the program. In correspondence with the subcommittee, Dr. Groder has repeatedly indicated that the mechanisms for deriving informed consent have not yet been developed.⁴⁴ It is also unclear what the status of the participants will be if sufficient numbers of inmates do not volunteer for the program. As of August of 1974, no information had been received by the subcommittee indicating how these questions are to be resolved, and when and how an institutional review structure for the Center is to be established.

Law Enforcement Assistance Administration

In the course of its investigation, the subcommittee became aware of a number of programs dealing with the prediction, identification, and control of various forms of abnormal behavior funded by the Law Enforcement Assistance Administration. As the widespread urban riots of the late 1960's and the resulting calls for law and order led to a growing preoccupation in the research community with studies of violent behavior, LEAA, because of its law enforcement mission and large appropriations, attracted a wide variety of grant requests dealing with this type of research. Many of these research projects involved the study and use of coercive methods designed to deal with violence which appear to pose substantial threats to the privacy and self-determination of the individuals against whom the methods are directed.

For example, a description by the researchers of one LEAA-funded project states that:

The goal of the project for early prevention of individual violence is the development of effective tools with which to bring about prevention of individual violent behavior. It is the primary objective of this project to identify potential early warning signs of individual violent behavior, to determine appropriate community and individual responses to these signs, and to make this and other preventive action program information identified during the project available to community resources and to individuals who can utilize the information for early prevention of individual violent behavior * * *. The project is also concerned with the development of a central computerized information bank that will provide bibliographic references on potential early warning signs and individual violent crime as well as preventive action information regarding community resources and responses to individual violence and crime.⁴⁵

⁴⁴ See, e.g., letter from Dr. Martin Groder to Chairman Sam J. Ervin, Jr., April 30, 1974, printed in the Appendix as Item II.A.12.

⁴⁵ Excerpts from Computer Printout Listing Behavior-Related Projects, April 10, 1974, printed in the Appendix as Item III.B.5.

Other behavioral research projects funded by LEAA appear to pose similarly difficult questions concerning individual rights. One LEAA funded project conducted at the Massachusetts General Hospital investigated various causes and predictors of violence. Theories were tested that suggested that fingerprint classifications and a particular chromosome configuration indicate that certain individuals were more prone to commit acts of violence than others. Although such projects as this appear to pose no direct, immediate threat to individual rights if conducted under ethical principles, critics point out that potential applications of such theories to label or isolate persons thought to be potentially violent from society raise profound questions with respect to due process, privacy, and individual liberties.

Center for the Study and Reduction of Violence.—It was the proposed grant request by the Center for the Study and Reduction of Violence to be established under the auspices of the Neuropsychiatric Institute of the University of California at Los Angeles that first attracted the subcommittee's attention to LEAA behavioral research programs. Of particular concern were reports that the Center planned to test various radical forms of behavior modification, including chemotherapy, electro-physiology, and several other forms of direct behavior control. In an in-house memorandum describing methods of dealing with violent sexual offenders, a staff psychologist of one of the institutions participating in the planned UCLA Center described a wide variety of applications of present methods for the modification of the behavior of sexually deviant individuals:

Within our electro-physiological laboratory we presently have the capability of (1) programming the wide variety of audio-visual stimuli, with concurrent recording of (2) heart rate, both directly and in beats per minute, (3) galvanic skin response, (4) changes in penis volume, (5) electromyographic responses, and (6) alpha and beta brain waves. We presently are in the process of developing portable bio-feedback devices which can be used for self-monitoring *in vivo*.⁴⁶

The planned use of a number of satellite facilities outside of UCLA, notably Atascadero, Camarillo, and Vacaville state hospitals, raised additional questions of control, and made it more difficult to monitor carefully the activities of the CSRV. Moreover, Vacaville and Atascadero were state facilities that had attracted substantial notoriety for allegedly unethical procedures over the past several years.⁴⁷

Moreover, among the principal figures involved in the formulation of plans for the Center were a number of controversial researchers in the field of behavior control technology, notably, several psychosurgeons and proponents of electrophysiological methods of behavior control. One was a researcher who had conducted substantial research into methods of electronic control of human behavior, in-

⁴⁶ Memorandum from Richard Laws, Ph. D., Staff Psychologist, Atascadero State Hospital, to the UCLA Center for the Study and Reduction of Violence, March 29, 1973, printed in the Appendix as Item III.B.2.c.

⁴⁷ "Memorandum on the Center for the Study of Violent Behavior." Prepared by the Committee Opposing Psychiatric Abuse of Prisoners, April 6, 1973, printed in the Appendix as Item III.B.2.c.

cluding the use of radio transmitter-receivers to determine the location, activities, and even thoughts of the individual using the device.⁴⁸

Responding to reports of these controversial projects, the subcommittee directed a series of inquiries to LEAA Administrator Donald E. Santarelli concerning possible LEAA funding for the Center for the Study and Reduction of Violence and other behavioral research projects. In response to initial inquiries, Mr. Santarelli indicated that LEAA funded seven behavioral research programs, and included a copy of a proposed grant request to LEAA for funding for the Center for the Study and Reduction of Violence. After further investigation, the subcommittee found that several programs of a controversial nature were being considered for the Center, and that each of the various programs under consideration raised a number of questions concerning the rights of the subjects. In one letter, Dr. Louis Jolyon West, director of the proposed Center, discussed the possible acquisition of an old Nike missile base for the location of the Center:

Such a Nike missile base is located in the Santa Monica Mountains, within a half-hour's drive of the Neuropsychiatric Institute. It is accessible, but relatively remote. The site is securely fenced, and includes various buildings and improvements making it suitable for prompt occupancy.

If this site were made available to the Neuropsychiatric Institute as a research facility, perhaps as an adjunct to the new Center for the Prevention of Violence, we could put it to very good use. Comparative studies could be carried out there, in an isolated but convenient location, of experimental or model programs for the alteration of undesirable behavior.⁴⁹

Actual plans for the Center for the Study and Reduction of Violence have gone through several revisions and remain somewhat unclear. But it is apparent that several radical forms of behavior modification were considered originally for experimental tests at the Center. An early project description dated September 1972 stated:

Considerable attention will focus on violent individuals who, because of biological, emotional, or characterological disturbances, are prone to life-threatening behavior. The Center's mission will be to reduce manifestations of violence by such people. To accomplish this, they must be studied carefully. Methods of preventing or modifying their violent behavior must be developed. Furthermore, the Center should be organized and operated in such a way that is continually translating new research into positive action, and transmitting new knowledge to others.⁵⁰

This project description outlined five major lines of research: (1) "epidemiological" attempts to develop statistical means whereby violence can be predicted; (2) "biological factors" research both to determine whether chromosome abnormalities and inherited characteristics can be used to predict predisposition toward violent behavior, and to test biochemical methods of controlling violence; (3) "neurological and neuropsychological" studies to determine the relationship between the brain and violent behavior; (4) "psychological factors" research to determine what external influences on

⁴⁸ See, Center for the Study and Reduction of Violence, Project Description, September, 1, 1972, printed in the Appendix as Item III.B.2.a.; and Excerpts from Grant Request to LEAA from the Center for the Study and Reduction of Violence, printed in the Appendix as Item III.B.2.b.

⁴⁹ Letter from Louis Jolyon West, M.D., Medical Director, Neuropsychiatric Institute, UCLA, to J. M. Stubblebine, Ph. D., Director of Health, Office of Health Planning, State of California, January 22, 1973, printed in the Appendix as Item III.B.2.f.

⁵⁰ Center for the Study and Reduction of Violence, Project Description, *supra*.

personality have a bearing on violent behavior; and (5) animal models, using animal behavior studies to provide information for the study of aggressive behavior by humans.⁵¹

A number of radical approaches to diminishing violence were also apparently intended to be tested at the Center. For example, the project description describes possible testing of violence-controlling drugs:

New drugs now being tested in Europe and (very recently) America hold promise for diminishing violent outbursts without dulling other brain processes. These drugs should be tested in the laboratory and then in the prisons, mental hospitals, and special community facilities. Preliminary studies reported thus far have been largely clinical without rigorous scientific controls. Proper experiments must be done as soon as possible.⁵²

One group expressed concern that one of the drugs to be tested in this particular project would be cyproterone acetate, a chemical castration drug.⁵³

The neurological and neurophysiological section of the Center apparently did intend to study various aspects of violent behavior as caused and controlled by brain functions, with emphasis placed on the practical control of such violence. For example:

It is even possible to record bioelectrical changes in the brains of freely moving subjects, through the use of remote monitoring techniques. These methods now require elaborate preparation. They are not yet feasible for large-scale screening that might permit detection of violence predisposing brain disorders prior to the occurrence of a violent episode. A major task of the Center should be to devise such a test, perhaps sharpened in its predictive powers by correlated measures of psychological test results, biomedical changes in urine or blood, etc.⁵⁴

Studies of hyperkinetic children were also planned as part of the Center's research.

LEAA Review Procedures.—In response to the subcommittee's questions concerning review structures for LEAA-funded research projects such as the Center for the Study and Reduction of Violence, LEAA informed the subcommittee that LEAA policy concerning rights of human subjects consisted solely of the following:

Medical research conducted by any grantee or subgrantee financed by LEAA and not specifically detailed in state plans as to type of research; place and persons conducting the research; amount of research funds available; and research methodology, including data on use of chemical agents or medical procedures, use of human volunteers or animal subjects, and a description of any anticipated experiments, must receive prior approval by LEAA.⁵⁵

By comparison with the Department of Health, Education, and Welfare's forty pages of guidelines, LEAA's solitary sentence appears inadequate at best.

One major factor behind the inadequacy of LEAA's ability to protect the rights of human subjects of its funded research projects is the philosophy behind the agency. Established as a revenue-sharing mechanism for local law enforcement agencies, LEAA distributes grants on a decentralized basis. A product of the "New Federalism," its basic philosophy is the decentralization of government control over local law enforcement matters, and a minimum of authority is main-

⁵¹ *Id.*

⁵² *Id.*

⁵³ "Memorandum on the Center for the Study of Violent Behavior," *supra*.

⁵⁴ Center for the Study and Reduction of Violence, Project Description, *supra*.

⁵⁵ Letter from Administrator Donald Santarelli to Chairman Sam J. Ervin, Jr., May 10, 1973, printed in the Appendix as Item III.A.4.

tained over individual grantees. This is true even in the case of so-called discretionary grants that are administered directly by LEAA.⁵⁶ Because it depends primarily upon indirect means of providing funds for individual research projects, the agency has never developed the extensive review mechanisms and guidelines necessary for the adequate protection of the rights of human subjects of LEAA-funded programs.

Cessation of LEAA Funding for Behavioral and Biomedical Research.—In January, 1974, Chairman Ervin wrote to Administrator Santarelli and asked for detailed information about LEAA funding for behavioral research and the agency's review procedures.

As you are aware, HEW and the Congress are now subjecting the question of federal financing of human behavioral research to close scrutiny. A series of ethical and administrative standards have been developed both in legislation and in regulations. I believe that LEAA ought to consider a moratorium on the further use of its funds for these purposes until it develops guidelines at least as comprehensive as those now under consideration by the Congress and HEW. These guidelines should provide for specific approval by a special committee on research and ethics within LEAA and the Administrator's Office of any project, whether funded by block or discretionary grant, in the field of human behavior research.⁵⁷

In a press release four weeks later, Administrator Santarelli responded by announcing the cancellation of all LEAA funding for medical research, chemotherapy, psychosurgery, and behavior modification because, in his words, there "are no technical skills on the staff to screen, evaluate, or monitor such projects."⁵⁸

In response to a request for information detailing the nature and extent of LEAA-funded behavioral research projects, the agency produced a computer printout describing some 537 research projects dealing in some way with the modification of human behavior.⁵⁹ This printout indicates that LEAA funds a substantial number of projects that fall within the subcommittee's sphere of interest in addition to the seven described in the agency's response to the subcommittee's initial inquiry regarding violent behavior research. Among the projects listed in the printout, there were many that would require a thorough technical evaluation of the kind Director Santarelli indicated that LEAA was not able to conduct.

The intention of the agency's February, 1974 press release seems clear—all biomedical and behavioral research conducted by LEAA would be curtailed immediately. But the policy statement subsequently drafted to implement the new directive is more ambiguous:

[I]t is LEAA policy not to fund grant applications that involve the use of research of such procedures (for the modification or alteration of criminal and other antisocial behavior) particularly applications that involve any aspect of psychosurgery, behavior modification (e.g. aversion therapy), chemotherapy, except as part of routine clinical care, and physical therapy of mental disorders * * *. This policy does not apply to a limited class of programs involving procedures generally recognized and accepted as not subjecting the patient to

⁵⁶ LEAA employs two basic systems of grant disbursement: discretionary grants and block grants. Discretionary funds are granted and administered directly by the main office in Washington. Block grants are distributed to individual state criminal justice planning agencies, which, in turn, distribute funds to individual grantees.

⁵⁷ Letter from Chairman Sam J. Ervin, Jr., to Administrator Donald B. Santarelli, January 14, 1974, printed in the Appendix as Item III.A.9.

⁵⁸ News Release Announcing Cancellation of LEAA funds for Behavior-Related Projects and Medical Research, February 12, 1974, printed in the Appendix as Item III.B.6.

⁵⁹ Excerpts from Computer Printout Listing Behavior-Related Projects, *supra*.

physical or psychological risk (e.g. methadone maintenance and certain alcoholism treatment programs), as specifically approved in advance by the Office of the administration, after appropriate consultation with and advice of the Department of Health, Education, and Welfare.⁶⁰

In an effort to ascertain the effectiveness of the LEAA policy, Chairman Ervin addressed an inquiry to the agency on June 3, 1974. In that inquiry, the chairman requested:

By way of providing further information for the subcommittee's investigation of biomedical and behavioral research, would you please forward a list of all projects described in the printout whose funding has been canceled pursuant to the LEAA press release of February 14 and the resulting guideline.⁶¹

LEAA responded on June 25, 1974, by stating that only two or three grants had been cancelled, and that this had occurred prior to the February guideline. When the subcommittee requested LEAA to respond to the question asked, the agency replied by stating that a thorough review would now be conducted of all of the projects listed in the printout in an effort to determine whether any should be discontinued.

In a letter to the Subcommittee, dated August 29, 1974, LEAA responded with the results of the survey it conducted. According to its findings, of the 537 projects listed on the computer print-out which dealt in some way with behavior modification, 390 had been terminated prior to the issuance of the LEAA guideline. Of the remaining 147, 110 were found to involve no medical procedures, and 35 involved only routine medical procedures. Of the two remaining projects, LEAA has determined that one did not violate the February guideline, and has requested further information to evaluate the legality of the other.⁶²

VETERANS ADMINISTRATION

As it became apparent that the Federal Government funds a large number of behavioral research and modification programs, the subcommittee discovered that a number of other departments and agencies were involved in activities relating to the modification of human behavior. The most notable of these is the Veterans Administration, which, in testimony at joint hearings before the Senate Health Subcommittee, and the Subcommittee on Health and Hospitals of the Senate Committee on Veterans' Affairs, admitted conducting numerous psychosurgical operations.⁶³ Of particular note are the following aspects of the Veterans Administration's policy concerning psychosurgery:

Approval for individual operations is secured from the central office of the Veterans Administration. No higher authority is required.

⁶⁰ LEAA Guideline re: Use of LEAA funds for Psychosurgery and Medical Research, February 14, 1974, printed in the Appendix as Item III.B.7.

⁶¹ Letter from Senator Sam J. Ervin, Jr., to Administrator Donald E. Santarelli, June 3, 1974, printed in the Appendix as Item III.A.16.

⁶² Letter from Geoffrey M. Alprin, Director, Office of Research Programs, LEAA, to Lawrence M. Baskie, Chief Counsel, Subcommittee on Constitutional Rights, August 29, 1974, printed in the Appendix as Item III.A.19.

⁶³ Joint Hearing on Psychosurgery in Veterans Administration Hospitals Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare and the Subcomm. on Health and Hospitals of the Senate Comm. on Veterans Affairs, 93d Cong., 1st Sess. at 17018 (1973).

Although the Veterans Administration has guidelines restricting the use of psychosurgery, it considers the practice to be therapy and not an experimental technique.

The Veterans Administration participated in HEW's studies of psychosurgery and violent behavior research, discussed above. The nature of the Veterans Administration's response to the two HEW studies has not yet been determined.

In testimony at the joint hearings, the Veterans Administration stated that the lobotomies popular in the 1950's were a poor method of behavior therapy; but the agency presented no evidence that present methods of psychosurgery aimed at producing a more "normal" human being were any more effective.

At the joint hearings, the Veterans Administration indicated that it considered drug users and alcoholics as potentially violent patients, and therefore possible subjects for psychosurgery.

In response to the Constitutional Rights Subcommittee's inquiries, the Veterans Administration confirmed that it participates in various forms of biomedical and behavioral research, and that it employs a wide variety of behavioral modification techniques, including psychosurgery, as therapy. In the year prior to the subcommittee's inquiry, five psychosurgical operations were conducted in Veterans Administration hospitals.⁶⁴ Shortly before the Veterans Administration received the subcommittee's inquiry, a new agency policy had been implemented placing stricter controls on the use and practice of psychosurgery, and limiting the number of hospitals where it could be conducted to four.⁶⁵ Before further revising its own policies with respect to psychosurgery, the Veterans Administration indicated that it was awaiting release of the HEW psychosurgery report. It is not clear at present whether the Veterans Administration is continuing to perform psychosurgical operations, nor is it clear whether any substantive efforts are being made by the agency to implement the HEW policy recommendations.

The agency told the subcommittee that its guidelines concerning human behavior were similar, but not identical to those used by HEW. No centralized control is maintained over individual research projects. The Veterans Administration emphasized the therapeutic nature of the activities the Veterans Administration undertakes, and the policy that no technique will be applied to a patient unless it is in his best interest.⁶⁶

The subcommittee was concerned both by the fact that Veterans Administration research is decentralized and subject to no agency-wide coordination and control, and by the fact that many techniques employed by the VA are considered "therapy" even though other federal departments and agencies consider the same techniques "experimental." Moreover, the agency indicates that a patient could be subjected against his will to a process designed to alter his behavior:

As to whether a patient might refuse psychotropic or behavioral modifications programs or psychosurgery drugs, this must be determined by the same criteria

⁶⁴ Letter from Administrator Donald E. Johnson to Chairman Sam J. Ervin, Jr., May 10, 1973, printed in the Appendix as Item IV.A.2.

⁶⁵ Circular 10-73-18 "Surgery for Abnormal Behavior (Psychosurgery)," printed in the Appendix as Item IV.B.2.

⁶⁶ Letter from Administrator Donald E. Johnson, *supra*.

that determines the patient's capacity to give informed consent for any treatment. Good professional practice seeks to find a way to engage the patient in doing those things which are likely to be beneficial to him, recognizing that at times the individual's capacity to form sound judgments for himself is seriously impaired. Under these latter circumstances, a variety of considerations must be reviewed by the physician with the conclusion, at times, that treatment must be insisted upon despite the patient's temporary objections. In many circumstances, it may be that a judgment will have to be made by a responsible person legally entitled to act on behalf of the patient.⁶⁷

The Veterans Administration's guidelines concerning research appear to be more advanced than those of the Law Enforcement Assistance Administration, but less elaborate than those of the Department of Health, Education, and Welfare. The decentralized nature of Veterans Administration research programs, the accepted use of psychosurgery, and the notion that many of the behavioral modification techniques that it uses are therapeutic and not experimental, all raise questions about the extensive involvement of the Veterans Administration in a variety of methods of altering the behavior of individuals, possibly in violation of their rights. Clearly the involvement of the Veterans Administration requires further inquiry.

OTHER AGENCIES

A letter of inquiry was sent ten other departments and agencies which the subcommittee reasonably felt could be involved in research connected with the modification or control of behavior. The letter stated:

The Senate Subcommittee on Constitutional Rights is currently engaged in a survey of federally-funded biomedical and behavioral research projects which are designed to alter the behavior of individual subjects. Our purpose is to determine the nature and extent of such research in order that we may better evaluate the need for legislative action in this area.⁶⁸

Each department was asked to list and describe briefly every behavioral research project that it participated in and to:

Describe the review procedures which apply to such research projects, both prior to [the department's] participation and during the course of such research, with particular emphasis on ethical considerations, such as informed consent. Include copies of all relevant guideline manuals, regulations, and other documents which set forth these procedures.⁶⁹

Of the ten departments queried, the Atomic Energy Commission, the Department of Agriculture, the National Aeronautics and Space Administration, the Special Action Office for Drug Abuse Prevention, the Environmental Protection Agency, and the Department of Commerce all responded by stating that these departments conduct no projects designed to "alter the behavior of individual subjects."⁷⁰

⁶⁷ Survey Letter from Chairman Sam J. Ervin, Jr., printed in the Appendix as Item V.A.1.

⁶⁸ *Id.*
⁶⁹ Each Agency's response is printed in the Appendix: Atomic Energy Commission—April 23, 1974, response from Dixy Lee Ray, Chairman, Item V.A.3.; Department of Agriculture—April 26, 1974, response from T. W. Edminster, Administrator, Agricultural Research Service, Item V.A.2.; National Aeronautics and Space Administration—April 10, 1974, response from Gerald D. Griffin, Assistant Administrator for Legislative Affairs, Item V.A.9.; Special Action Office for Drug Abuse Prevention—May 14, 1974, response from Robert L. DuPont, Director, Item V.A.10.; Environmental Protection Agency—May 3, 1974, response from Russell E. Train, Administrator, Item V.A.7.; Department of Commerce—April 22, 1974, response from Frederick B. Dent, Secretary, Item V.A.4.

Several departments did, however, respond affirmatively to the subcommittee's inquiry. The Department of Defense listed thirteen projects that it felt fell within the parameters of the subcommittee's concern. Generally, the projects listed were concerned with endurance, and means of preventing such natural occurrences as frost-bite and sleepiness.⁷¹

The Department of Labor informed the subcommittee that it conducts several experiments dealing with behavior modification methods of increasing individual responsiveness and production. Using mainly token economy techniques, the department's research was conducted in prisons. The department has also devoted a great deal of effort to the legal and ethical issues involved in the use of these techniques.⁷²

Of particular interest was the response from the National Science Foundation, an independent agency that provides funds on a decentralized basis for the advancement of science. The Foundation responded by saying:

We can state that the National Science Foundation does not support any biomedical or behavioral research designed to alter the behavior of human subjects. The Foundation does, however, support a substantial amount of research in social sciences, psychobiology, and neurobiology directed at understanding human behavior, and this research often requires the participation of human subjects.⁷³

Although the National Science Foundation indicated that it conducted a substantial amount of research dealing with "understanding human behavior," it did not include information concerning these projects in its response. Further, the National Science Foundation indicated that its guidelines concerning the rights of human subjects and the propriety of individual research projects are very general in nature. Similar to the Law Enforcement Assistance Administration, the National Science Foundation guidelines consist of a single paragraph under the miscellaneous section of the National Science Foundation Grants Administration Manual:

Safeguarding the rights and welfare of human subjects involved in activities supported by NSF Grants is the responsibility of the grantee institution. Pending promulgation of NSF guidelines, grantees are referred to DHEW publication (NIH) 72-102, the "Institutional Guide to DHEW Policy on Protection of Human Subjects." NSF grantees shall not conduct or support research on a human fetus which is outside the womb of its mother and which has a beating heart.⁷⁴

National Science Foundation policy concerning human subjects is further governed by the following resolution adopted in 1967 by the National Science Board:

The Board unanimously authorized the Foundation to (1) make known to grantees engaged in biomedical, social, or behavioral research its concern over the rights of privacy of persons individually or collectively involved in such

⁷¹ Letter from Malcolm R. Currie, Director, Defense Research and Engineering, Department of Defense, to Chairman Sam J. Ervin, Jr., May 3, 1974, printed in the Appendix as Item V.A.5.

⁷² Letter from William H. Kolberg, Assistant Secretary for Manpower, Department of Labor, to Chairman Sam J. Ervin, Jr., May 1, 1974, printed in the Appendix as Item V.A.6.

⁷³ Letter from H. Guyford Stever, Director, National Science Foundation, to Chairman Sam J. Ervin, Jr., April 30, 1974, printed in the Appendix as Item V.A.8.

⁷⁴ NSF Grants Administration Manual, paragraph 272, printed in the Appendix as part of Item V.A.8.

research, and (2) as necessary, satisfy itself that grantees are taking appropriate measures for securing the subject's informed consent, maintaining the confidentiality of data, and otherwise safeguarding his right to privacy.⁷⁵

As with LEAA, the subcommittee is concerned that a mere statement of intent on the part of the National Science Foundation falls short of minimum standards for the adequate protection of the rights of human subjects and the propriety of individual behavioral research projects. Although grantees are referred to HEW policies concerning the protection of human subjects, it is not known whether grantees are bound by the same system of assurances and institutional review boards as HEW. In short, from its response, the National Science Foundation does not utilize a system of review mechanisms adequate to protect the constitutional rights of persons involved in National Science Foundation-funded research.

As experience with the Department of Justice and other agencies has demonstrated, there is wide variation in the understanding of what behavior modification is. One might expect each of the ten agencies to have difficulty in deciding which programs fell within the scope of the subcommittee's inquiry. It is also reasonable to expect that other agencies besides LEAA might have difficulty discovering all its pertinent projects. These considerations point to the need for an intensive legislative inquiry into behavior modification throughout the government.

⁷⁵ Letter from H. Guyford Stever, Director, National Science Foundation, *supra*.

CONCLUSION

The focus of the Constitutional Rights Subcommittee's study of the federal involvement in behavior control technology in the United States has been both on the rights of human subjects, and on the propriety of government funding for research into methods designed to alter individual behavior. No attempt has been made to evaluate the efficacy of individual projects from a scientific viewpoint. It is clear that a large number of the projects that have come to the subcommittee's attention raise important and immediate questions of constitutional rights, and should be subject to the most careful and continued review. Nevertheless, the subcommittee found that the federal government, through a number of departments and agencies, is going ahead with behavior modification projects, including psychosurgery, without a review structure fully adequate to protect the constitutional rights of the subjects. Public concern that many of the ethical and constitutional problems of medical research have not yet been fully considered is growing as behavioral control technologies are rapidly being developed. The newly created National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research will, hopefully, be able to consider and resolve many of these important issues. In any case, as psychological and biological research continues, it may well be that Congress may have to define by law the limits of scientific research in these fields as they affect the constitutional guarantees of liberty.

Certainly continuing legislative oversight is necessary to ensure that constitutional rights and privacy are well protected in this field of science.

Respectfully submitted by

LAWRENCE M. BASKIR,
Chief Counsel and Staff Director.

October 3, 1974.

(45)

APPENDIX

75

I. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

A. Correspondence

[Item I.A.1]

SEPTEMBER 28, 1972.

HON. WARREN G. MAGNUSON,
Subcommittee on Labor-HEW Appropriations,
Washington, D.C.

DEAR WARREN: It has come to my attention that funding for the Departments of Labor and Health, Education, and Welfare and related agencies (H.R. 16654), now under consideration before your Subcommittee, includes a one million dollar appropriation for a study of violent behavior.

As you know, the Subcommittee on Constitutional Rights has done extensive research and expended much time on preserving privacy of individuals and human dignity. Our survey of data banks has brought attention to the federal funding of psychological testing and its invasion of the individual's right of privacy and the threat to other civil liberties.

As the report on the bill (Senate Report No. 92-804) makes no mention of what the money will fund—exactly what type of program or to what purpose, I feel it is important for the Subcommittee on Labor-HEW Appropriations to clarify and set forth more specifically to what ends the appropriations are directed with a view toward the possible impact on the civil liberties of American citizens.

My best wishes to you.

Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.2]

U.S. SENATE,
COMMITTEE ON APPROPRIATIONS,
Washington, D.C., October 9, 1972.

HON. SAMUEL ERVIN,
U.S. Senate,
Washington, D.C.

DEAR SENATOR ERVIN: This is in response to your letter of September 28 regarding the study of violent behavior and brain disease. In view of the information and misinformation circulating about this issue, I can readily understand your concern.

The Committee, in its report on the Labor-HEW bill, earmarked one million dollars for biomedical research into violent behavior and brain disease. This amount was subsequently reduced to \$400,000 in the House-Senate conference bill that the President vetoed and is included at the same amount in the new Labor-HEW appropriation bill that was recently considered by the Senate.

I want to assure you that the selection of specific grantees and the specific areas of research continue to be left to the usual peer review process used by the National Institutes of Health in awarding all their grants. This process is designed to result in selection of the best research proposals on the basis of scientific merit as judged by nongovernmental experts. The NIH also uses other safeguards to protect any human subjects who may participate in medical research projects.

For your information, I am enclosing an exchange of correspondence with Dr. Robert Q. Marston, Director, National Institutes of Health. I hope this will reassure you that any funds in the Labor-HEW bill added by this Committee for research into brain disease and violent behavior will be awarded to com-

petent scientists and only after such scientists meet the high ethical and medical science standards demanded by the established NIH peer review process.

Sincerely,

WARREN G. MAGNUSON,
*Chairman, Subcommittee on Labor-
Health, Education, and Welfare.*

[Item I.A.3]

U.S. SENATE,
COMMITTEE ON APPROPRIATIONS,
Washington, D.C., September 22, 1972.

Dr. ROBERT Q. MARSTON,
*Director, National Institutes of Health,
Bethesda, Md.*

DEAR DR. MARSTON: This is to call your attention to a passage on page 55 of the Senate report (92-894) accompanying the first 1973 Labor-HEW appropriation bill. The report had earmarked \$1 million to continue and expand studies of violent behavior related to brain disease.

Subsequent to Senate action on the first 1973 Labor-HEW bill, the Committee has received several disturbing published reports regarding the use of an earlier appropriation of \$500,000 for this work. Consequently, it would be appreciated if NIH would delay the funding of this work at this time. It is the desire of the Committee that, as a condition precedent to the award of any funds to continue such work, the NIH should thoroughly study the earlier work conducted with appropriated funds and determine that the adverse reports regarding this project are without merit.

In the interim, the Committee would also appreciate receiving from you a statement on NIH policy concerning research into the relationships between brain disease and violent behavior.

Thank you for your cooperation.

Sincerely,

WARREN G. MAGNUSON,
*Chairman, Subcommittee on Labor-
Health, Education, and Welfare.*

[Item I.A.4]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md., October 2, 1972.

Hon. WARREN G. MAGNUSON,
*U.S. Senate,
Washington, D.C.*

DEAR SENATOR MAGNUSON: Thank you for your letter of September 22 about the funding of research on the relationship of brain disease to violent behavior.

We are well aware of the criticism that has been directed toward earlier research projects in this field which were supported by other agencies. We are also, of course, anxious to ensure that there shall be no valid basis for similar criticism in any future work that NIH might support through the appropriation for the National Institute for Neurological Diseases and Stroke.

The policy of NIH, briefly stated, is as follows:

1. There is evidence that some kinds of uncontrolled violence and other forms of unacceptable human behavior are due to abnormal brain development or brain disease. However, the evidence is fragmentary, scattered, and equivocal. We believe that further research is necessary but that a first step should be to collect, correlate, and assess the evidence currently available in order to determine what direction further research should take.

2. Consequently, the National Institute of Neurological Diseases and Stroke has established a task force, as a subcommittee of its Advisory Council, to plan a series of workshops on brain disease in relation to violence. The National Institute of Mental Health—which is not part of NIH but which has previously supported research in this field—has set up a similar task force to study the more restricted topic of psychosurgery. Close liaison is being maintained between these two task forces.

3. Research projects on abnormal behavior and on the physiological factors affecting behavior in animals, including non-human primates, will be supported if they are of high scientific merit and appear to be relevant to the elucidation of behavioral problems in man.

4. Research projects on the genetic, hormonal, biochemical, and neurological factors in abnormal human behavior will be considered only if they conform to the established guidelines governing all research involving human subjects. These guidelines will be most rigorously enforced. The conditions include (a) a thorough initial review and continued surveillance by a multi-disciplinary committee at an institution of high repute that can, and does, accept responsibility for the protection of the subjects involved; and (b) specific grant or contract terms providing for the protection of human subjects including the right of privacy, and requiring their informed consent.

I can give you a firm assurance that no commitment to fund research projects using human subjects for the study of the relationship between brain disease and violent behavior will be made until the results of the discussions now being initiated by the NINDS task force have been completed and considered.

Please be assured of my personal concern in this matter and of my full appreciation of the committee's interest in it.

Sincerely yours,

ROBERT Q. MARSTON, M.D.,
Director.

[Item I.A.5]

OCTOBER 26, 1972.

HON. ELLIOT L. RICHARDSON,
*Secretary,
Department of Health, Education, and Welfare,
Washington, D.C.*

DEAR MR. SECRETARY: Part of Title II of H.R. 16054, the recently passed Labor-HEW appropriations bill, proposes to provide \$400,000 to fund projects, under the direction of the National Institute of Neurological Disease and Stroke (NINDS), which would explore the sources of human violence and develop some form of testing and identification.

The appropriation has caused apprehension among members of Congress, medical authorities and the press. Senator Magnuson has expressed his concern in a letter to Dr. Marston of NIH. One source of worry is that a book, *Violence and the Brain*, by three potential grant recipients, Drs. Vernon Mark, Frank Ervin and William Sweet, reveals some insensitivity to the principles of the First and Fifth Amendments. I understand that their study, funded by LEAA and NIMH concerning violent behavior classification, has been completed. I would appreciate your sending a copy of this report to the Subcommittee on Constitutional Rights.

I want at this time to express my hope that any funding under this section would be preceded by consideration of such constitutional questions. Could you therefore send copies of all proposals submitted under this section as they are received, as well as those projects accepted for funding as they are approved, to the Subcommittee.

Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.6]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., November 16, 1972.

HON. SAM J. ERVIN, JR.,
*Chairman, Subcommittee on Constitutional Rights, Committee on the Judiciary,
U.S. Senate, Washington, D.C.*

DEAR SENATOR ERVIN: Thank you for your letter of October 26 about studies of violent behavior. I, too, am particularly concerned about this subject.

With respect to the research project supported by the National Institute of Mental Health (NIMH) which you mention, the termination date has been extended until March 31, 1973. As a result, no final report is available, but when it is, the Institute will provide you with a copy. NIMH staff has closely monitored the project via quarterly reports, three site visits, and frequent

communication by telephone and mail. No psychosurgical procedures have been carried out under this contract. There is some indication that nonsurgical treatment using psychotherapy may be effective in helping patients control their violent behavior.

As you know, the President vetoed the Labor-Health, Education and Welfare appropriations bill. Before the President's action on the appropriations bill, Dr. Marston wrote to Senator Magnuson about funding of research on the relationship of brain disease to violent behavior. He indicated to the Senator that the National Institutes of Health will make no commitment to fund research of this nature until the task force established by the National Institute of Neurological Diseases and Stroke (NINDS) has completed its review of the relationship of brain disease to violence. Dr. Marston's letter is enclosed for your information.

The NINDS does not have on hand any applications for this type of research at the present time. However, you will be kept informed of the results of the NINDS task force study. In addition, we will keep you apprised of the efforts of a study group which the NIMH has established to look into the subject of psychosurgery. It will work along with the NINDS group. When the groups have completed their work, I will be pleased to share the results with you.

With kindest regards,

Sincerely,

ELLIOT L. RICHARDSON,
Secretary.

[Item I.A.7]

JANUARY 24, 1973.

Dr. ROBERT Q. MARSTON,
*Director, National Institutes of Health,
Bethesda, Md.*

DEAR DR. MARSTON: It is my understanding that the financial authorization for the violent behavior research project currently supported by the National Institute of Mental Health will expire on March 31, 1973. Should the Labor-HEW appropriations bill be passed by the Congress before that time, it is likely that an appropriation to the National Institute of Neurological Disease and Stroke for a study of violent behavior, called for in Senate Report 92-894, will be made.

On October 2, 1972, in response to Senator Magnuson's inquiry of September 22, 1972, you stated that NINDS would create a task force to study the problem of brain disease and violence. If this task force has completed its work, I would appreciate a copy of any reports prepared by the group.

Senator Magnuson asked that NIH study the earlier work done in this area and show that all adverse criticism was false. I would appreciate a copy of any NIH or NINDS study discussing NIMH research or any earlier work in the area of violent behavior research.

It was reassuring to note that all research grants would provide for the protection of the right of privacy and for the assurance of informed consent. These protections of basic civil liberties are imperative in a situation where layman and physician meet.

Your cooperation in this matter which affects the constitutional rights and civil liberties of all Americans will be appreciated.

Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.8]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md., February 7, 1973.

Hon. SAM J. ERVIN, Jr.,
*U.S. Senate,
Washington, D.C.*

DEAR SENATOR ERVIN: This is in answer to your letter of January 24 to Dr. Marston concerning an item in the National Institute of Neurological Diseases and Stroke (NINDS) appropriation for a study of violent behavior

and a request for a report from the task forces established to study the problem.

As you have stated, should the Labor-HEW appropriation bill, as vetoed, be passed, it would contain \$1 million for NINDS for a study of violent behavior. Under this appropriation, NINDS was to receive \$130,403,000. At the present time, as you undoubtedly know, the NINDS is operating on a Continuing Resolution at a level of \$107,640,000. This amount, of course, will not provide funding for new programs such as the one to which you refer. Additionally, as shown in the correspondence between Senator Magnuson and Dr. Marston and reprinted in the Congressional Record (attached), Dr. Marston assured Senator Magnuson that "no commitment to fund research projects using human subjects for the study of the relationship between brain disease and violent behavior will be made until the results of the discussions now being initiated by the NINDS task force have been completed and considered."

The NINDS Council Subcommittee on the Neurological Bases of Violent Behavior is holding a series of four workshops to examine the existing knowledge. This includes the anatomical and physiological aspects; biochemical, genetic and pharmacologic factors; behavioral studies, including both animal and human studies; and the clinical aspects including neurology, neurosurgery, EEG, neuropathology and psychiatry.

Medical and research experts in each of these fields are participating in these workshops. They will be completed by June of this year, at which time a review committee composed of at least two representatives from each of the workshops will meet in Princeton, New Jersey and draft a final report on the findings and conclusions.

A similar procedure has been initiated by the NIMH task force on psychosurgery, which will be investigating all prior research on this subject. This task force, together with the NINDS task force are maintaining a close liaison and operating under what is called the Joint NINDS-NIMH Inter-Institute Planning Work Group on Brain and Behavior.

At the present time, research projects on abnormal behavior in animals and on the physiological factors affecting behavior in animals, including non-human primates, may be supported if they are of high scientific merit and appear to be relevant to understanding behavioral problems in man.

In addition, research projects on the genetic, hormonal, biochemical and neurological factors in abnormal human behavior will be considered only if they conform to the established guidelines governing all research involving human subjects. These guidelines will be rigorously enforced. They include a thorough initial review and continued surveillance by a multi-disciplinary committee at an institution of high repute that accepts responsibility for the protection of the subjects involved, and specific grant or contract terms providing for the protection of human subjects, including the right of privacy and requiring their informed consent.

We share with you the strong conviction that the rights of privacy and informed consent are imperative, and appreciate your concern and interest in this matter in regard to clinical research on violent behavior.

Sincerely yours,

ELDON L. EAGLES, M.D., C.M., Dr. P.H.,
*Acting Director, National Institute of
Neurological Diseases and Stroke.*

[Item I.A.9]

FEBRUARY 13, 1973.

Hon. CASPAR W. WEINBERGER,
*Secretary,
Department of Health, Education, and Welfare,
Washington, D.C.*

DEAR MR. SECRETARY: In a letter of November 16, 1972, Secretary Elliot Richardson informed me that his office was monitoring the work of the National Institute of Mental Health and the National Institute of Neurological Diseases and Stroke in relation to violence behavior research. Secretary Richardson noted that reports would be forthcoming concerning the NIMH project conducted during the past year by Dr. William Sweet and the findings of a task force at NINDS investigating psychosurgery.

If any of the expected information concerning this project is available now, I would appreciate your forwarding it to the Subcommittee on Constitutional Rights.

Thank you for your cooperation in this matter.

With kindest wishes,

Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.10]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., March 26, 1973.

HON. SAM J. ERVIN, Jr.,
*Chairman, Subcommittee on Constitutional Rights, Committee on the Judiciary,
U.S. Senate, Washington, D.C.*

DEAR SENATOR ERVIN: This is in further response to your letter of February 13, requesting information on the National Institute of Mental Health (NIMH) project conducted during the past year by Dr. William Sweet, and on the National Institute of Neurological Diseases and Stroke (NINDS) task force findings on psychosurgery.

I assume that by now you have received the February 7 letter from Dr. Eldon L. Eagles, Deputy Director of the National Institute of Neurological Diseases and Stroke, explaining that the information from NINDS in which you are interested will not be available until about June of this year. The report will be based on findings of four workshops in which leading experts will participate.

The NIMH task force which will be reviewing all prior research on psychosurgery will be following a similar procedure. A close liaison is being maintained between these two task forces under the Joint NINDS-NIMH Inter-Institute Planning Work Group on Brain and Behavior.

Presently, support may be extended to research projects on abnormal behavior only if they are of high scientific merit and appear relevant to understanding behavioral problems in man.

Research projects on neurological, biochemical, genetic or hormonal factors in abnormal human behavior will be considered only if they conform to the established guidelines governing all research involving human subjects.

We appreciate and share your strong interest in the task force reports, and will make them available to you as soon as they are presented.

Sincerely,

CASPAR W. WEINBERGER,
Secretary.

[Item I.A.11]

OCTOBER 23, 1973.

DR. BERTRAM S. BROWN,
*Director, Alcohol, Drug Abuse, and Mental Health Administration,
Parklawn Building, Rockville, Md.*

DEAR DR. BROWN: Recently it has been brought to my attention that a program known as "The Seed," directed by Mr. Art Barker, has been operating under a \$230,000 grant from N.I.M.H. in Ft. Lauderdale and Miami, Florida.

I would appreciate your forwarding to me copies of all the grant proposals, requests, awards, and contracts pertaining to Mr. Barker and "The Seed." I would also like you to send a photocopy of the institutional assurance required by chapter 1-40-40-A of the D.H.E.W. Grants Administration Manual.

I look forward to your cooperation in this matter.

With kindest wishes,

Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.12]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
Rockville, Md., November 9, 1978.

Hon. SAM J. ERVIN, Jr.,
Chairman, Subcommittee on Constitutional Rights, Committee on the Judiciary,
U.S. Senate, Washington, D.C.

DEAR SENATOR ERVIN: Your letter of October 23 to Dr. Bertram S. Brown, Director, National Institute of Mental Health, requesting certain information regarding a drug abuse service grant awarded to The Seed, Inc., Fort Lauderdale, Florida, has been referred to me for reply.

Enclosed is a complete copy of the grant application and appendices submitted by The Seed, and related grant award documents, in support of the drug abuse services project grant funded initially on January 18, 1972, by the National Institute on Drug Abuse (NIDA). The material enclosed is in reply to your request for "... copies of all grant proposals, requests, awards, and contracts ..." and is submitted in compliance with the Freedom of Information Act (P.L. 901-23), and the implementing Department of Health, Education, and Welfare regulation.

Your letter also requested a copy of the institutional assurance required by the Department's Grants Administration Manual, Chapter 1-40, Protection of Human Subjects. Chapter 1-40 of the Grants Administration Manual provides that an institutional assurance be negotiated with the Department if the grant application or contract proposal involves human subjects "at risk." The final determination of "at risk" resides with the awarding agency based on the provisions of Chapter 1-40, Section 1-40-30 Applicability. It was determined during the programmatic review process that the grant application from The Seed did not involve human subjects "at risk," and, therefore, a negotiated institutional assurance under Chapter 1-40, Section 1-40-40 was not applicable.

The issue and policy requirements regarding the "protection of human subjects," however, are reviewed and monitored by NIDA staff during on-site evaluation of drug abuse project grants, and at the time that applications for continuation support are received and evaluated for continued NIDA support.

If I can be of any further assistance, please let me know.

Sincerely yours,

KARST J. BESTEMAN,
Deputy Director,
National Institute on Drug Abuse.

[Item I.A.13]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md., October 19, 1978.

Hon. SAM J. ERVIN, Jr.,
Chairman, Subcommittee on Constitutional Rights,
U.S. Senate,
Washington, D.C.

DEAR SENATOR ERVIN: In response to a telephone request by Mr. Joseph Kluttz of the staff of the Subcommittee on Constitutional Rights, we are enclosing copies of the 1966, 1969, and 1971 versions of the Department of Health, Education, and Welfare policy on protection of human subjects, the most recent list of institutions in compliance with the policy, and, most recent, a proposed rule making codifying the 1971 policy as 45 CFR 46.

Also included is the "Institutional Guide" to the HEW policy which interprets those parts of the policy applicable to institutions. Not included are the implementing documents of the National Institutes of Health and other component organizations, and the operating guides for internal review groups at the NIH and other Federal agencies.

Basically, the policy requires two review systems: first, one at the institution which provides for initial review of the proposal before its submission and for continuing review of any supported project; second, a system providing for review in depth by DHEW prior to award of support. The two review systems are complementary. One does not substitute for the other. Institutional review requires a committee broadly based both in scientific and nonscientific areas. It reflects local concerns. The review at the Department is essentially limited to science and to the ethics of the professional groups involved in that review. It reflects national standards in these areas.

The policy applies to all grant and contract supported activities in which subjects are "at risk" of exposure to other than standard and accepted procedures applied to meet the needs of subjects. While such risks occur primarily in the course of research and development activities, they may occur in other settings, notably during the spread of a practice from a region in which it is "standard and accepted" to a new region. There are also types of service so poorly developed medically that there are no naturally "standard and accepted" practices. Here too the policy may be applicable.

Three review criteria are outlined. The availability of adequate and appropriate informed consent procedures is the third of these criteria. We recognize this as a professional courtesy and a legal necessity. However, past experience indicates that it is entirely possible to obtain consent to involvement in some very poor research, not because the investigator failed to inform the subject of known risks, but because certain risks were not known or appreciated by the investigator himself. For this reason we feel that our first two criteria, concerned with the provision of adequate safeguards for the physical, mental, and social well being of the subject, and a determination of the risk/benefit ratio, are necessary preliminaries to a decision that the subject can even be approached with a request for consent.

If you have any further questions in this regard, we will be glad to reply to them.

Sincerely yours,

D. T. CHALKLEY, Ph.D.,
Chief, Institutional Relations Branch,
Division of Research Grants.

[Item I.A.14]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md., October 19, 1973.

Hon. SAM J. ERVIN, Jr.,
U. S. Senate,
Washington, D.C.

DEAR SENATOR ERVIN: Mr. Joe Kluttz of the staff of the Subcommittee on Constitutional Rights of the Senate Committee on the Judiciary has asked for information on additional regulations now in preparation for the protection of human subjects in biochemical research. Mr. Kluttz asked for an outline of the general issues addressed by the DHEW/NIH Study Group on the Protection of Human Subjects in Biomedical and Behavioral Research. Specifically, he requested a copy of the Study Group's draft report.

To fully explain the activities of the Study Group it is necessary to sketch in the background of current policies and practices dating from the mid-sixties when the Public Health Service compiled and issued guidelines on the protection of human subjects. These policies have governed the activities of NIH grantees since that time, though they were not formalized as Departmental Regulations.

Proposed formal regulations, based on a tightened version of the current DHEW policy, were first published in the Federal Register on October 9 under

rule-making procedures. The proposed new rules are basic and encompass all research activity involving human subjects. However, we recognize the desirability of, if not the necessity for further elaboration of policy with respect to the validity of informed consent by or on behalf of children, prisoners and the mentally infirm.

The Study Group was set up to deal with the policy issues related to informed consent and to propose appropriate additional regulations. A draft report by the group has been submitted to the Office of the Director, NIH. After preliminary discussions, it was decided to redraft the introductory and explanatory section of the Study Group's submission. This redraft and the proposed regulations will be subjected to final review and amendment by the NIH Director's staff, and submitted to the Assistant Secretary for Health, DHEW, and subsequently to the Secretary, DHEW, for final approval and publication in the Federal Register under rule-making procedures.

The "redraft" will be made available to the Subcommittee as soon as it is completed, but as pointed out in our telephone conversations with Mr. Klutts, it seems quite likely that this document will be subjected to extensive modifications in the review process. We will ask, therefore, that the subcommittee consider it as preliminary and tentative, and subject to revision as to form and content.

The draft policies now being reviewed by the NIH are supplemental to the above mentioned proposed regulations and are concerned almost exclusively with the issues surrounding consent. The philosophical approach of the working group to the problems of consent is stated in the introduction to its draft report.

"An uncoerced person of adult years and sound mind may consent to the application of standard medical procedures in the case of illness, and when fully and properly informed, may legally and ethically consent to accept the risks of participating in research activities. Parents and legal guardians have authority (in fact, a duty) to consent on behalf of their child or ward to established therapeutic procedures when the patient is suffering from an illness, even though the treatment may involve some risk to the patient.

"There is no legal basis, however, for parental or guardian consent to participation in research on behalf of subjects who are incompetent, by virtue of age or mental state, to understand the information provided and to formulate the judgments on which valid consent must depend. In addition, current guidelines for clinical research afford them inadequate protection. Nonetheless, to proscribe research on all such subjects, simply because existing protections are inadequate, would be to deny them potential benefits, and is therefore no solution. Knowledge of some diseases and therapies can be obtained only from those subjects (such as children) who suffer from the disease or who will be receiving therapy. Without their participation in research, progress in those fields of medicine cannot be made. These subjects need protection not currently offered, when their participation in research is considered.

"There are other individuals who may be able to comprehend the nature of the research, but who are involuntarily confined in institutions. Insofar as incarceration may diminish their freedom of choice, and thus limit the degree to which informed consent can be freely given, they too need protection. Current regulations do not recognize the limitations on voluntariness which emanate from incarceration."

The draft regulations prescribe an additional step in the review process when the research proposal involves human subjects. Supplemental to the review by advisory groups concerned with the merit and other scientific considerations related to the individual proposal, the draft regulations call for review by committee to be established at the Federal and institutional level. The new committees would approve proposals and monitor research performance in the light of ethical considerations.

Under the proposal, the consent of these new Institutional Committees would be required for research involving children, in addition to parental consent. When the subjects are more than six years of age they too must consent.

Similarly, additional protections are proposed for prisoners through the establishment of committees concerned with the conditions under which prisoners' consent is elicited.

The proposal would limit research involving the mentally infirm to projects which deal with the diagnosis, treatment, prevention or etiology of the disability from which the subject may suffer or to studies concerning institutional life *per se*.

While extended discussions of the proposals have been confined so far to the working group, it appears that subsequent review will focus on the proposed mechanisms for carrying out the agreed-upon objective; that is, to provide better protection for research subjects whose ability to give voluntary and informed consent may be impaired or unclear.

If additional information would be helpful at this time, please let me know.

Sincerely yours,

STORM WHALEY,
Associate Director
for Communications.

[Item I.A.15]

OCTOBER 24, 1973.

DR. SALEEM A. SHAH,
Director, National Center for the Study of Crime and Delinquency,
Rockville, Md.

DEAR DR. SHAH: In recent months, a great deal of concern has been expressed about the use of human subjects in biomedical and behavioral research. As chairman of the Senate Subcommittee on Constitutional Rights, this has been an area of particular concern to me.

In a recent telephone conversation with an official at the Department of Health, Education, and Welfare, a member of my staff learned that the National Center for the Study of Crime and Delinquency is conducting a series of behavioral research projects at various prisons around the country. As recent cases have recognized, biomedical and behavioral research on human subjects in coercive environments raises difficult constitutional issues. By way of providing general information, I would appreciate your response to the following questions:

1. Would you please give brief descriptions of the types of behavioral and biomedical research projects involving human subjects conducted by, sponsored by, or participated in by N.C.S.C.D. Please describe in detail any such projects conducted in prisons, mental institutions, or schools. For each of these institutions, would you please include in the description a photocopy of the written assurance required by part 1, chapter 40-40-A of the D.H.E.W. Grants Administration Manual.

2. What measures has N.C.S.C.D. taken to safeguard the rights of subjects of these research projects? Please supply copies of all policy statements N.C.S.C.D. may have issued concerning research on human subjects.

3. Are uninformed subjects ever used in such projects? If so, would you please describe in detail those situations in which informed consent is not obtained.

4. Has N.C.S.C.D. ever sanctioned the use of any experimental drug (or experimental drug dosage) or experimental surgical technique in any agency-sponsored research project?

5. To what extent does N.C.S.C.D. conduct research in Federal Prisons? Particularly, is N.C.S.C.D. involved in any capacity with the Bureau of Prisons research facilities at Springfield, Missouri (Project START) or at Butner, North Carolina (under construction)? Is N.C.S.C.D. involved in any capacity with "The Seed," a Florida-based program directed by Mr. Art Barker?

6. What is N.C.S.C.D.'s general policy on interdepartmental cooperation with respect to research involving human subjects? Specifically, has your agency ever collaborated with the Law Enforcement Assistance Administration of the Justice Department?

Please allow me to stress the general fact-seeking nature of this inquiry, and to emphasize that I have received no indication of any unethical practices conducted under N.C.S.C.D. sanction. Though I realize these questions are wide-ranging and require a significant amount of information, I will appreciate your thoughtful response.

With kindest wishes,

Sincerely yours,

SAM J. ERVIN, Jr., Chairman.

(Item L.A.161)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
ALCOHOL, DRUG ABUSE, AND
MENTAL HEALTH ADMINISTRATION,
Rockville, Md., December 19, 1973.

Hon. SAM J. ERVIN, Jr.,
Chairman, Subcommittee on Constitutional Rights, Committee on the Judiciary,
U.S. Senate, Washington, D.C.

DEAR SENATOR ERVIN: This is in further response to your letter of October 24 in which you requested information on several questions pertaining to the use of human subjects in biomedical and behavioral research supported by the Center for Studies of Crime and Delinquency of the National Institute of Mental Health. We appreciate this opportunity to provide you with information about particular projects relevant to your query, as well as about the policies and procedures currently employed regarding the protection of human subjects involved in research supported by the Center.

Before proceeding to your particular questions you may be interested in the following general information about the Center for Studies of Crime and Delinquency. It is the focal point in NIMH for research, training, and related activities in the areas of crime and delinquency, individual violent behavior, and law and mental health interactions. The Center places primary emphasis on efforts to understand and cope with problems of mental health as these are or may be reflected in various types of deviant, maladaptive, aggressive, and violent behaviors that frequently involve violations of criminal or juvenile law. The Center's conceptualization of its mission further requires that attention be given both to the individuals who engage in the behaviors mentioned and to the larger social contexts in which the behaviors develop, are observed, and are responded to in accordance with prevailing social norms and legal rules. The programs supported by the Center encompass problems in areas of individual and community mental health that are also of concern to law enforcement agencies, criminal justice agencies, schools, social welfare agencies, and other public and private agencies at national, State, and local levels.

Since the Center for Studies of Crime and Delinquency is part of the National Institute of Mental Health, the research projects supported by the Center are subject to Institute and Departmental policies and requirements regarding the protection of human subjects. This Center and the Division of Special Mental Health Programs, of which the Center is a part, have been particularly concerned with the rights of human subjects including issues of confidentiality, informed consent, and potential risks to research subjects. As a result, special precautions and considerations have been taken and every effort continues to be made to strengthen these safeguards. Further elaboration of these procedures is reflected in the response to your second question.

The following information responds to the specific questions posed in your letter:

1. Would you please give brief descriptions of the types of behavioral and biomedical research projects involving human subjects conducted by, sponsored by, or participated in by N.C.S.C.D. Please describe in detail any such projects conducted in prisons, mental institutions, or schools. For each of these institutions, would you please include in the description a photocopy of the written assurance required by part 1, chapter 40-40-A of the D.H.E.W. Grants Administration Manual.

The NIMH Center for Studies of Crime and Delinquency supports a variety of biomedical, psychological and social research studies in the area of crime and delinquency, individual violence, and law and mental health interactions. The major research areas include: (1) the development of needed scientific knowledge on sources and patterns of crime and delinquency-related behaviors; (2) the development, testing, and evaluation of new program models for handling and coping with delinquent, criminal and violent behaviors; (3) special studies on critical issues in the area of law and mental health interactions.

The research supported by this Center takes place in a variety of settings, such as community based and institutional correctional facilities, schools, courts, community agencies, hospitals, natural homes, and within the com-

munity at large. The setting is very much dependent upon the nature of the study and the specific objectives to be accomplished.

Nineteen of the Center's currently active research projects fall within areas of particular concern to you. For convenience in organizing the material, we have divided the projects into those in which all or part of the research populations come from (1) prisons and correctional institutions, (2) mental institutions, and (3) schools. A description of each of the 19 projects is attached. (See Appendix A1-3). A copy of the general or special assurance filed by each institution and the policies and procedures used by each institution in the review and monitoring of each project for which it is responsible is also attached. (See Appendix B).

(1) There are 11 research projects which are conducted either entirely or in part within correctional institutions. These studies are generally concerned with efforts to improve mental health assessment and prediction procedures and development of appropriate treatment approaches. In particular, these studies include research to learn about: the prevalence rates for chromosomal and other genetic abnormalities; improved prediction of antisocial, aggressive and violent behavior; the design and evaluation of treatment strategies and alternatives; and differential attitudes and responses of incarcerated populations to criminal sanctions and filmed aggression. It should be noted that with the advent of such criminal justice support programs as the Office of Law Enforcement Assistance and the Law Enforcement Assistance Administration in the U.S. Department of Justice, the number of research projects with prison populations supported by the Center, especially studies in the area of improved case management and correctional programs has declined.

(2) Three of the 19 studies draw populations from mental institutions and from patients released from mental hospitals. These studies are focused on efforts to improve criteria and decision-making with regard to psychiatric and psychological assessments of dangerousness of mentally disordered offenders. Various assessments typically are used by mental health and legal professions and by courts for making rather critical decisions about mentally disordered offenders. There is reason to believe that over-use of involuntary commitment often results because these assessments are not presently scientifically well founded. The research the Center is supporting is designed to improve the scientific quality of assessment techniques and thus to reduce involuntary and indeterminate commitments. Another study in this area is attempting to improve the criteria by which the adequacy of treatment provided to offenders can be more accurately and reliably determined by mental health, legal, and judicial personnel.

(3) Finally, five studies which include school populations are concerned with efforts to improve academic and social skills of children with problem behaviors; also, to strengthen the existing school programs to enable them to handle problem behaviors without resorting to juvenile justice processing. By not removing such children from the school and by working with an entire school population, it is possible to avoid attaching stigmatizing labels.

2. What measures has N.C.S.C.D. taken to safeguard the rights of subjects of these research projects? Please supply copies of all policy statements N.C.S.C.D. may have issued concerning research on human subjects?

In December 1971, a brochure was issued entitled, "The Institutional Guide to DHEW Policy on Protection of Human Subjects," a copy of which is attached (Appendix C). This document details the Department of Health, Education, and Welfare's policy and criteria regarding the protection of human subjects and specifies certain procedures which must be implemented by grantee institutions with respect to the provision of assurances that the rights and welfare of human subjects will be protected in any projects they sponsor.

In addition to the general requirements followed by the National Institute of Mental Health, the Center for Studies of Crime and Delinquency helped to develop and has been using special guidelines and forms to ensure that the rights of human subjects involved in research projects supported by the Center are being protected. The Center is keenly aware of its responsibility to ensure that proper procedures are followed in this regard on *all* projects supported by the Center.

In 1970, a form specifically addressing issues of confidentiality, informed consent and potential risks to human subjects was developed and subsequently revised. In January 1971, this form (MH-284, see Appendix D) was incorpo-

rated into the grant review process of the Center for Studies of Crime and Delinquency and the Division of Special Mental Health Programs.

As explained by the covering instruction letter (see Appendix F), this Human Subjects form requires every applicant seeking research funds from the Center for projects involving human subjects to provide information concerning the characteristics of the research subjects, the data source, the confidentiality of the data, permission and informed consent obtained, and the possible risks involved. Both the staff of the Center and the Crime and Delinquency Review Committee at the time of initial review use this information to evaluate the adequacy of the procedures to be taken by the investigator to protect the rights and welfare of human subjects. In some cases, the Center staff request further information from applicants, and staff may also seek additional opinions from appropriate Institute and Departmental staff (e.g., legal consultation) on problematic legal and ethical issues. Consideration of this matter is also given by the National Advisory Mental Health Council as part of their review prior to funding. In any case, no grant will be funded before there is adequate and sufficient assurance that the rights and welfare of human subjects will be protected.

Largely as a result of the experimental use of the Protection of Human Subjects Guides for Grant Review (MH-284) by the Center for Studies of Crime and Delinquency and the Division of Special Mental Health Programs, the National Institute of Mental Health developed two forms (MH-440 and MH-441) in September 1973 related to the protection of human subjects (see Appendix G 1-2). The Center has contributed to the development of these new forms. Use of these forms by research grant applicants and by the Review Committee is mandatory for all projects involving human subjects submitted to the Center for Studies of Crime and Delinquency and the Division of Special Mental Health Programs. The evaluation of the Human Subjects forms by Review Committee members and the active involvement and review by Center and Departmental staff detailed above are followed for *all* research grants.

It is important to emphasize that these procedures followed by the Center for Studies of Crime and Delinquency are *in addition* to the general or special assurances filed by grantee institutions as required by the Department of Health, Education, and Welfare.

3. Are uninformed subjects ever used in such projects? If so, would you please describe in detail those situations in which informed consent is not obtained.

With few exceptions, as noted below, informed consent is obtained by the grantee from subjects participating in *all* research projects supported by the Center for Studies of Crime and Delinquency. As noted in the policy statement, "An Institutional Guide to DHEW Policy on Protection of Human Subjects" and the instructions on the various Human Subjects Review Forms, informed consent should be obtained whenever possible from subjects of research projects. Informed consent is to include a fair explanation of the procedures to be followed; a description of discomforts, possible risks or side effects the subject might experience; a description of the benefits to be expected; an offer to answer inquiries concerning the procedures; and an instruction that participation is voluntary and that the subject may withdraw his participation at any time. In addition, the Center requires that the researchers disclose to subjects the confidential nature of information obtained on or disclosed by subjects. Also, the researchers are urged to provide to subjects or others (viz., parents) any medical or other useful information resulting from a subject's participation in the study. Written consent is the general rule. However, in those cases where written consent may endanger anonymity or confidentiality *oral* consent is permissible.

In two research projects, MH18468 "A Program of Research on Antisocial Behavior," and MH23075 "The XYY Syndrome" (see attachment A-1), some of the subjects are not directly informed of the research nature of their participation in taking various tests. In both cases these subjects are subjected *routinely* at intake to a battery of psychological and/or medical screening. The information which is gathered by the correctional and other authorities for their purposes is the same information used by the researcher to meet the research objectives. Informed consent is obtained, however, from subjects who are subjected to any additional or non-routine tests, such as was the case with

the psycho-physiological testing conducted under the research grant MH18408. Similarly, informed consent was obtained from the Denmark sample in the grant MH23076, because they would not have been subjected to any such routine data gathering. It might be noted that although both these projects were approved and funded prior to the formal adoption by the Department and the Center for Studies of Crime and Delinquency of more stringent criteria, the procedures are indeed adequate. Furthermore, data gathering from research subjects is either completed or near completion for both projects.

In another project (MH21303 "Assessment of Adequacy of Treatment," see attachment A-2) informed consent is obtained for all research groups included in the study except one. In this instance, the routine, daily activities on the ward of approximately 40 patients are observed primarily by hospital personnel for two to three weeks on a time-sampling basis. All the observational data is anonymously coded as part of the standard ward procedure, and individual written permission is specifically not obtained in order to protect identity. Any patients who object are excluded from the study.

Finally, informed consent is obtained from the parents or legal guardians, but not from the students themselves, for the research projects conducted with school populations. The Center for Studies of Crime and Delinquency is now insisting that wherever possible, especially with older youth, permission and informed consent also be obtained from the students *in addition* to parental consent. Such is the case, for example, with MH19706 "Behavioral Programs in Learning Activities for Youth" (see Appendix H).

4. Has N.C.S.C.D. ever sanctioned the use of any experimental drug (or experimental drug dosage) or experimental surgical technique in an agency-sponsored research project?

The Center for Studies of Crime and Delinquency does not generally support research projects in which experimental drugs or surgical techniques are used. In one active project, however, two drugs are used as part of the research MH21035, "Clinical Prediction and Treatment of Episodic Violence" being conducted at the Patuxent Institution in Maryland. This project involves identifying subgroups of aggressive inmates utilizing the electroencephalogram and other more clinical psychiatric techniques. Subsequent differential treatment is offered to the patients on the basis of these findings. An experimental drug, alpha-chloralose, is employed to produce activation of the electroencephalogram for initial diagnostic purposes. This is essentially a safe procedure but one which may have certain minor side effects, such as sleepiness, which the experimenter explicitly explains to the subject in obtaining informed consent. The inmate signs a separate permission form which is witnessed by a third party. Participation in the study is voluntary, and the inmate is free to withdraw from the study at any time.

A later phase of the study requires the inmate to take a medication, Primidone (Mysoline) which is a medically recognized and accepted anti-convulsant drug used for the treatment of seizure disorders. The use of the drug for non-classical seizure disorders would still be considered experimental. The present research is designed partly to test whether such a drug is useful for the treatment of certain types of aggressive behavior manifested by persons whose activated electroencephalographic patterns are abnormal. A written consent form is obtained from the study subject which stipulates his agreement to take medication as well as to participate in other parts of the study. Minor side effects of the drug, such as dizziness or allergic skin reactions, which may occur are explained to the inmate prior to obtaining consent. Participation is voluntary. Moreover, very careful monitoring of drug effects is undertaken while the Mysoline is given; administration of the drug is stopped in the event of discomfort or other side effects. To date there have been no serious side effects from the drug regimen. The regimen has been discontinued on two subjects, even though their complaints were ultimately thought not to be related to the drug treatment.

5. To what extent does N.C.S.C.D. conduct research in Federal Prisons? Particularly, is N.C.S.C.D. involved in any capacity with the Bureau of Prisons research facilities at Springfield, Missouri (Project START) or at Butner, North Carolina (under construction)? Is N.C.S.C.D. involved in any capacity with "The Seed," a Florida-based program directed by Mr. Art Barker?

The Center for Studies of Crime and Delinquency is supporting only one research project in a Federal prison. This project is MH18468, "A Program

of Research on Antisocial Behavior and Violence," which is in its terminal year and is a multi-dimensional research program to examine personality factors involved in antisocial and aggressive behavior. In addition to the review process of the NIMH Center for Studies of Crime and Delinquency, this project was also subjected to review by the Federal Bureau of Prisons of the U.S. Department of Justice prior to NIMH funding. The Bureau of Prisons contributed financially to the project by assuming the costs of the alterations in the building to accommodate the research component.

The Center for Studies of Crime and Delinquency is not involved in any capacity with the Bureau of Prisons research facilities at Springfield, Missouri, at Butner, North Carolina, or with "The Seed" project in Florida.

6. What is N.C.S.C.D.'s general policy on interdepartmental cooperation with respect to research involving human subjects? Specifically, has your agency ever collaborated with the Law Enforcement Assistance Administration of the Justice Department?

Other than the research project noted in response to Question 5, the NIMH Center for Studies of Crime and Delinquency is not involved with any other Federal Department in the support of any research projects. If any such research projects were to be considered for support in the future, the projects would be subjected to the same Departmental and Institute/Center guidelines and policies detailed earlier in this letter.

The NIMH Center for Studies of Crime and Delinquency does have close communication with the Law Enforcement Assistance Administration, particularly with the research arm of LEAA, viz., the National Institute of Law Enforcement and Criminal Justice. However, the Center has never collaborated with LEAA in the support of any research project. The Center and the National Institute of Mental Health have collaborated with LEAA on several conferences and workshops, such as the Joint Conference on Alcohol Abuse and Alcoholism, jointly sponsored with the U.S. Department of Transportation. In addition, the Center has provided technical assistance and consultation on several applications dealing with research in biomedical and physiological areas submitted to the National Institute of Law Enforcement and Criminal Justice.

Once again, we appreciate having the opportunity to respond to your thoughtful questions. As we hope we have indicated, the issues of protection of the rights and welfare of human subjects are very much of concern to us. We will continue our efforts to see that our investigators conscientiously guarantee and protect their subjects' right. If we can provide any additional information, please feel free to contact us.

Sincerely yours,

BERTRAM S. BROWN, M.D.
Director.

(Item I.A.17)

JANUARY 11, 1974.

Hon. CASPAR WEINBERGER,
Secretary, Department of Health, Education, and Welfare,
Washington, D.C.

DEAR Mr. SECRETARY: I have noted with interest that the Department of Health, Education, and Welfare has proposed the codification of existing Departmental guidelines concerning experimentation on human beings. As chairman of the Senate Subcommittee on Constitutional Rights, I wish to urge that the final regulations provide increased protection of the rights of the subjects of such experimentation.

There are two major weaknesses in the Department's proposal: First, it is based upon existing guidelines that have been demonstrated to be inadequate a number of times, perhaps most convincingly in the recent report of the HEW Investigative panel. Unfortunately, the department has not seen fit to implement the recommendation of its own expert committee. Second, the codification of these guidelines is significantly weaker than legislation which is presently pending in the House. This legislation also includes needed statutory remedies that HEW itself lacks the authority to implement.

The field of biomedical and behavioral research concededly is very complex. Forward thinking researchers have made startling breakthroughs and they must be encouraged to continue to do so. But when medical research is con-

ducted with human subjects there is a real danger that purely scientific interests may lead some researchers to give insufficient attention to the rights of the persons who are experimental subjects. Great care must be taken to anticipate potential abuses, and to insure that individual rights take the first priority whenever human subjects are used in medical research. Scientific interests alone cannot be seen as a justification for the violation of constitutionally protected rights.

Minimum standards concerning informed consent and other ethical considerations must be defined and enforced, not just for the Department of Health, Education, and Welfare, but for all experimentation involving human beings that is conducted under grant or sponsorship from the Federal government. Regrettably, the proposed guidelines do not clearly define many of the ethical problems that are faced in medical research, they do not provide for adequate continuing review by HEW and of course they can be applied only to experiments that relate to the Department of Health, Education, and Welfare. There have already been indications that other government departments and agencies which look to your Department for guidance are considering adopting the HEW proposals. HEW has a responsibility to establish the strongest possible ethical guidelines in the field of the protection of the rights of human subjects to serve as a model for other federal, state and private research.

The proposed rules are not a substitute for important legislation that is now pending in the House. Two of these bills are especially attractive, and neither would place unwarranted restrictions upon the ability of the researcher to make the kinds of scientific breakthroughs that are so essential. Senator Kennedy's amendment to H.R. 7724 incorporates many of the suggestions of the HEW panel. Among other things, it would establish a central review board within HEW whose purpose it would be to define present ethical standards to review further problems that will arise, as most assuredly they will. H.R. 10573, introduced in the House by Congressman Richardson Preyer, represents a stronger version of H.R. 7724. Most important, it expands the jurisdiction of a National Human Experimentation Standard Board to cover all research projects that receive federal funds. Both of these bills represent significant improvements over the HEW proposals.

Because it conducts more experimentation than perhaps any other research organization in the United States, the Department of Health, Education, and Welfare is in a position to exert strong leadership in this field. I would urge that the proposed HEW ethical rules be changed to provide the greatest possible protection for Americans who are the subjects of medical research.

With kindest wishes,
Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.18]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., January 30, 1974.

Hon. SAM J. ERVIN, Jr.,
*Chairman, Subcommittee on Constitutional Rights, Committee on the Judiciary,
U.S. Senate, Washington, D.C.*

DEAR SENATOR ERVIN: Thank you for your letter of January 11 regarding the proposed regulations for experimentation on human beings.

I share your concerns for the care that must be exercised in order to prevent potential abuses, and to insure the individual rights of human subjects used in medical research. All comments on the draft proposed rules are now being studied by my staff at the National Institutes of Health as part of their general review of responses to the notice published in the November 16, 1973, *Federal Register*. I can assure you that your views will be considered during this period preceding the issuance of final regulations.

With kindest regards,
Sincerely,

CASPAR WEINBERGER,
Secretary.

[Item I.A.19]

JANUARY 15, 1974.

ROBERT Q. MARSTON,
Director, National Institutes of Health,
Bethesda, Md.

DEAR DR. MARSTON: In a letter to former HEW Secretary Elliot Richardson dated October 26, 1972, I expressed my concern that psychosurgery and other forms of behavior modification raise fundamental moral and ethical questions, particularly with regard to the Bill of Rights. As Chairman of the Senate Subcommittee on Constitutional Rights, I expressed my opinion that every effort should be made to protect the rights of the human subjects of such medical techniques.

In his response, Secretary Richardson enclosed a copy of a letter dated October 2, 1972 which you made in response to an inquiry from Senator Warren Magnuson. In the letter you stated that "I can give you a firm assurance that no commitment to fund research projects using human subjects for the study of the relationship between a brain disease and violent behavior will be made until the results of the discussions now being initiated by the NINDS task force have been completed and considered." The NINDS task force mentioned was an *ad hoc* committee set up to study the propriety of research involving psychosurgery. I understand that while a rough draft of the report of the task force has been completed, the final version of the report will not be issued for some time.

In a draft of guidelines recently proposed for the Law Enforcement Assistance Administration concerning psychosurgery, the director, Donald E. Santarelli, has said that "application involving psychosurgery and the criminal personality should be directed to the National Institutes of Health for funding consideration." Has NIH funded, participated in, sanctioned, or in any way become involved in programs using psychosurgery since October of 1972? What is the status of the corresponding studies of psychosurgery being conducted by the National Institute for Neurological Diseases and Stroke and the National Institute of Mental Health? If any reports or drafts have been completed by either of the committees, would you please include copies. Also, would you please include project descriptions and grant requests for all violence studies or behavior modification programs that NIH is presently associated with in any capacity?

Thank you for your cooperation, and I look forward to hearing from you.

With kindest wishes,
 Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.20]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
 PUBLIC HEALTH SERVICE,
 NATIONAL INSTITUTES OF HEALTH,
Bethesda, Md., January 30, 1974.

HON. SAM J. ERVIN, JR.,
U.S. Senate,
Washington, D.C.

DEAR SENATOR ERVIN: Thank you for your letter of January 15, 1974, in regard to National Institutes of Health participation in and support of research in the area of psychosurgery. In order to be precise in reply to your questions, I will use the term "psychosurgery" as meaning research on human subjects whose primary objective is the surgical diagnosis or treatment of behavioral or psychiatric disorders.

Since October 1972, the NIH has not participated in or funded research in the area of psychotherapy. The National Institute of Neurological Diseases and Stroke, a division of the NIH, has completed a "Report on the Biomedical Research Aspects of Brain and Aggressive Violent Behavior." A condensed version of the scientific aspect of the NINDS Report has been published in the January 1974 issue of the *Archives of Neurology*, Volume 30, Number 1, pages 1-35. The full Report is being reviewed by the Office of the Assistant

Secretary for Health, Department of Health, Education, and Welfare. Enclosed is a copy of the NINDS Report. The National Institute of Mental Health, a division of the Alcohol, Drug Abuse, and Mental Health Administration, is preparing a report on the clinical aspects of psychosurgery. It is my understanding that the NIMH Report is not yet completed.

The NIH presently is not supporting or reviewing any proposals for research on the biomedical aspects of violence.

If we can provide additional information please call on us.

Sincerely yours,

ROBERT S. STONE, M.D.,
Director.

[Item I.A.21]

FEBRUARY 22, 1974.

HON. CASPAR WEINBERGER,
Secretary, Department of Health, Education, and Welfare,
Washington, D.C.

DEAR MR. SECRETARY: Over the past year I have conveyed to you my increasing concern about the many difficult problems raised by biomedical and behavioral research designed to alter the behavior of human subjects. Although forward-thinking researchers must be enthusiastically encouraged to continue their work, strong ethical guidelines must be applied in order to preserve the individual liberties of persons affected by that research.

The Senate Subcommittee on Constitutional Rights is currently engaged in a survey of federally-funded biomedical and behavioral research projects which are designed to alter the behavior of individual subjects. Our purpose is to determine the nature and extent of such research in order that we may better evaluate the need for legislative action in this area.

Various federal agencies are being surveyed on this subject, including the Law Enforcement Assistance Administration. As you may know, LEAA recently accepted my suggestion to terminate their programs because it lacks the administrative structure and expertise to give adequate review to the extraordinary projects that were being conducted under its direct and indirect grants. All LEAA grant requests concerning biomedical and behavioral research are now being forwarded to the Department of Health, Education, and Welfare for funding consideration.

In light of these recent developments, the subcommittee has decided to conduct a comprehensive survey of all federal involvement in research aimed at altering the behavior of human beings. Because the Department of Health, Education and Welfare conducts or sponsors a substantial percentage of the biomedical and behavioral research funded by the federal government and will now apparently be responsible for even more, your cooperation in providing the subcommittee information pertaining to departmental involvement in behavioral and biomedical research designed to alter human behavior is particularly important.

Although the subcommittee has made some specific inquiries of certain DHEW operating agencies, I would appreciate your collecting the following information for each of the DHEW operating agencies which supports or conducts biomedical and/or behavioral research which is designed to alter the behavior of human subjects:

1. List each research project by:

(a) Name of grantee and principal researcher (individual and institution); (b) dates of DHEW involvement; (c) amounts of money involved (total and FY-74); and (d) a brief description of the project.

2. Describe the review procedures which apply to such research projects, with particular emphasis on ethical considerations. Include copies of all relevant guidelines, manuals, regulations and other documents which set forth these procedures.

I realize that DHEW and certain of its operating agencies (such as the Center for the Study of Crime and Delinquency) have in the past supplied information similar to that now requested by the subcommittee. However, it is important for the subcommittee to have up-to-date, complete information regarding all DHEW agencies and programs (including the Center) in the format described above.

The subcommittee expects to use the information we have requested in preparing a report on the federal involvement in biomedical and behavioral research aimed at altering human behavior. Since this report is to be published within the very near future, the subcommittee would appreciate your cooperation in making sure that we will receive this information no later than March 22, 1974. Though this request may appear to involve considerable information, I am confident that your existing review procedures will enable you to gather this information expeditiously.

Let me take this opportunity to commend DHEW for taking substantial steps toward the protection of human subjects. As I noted in my letter of January 11, 1974, I sincerely hope that DHEW will continue to assert its leadership in this endeavor as we search for answers to the very many difficult questions raised by biomedical and behavioral research designed to alter human behavior.

With kindest wishes,
Sincerely yours,

SAM J. ERVIN, Jr., *Chairman.*

[Item I.A.22]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., May 10, 1974.

Hon. SAM J. ERVIN, Jr.,
U.S. Senate,
Washington, D.C.

DEAR SENATOR ERVIN: This is in further response to your letter of February 22 requesting information about Departmental research programs aimed at altering human behavior. I am enclosing with this letter the pertinent information for the Public Health Service; and, as soon as we finish canvassing the other agencies of the Department, I will be in touch with you. I am sorry about the long delay in gathering this information.

The projects included in the enclosed listing fall within the defined area of behavioral modification, i.e., the systematic application of psychological and social principles to bring about desired changes in or to prevent development of certain "problematic" behaviors and responses. Among the many types of projects included in our response are those designed to teach narcotic addicts or alcoholics to develop self-control over their drug-taking behavior; to alter behavior of persons with serious psychiatric or behavioral problems such as chronic schizophrenia, autism, or learning disabilities; and develop methods for training persons responsible for children, such as parents, teachers or child welfare workers, to use behavioral principles in fostering child development and preventing or dealing with problem behaviors.

A number of types of research, which might fall within a wider interpretation of research designed to alter human behavior, were not included in this inventory. Investigations of medical, surgical and psychological procedures addressing a known organic etiology or a known organic syndrome (such as coronary artery disease or peptic ulcer) have not been included; studies of the medical or surgical therapy of brain tumor and the psychological therapy of aphasia will not be found in the attached list. Other examples of research not included are studies of psycho-social therapies which are based on psychoanalysis and other nonlearning theories; studies involving treatment with tranquilizers, psychoactive drugs and other somatic treatment such as electroconvulsive therapy; and bio-feedback studies, such as those which explore methods for teaching people to voluntarily control such problems as asthma attacks or gastric hyperacidity. Also excluded are health education studies aimed at increasing community and personal attention to problems such as smoking, dental caries, or the control of hypertension. The Public Health Service is not supporting research involving human subjects on psychosurgery or on other medical-surgical methods for the control of behavioral disorders.

If our operational definition omits projects of major interest to you, we would, of course, be happy to provide information on additional categories of projects should you so desire. Please contact my office if you or your staff would like to discuss these and other projects with knowledgeable staff in the Public Health Service.

The second part of your request has to do with the Department of Health, Education, and Welfare procedures that provide for the protection of human subjects who are part of research projects. I am enclosing for your use the current Departmental administrative chapter addressing those procedures. As you noted in your letter to me of January 11, we are formally codifying these procedures as Departmental regulations; as soon as those are available, I will make sure you get a copy.

Let me reaffirm my view that the protection of the individual rights of those participating in research is a major concern of this Department. The development of our policy has evolved over many years and will continue to be modified and developed into the future in response to the concerns articulated by the research community, the Department and the American public.

Sincerely,

FRANK CARLUCCI,
Acting Secretary.

[Item I.A.23]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., July 12, 1974.

HON. SAM J. ERVIN, JR.,
U.S. Senate,
Washington, D.C.

DEAR SENATOR ERVIN: This is in further response to Secretary Weinberger's letter to you of May 10 concerning the protection of human subjects. Please forgive the delay in providing you with this information.

Enclosed are copies of the document published in the *Federal Register* of May 30 which sets forth procedures governing the protection of those human subjects who participate in research projects sponsored by the Federal government. This issuance, which constitutes Part 46 of Title 45 of the *Code of Federal Regulations*, became effective July 1.

Sincerely yours,

CHARLES C. EDWARDS, M.D.
Assistant Secretary for Health.

[Item I.A.24]

JULY 12, 1974.

HON. CASPAR W. WEINBERGER,
Secretary, Department of Health, Education, and Welfare,
Washington, D.C.

DEAR SECRETARY WEINBERGER: I was concerned to learn in a *Washington Post* article of June 5 that no definitive action has been taken concerning the findings of a study of psychosurgery conducted by the Mental Health Division of the Alcohol, Drug Abuse, and Mental Health Administration. To quote from the January 21 report of the study, "Psychosurgery should be defined as an experimental therapy at the present time. As such it should not be considered to be a therapy which can be made generally available to the public because of the peculiar nature of the procedure and of the problem with which it deals." I would like to know why the report has not yet been formally released, and why no action concerning its recommendations has been taken.

Psychosurgery is a practice that poses a profound threat to individual privacy and freedom. I am disturbed that the Department of Health, Education, and Welfare has not taken the steps recommended in the report of its study to minimize this threat, and thereby provide the leadership it should as the premiere health organization in the world. While the merits of psychosurgery may be debatable, the rights and well-being of individual citizens cannot be compromised. I suggest that action on the recommendations of the study be taken at once, and that a formal moratorium be placed on the practice until the vital questions concerning its use can be thoroughly considered and resolved.

This report would have an important and positive impact on the growing controversy surrounding psychosurgery. As such, it should be made generally avail-