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ABSTRACT

This project identifies institutional research management problems imposed by certain requirements of the sponsoring Federal agencies; assesses the impact on the institution when meeting the requirements; and, where appropriate, recommends standardization or modification of the requirements or their implementation. One fundamental DHEW requirement is that no grant or contract involving human subjects will be made unless the research design has been reviewed and approved by an institutional review committee composed of research professionals. Chapters 1 and 2 of this report provide the background on this requirement and describe the Berkeley campus policy and process for implementation of this requirement. Appendix A describes the seven impact elements used. These elements are: (1) benefits, (2) costs, (3) delays, (4) introduction of conflict, (5) nonstandard requirements, (6) recordkeeping, (7) time and effort. Appendix B gives a description of each major requirement area considered for study and the nine areas chosen for individual research projects. The studies include: (1) cash flow, (2) cost recovery, (3) federal management, (4) health and safety, (5) human subjects, (6) procurement, (7) property management, (8) proposal preparation, (9) negotiation and award, (10) time and effort reporting. (Author/KE)

THE DHEW REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS: ANALYSIS AND IMPACT AT THE UNIVERSITY OF CALIFORNIA, BERKELEY

One of a Series of Analyses and Impact Reports of Major Federal Requirement Areas

Eugene J. Millstein

University of California, Berkeley

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Description of the Project

This report is one of several studies conducted as part of the University of California Research Management Improvement Project supported by a grant from the National Science Foundation. The principal investigator is John A. Perkins, Vice President--Administration for the University. The co-principal investigators are Herman D. Johnson, Vice Chancellor--Business and Finance for the San Diego campus, and Robert F. Kerley, Vice Chancellor--Administration for the Berkeley campus.

The Research Management Improvement Project (RMIP) is composed of two major projects, with the principal research conducted at the Berkeley and San Diego campuses and in the Office of the Vice President. This study is a product of Project 1. The major research objectives of Project 1 are to identify institutional research management problems imposed by certain requirements of selected Federal sponsoring agencies as a consequence of accepting contracts and grants; to assess the impact on the institution when meeting the requirements; and, where appropriate, to recommend standardization or modification of the requirements or their implementation. Project 2 will include analysis of administrative systems which also support research.

Description of the Impact Studies

In conducting the research for the nine Project 1 impact studies, impact was measured in terms of the seven impact elements described in Appendix A. That appendix also indicates the nine Federal sponsoring agencies selected for the study. These agencies comprise approximately 80 percent of the total Federal contract and grant activity at the University of California. Appendix B describes each of the major requirement areas considered for study, and indicates the nine areas chosen for individual research projects.

The nine impact studies include: Cash Flow, Cost Recovery, Financial Management, Health and Safety, Human Subjects, Procurement, Property Management, Proposal Preparation, Negotiation and Award, and Time and Effort Reporting.

The impact studies will be published in three separate publications: A complete set of the nine studies with an overview of the entire research project; summaries of the findings and recommendations of each impact study with the overview; a separate publication of each impact study.

About the University of California

The State of California higher education system consists of the University of California, the California State University System and the Community College complex.

The University of California, created by the State Legislature in 1869, is a statewide university system consisting of nine campuses and approximately 120,000 students. The population of the Berkeley campus is 30,000 students. Enrollment at the San Diego campus is nearly 8,000.

Research is an integral part of the University's function, with nearly 10 percent of total Federal research funds awarded to higher education received by the University of California. The Berkeley academic staff numbers 3,839, with approximately 25 percent of the total engaged in research. The contract and grant awards at Berkeley averaged $53 million for the last five years. Average expenditures on that campus for five years totaled $51 million. On the San Diego campus, the academic research staff includes 25 percent of the total academic staff of 1,435. On that campus contract and grant awards averaged $51 million over the past five years, with expenditures averaging $41 million over the same time period.

Acknowledgments

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Many others reviewed and commented on individual reports and their contributions are acknowledged in the pertinent report.

RMI Project Staff

University of California-Office of the President: John A. Perkins, Principal Investigator; Gerald Griffin, Project Manager; Wesley Hall, Researcher.

Berkeley Campus: Robert F. Kerley, Co-Principal Investigator; Theodore Chenoweth, Project Coordinator; David Concepcion, Assistant Project Coordinator; Eugene J. Millstein, Project Researcher; William Mosher, Researcher; Phyllis Trudeau, Researcher.

San Diego Campus: Herman D. Johnson, Co-Principal Investigator; R. C. Cornett, Project Coordinator; Arthur Jebens, Project Researcher; Earl Z. Irvin, Researcher.

Ordering Copies of Reports

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PREFACE

Scope of the Study*

This paper deals with the impact on the University of governmental requirements for the protection of human subjects. It includes a brief review of the requirements, a description of campus policies for satisfying these requirements, a discussion of the benefits of the requirements and the costs (both monetary and non-monetary), a discussion of recommended principles which should be the basis of any set of requirements for human subjects, and a discussion of how the campus might improve its process for protecting human subjects.

The Author

Dr. Eugene Millstein received his doctorate in behavioral research from Harvard University. He has been active in the development, administration, and evaluation of educational and research programs at American Institutes for Research and at the University of California, Berkeley. He is currently serving as the Director of the Berkeley Campus Research Management Improvement Project.

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The author expresses his thanks for the insight and information provided by Professor Herbert Phillips, Chairman of the Committee for the Protection of Human Subjects; Professor Bernard Diamond, former Chairman of the Committee; August Manza, Manager of the Campus Research Office; Lorraine McGraw, Executive Officer of the Committee for the Protection of Human Subjects; and to the other committee members, researchers, and administrators who were interviewed as part of the research for this study.

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*The findings, conclusions, opinions, and recommendations expressed in this study are those of the author and do not necessarily reflect the views of the National Science Foundation or the University of California.

THE DHEW REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS: ANALYSIS AND IMPACT AT THE UNIVERSITY OF CALIFORNIA, BERKELEY

S U M M A R Y

I AND II. BACKGROUND AND IMPLEMENTATION OF THE REQUIREMENTS

The fundamental DHEW requirement is that no grant or contract involving human subjects will be made unless the research design has been reviewed and approved by an institutional review committee composed of research professionals. Chapters I and II of the report provide the background on this requirement and describe the Berkeley campus policy and process for implementation of the requirement.

III. IMPACT OF THE DHEW REQUIREMENTS

Benefits

The direct and indirect benefits which have been identified and analyzed at Berkeley include the following:

1. Protection which results from committee review;
2. Protection which results from a general campus consciousness raising;
3. The development of a group of professionals with special knowledge in protecting human subjects;
4. The development of a collection of case histories on the ethical considerations and research procedures for protecting human subjects; and
5. The protection of the University against bad public relations and legal action.

Costs

The direct and indirect costs identified and analyzed include the following:

1. The financial costs;
2. The negative effects on research of the informed consent requirement;
3. The threat to academic freedom;
4. The negative effects on the direction of research;

5. Delays; and

6. The distraction of the researcher from his primary task.

Other Impacts of the Requirements

The requirements created a major controversy over the concept of social risk at Berkeley. This controversy is described and analyzed.

IV. BASIC PRINCIPLES OF AN IDEAL SET OF REQUIREMENTS

This chapter discusses basic principles relevant to any further revisions in the DHEW requirements and to any new set of requirements issued by any other government agency. The principles include the following:

1. Self responsibility of the researcher;

2. Local peer group review;

3. A simple administrative procedure to clear minor risks;

4. Emphasis on the positive benefits of human subject research;

5. Minimization of the dangers of centralized control and government censorship;

6. Emphasis on the importance of academic freedom;

7. Provision for a waiver of written informed consent;

8. Avoidance of heavy additional procedures for clearing vulnerable subject experimentation;

9. Elimination of any requirement for completed institutional review before a proposal is submitted for federal funding; and

10. Provision for rotating membership on the institutional review committee.

V. IMPROVEMENT IN THE CAMPUS PROCESS FOR PROTECTING HUMAN SUBJECTS

This chapter discusses a new process developed by the Berkeley campus for clearing non-DHEW funded human subject research.

THE REPORT

PROLOGUE

Stanley Milgram, a Yale psychologist set up an experimental situation where subjects were instructed to administer electric shocks to trainees.* These trainees behaved as if they suffered considerable and sometimes excruciating pain from the shocks. They groaned, screamed, yelled out that they could not stand the pain, and at times demanded to be freed. Actually, however, the trainees were collaborators in the experimental design and only pretended to be in great pain. The subjects who administered the electric shocks, and who believed the trainees were genuinely suffering, reacted to the experimental situation by following the authoritarian orders of the researcher even though they believed they were causing great pain and even the possibility of near lethal physical harm. The experiment yielded profound research information on human behavior – specifically on the willingness of people to follow authoritarian orders, regardless of the moral implications.

The experiment also placed the human subjects who administered the shocks in a situation of extreme stress. In Milgram's own words, "there were powerful reactions of tension and emotional strain in a substantial proportion of the subjects. Persons were observed to sweat, tremble, stutter, bite their lips, and groan as they" administered stronger and stronger shocks. The transcript of one of the subjects reveals the following interchange:

> 240 volts delivered. Aw, no! You mean I've got to keep going up with the scale? No sir. I'm not going to kill that man! I'm not going to give him 450 volts! [The experimenter says: 'The experiment requires that you go on.'] I know it does, but that man is hollering in there, sir...

Despite his numerous, agitated objections, which were constant accompaniments to his actions, the subject unfailingly obeyed the researcher, proceeding to administer the highest shock level on the generator.

Because of the immense amount of stress placed on the subjects, this experiment has been considered unethical by many researchers. In addition to the danger of physical harm created by intense anxiety, the subject was exposed to the possibility of psychological harm and deep personal humiliation.

Cases such as this have resulted in the increasing societal and governmental concern with the protection of human subjects. This concern is complicated by the need to balance conflicting principles. While it is clear that human subjects must be protected against unreasonable harm, it should be equally clear that research, sometimes involving risk to human subjects, carries great potential for improving the condition of mankind.

The safety and privacy of individuals must be weighed against the larger community interest in research for the general good. The federal government has instituted requirements, and the University has implemented policies, which attempt to protect human subjects while allowing research to proceed with a minimum of interference. This paper presents an analysis of that attempt.

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* Stanley Milgram. "Some Conditions of Obedience and Disobedience to Authority." Human Relations (1965). Pp. 57-75.

I. BACKGROUND

History

In 1965, the National Advisory Health Council sent to the Surgeon General of the United States Public Health Service the following resolution:

> Be it resolved that the National Advisory Health Council believes that Public Health Service support of clinical research and investigation involving human beings should be provided only if the judgment of the investigator is subject to prior review by his institutional associates to assure an independent determination of the protection of the rights and welfare of the individual or individuals involved, of the appropriateness of the methods used to secure informed consent, and of the risks and potential medical benefits of the investigation.

In response, the Surgeon General in 1966 and again in 1969 established policies and procedures governing the use of human subjects for all recipients of contracts and grants from the U.S. Public Health Service. University of California President Charles J. Hitch extended these regulations to all University experiments involving human subjects regardless of funding source.

In 1971, the Department of Health, Education and Welfare (DHEW), in effect, extended the U.S. Public Health Service policies and regulations to all grants, awards and contracts funded by DHEW. Again the University issued a directive which made DHEW regulations apply regardless of the source of funds.

As this report is written, Congress and Federal Agencies are discussing additions and modifications to the requirements. The principles and issues discussed in this report are relevant to these proposed changes. The dollar impact analysis is based on the 1971 DHEW requirements.

Summary of DHEW Human Subject Requirements*

Responsibility for Protecting Human Subjects

Safeguarding the rights and welfare of human subjects is the responsibility of the institution receiving DHEW funds. No grant or contract involving human subjects at risk will be made to an individual unless he is affiliated with or sponsored by an institution which assumes responsibility for the protection of the subjects involved.

Institutional Review Committee

Each institution must have an appropriate institutional review committee. No grant or contract involving human subjects shall be made unless the application for such support has been reviewed and approved by the institutional committee.

The institutional committee review shall determine that the rights and welfare of the subjects involved are adequately protected, that the risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained, and that informed consent is to be obtained by methods that are adequate and appropriate.

* Summarized from Department of Health, Education, and Welfare. Grants Administration. Chapter 1-40. "Protection of Human Subjects." April 15, 1971.

Definition of Risk

A human subject is considered to be "at risk" if he may be exposed to the possibility of harm — physical, psychological, sociological, or other. The determination of risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question.

Informed Consent

Informed consent is to be obtained from each subject. The basic elements of informed consent are:

1. A fair explanation of the procedures to be followed, including an identification of those which are experimental;
2. A description of the attendant discomforts and risks;
3. A description of the benefits to be expected;
4. A disclosure of appropriate alternative procedures that would be advantageous for the subject;
5. An offer to answer any inquiries concerning the procedures;
6. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

Informed consent is customarily obtained in writing. If strong cause exists, waiver of written consent or modification of the six basic elements above may be permitted by the Committee, but the reasons must be individually and specifically documented in the Committee minutes and signed by the chairman. Granting of permission to use modified consent procedures imposes additional responsibility upon the review committee to establish that the risk to any subject is minimum, that use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and that any reasonable alternative means for attaining these objectives would be less advantageous to the subject.

Documentation of Committee Activities

Committee activities must be documented. Files must include copies of all documents presented or required for initial and continuing review, and all transmittals on Committee actions. Meeting minutes, including records of discussions of substantive issues and their resolutions, are to be retained by the institution and be made available upon request to representatives of the DHEW.

Assurance of Compliance

Each institution performing DHEW funded human subject experimentation must provide written assurance that it will abide by DHEW policy. The assurance shall embody a statement of compliance with DHEW requirements for initial and continuing committee review of the supported activities; a set of implementing guidelines, including identification of the committee; and a description of its review procedures.

II. BERKELEY CAMPUS POLICIES AND ADMINISTRATION

Campus policies and federal requirements are implemented by the Committee for the Protection of Human Subjects (CPHS) and by the Campus Research Office which serves as the executive arm of the Committee.

Every researcher planning to perform experiments involving human subjects is required to submit a protocol describing the research to the Committee for the Protection of Human Subjects. The Committee then reviews the protocol and takes action regarding approval.

Protocol Format

A protocol is a statement of the researcher's responsibilities toward the human subjects involved in his research, and contains the following information:

1. A brief description of the research;
2. A description of the benefits of the research to the human subjects, if any, and of the benefits to human or scientific knowledge;
3. A description of how the subjects will be used;
4. A description of the subjects, indicating explicitly whether any are minors (under age 18 per California law) or otherwise members of "vulnerable" populations;
5. A description of the risks and discomforts, if any, to the subjects. Such deleterious effects may be physical, psychological or social. Some research involves neither risks nor discomforts but rather violations of normal expectations. Such violations, if any, should be specified;
6. A description of the means to be taken to minimize each such deleterious effect or violation, including the means by which the subject's personal privacy is to be protected and confidentiality of information received maintained;
7. A copy of the consent form that is to be used with the subjects;
8. If a waiver of written informed consent is desired, a justification of that desire;
9. Any other information pertaining to the researcher's ethical responsibilities to his subjects.

Committee Review

The Committee, or in some cases a subcommittee, reviews the protocol and takes one of the following actions:

1. Clears the research as "no risk." No risk projects are those which involve no danger whatsoever to the subjects. This includes procedures such as anonymous opinion questionnaires, activities similar to standard classroom work such as arithmetic tests, measurements which involve no risk such as reaction times or hand-eye coordinations, and interviews on non-threatening topics. Written informed consent is not required in no risk projects.

In 1973, 31% of the projects submitted to the CPHS were declared to be no risk projects.

2. Approves the research. In such cases, the research may involve some risk to subjects. But the Committee finds that this risk is not unreasonable, and that the researcher has taken all practical steps to minimize these risks.

   Beyond the 31% cases declared no risk, an additional 30% were approved by the Committee in 1973.

3. Conditionally approves the research. This action entitles the researcher to proceed with the project as long as he fulfills certain conditions set by the Committee. Conditions include items such as revising the consent form to explain the procedure more clearly, adding a Spanish version of a consent form, receiving clearance from the student health service, etc.

   Twenty-three percent of the cases in 1973 were conditionally approved.

4. Asks that the researcher resubmit the protocol. This occurs when the Committee feels that it has insufficient information to take action, or when it feels the research design contains dangers and should be revised to reduce risks to human subjects. The Committee may ask the researcher to provide for emergency back-up medical care, to take further steps to protect the confidentiality of subjects, or to develop a substitute procedure for administering an injection.

   In 1973, 16% of the researchers submitting protocols were asked to resubmit them with further information or improved research designs.

5. Disapproves the research. The Committee avoids a flat disapproval whenever possible. Instead, the Committee works with the researcher, suggests revisions in the research design, and asks that the researcher re-think his experimental procedure and resubmit a protocol.

   In its entire operating history, the Berkeley CPHS has flatly disapproved a project only once. This involved the administration of a narcotic and the observation of the reaction of certain parts of the body. The project was proposed by a student, involved the illegal use of drugs, and did not have the support of members of the student's department.

Source of Protocols

Table 1 shows the schools, departments and institutes from which protocols were submitted in 1973. There are a number of academic disciplines, e.g., history, literature, etc., which do not perform human subject experimentation. These are not listed in the table. Table I shows that most protocols are submitted from the Schools of Education, Public Health, and Criminology, and from the departments of Psychology, Physical Education, and Anthropology.

Table I

Origin of Submitted Protocols, 1973
University of California, Berkeley Campus

Source	Percentage of Total Campus Protocols	
Professional Schools and Colleges		
College of Agricultural Sciences	2.1	
School of Business Administration	1.5	
School of Criminology	6.4	
School of Education	21.0	
College of Engineering	1.5	
College of Environmental Design	<1.0	
School of Forestry & Conservation	<1.0	
School of Law	<1.0	
School of Optometry	1.1	
School of Public Health	12.2	
Graduate School of Public Policy	1.5	
School of Social Welfare	2.1	
		51.1%
Graduate Division		
Institute of Human Development	3.2	
Institute of Industrial Relations	<1.0	
Institute of International Studies	<1.0	
Center for Research & Development in Higher Education	1.5	
Center for Study of Law & Society	<1.0	
Survey Research Center	<1.0	
Institute of Urban & Regional Development	1.0	
White Mountain Research Center	1.0	
		8.2%
College of Letters and Science		
Anthropology	4.8	
Bacteriology & Immunology	<1.0	
Biochemistry	<1.0	
Economics	1.0	
Geography	1.1	
Linguistics	<1.0	
Mathematics	<1.0	
Physical Education	5.6	
Physiology-Anatomy	1.3	
Political Science	2.1	
Psychology	12.0	
Sociology	2.1	
Institute of Governmental Studies	1.1	
Institute of Human Learning	2.1	
Institute of Personality Assessment	1.5	
		35.9%
Other		
Student Health Service	<1.0	
Lawrence Berkeley Laboratory	2.1	
Counseling Center	<1.0	
Bancroft Library	<1.0	
Naval Biomedical Research Laboratory	1.1	
		4.8%
		100.00

* This Table is page 9 of Millstein, E.J. The DHEW Requirements for the Protection of Human Subjects: Analysis and Impact at the University of California, Berkeley. University of California, Berkeley. July, 1974.

Waiver of Written Informed Consent

The DHEW rules allow modification of the written informed consent requirement only if the reasons are carefully justified and documented.

The Berkeley Committee for the Protection of Human Subjects has followed the policy of allowing a waiver of written informed consent if one of the following conditions exists:

1. The subjects are from non-literate cultures. Written informed consent has little meaning in this context. It does not provide the subject with more protection, and it does interfere with the research. Legalistic written documents are threatening and can easily destroy the rapport needed between the researcher and the subject. Anthropologists are generally granted a waiver of written consent when they study non-literate communities.

2. The subject is a voluntary participant in an adequately publicized activity. In this situation, the subject demonstrates his implicit consent by volunteering.

3. The subject comes from a class of people well able to protect themselves. This includes public officials, university administrators, etc. If a researcher were investigating efficiency in city government by interviewing public officials, he would probably not be required to obtain written informed consent from each official he interviewed. Public officials are quite accustomed to being interviewed and questioned. The DHEW rules are written to protect naive subjects from harm. The Committee sees no need to invoke complicated, perhaps negative procedures, when the subjects are well able to protect themselves.

4. The research is performed using existing data held by a third party. Researchers occasionally use existing data such as union membership records or the results of a questionnaire conducted by others. In such cases it is often very difficult and sometimes impossible to obtain written consent from the individuals who were the subjects of the original data. When there is no substantial risk to the subjects, either from invasion of privacy or other cause, the CPHS will waive the requirement for written informed consent.

5. Written informed consent would make the research impossible. In addition to the items listed above, other conditions, such as the need for a random sample, sometimes make informed consent impossible. The Committee will waive the requirement under these conditions if it believes no substantial risk exists.

Composition of the CPHS

The Committee for the Protection of Human Subjects is an administrative subcommittee of the Graduate Council. The Graduate Council is a standing committee of the Berkeley Division of the Academic Senate.

Appointment of the chairman and members of the CPHS is made by the Graduate Council, and the term of service is at the discretion of this Council. The CPHS must consist of at least five members, one of whom is the director of the Student Health Service. Two must be licensed to practice the healing arts. Membership, as of July 1974, consisted of a professor of anthropology, the Director of the Student Health Service, the Dean of the School of Social Welfare, a professor of

education, two professors of psychology, a research physician, a professor of nutritional science, a professor of law, a professor of sociology, a professor of physical education, a professor of public health, the Dean of the School of Public Health, and the Committee executive officer.

Role of the CPHS

It is the role of the Committee to review and approve all research involving human subjects. The Committee also helps determine its own policy and procedure for such clearance work, and develops general guidelines and principles relevant to human subject experimentation.

Duties of the CPHS Chairman

The Chairman of the Committee performs the following duties. He reviews all research submitted to CPHS to determine the presence or absence of risk to human subjects. He brings those projects involving risk to the attention of the CPHS and convenes and chairs CPHS meetings. He prepares written reports of the Committee's decisions. He negotiates with researchers in those instances where the CPHS sets conditions on the conduct of the project or requires additional information before approving the project. He meets with individual researchers to explain and amplify CPHS decisions and policies. He periodically monitors high risk or sensitive projects.

The Chairman also performs an important role as educational liaison to the campus community. This involves explaining what the CPHS does, how and why it came into existence, and how it operates. It entails working on a face-to-face basis with other administrative and Academic Senate committees and with chairmen of individual departments and organized research units.

The Chairman has also been involved in the development of University responses to national policy and legislation regarding the protection of human subjects. This involves definition of the University position and communication with DHEW officials and Congressional Committees.

Because of the heavy duties placed on the Chairman, he is granted 50% released teaching time.

Role of the Campus Research Office

As the executive arm of the CPHS, the Campus Research Office performs the following functions:

1. Provides logistic support for Committee meetings, including scheduling, notification of members, agenda and minutes;

2. Maintains necessary records and files;

3. Reviews all extramural support proposals for possible use of human subjects and requests protocols if not furnished;

4. Reviews protocols for procedural compliance;

5. Provides advice and assistance to campus community on human subject policy and implementing procedures;

6. Coordinates information among DHEW, the Committee, General Counsel, Office of the Chancellor, and Principal Investigators.

For the 1974-75 fiscal year, support in the Campus Research Office devoted solely to human subjects activities will consist of the Committee Executive Officer, an administrative assistant, and a clerk.

Duties of the Committee Executive Officer

The Committee Executive Officer is the chief administrative officer for the Committee. The Executive Officer serves as a voting member of the Committee, participates in all Committee meetings, and in assisting the Chairman performs the following:

1. Serves as the Committee historian; keeps the Committee informed of precedent, and helps provide continuity to its decisions;

2. Reviews protocols for conformity to campus policy and Committee requirements;

3. Provides advice and assistance to project leaders contemplating use of human subjects;

4. Communicates with project leaders as to Committee decisions, including requests for additional information;

5. Coordinates administrative information among DHEW, Chancellor's Office, and Office of the President;

6. Supervises the Administrative Assistant to ensure that all records and files are properly maintained.

Duties of the Administrative Assistant and Clerk

The administrative assistant and clerk provide clerical support to the Committee, Chairman and Executive Officer. Duties include the transcribing of meeting minutes, scheduling and logistical arrangements for meetings, preparation of correspondence, records, files, follow-up on protocols, additional information, and the performance of additional assignments as required.

III. IMPACT OF THE DHEW REQUIREMENTS

Benefits

The basic goal of the DHEW requirements is increased protection for human subjects. Unfortunately, progress toward this objective is not easily assessed. Risk and harm to human subjects in research are difficult to measure. Concrete incidents of harm are rare and thus there is no baseline rate, such as an accident rate in manufacturing industries. Furthermore, when incidents do occur, the degree of harm is difficult to quantify. How seriously has a subject's privacy been invaded? Has the subject suffered humiliation? Has psychological or sociological harm occurred? Physical harm is more easily identified and measured – bad side effects from an experimental medical procedure, for example. But incidents of this nature occur so infrequently that no measurable improvement can be detected since the federal requirements have taken effect.

Since no empirical evidence on the protective effects of the DHEW requirements exists, this analysis must rely on the insights of the researchers and administrators involved in the process.

It is the general opinion of Berkeley researchers and research administrators that the DHEW requirements and the campus policy of implementation have resulted in increased protection for human subjects.

Protection Which Results from Committee Review

An analysis of the performance of the Berkeley Committee for the Protection of Human Subjects does not reveal dramatic examples of Committee action taken to save subjects from harm. Berkeley researchers are careful. Large risks in research design are not found in the protocols that reach the Committee. But smaller oversights do occur, and the Committee has required changes in design which probably have increased the safety of human subjects.

The Committee has made a number of suggestions to researchers which have reinforced the maintenance of confidentiality. In one instance a standard coding system was suggested to link a subject's number, rather than name, with his data. The researcher alone had the coding key; research assistants had access only to anonymous data. In a more complex example, a researcher studying the use of illegal drugs by teenagers planned to collect information on drug use by specific individuals. The information would be coded to maintain confidentiality, but a key to the code would exist. The researcher was conscious of the need for confidentiality and, therefore, the main threat was external – the possibility that a law enforcement agency would subpoena the information and use it against specific individuals. The Committee recommended that the researcher seek an exemption from subpoena from the Attorney General. If the Attorney General refused the exemption, the Committee recommended that confidentiality be maintained through deposition of the code key in a foreign country.

In the area of possible physical harm, the Committee has become involved in such issues as the dosage in radio isotopes to be used as tracers in a physiology experiment, and the use of a match lighting test in research on the coordination abilities of pre-school children.

A psychology experiment in the area of persuasion indicates another way the Committee may have prevented some harm. The experiment used as a tool a persuasive essay written to warn subjects against the use of chest x-rays as a method of detecting tuberculosis. The essay contained strong and misleading statements

on the possible relationship between cancer and chest x-rays. The researcher had made no provision for debriefing after the experiment to prevent misconceptions on the part of the subjects. Thus, the possibility existed that a subject would be so affected by the essay that, at some future time, he would refuse to take an x-ray or respond irrationally or with fear when such was prescribed. The Committee recommended procedures which would alleviate this danger.

The Committee may have protected subjects against psychological harm when it recommended that an experiment which involved hypnosis include a device to screen out those subjects for whom hypnosis may be dangerous.

In general, observers believe that committee review has resulted in some amount of increased protection for the physical safety, the psychological balance, the civil and legal rights, and the privacy of human subjects.

Protection Which Results from a General Consciousness Raising

The DHEW requirements and the Berkeley Committee for the Protection of Human Subjects have probably increased the protection of subjects independently of any actual action taken by the Committee. This is the result of the awareness created by the mere existence of the requirements and the Committee. Issues such as informed consent and ethical responsibility, the limits of social risk, and vulnerable populations are discussed informally and formally on campus. Many believe this process results in researchers putting greater thought and care into the protection of subjects in their original research design. Greater emphasis is placed on pursuing knowledge with a minimum of risks. Thus a safety benefit occurs before the research protocol ever reaches the CPHS.

Development of a Group of Professionals With Special Knowledge in Protecting Human Subjects

The existence of the Committee produces a group of professionals on campus with special knowledge in protecting human subjects. This indirectly increases the protection to human subjects. Faculty members who serve on the CPHS review hundreds of research designs per year. They develop skill in the many techniques and procedures for minimizing risks to subjects while efficiently pursuing research knowledge. They also expand their ethical understanding and judgment. Several members of the Committee commented that they had learned a great deal from serving on the Committee, that they were better professors because of it, and that they were better able to give advice on research design. The existence on campus of a group of professionals with such specialized knowledge provides a significant resource for the research community. Researchers seek the advice of present and past members of the Committee and receive assistance which makes a difference in their research design. This is not a frequent occurrence.

Collection of Cases

The collection of case histories is another result of the requirements which indirectly increases protection to human subjects. The Committee maintains complete files for each case on the original research design, the concerns of the Committee, negotiation with the Committee, and final modifications in the research design. These files constitute a significant storehouse of information on ethical considerations, and on how research designs may be modified to meet ethical considerations. The Committee chairman currently has plans to use these files to create a concrete operational set of guidelines with the use of many examples. Such a manual could prove a significant step in the effort to protect human subjects.

Protection of the University

The functions of the CPHS serve to protect the University against both bad public relations and legal action. Members of the Committee generally do not view this as their role, but it is an inevitable effect of the nature of the Committee. When the dangers to human subjects are reduced, the possibility of bad public relations and legal action are reduced. The existence of the CPHS structure is one of the ways the University demonstrates its corporate responsibility. The structure helps to reassure the general public and the federal government that their support of human subject research will not result in the abuse of human dignity and life.

Other Indirect Benefits

The requirement for the submission of a protocol to the CPHS forces student researchers to articulate their experimental procedure in advance of the experiment. Some professors feel this has resulted in students giving more thought not only to the ethical considerations of their research design, but also to the effectiveness and efficiency of the design. Thus the quality of research may have been improved.

Similarly, deliberations with the CPHS have occasionally resulted in improved experimental designs independent of ethical considerations. Committee members note, however, that their primary function is to review ethics and not scientific design, and that if no ethical risk is involved, they usually say nothing about the merits of the experimental design.

Costs

This section will review financial costs and other costs such as delays in research, frustration to the researcher, and negative effects on the quality and direction of research.

Financial Costs

The overall costs of the Berkeley campus process for the protection of human subjects can be divided into three categories:

1. The costs of the Committee, including the time of the members and the Chairman;
2. The costs to the Campus Research Office which serves as the executive arm of the Committee; and
3. The costs incurred by researchers who must prepare protocols and negotiate with the Committee.

Table 2 outlines these costs for fiscal year 1973-74. Footnotes explain considerations behind some of the estimates.

Overall cost of the process is estimated to be $86,900. This includes $27,900 in costs of the Committee; $41,400 in costs to the Campus Research Office; and $17,600 in costs incurred by researchers.

For fiscal year 1974-75, costs of the process are expected to rise to $99,800.* This is due to an expected 35% rise in the number of protocols submitted to the Committee and to general inflation.

* Because protocols submitted are expected to increase by 35%, costs incurred by researchers should rise 35% to $23,760. The added workload will require the clerk to be full time, and thus bring the costs to the Campus Research Office to $43,400. Except for inflation, costs to the Committee would probably remain about the same at $27,900. Summing these three figures and adding 5% for inflation yields $99,800.

Table 2*

Overall Costs of Berkeley's Process for the Protection of Human Subjects

University of California, Berkeley

Fiscal Year 1973-74

Costs of the Committee for the Protection of Human Subjects		
Committee Chairman (half-time)[1]	$14,600	
Other Committee Members (5% time for 13 faculty members)[2]	12,600	
High level campus administrator (one week)[3]	700	
		$27,900
Costs to the Campus Research Office		
Committee Executive Officer (full-time)	$18,400	
Administrative Assistant (full-time)	9,100	
Principal Clerk (half-time 6 months; full-time 6 months)	5,900	
Fringe Benefits	4,000	
Supplies and Expenses (estimate)	3,000	
Equipment (estimate)	1,000	
		41,400
Costs incurred by the Researchers		
Researcher's Time[4]	$14,600	
Secretarial Time[5]	900	
Xerox Expenses[6]	2,100	
		17,600
		$86,900

Notes to Table 2

* This Table is page 18 of Millstein, E.J. The DHEW Requirements for the Protection of Human Subjects: Analysis and Impact at the University of California, Berkeley. University of California, Berkeley. July, 1974

[1]The Committee chairman has estimated he spends, at a minimum, the equivalent of half time on Committee duties. He is granted 50% released teaching time.

[2]Committee members were interviewed. The proportion of a professor's overall work time estimated to be spent on Committee duties averaged 5%. As of June 1974, there were fourteen members on the Committee. (The salary of the Committee Executive Officer who is a member is covered in the costs of the Campus Research

Notes to Table 2 (continued)

Office.) The average faculty salary at Berkeley is $21,000. Thus the overall cost of Committee members, not including the Chairman and the Executive Officer, can be estimated at 12 x .05 x$21,000 = $12,600

3 It is estimated that the Dean of the Graduate Division spends the equivalent of about one week per year making appointments, handling complaints, etc., relevant to the human subjects protection policy.

4 In estimating the amount of time researchers spend preparing protocols and negotiating with the Committee, several variables must be considered.

1) Professors do not write all of the protocols. Many are written by graduate students and signed by professors.

2) Most cases are straight forward, present no problems, and require little time, but a small number of cases do contain complications and require substantial time.

According to Committee records of 1973, 53% of the total number of protocols were submitted by a professor alone. The remaining 47% were submitted jointly by a graduate student and professor. Most of the researchers interviewed estimated that 85% of the cases were straight forward and simple. In these cases it was estimated that the professor, whether or not he actually writes the protocol, spends about an hour on the protocol and on communicating with the Committee. (The 85% estimate matches another figure derived independently from Committee files. Records show that 84% of Committee cases are rated no risk, approved, or conditionally approved. The remaining 16% require further negotiation and resubmission to the Committee.)

The 15% (or 16%) of the cases which do contain problems are estimated to require about 5 hours of the professor's time. Complicated cases require the professor to spend more time on the protocol, to negotiate with the Committee, and sometimes to appear before the Committee.

The average hourly rate of a professor at Berkeley is estimated to cost $13 per hour (average salary of $21,000 divided by 1600 (nine months).

Thus, the total cost of researcher's time is estimated to be as follows:

> Of the total of 700 cases, 595 or 85% are one-hour cases resulting in 595 professor-hours. 105 or 15% are five-hour cases resulting in 525 professor-hours. Total professor hours is 1120, which at a cost of $13 per hour equals $14,500 (rounded off).

5 Secretarial time is estimated at 1/3 hour per case. 700 cases x 1/3 hour x $4 per hour equals $900 (rounded off).

6 Approximately 60 copies per case at $.05 per copy for 700 cases.

Negative Effects of the Informed Consent Requirement

The basic requirement of informed consent can significantly interfere with the scientific merits of a research design. Much research, particularly in the social sciences, depends on the use of a random sample. Informed consent reduces randomness. When particular subjects decline to participate in research, there may be some underlying reason. The subjects who remain in the research then constitute a biased sample rather than a random sample.

Suppose, for example, research is being performed on the impact of religious training on a certain group of teenage boys. If the boys are given the choice of whether or not to participate in the interviews, some may decline. It is possible that those who decline are, say, the most negative about their training. The remaining sample is, thus, not random but biased. Research conducted on this remaining group may not reflect the true impact of the training.

It should be noted that, as previously described, the DHEW regulations do allow a waiver of informed consent under certain circumstances. Thus the cost of the informed consent requirement, in terms of reduced scientific accuracy, is not as great as it would be if the requirement were absolute.

Threat to Academic Freedom

There is no question that the DHEW requirements give the campus Committee strong potential power over the kind of research that is conducted. The power is contained in a before-the-fact review so that research can actually be prevented. This is a significant departure from the previous process in which researchers were free to use any design they selected, and abuses were controlled with after-the-fact censure by colleagues in the field. An after-the-fact censure does not hold nearly the same threat to freedom of research.

The before-the-fact review presents the possibility that unpopular research will be harrassed or even prevented. So far this has not happened at Berkeley. But this potential must be viewed as a cost of the increased protection afforded human subjects.

Negative Effect on the Direction of Research

There is a possibility that the existence of the DHEW requirements and the CPHS may affect the direction of research. The Committee may encourage a kind of conservatism. Researchers may become afraid to take on controversial subjects. They may be simply unwilling to go through discussions and arguments with faculty members and administrators in order to be able to perform certain experiments.

It is difficult to find hard evidence relevant to this possibility. One of the researchers interviewed said that the DHEW requirements have definitely affected the direction of his own research. He refuses to collect new data because it means going before the CPHS; and he will not go before the CPHS because of his belief in the autonomy of research. He has also steered his graduate students away from certain types of research because of the Committee and the DHEW requirements.

Delays

The somewhat complex procedure required for clearance of projects suggests that it could be the cause of significant delays in the performance of research. Interviews indicate, however, that this has not been a problem for researchers,

although it may be a problem for students. The problem does not exist for researchers for three apparent reasons:

1. The Committee operates efficiently. No risk projects are usually approved by a subcommittee within several days of submission. The subcommittee meets once a week, and more often when necessary. More complex projects are dealt with promptly by the entire Committee which, to date, has met more than once per month.

2. When funded research is being considered, the Committee frequently reviews the protocol at the same time that the proposal is being considered for funding in Washington. Thus, review by the Committee is not a factor in delaying research.

3. When non-funded research is being reviewed, the researcher sometimes begins work before receiving approval from the Committee. This is a violation of campus policy, but there is no real enforcement procedure. Researchers candidly admit that such violations take place.

Delays can be a problem for students, however. This is particularly true for a student who wishes to perform a research project entirely within one eleven-week quarter. After spending several weeks designing his research, the student sometimes cannot allow even two weeks for CPHS approval, and still have time to complete the research.

It should be noted that the possibility of delay depends upon the operation of the Committee. Delay is not an inherent part of the process of satisfying the DHEW requirements, but it is a likely outcome. The Berkeley campus is fortunate in having a Committee which has taken effective steps to minimize delay.

Bureaucratic Procedures Which Distract the Researcher from his Central Task

One issue explored in this study was the possibility that researchers would find the added bureaucratic procedures a real source of frustration and distraction from their primary work. This does not seem to be the case. Most researchers find the extra burden mild, and claim it has virtually no effect on their creative work. One researcher commented that the interference was insignificant compared to other government factors such as the unpredictability of funding.

Although this particular procedural burden makes little difference, the principle of minimizing bureaucratic procedure still holds. If requirements continually expand, a point will be reached where they significantly hamper the creative process of research.

Costs Versus Benefits

Are the benefits of the DHEW requirements worth the costs? This is, of course, the critical question. The answer is a value judgment, and there is no general consensus on the Berkeley campus.

Supporters say the requirements have resulted in greater protection for human subjects. Researchers do take greater care; and the consequence is increased protection for the physical safety, the psychological balance, the civil and legal rights, and the privacy of human subjects.

Opponents say the benefits are not worth the costs. The number of abuses are tiny in the first place, and the requirements do not really end these abuses. The requirements do create a vast bureaucratic process which is costly, interferes with scientific design, threatens academic freedom, and changes the direction of research.

In the judgment of this author, the benefits are worth the costs, but only if certain principles are strictly followed in the enforcement process. These principles are discussed in Chapter III. They are designed to reduce the threat to academic freedom and the direction of research, and to keep costs of enforcement low by structuring the minimum amount of bureaucratic procedure consistent with substantive protection for human subjects. If these principles are followed, I believe we will reduce the number of occasions in which human health and dignity is abused in experimentation. The cost for such protection is a very small proportion of the total expenditure for human subject research.

Other Impacts of the DHEW Requirements

The DHEW requirements have created several academic conflicts. These are not clearly costs or benefits, but they represent significant impacts of the requirements. The most prominent academic conflict has been the debate over social risk.

Social Risk

The DHEW regulations state that "An individual is considered to be 'at risk' if he may be exposed to the possibility of harm - physical, psychological, sociological, or other..." Berkeley campus policy expands on this statement by defining physical, psychological and sociological risk. Sociological risk is defined as follows:

> ...Social risks are related in the main to procedures that may place the reputation or status of a social group or an institution in jeopardy. Procedures designed to measure the characteristics of easily defined subgroups of a culture may entail risk if the qualities measured are ones which have positive or negative value in the eyes of the group. Even when research does not impinge directly on it, a group may be derogated or its reputation injured. Likewise, an institution such as a church, a university, or a prison, must be guarded against derogation, for many people may be affiliated with, or employed by, the institution, and pejorative information about it would injure their reputations and self-esteem. In evaluating social risk, an investigator should ask himself how the findings will appear to persons belonging to any identifiable group--or affiliated with an institution--studied and reported upon. These cautions are as equally warranted in the case of anthropological field research in distant cultures as in studies performed in domestic settings.

The definition explains the point of view of those professionals who favor it. They believe that an individual can suffer harm if a social group to which he belongs is derogated or embarrassed. For example, if an Eskimo participates in an experiment which concludes that Eskimos have lower I.Q.'s than other groups, this Eskimo may suffer harm even though his individual identity is never revealed.

Supporters of this social risk concept say that the definition does not mean that research derogatory to groups and institutions is prohibited. It only means that the possible risks must be considered and the ethical issues reviewed.

Opponents of this social risk concept view the definition as a severe threat to academic freedom. They believe that academic freedom, like freedom of the press, is the freedom to pursue knowledge and truth even if the results are potentially embarrassing to a social group or institution. They believe that this pursuit of truth is healthy for society. They fear that the social risk concept could easily be used to prevent controversial research. It could also be misused by a local or national power group to prevent research which may be dangerous to itself.

Opponents of the social risk concept, centered in the campus Academic Freedom Committee, have proposed an alternate definition for social risk. It is confined to a loss of <u>personal</u> reputation. No reference is made to institutions or groups. The definition is as follows:

> Sociological risks exist when there is the possibility that research may cause the subject to suffer a loss of personal

> reputation or other personal degradation in the eyes of other persons. Ordinarily, such risks can be minimized if the researcher safeguards the confidentiality of his files and conceals the identities of his subjects in his published findings. In some cases, additional safeguards may be necessary.

A compromise to these two points of view has been suggested. It involves accepting the narrow personal risk definition, but at the same time expanding the concept of informed consent. Informed consent would include a reasonable attempt to ensure that each subject has a clear understanding of the purpose of the research. Thus, in the case of the Eskimo, he would be informed that the purpose of the research is to compare the I.Q. of his ethnic group with other groups. The Eskimo would then have the option of choosing whether or not to participate in such research.

The suggestion of expanding informed consent has created an additional debate. Those in favor of expanded informed consent argue that human subjects have the right to know to what research enterprise they are contributing so they may make intelligent decisions as to whether or not they wish to participate. This is viewed as a simple expression of the human obligations that a researcher has to other human beings, his subjects. In pressing this point of view, Chairman Phillips of CPHS argues the following:

> I assume researchers are quite ready to accept the consequences of being honest with the human subjects who represent their data base. If one result of providing their subjects with a 'fair, clear, and succinct' statement of their research purposes is the refusal of some of these subjects to participate, so be it. In my judgment, such refusal must properly be considered a commonplace problem of conducting research on a controversial subject. This Committee has no more business becoming involved in assisting researchers to overcome their problem (by sanctioning their denying decisive information to their subjects) than it has in trying to prevent them from conducting the research in the first place.

Those against a concept of informed consent which includes a statement of the purpose of the research make an analogy to news reporting. The reporter pursues truth without being required to inform each person he interviews of the purpose or goal of his search. This is considered healthy for society. The researcher should be accorded the same freedom. Forcing a researcher to inform each subject of the purpose of his research may prevent very useful but controversial research from ever being performed. This is particularly true because research, by revealing new facts and principles, threatens the status quo.

Chairman Johnson of Berkeley's Academic Freedom Committee argues the following:*

> People have a right to protection from invasion of their personal privacy and against medical research that might be harmful. But to prevent data that derive from them because they find the ideas unpleasant or because they don't like the conclusions is another matter.

Much effort, time, and passion has been expended on the social risk controversy. To date it has not been resolved. The fact that the CPHS has not actually ever prevented research on the basis of social risk makes it possible for the research community to tolerate a slow resolution.

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* William A. Sievert. Human Rights Versus Research Stirs Berkeley. Chronicle of Higher Education. September 24, 1973.

IV. THE BASIC PRINCIPLES OF AN IDEAL SET OF REQUIREMENTS

This section discusses some of the basic principles favored by researchers on the Berkeley campus. These principles are relevant to any further revisions in the DHEW requirements and to any new set of requirements issued by any other government agency.

Self-responsibility

Any set of requirements emanating from Washington should be based on the principle that the researcher himself is primarily and ultimately responsible for the protection of his human subjects. Justification of this is based both on pragmatism and principle. Within practical limits, no other system can work. No amount of policing and investigation can prevent the abuse of human subjects if the researcher feels no responsibility himself. When experiments actually occur, only the researcher and perhaps some assistants perform and observe the procedure. Thus the researcher has ultimate control over his subjects. Any attempt to police this control would involve a system in which informed technical observers were present at experiments. Such a system would be expensive and hostile to the researchers. It would also discourage research in controversial areas.

Because primary responsibility rests with the researcher, federal requirements should be directed toward developing the ethical understanding of researchers. The central role of a campus Committee should be education rather than regulation. Academic disciplines have traditions and codes of ethics relevant to human subjects. Federal requirements should build on these.

Requirements should not involve a Federal review of the adequacy of protection of human subjects. Such a review would be too distant from the actual procedures of the research to be effective. Such a review would also tend to remove responsibility from the individual researcher. Similarly, requirements should avoid the trend of making the campus Committee more and more responsible, and the individual researcher less and less responsible for the protection of subjects.*

Local Peer Group Review

Among those researchers that favor some sort of before-the-fact review, there is a strong feeling that this should be a local cross discipline peer group review. Local committees are much closer to the details of the research and are in a far better position to determine where the dangers lie and how the researcher may minimize them. A Federal review would create serious obstacles without increasing protection. The distance, procedures, and problems of communication would make it far more difficult to work out modifications in research design to meet objections.

* There is a minority view on this issue endorsed by a small number of researchers. The minority view runs counter to the principles listed above and is as follows: There is clear evidence to show that researchers cannot be trusted to make their own decisions on risk to their subjects. The researcher's heavy involvement in the goals of his research may overcome his ethical awareness. Because of this, researchers must be subject to not only a before-the-fact review but also a policing operation. The policing operation would consist of events such as having a monitor accompany a researcher to a mental institution to observe how the researcher uses confidential files.

Local peer review also avoids the danger of too much centralized power in Washington and the concomitant potential of government censorship.

The DHEW regulations appear to support the principle of local peer group review. But, in 1973, NIH-NIMH began the use of form MH441 (8/73) which seems to contradict this principle.

The NIH form requests detailed information on

1. The characteristics of the human subject groups involved;
2. type of consent;
3. confidentiality of data;
4. possible risks involved; and
5. a comparison of the risks involved with the benefit of the knowledge to be gained.

The information will be used by agency reviewers to assess the dangers to human subjects. This additional layer of centralized review conflicts with the principle of local peer group review.

Simple Administrative Procedure to Clear Minor Risk

The requirements must permit a simple administrative procedure for clearing minor and no risk projects. There are large numbers of such projects and the full Committee must not be burdened with their review. A simple procedure would free the Committee to devote maximum attention to the projects where significant risk is likely, and would thus increase the overall protection of human subjects.

In keeping with this principle, federal requirements should not demand that a quorum of the Committee is necessary to determine risk.

One general rule in developing requirements is to search for methods of protecting human subjects with a minimum of bureaucratic procedures.

Emphasize the Positive Benefit of Human Subject Research

Federal requirements should include a positive statement expressing the obligation of researchers to continue studies of the human condition in the interest of understanding and ultimately ameliorating human suffering. The impact of the rules should not be to discourage the conduct of research on humans, but rather to recognize both the protection of human subjects and the importance of such research.

The chilling effect on research has been most strongly stated by a Berkeley Psychology professor:

> What is most worrisome about the direction we are headed is the chilling effect increasingly bureaucratic controls are likely to have on research on the human condition. There has never been more need to improve the quality of human life and to reduce human suffering by understanding than now. In a shrinking world we have yet to learn to live together successfully. In the context of this need for vigorous, innovative, and effective research in the behavioral and biomedical sciences, the behavior of NIH seems very strange to me. Here is an agency

presumably having the mission, in part, of cultivating and supporting research relevant to human health and welfare, yet this agency acts as though it does not wish behavioral scientists to do any human research at all by setting up increasingly arbitrary and unreasonable roadblocks.*

Minimize Dangers of Centralized Control and Government Censorship

The before-the-fact review of research design carries with it the potential danger of censorship. The requirements should be designed to minimize this danger. Emphasis on the self-responsibility of the researcher, and on local peer group review, provide the basic framework for minimizing the danger.

Emphasize the Importance of Academic Freedom

Federal requirements are stated in a way which gives much power to the Chairman and members of the institutional committee. The instructions to this Committee should include emphasis on the importance of academic freedom, and the need to protect human subjects with a minimum of interference with academic freedom.

Provide for a Waiver of Written Informed Consent

Early sections of this paper describe the DHEW procedures for allowing a waiver of informed consent and the policies the Berkeley Committee follows in issuing a waiver.

There is a strong belief among researchers that any set of requirements must provide for such a waiver. Informed consent is impractical or impossible in a number of different circumstances.

1. Where subtle attitudes are being measured, knowledge by the subject of what is being sought is almost certain to distort results. A researcher cannot, for example, study the effects of social pressure on the opinions of an individual if the individual is aware of the purpose of the experiment. Such awareness will doubtlessly affect the individual's resistance to social pressure. Many experiments are impossible if truly informed consent is required.

2. Much research, particularly in anthropology, depends on establishing good rapport between the researcher and the subject. Rapport can be completely destroyed when a subject is asked to sign a legal document. This may be true whether the subject is an urban Black, a factory worker, a policeman, or a university administrator.

3. In some cases, informed consent has little meaning. It is inappropriate to explain theoretical constructs to Trobriand Islanders who may be the subjects of an anthropological study.

4. Where a close approximation to a true random sample is essential to the research, informed consent is impossible. This has been discussed in an earlier section.

* Richard S. Lazarus, Professor of Psychology. In a letter to Senator Abraham Ribicoff, March 6, 1974.

Avoid Heavy Additional Procedures for Clearing Vulnerable Subject Experimentation

Children, prisoners, and the mentally infirm are considered vulnerable subjects because they have limited capacity to consent to their involvement in experiments. The potential for abuse of these subjects is therefore higher.

In November 1973, DHEW published for public comment an early draft of proposed rules to protect vulnerable subjects. In addition to the existing Institutional Review Committee, the proposed rules establish Institutional Protection Committees and Agency Ethical Review Boards. According to the rules it appears that before research can be performed, the following must occur:

1. The organizational review committee must approve the protocol.
2. The protection committee must approve the protocol.
3. The protection committee must approve the selection of subjects.
4. The protection committee must approve each subject's participation.
5. The ethical review board must approve the research design.

Researchers at the Berkeley campus feel that the capacity of the current system for protecting vulnerable subjects should be evaluated before the heavy procedures proposed above are instituted. In the words of Chairman Phillips of the Berkeley Committee for the Protection of Human Subjects:

> ...DHEW is prepared to establish a complex, costly, and perhaps vast bureaucratic structure for dealing with research problems associated with these vulnerable human subjects with little apparent information about the need for such a structure....
>
> ...We do not understand why DHEW would attempt to alter the current system for protecting human subjects — as represented by local "institutional review committees" ...without first evaluating the efficacy of that system in protecting human subjects including the most vulnerable subjects.... [DHEW should] utilize the experience of those most intimately concerned with such protection before instituting any new procedures.
>
> ...We feel that the net result of establishing a new, complex tier of review committees — particularly the Ethical Review Boards and Protection Committees — will be obfuscation of ethical principles and the diffusion of ethical responsibility, not their clarification and sharpening. We expect that this will be particularly true with regard to responsibilities where many may attempt 'to get into the act,' but where few will acknowledge or accept ultimate accountability.*

Many researchers believe that the proposed rules are dangerously burdensome.

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* Herbert P. Phillips, Chairman of the Committee for the Protection of Human Subjects. In a letter to the Director, National Institutes of Health, January 2, 1974.

David A. Dorinson, Assistant Counsel of The Regents of the University:

> I question whether this procedure will not unduly burden research involving children or prisoners to the degree that principal investigators will be so thwarted in their efforts to obtain approval that they will place their efforts elsewhere.*

Richard S. Lazarus, Professor of Psychology:

> In the past few years at Berkeley, I do not believe we have seriously impared behavioral science research, though it has taken countless man hours to set up a meaningful pattern of peer review of research with human subjects, and we have worked exceedingly hard to create an effective method of policing such research. I believe, however, that we are now at a turning point where review on top of review is contemplated, where excessively restrictive procedures are being pressed on us, and where every investigator or every campus review committee is assumed to be guilty until proven innocent, a pattern that is becoming dangerously counterproductive.**

Do Not Require Institutional Review Before a Proposal is Submitted for Federal Funding

The DHEW rules which become effective July 1, 1974, require institutional review before a proposal is submitted for funding (unless the Secretary of DHEW otherwise provides).

Campus researchers and administrators vigorously oppose this new requirement. The pressure in meeting proposal deadlines is already severe. The imposition of a further complex bureaucratic procedure is likely to seriously limit the investigator's flexibility and ability to respond rapidly to research opportunities and availability of funds. In addition, this requirement does nothing to increase protection for human subjects. Indeed it may have the opposite effect by placing the Committee under compulsion and time pressure to approve the protocol.

Adequate protection is provided by prohibiting the implementation of research before institutional review. If a stricter framework than this is desired, final award of funding may be withheld until institutional review has occurred.

Provide for Rotating Membership on the Review Committee

There are two basic advantages to a rotating committee:

1. It would prevent a fixed bias from developing on the committee. It would diminish the probability of committee insularity and increase the chances for objective analysis.

*David A. Dorinson, Assistant Counsel of The Regents of the University of California. In a memorandum to Ruth H. Haynor, Health Affairs Specialist. December 11, 1973.

**Richard S. Lazarus. Professor of Psychology. In a letter to Senator Abraham Ribicoff. March 6, 1974.

2. It would provide the opportunity for more researchers to serve on the committee. Thus the educational benefits of service on the committee — increased ethical awareness and greater familiarity with designs which avoid risk — would be more widespread.

Non-manipulative Research

It is the opinion of some researchers that non-manipulative research should be exempted from any requirements. Proponents of this view argue that the requirements are really designed for medical or psychological experiments in which the subject is treated or manipulated in some way, e.g., given a pill, administered a special diet, exposed to deceptive social pressures, etc. The requirements are not relevant to non-manipulative research, including virtually all anthropological studies. In these studies, subjects are only interviewed; they are not part of an experimental procedure, and thus are not exposed to risk.

The opposing argument is that risk does exist in non-manipulative studies, primarily in the possibility of a breach of confidentiality. Because risk exists, such studies should be subject to ethical review.

No recommendation on this issue is made because of a lack of consensus.

Review Committee Membership from Outside the Institution

The new July, 1974, rules require that at least one of the members of the committee be from outside the institution. The argument in favor of this stipulation is that it provides protection against insular or parochial committee attitudes, assists in maintaining community contacts, and augments the credibility of the committee's independent role. In small organizations a committee composed entirely of fellow researchers might tend to lose its objectivity.

The argument against this requirement is that at large, diverse institutions it is unnecessary and administratively burdensome. Unnecessary because a Committee composed of members from a large faculty of diverse disciplines is not likely to be insular. Burdensome because of the logistics and expense of scheduling meetings and reimbursing outside members for reviewing hundreds of cases per year.

To meet the potential danger of insularity in smaller organizations, a suggestion was made that DHEW require outside Committee membership for institutions having less than 100 employees and, perhaps, less than five disciplines. Alternatively, the requirement for outside membership could be specifically waived for educational institutions.

V. IMPROVEMENT IN THE CAMPUS PROCESS FOR PROTECTING HUMAN SUBJECTS

Non-DHEW-Funded Research

When review procedures were developed to meet DHEW requirements, the University adopted the policy that all human subject research, regardless of funding source, must undergo the review. The policy was defended on the grounds that protection of human subjects is important, and that the review procedures are reasonable to apply to all research. The value of a standardized procedure, regardless of funding source, was also noted.

The decision to apply the requirements to all research has been much criticized. The Dean of the Graduate Division referred to it as a "ghastly mistake from the beginning, putting us to inordinate and unnecessary labor, counterproductive, and frustrating, with little or no positive return."*

The argument is made that the procedures are too cumbersome to apply to all research. The Chairman of the Academic Freedom Committee explains this as follows:

> The HEW policy of having a sizable committee screen every research proposal in advance was never intended to apply to anything but major grant proposals. It is simply impossible for a committee of deans and professors on a large campus to approve in advance every research project. Bear in mind that, under presently applicable definitions, every graduate and undergraduate student is engaging in research involving human subjects whenever he wants to ask somebody some questions in connection with a paper for a class. ... The most recent choice for Chairman of the Human Subjects Committee has had to decline the responsibility because of the absurd workload, and the system would have collapsed long ago except that many students and professors simply ignore it.**

In response to this problem, a group of faculty members have developed a proposal for dealing with non-DHEW funded human subject research on the Berkeley campus.***

The system is ultimately dependent on the good will and motivation of the individual researcher. It attempts to develop a mechanism which will induce researchers to think about and address explicitly human subject issues. It does not attempt to insure protection in iron-clad terms. The latter is considered unobtainable — unless the university is willing to pay the price of a harassing policing system and intimidated or hostile researchers. The process contains the following components:

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* Sanford S. Elberg, Dean of the Graduate Division. In a memorandum to Clinton Powell. November 5, 1973.

** Phillip E. Johnson. Chairman of the Academic Freedom Committee. In a memo to Chancellor Bowker. October 25, 1973.

*** The proposal described here is detailed by Herbert Phillips in a memorandum to Sanford Elberg on February 25, 1974. The proposal was developed by Herbert Phillips, Chairman of the CPHS, Lorraine McGraw, CPHS Executive Officer; Paul Mishkin, Professor of Law; Milton Chernin, Dean of the School of Social Welfare; Eugene Bardach, Professor in Public Policy; Phyllis Blair, Chairperson of the Committee on Research; and Phillip Johnson, Chairman of the Academic Freedom Committee.

Type of risk. There will be four categories: no risk, minimal risk, significant risk, and major risk. Although these are difficult to define abstractly, they can in fact be defined operationally, and this will be done with numerous illustrations based upon the 1,500 cases CPHS has already reviewed. All projects involving vulnerable populations will be defined as major risks and will automatically go to the campus CPHS. Vulnerable populations are children, prisoners, parolees, UC students, and the mentally infirm. The physically infirm may also be included here.

Judgment of risk. The judgment as to whether a project is no risk, minimal, significant, or major will be made by the investigator himself. He will sign a Statement of Compliance, which he will prepare himself, describing his project, the risks (if any) to his subjects, the safeguards that he has built into his design, etc. In signing the Statement of Compliance he indicates that he has read the CPHS materials on protecting human subjects and that in his judgment he has fulfilled the requirements that they describe. The CPHS materials will include:

1. A revised Statement of Policies and Procedures Governing the Protection of Human Subjects; and

2. a handbook-like document that will discuss human subjects issues, problems, operational definitions, and decisions on actual cases.

The compliance process.

1. In those cases where the researcher judges his project to be either no risk or minimal risk, he will simply file his Statement of Compliance with his department.

2. In those cases where he judges his project to contain significant risks he will be required to consult an individual member of a "Panel of Consultants." This "Panel" will be comprised of current and recent members of the CPHS and perhaps other individuals. The role of the consultant is to advise the researcher on how to deal with his significant risk problem, not to approve the project; accountability must reside with the researcher himself, not the consultant. However, the Statement of Compliance should provide the name of the consultant, the nature of the consultation; the advice accepted or rejected, the justifications for the latter, and any unresolvable differences. Such consultations may result in the researcher bringing his problem to the CPHS for further advice, but in such cases, the initiative must come from the researcher, not the consultant. In cases where no agreement is reached between the researcher and the consultant, the consultant will write to the chairman of the researcher's department and the Dean of the College setting forth the differences. Responsibility for redesign of the experiment rests completely with the researcher, the department chairman, and the dean. The CPHS will not entertain complaints or grievances from any individual consultants. Responsibility must reside with the researcher, and in signing his Statement of Compliance he indicates his willingness to assume such responsibility. The consultation with a panel member may result in redefining the project as a major risk project in which case it would automatically come to the CPHS for final approval. Presumably most consultations will result in agreement between the researcher and the panel member; in such cases the researcher will sign the Statement of Compliance and file it with his department.

3. Any project that is judged by a researcher to involve major risks will go

to the CPHS for consideration and approval. The CPHS will continue to have the authority to prohibit the pursuit of such projects.

4. A researcher may approach the CPHS at any time for advice and, if desirable from his point of view, for formal approval of his project — irrespective of the type of risk that it contains.

Auditing. The CPHS will regularly audit departmental Statement of Compliance records, but will have no authority to police retroactively any individual project. The purpose of the audit is to determine how well the system is working and to discover examples or classes of problems for which new operational policies should be developed. This auditing process will serve educational, not regulatory, purposes. It is only through the recurrent discovery of unanticipated issues and problems that the system can be informed and be changed.

Scope. This system will apply to all faculty, all researchers, all members of the administrative staff, and all graduate students and undergraduates conducting dissertation or tutorial research involving human subjects. The issue of whether to include seminar research or undergraduates conducting research as part of their regular course work has not been resolved. Research will be defined as any investigative effort which entails the preparation of a research proposal or any other prior written statement of investigative plans and intentions. Thus "research," which is the result of happenstance or "Eureka"-type experiences, is happily excluded.

Consequences. The consequence of this proposed procedure is that the CPHS will deal directly and in a regulatory manner with major risk and DHEW projects only. On all other projects the role of the CPHS will be educational and advisory. The educational process can now proceed because the approximately 1,500 cases already reviewed represent a sufficient data base for providing substance and meaning — and not merely the form of bureaucratic authority — to the effort of protecting human subjects. The tenability of this approach is based upon the premise that ultimately researchers are as interested in protecting their human subjects as the Committee. The proposed procedure also helps alter the role of the CPHS — from the status of being a tribunal for judging the professional purity of colleagues to the status of being a committee for conducting research on human subjects issues.

Comments on the proposal. There is really no mechanism for ensuring fool-proof compliance. In this respect, the current stricter system is no more fool-proof than this proposal; and the current system has the added disadvantages of creating enervating amounts of paper work and a false sense of security. Initially most researchers will probably deal with the proposed system as merely another kind of bureaucratic chores, although perhaps easier to carry out than the current one. It is the hope of the Committee, however, that the handbook documentation of the experiences of Berkeley colleagues will persuade researchers of the seriousness of the matter and of the necessity to give as much attention to human subjects as to research results.

APPENDIX A

Impact Elements and Selected Agencies

Impact Elements: The following are those areas of potential impact used by the RMIP staff in analyzing each of the Federal requirement areas.

Benefits: Benefits which may accrue to the University in implementing a Federal requirement.

Cost: Identifiable dollar costs of achieving requirements fulfillment by various University units and/or individuals responsibile for compliance.

Delays: Delay, for example, in the research effort due to the need for obtaining clearances required by various agencies (and within the University to the extent that the process is caused by an agency requirement); delay in payments for reimbursement of University working capital used to fund contract and grant activity; delay in the processing of documents.

Introduction of Conflict: Policies, procedures and requirements introduced into the University's environment which are divergent from the normal mode of University operations and which may cause turbulence either between elements of the University or between the University and an outside agency. Academic issues are also examined in this category.

Non-Standard Requirements: Variations among the requirements of Federal agencies in the same area, such as reporting, recording property or obtaining prior approvals.

Record Keeping: Requirements for a variety of records, such as detail of records to be kept, manner of recording and time limitations.

Time and Effort: Time of campus personnel in carrying out a requirement, for example, meetings of campus Human Subjects Committee, time to prepare proposals, or time to prepare detailed progress reports of projects.

APPENDIX A (cont'd)

Impact Elements and Selected Agencies

Agencies: The following Federal sponsoring agencies are included in the impact studies:

(1) Atomic Energy Commission*

(2) Environmental Protection Agency

(3) National Aeronautics and Space Administration

(4) National Institute of Education

(5) National Institutes of Health

(6) National Oceanic and Atmospheric Administration

(7) National Science Foundation

(8) Office of Naval Research

(9) United States Air Force

*On February 6, 1975 the Atomic Energy Commission will become the Energy Resource and Development Agency. For purposes of this report, Federal requirements pertaining to the AEC and discussed in the impact studies will be those in effect before the above changeover date.

APPENDIX B

Description of Major Federal Requirement Areas

The following is a description of the major Federal requirement areas considered for study by the RMIP staff. Nine areas (indicated by an asterisk) were selected for in-depth study. The studies provide an analysis of the impact certain Federal requirements impose on an institution as a result of accepting Federal contracts and grants.

Federal Requirement Areas:

Affirmative Action: Actions which must be taken to achieve the goals of the Federal Equal Employment Opportunity program, include: 1) record-keeping; 2) determination of patterns; 3) goal setting; 4) recruitment of minorities and women; 5) special training; 6) affirmative action committee operations; 7) special staff, such as coordinators; 8) continuing review and reporting to management on goal achievement.

*Cash Flow: Maintaining the cash flow for Federally funded projects, which includes letters of credit, advance by Treasury check, or reimbursement by Treasury check.

Consultants: Procedures which must be followed in the utilization of both internal and external consultants funded by research project sources include: 1) assuring compliance with agency restrictions on use of internal consultants; 2) justification in proposals for use of particular persons selected as consultants and amounts of fees; 3) procedures to comply with agency requirements for contracting with external and faculty consultants; 4) making required reports; 5) determination of whether specific arrangement should be treated as a consulting contract or employee status.

*Cost Recovery: Procedures necessary to document and demonstrate direct and indirect costs arising under Federal projects so as to recover costs for the institution. The procedures include: 1) accumulation of data, development of proposal and negotiation of indirect cost rates; 2) accumulation of data, development of proposal and negotiation of computer rates; 3) application of indirect cost rates; 4) impact of the CASB; 5) negotiation of Patient Care Cost Recovery Rates.

Cost Sharing: Actions which must be taken to comply with policies requiring institutions to contribute a certain portion of project costs. Those actions include: 1) setting methods for making the contribution, either through salaries of faculty or by forgoing indirect costs; 2) maintenance of records required to establish sharing; 3) negotiation of agreements with agencies, either institutional or individual; 4) audit of evidence of compliance; 5) preparation of final reports.

Environmental Impact: Actions taken to meet Federal and State legislation requiring environmental impact studies concerning land use planning prior to construction. The actions include the preparation and processing of environmental impact studies and reports.

APPENDIX B (cont'd)

Description of Major Federal Requirement Areas

*Financial Management: Budgeting, accounting and determination of allowable costs. These actions encompass: 1) expenditure limitations; 2) submission of financial reports; 3) rebudgeting, including program and budget deviations; 4) record-keeping; 5) close-out of project.

*Health and Safety: Procedures to assure a healthful and safe environment in areas under campus jurisdiction for students, faculty, staff and the general public, and to minimize loss of people power, facilities and money. The area encompasses: 1) OSHA requirements; 2) radiation and biological hazards; 3) waste disposal; 4) air and water pollution; 5) equipment safety; 6) fire and explosion safety.

*Human Subjects Protection: The process of assuring the protection of human beings at risk in research projects including physical, social and psychological risks. The process includes: 1) review of proposals for human subject utilization; 2) writing protocol; 3) operations of the Human Subjects Committee including study of protocols, review and approval of protocols, record-keeping, educating and consulting with the campus, continuing review of project operations, principal investigator's adherence to required standards; 4) use of Consent Forms by the principal investigator and audits by Committee.

Inventions and Patents: Resolution of the interests of the researcher, institution, agency and public in inventions and patents resulting from the research. The area encompasses: 1) negotiations of conflict between institutional and agency policies; 2) entering into patent agreements with Federal sponsors; 3) complying with agency requirements for disclosure statements; 4) making agreements concerning division of royalties; 5) development of institutional policy; 6) interim and close-out reports.

Laboratory Animals, Care of: Observance of requirements for the health and care of animals used in research projects. The area encompasses: 1) provision of proper facilities as required by law; 2) animal care and use committee operations; 3) maintaining and obtaining accreditation; 4) campus surveillance of animal activities and compliance surveys; 5) individual certification of projects; 6) arrangements for services of veterinarians.

Narcotics and Dangerous Drugs: Actions required in acquisition, handling, storage, issue, use and dispensing of narcotics and dangerous drugs for research purposes in order to comply with laws and regulations. Those actions include: 1) obtaining required licenses and approvals for individual research projects; 2) maintenance of a control system at the institution; 3) cross-reference to "Human Subjects"; including any special protocols or reports required; 4) clearance by State Clearing House (peculiar to California).

APPENDIX B (cont'd)

Description of Major Federal Requirement Areas

*Procurement: those procedures involved in acquiring personal and real property and services other than permanent payroll staff, including procurement of outside consultants. The area includes: 1) vendor equal opportunity; 2) screening property; 3) agency prior approval; 4) use of GSA; 5) obtaining excess property; 6) record-keeping; 7) payment of State sales tax; 8) subcontract administration;

*Property Management: Actions to maintain, control, account for, report status on and dispose of property furnished by government funds include: 1) inventorying; 2) maintenance; 3) record-keeping; 4) reporting to agency; 5) restricted use; 6) title transfer; 7) disposition; 8) close-out of project; 9) transfer of property to another institution.

*Proposal Preparation, Negotiation and Award: Drafting and developing documents; institutional review, approval and submission; revisions; negotiation with agency and acceptance and execution of award. The area encompasses the following: 1) work of the principal investigator, 2) pre-proposal contact with the agency; 3) assistance of campus contract and grant office; 4) institutional levels of review; 5) assessment of applicability of agency terms and conditions; 6) review of legal form; 7) resources analysis/cost sharing; 8) other institutional requirements peculiar to California, such as State Clearing House, State Fire Marshal, Drugs, et.

Rights in Data: Resolution of the interests of the researcher, institutions agency and public in the data of knowledge developed in the research. The area includes: 1) negotiation of conflict between agency and institutional policies; 2) compliance with research agreement terms; 3) development and administration of institutional policy, including involvement of the faculty and administration; 4) resolution of problems concerning sponsor restrictions on publication data; 5) negotiating and carrying out of publication agreements; 6) disposition of data and close-out of project.

Technical Reports: Actions to provide the sponsoring agency with the substantive findings of the research project. The contracting institution reports, which might also include journal publications. The reports may be submitted in writing, film or tape. The researcher participates in the negotiations between the agency and the University involving the reporting requirements.

*Time and Efforting Reporting: Policies and procedures for complying with Federal contract and grant requirements to document and support direct charges for salaries and wages of academic and staff employees. The area encompasses: 1) time and attendance records and procedures for staff personnel; 2) entering of time and attendance data onto the payroll time sheets and processes; 3) adjustments in employment forms, payrolls and fund accounts to which payroll is charged on the basis of time and effort reports; 4) time and attendance records of academic personnel; 5) certification of payroll listings for academic employees; 6) audits of time and attendance reports, payroll records, and certification for academic employees.

APPENDIX B (cont'd)

Description of Major Federal Requirement Areas

Travel Approval: The process of complying with restrictions on travel funded from research project sources includes the following: 1) describing and budgeting travel in proposal; 2) obtaining special approval for foreign travel; 3) maintenance of institutional arrangements to assure compliance with contract and grant terms; 4) obtaining special approval for certain types of travel, e.g., meetings; 5) making reports of travel performed.

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