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THE INSTITUTIONAL GUIDE TO DHEW POLICY ON PROTECTION OF HUMAN SUBJECTS

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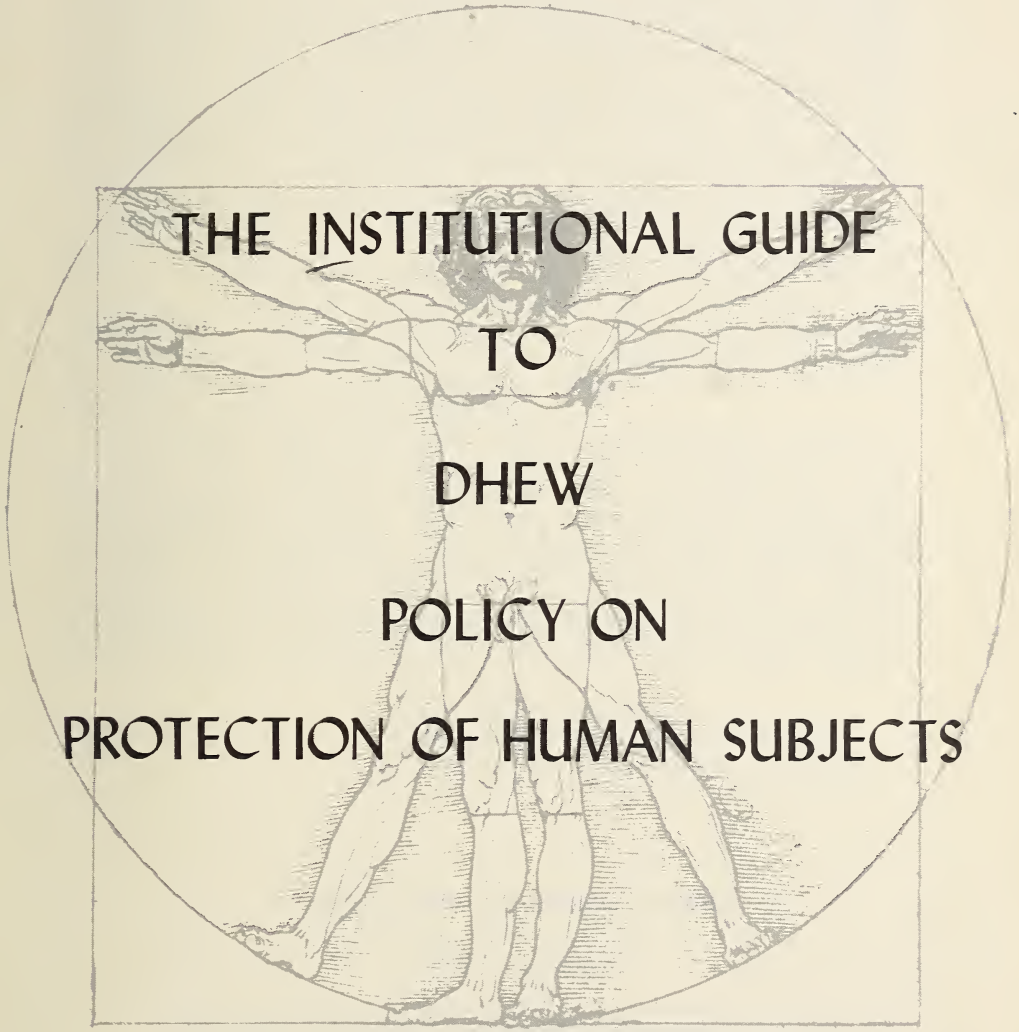

THE INSTITUTIONAL GUIDE TO DHEW POLICY ON PROTECTION OF HUMAN SUBJECTS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service National Institutes of Health

TO :

FROM : Office for Protection from Research Risks, OO, NIH

SUBJECT: DHEW Policy and Regulations on Protection of Human Subjects

We are enclosing a copy of the Institutional Guide to OHEW Policy on Protection of Human Subjects, dated December 1, 1971. This document became obsolete with the promulgation on March 13, 1975 of the Department of Health, Education, and Welfare regulations on protection of human subjects. As a result, the Institutional Guide must be read together with the regulations. A copy of the latter is enclosed.

Institutional Guide paragraphs which have undergone major changes in codification as regulation are as follows:

POLICY (p. 1) by § 46.2

APPLICABILITY (pp. 1 and 2) by § 46.3 (b)

INSTITUTIONAL REVIEW

A. 1 (Committee requirements, p. 4) by § 46.6 (b)

A. 2 c (Informed consent, p. 7) by § 46.3 (c)

TIMINC AND CERTIFICATION (p. 11) by § 46.11 and (see also para. J. p. 18915)

DOCUMENTATION OF INFORMED CONSENT (pp. 7 and 15) by § 46.IO

ENFORCEMENT (p. 17) by § 46.21

In addition § 46.3 (b), § 46.6 (d) and § 46.7 (e), § 46.8, § 46.15, § 46.17, and § 46.19 (b) represent major additions to the regulations as compared with the policy.

The Institutional Guide will be revised and reissued as soon as possible.

2 Enclosures

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FOREWORD

The Department's basic policy, quoted in the first few paragraphs of this Guide, is simple in concept. However, simplicity in conception is not always easily translated into simplicity in application. Many of the basic terms of the policy, such as subject, risk, and informed consent, are differently understood in the several professions that participate in the varied grant and contract programs supported by the Department. This Guide provides working definitions of the policy's more critical terms, and outlines flexible operating procedures which can be adapted to a variety of grant and contract mechanisms.

A flexible policy is essential. Research, development, and the reduction to practice of new ideas are not carried out in a practical, ethical, or legal vacuum. The public interest obviously would not be served by an inflexible approach to what can or should be done. Ultimately, the decisions required by this policy must depend upon the common sense and sound professional judgment of reasonable men. The Department's policy and the Guide are intended to provide room for the exercise of this judgment.

In its present form, the Guide reflects several years' experience with an earlier Public Health Service policy. It incorporates many comments and suggestions by representatives of grantee and contractor institutions, and by consultants and staff of the operating agencies of the Department. Future experience in the application of the policy in the fields of health, education, and welfare will simultaneously raise questions and suggest changes. Correspondence should be addressed to the Chief, Institutional Relations Section, Division of Research Grants, National Institutes of Health, Bethesda, Md. 20014.

D. T. Chalkley, Ph. D.
Chief, Institutional Relations Section
Division of Research Grants, NIH, DHEW

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NOTE

Bold face indicates policy as stated in DHEW Grant Administration Manual Chapter 1-40.

Light face indicates interpretation of DHEW policy.

POLICY

Safeguarding the rights and welfare of human subjects involved in activities supported by grants or contracts from the Department of Health, Education, and Welfare is the responsibility of the institution which receives or is accountable to the DHEW for the funds awarded for the support of the activity.

In order to provide for the adequate discharge of this institutional responsibility, it is the policy of the Department that no grant or contract for an activity involving human subjects shall be made unless the application for such support has been reviewed and approved by an appropriate institutional committee.

This 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.

In addition the committee must establish a basis for continuing review of the activity in keeping with these determinations.

The institution must submit to the DHEW, for its review, approval, and official acceptance, an assurance of its compliance with this policy. The institution must also provide with each proposal involving human subjects a certification that it has been or will be reviewed in accordance with the institution's assurance.

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 can and does assume responsibility for the protection of the subjects involved.

Since the welfare of subjects is a matter of concern to the Department of Health, Education, and Welfare as well as to the institution, no grant or contract involving human subjects shall be made unless the proposal for such support has been reviewed and approved by an appropriate professional committee within the responsible component of the Department. As a result of this review, the committee may recommend to the operating agency, and the operating agency may require, the imposition of specific grant or contract terms providing for the protection of human subjects, including requirements for informed consent.

APPLICABILITY

A. *General*

This policy applies to all grants and contracts which support activities in which subjects may be at risk.

B. *Subject*

This term describes any individual who may be at risk as a conse-

quence of participation as a subject in research, development, demonstration, or other activities supported by DHEW funds.

This may include patients; outpatients; donors of organs, tissues, and services; informants; and normal volunteers, including students who are placed at risk during training in medical, psychological, sociological, educational, and other types of activities supported by DHEW.

Of particular concern are those subjects in groups with limited civil freedom. These include prisoners, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline.

The unborn and the dead should be considered subjects to the extent that they have rights which can be exercised by their next of kin or legally authorized representatives.

C. *At Risk*

An individual is considered to be "at risk" if he may be exposed to the possibility of harm—physical, psychological, sociological, or other—as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs. The determination of when an individual is at risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question. Responsibility for this determination resides at all levels of institutional and departmental review. Definitive determination will be made by the operating agency.

D. *Types of Risks and Applicability of the Policy*

1. Certain risks are inherent in life itself, at the time and in the places where life runs its course. This policy is not concerned with the ordinary risks of public or private living, or those risks associated with admission to a school or hospital. It is not concerned with the risks inherent in professional practice as long as these do not exceed the bounds of established and accepted procedures, including innovative practices applied in the interest of the individual patient, student or client.

Risk and the applicability of this policy are most obvious in medical and behavioral science research projects involving procedures that may induce a potentially harmful altered physical state or condition. Surgical and biopsy procedures; the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exertion; subjection to deceit, public embarrassment, and humiliation are all examples of procedures which require thorough scrutiny by both the Department of Health, Education, and Welfare and institutional committees. In general those projects which involve risk of physical or psychological injury require prior written consent.

2. There is a wide range of medical, social, and behavioral projects and activities in which no immediate physical risk to the subject is involved; e.g., those utilizing personality inventories, interviews, questionnaires, or the use of observation, photographs, taped records, or stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, invasion of privacy, or may constitute a threat to the

subject's dignity through the imposition of demeaning or dehumanizing conditions.

3. There are also medical and biomedical projects concerned solely with organs, tissues, body fluids, and other materials obtained in the course of the routine performance of medical services such as diagnosis, treatment and care, or at autopsy. The use of these materials obviously involves no element of physical risk to the subject. However, their use for many research, training, and service purposes may present psychological, sociological, or legal risks to the subject or his authorized representatives. In these instances, application of the policy requires review to determine that the circumstances under which the materials were procured were appropriate and that adequate and appropriate consent was, or can be, obtained for the use of these materials for project purposes.

4. Similarly, some studies depend upon stored data or information which was often obtained for quite different purposes. Here, the reviews should also determine whether the use of these materials is within the scope of the original consent, or whether consent can be obtained.

E. *Established and Accepted Methods*

Some methods become established through rigorous standardization procedures prescribed, as in the case of drugs or biologicals, by law or, as in the case of many educational tests, through the aegis of professional societies or nonprofit agencies. Acceptance is a matter of professional response, and determination as to when a method passes from the experimental stage and becomes "established and accepted" is a matter of judgment.

In determining what constitutes an established and accepted method, consideration should be given to both national and local standards of practice. A management procedure may become temporarily established in the routine of a local institution but still fail to win acceptance at the national level. A psychological inventory may be accepted nationally, but still contain questions which are disturbing or offensive to a local population. Surgical procedures which are established and accepted in one part of the country may be considered experimental in another, not due to inherent deficiencies, but because of the lack of proper facilities and trained personnel. Diagnostic procedures which are routine in the United States may pose serious hazards to an undernourished, heavily infected, overseas population.

If doubt exists as to whether the procedures to be employed are established and accepted, the activity should be subject to review and approval by the institutional committee.

F. *Necessity to Meet Needs*

Even if considered established and accepted, the method may place the subject at risk if it is being employed for purposes other than to meet the needs of the subject. Determination by an attending professional that a particular treatment, test, regimen, or curriculum is appropriate for a particular subject to meet his needs limits the attendant risks to those inherent in the delivery of services, or in training.

On the other hand, arbitrary, random, or other assignment of subjects

to differing treatment or study groups in the interests of a DHEW supported activity, rather than in the strict interests of the subject, introduces the possibility of exposing him to additional risk. Even comparisons of two or more established and accepted methods may potentially involve exposure of at least some of the subjects to additional risks. Any alteration of the choice, scope, or timing of an otherwise established and accepted method, primarily in the interests of a DHEW activity, also raises the issue of additional risk.

If doubt exists as to whether the procedures are intended solely to meet the needs of the subject, the activity should be subject to review and approval by the institutional committee.

INSTITUTIONAL REVIEW

A. *Initial Review of Projects*

1. Review must be carried out by an appropriate institutional committee. The committee may be an existing one, such as a board of trustees, medical staff committee, utilization committee, or research committee, or it may be specially constituted for the purpose of this review. Institutions may utilize subcommittees to represent major administrative or subordinate components in those instances where establishment of a single committee is impracticable or inadvisable. The institution may utilize staff, consultants, or both.

The committee must be composed of sufficient members with varying backgrounds to assure complete and adequate review of projects and activities commonly conducted by the institution. The committee's membership, maturity, experience, and expertise should be such as to justify respect for its advice and counsel. No member of an institutional committee shall be involved in either the initial or continuing review of an activity in which he has a professional responsibility, except to provide information requested by the committee. In addition to possessing the professional competence to review specific activities, the committee should be able to determine acceptability of the proposal in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes.[1] The committee may therefore need to include persons whose primary concerns lie in these areas rather than in the conduct of research, development, and service programs of the types supported by the DHEW.

If an institution is so small that it cannot appoint a suitable committee from its own staff, it should appoint members from outside the institution.

Committee members shall be identified by name, occupation or position, and by other pertinent indications of experience and competence in areas pertinent to the areas of review such as earned degrees, board certifications, licensures, memberships, etc.

Temporary replacement of a committee member by an alternate of comparable experience and competence is permitted in the event a mem-

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[1] **In the United States, the regulations of the Food and Drug Administration (21 CFR 130) provide that the committee *must* possess competencies to determine acceptability of the project in these terms in order to review proposals for investigational new drug (IND) studies.**

ber is momentarily unable to fulfill committee responsibility. The DHEW should be notified of any permanent replacement or additions.

2. The institution should adopt a statement of principles that will assist it in the discharge of its responsibilities for protecting the rights and welfare of subjects. This may be an appropriate existing code or declaration or one formulated by the institution itself.[2] It is to be understood that no such principles supersede DHEW policy or applicable law.

3. Review begins with the identification of those projects or activities which involve subjects who may be at risk. In institutions with large grant and contract programs, administrative staff may be delegated the responsibility of separating those projects which do not involve human subjects in any degree; i.e., animal and nonhuman materials studies. However, determinations as to whether any project or activity involves human subjects at risk is a professional responsibility to be discharged through review by the committee, or by subcommittees.

If review determines that the procedures to be applied are to be limited to those considered by the committee to be established, accepted, and necessary to the needs of the subject, review need go no further; and the application should be certified as approved by the committee. Such projects involve human subjects, but these subjects are not considered to be at risk.

If review determines that the procedures to be applied will place the subject at risk, review should be expanded to include the issues of the protection of the subject's rights and welfare, of the relative weight of risks and benefits, and of the provision of adequate and appropriate consent procedures.

Where required by workload considerations or by geographic separation of operating units, subcommittees or mail review may be utilized to provide preliminary review of applications.

Final review of projects involving subjects at risk should be carried out by a quorum of the committee.[3] Such review should determine, through review of reports by subcommittees, or through its own examination of applications or of protocols, or through interviews with those individuals who will have professional responsibility for the proposal project or activity, or through other acceptable procedures that the requirements of the institutional assurance and of DHEW policy have been met, specifically that:

a. The rights and welfare of the subjects are adequately protected.

Institutional committees should carefully examine applications, protocols, or descriptions of work to arrive at an independent determination of possible risks. The committee must be alert to the possibility that investigators, program directors, or contractors may, quite unintentionally, introduce unnecessary or unacceptable hazards, or fail to provide adequate safeguards. This possibility is particularly true if the project crosses disciplinary lines, involves new and untried procedures, or involves established and accepted procedures which are new to the personnel applying them. Committees must also assure

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[2] Some of the existing codes or statements of principles concerned with the protection of human subjects in research, investigation, and care are listed in attachment C.

[3] In the United States, the quorum reviewing investigational new drug studies must satisfy requirements of the Food and Drug Administration (21 CFR 130).

themselves that proper precautions will be taken to deal with emergencies that may develop even in the course of seemingly routine activities.

When appropriate, provision should be made for safeguarding information that could be traced to, or identified with, subjects. The committee may require the project or activity director to take steps to insure the confidentiality and security of data, particularly if it may not always remain under his direct control.

Safeguards include, initially, the careful design of questionnaires, inventories, interview schedules, and other data gathering instruments and procedures to limit the personal information to be acquired to that absolutely essential to the project or activity. Additional safeguards include the encoding or enciphering of names, addresses, serial numbers, and of data transferred to tapes, discs, and printouts. Secure, locked spaces and cabinets may be necessary for handling and storing documents and files. Codes and ciphers should always be kept in secure places, distinctly separate from encoded and enciphered data. The shipment, delivery, and transfer of all data, printouts, and files between offices and institutions may require careful controls. Computer to computer transmission of data may be restricted or forbidden.

Provision should also be made for the destruction of all edited, obsolete or depleted data on punched cards, tapes, discs, and other records. The committee may also determine a future date for destruction of all stored primary data pertaining to a project or activity.

Particularly relevant to the decision of the committees are those rights of the subject that are defined by law. The committee should familiarize itself through consultation with legal counsel with these statutes and common law precedents which may bear on its decisions. The provisions of this policy may not be construed in any manner or sense that would abrogate, supersede, or moderate more restrictive applicable law or precedential legal decisions.

Laws may define what constitutes consent and who may give consent, prescribe or proscribe the performance of certain medical and surgical procedures, protect confidential communications, define negligence, define invasion of privacy, require disclosure of records pursuant to legal process, and limit charitable and governmental immunity (see, e.g., the University of Pittsburgh Law Manual).

b. The risks to an individual are outweighed by the potential benefits to him or by the importance of the knowledge to be gained.

The committee should carefully weigh the known or foreseeable risks to be encountered by subjects, the probable benefits that may accrue to them, and the probable benefits to humanity that may result from the subject's participation in the project or activity. If it seems probable that participation will confer substantial benefits on the subjects, the committee may be justified in permitting them to accept commensurate or lesser risks. If the potential benefits are insubstantial, or are outweighed by risks, the committee may be justified in permitting the subjects to accept these risks in the interests of humanity. The committee should consider the possibility that subjects, or those authorized to represent subjects, may be motivated to accept risks for unsuitable or inadequate reasons. In such instances the consent procedures adopted should incorporate adequate safeguards.

Compensation to volunteers should never be such as to constitute an undue inducement.

No subject can be expected to understand the issues of risks and benefits as fully as the committee. Its agreement that consent can reasonably be sought for subject participation in a project or activity is of paramount practical importance.

"The informed consent of the subject, while often a legal necessity is a goal toward which we must strive, but hardly ever achieve except in the simplest cases."

(Henry K. Beecher, M.D.)

c. The informed consent of subjects will be obtained by methods that are adequate and appropriate.

Note.—In the United States, adherence to the regulations of the Food and Drug Administration (21 CFR 130) governing consent in projects involving investigational new drugs (IND) is required by law.

Informed consent is the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.

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.**

In addition, the agreement, written or oral, entered into by the subject, should include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence.[4]

Informed consent must be documented (see Documentation, p. 35).

Consent should be obtained, whenever practicable, from the subjects themselves. When the subject group will include individuals who are not legally or physically capable of giving informed consent, because of age, mental incapacity, or inability to communicate, the review committee should consider the validity of consent by next of kin, legal guardians, or by other qualified third parties representative of the subjects' interests. In such instances, careful consideration should be given by the committee not only to whether these third parties can be presumed to have the necessary depth of interest and concern with the subjects' rights and welfare, but also to whether these third parties will be legally authorized to expose the subjects to the risks involved.

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[4] Use of exculpatory clauses in consent documents is considered contrary to public policy. *Tunkl vs. Regents of University of California*, 60 Cal. 2d 92, 32 Cal. Rptr.33, 383 P. 2d 441 (1963), Annot., 6 A.L.R. 3d 693 (1966).

The review committee will determine if the consent required, whether to be secured before the fact, in writing or orally, or after the fact following debriefing, or whether implicit in voluntary participation in an adequately advertised activity, is appropriate in the light of the risks to the subject, and the circumstances of the project.

The review committee will also determine if the information to be given to the subject, or to qualified third parties, in writing or orally, is a fair explanation of the project or activity, of its possible benefits, and of its attendant hazards.

Where an activity involves therapy, diagnosis, or management, and a professional/patient relationship exists, it is necessary "to recognize that each patient's mental and emotional condition is important . . . and that in discussing the element of risk, a certain amount of discretion must be employed consistent with full disclosure of fact necessary to any informed consent." [5]

Where an activity does not involve therapy, diagnosis, or management, and a professional/subject rather than a professional/patient relationship exists, "the subject is entitled to a full and frank disclosure of all the facts, probabilities, and opinions which a reasonable man might be expected to consider before giving his consent." [6]

When debriefiing procedures are considered as a necessary part of the plan, the committee should ascertain that these will be complete and prompt.

B. *Continuing Review*

This is an essential part of the review process. While procedures for continuing review of ongoing projects and activities should be based in principle on the initial review criteria, they should also be adapted to the size and administrative structure of the institution. Institutions which are small and compact and in which the committee members are in day-to-day contact with professional staff may be able to function effectively with some informality. Institutions which have placed responsibility for review in boards of trustees, utilization committees, and similar groups that meet on frequent schedules may find it possible to have projects re-reviewed during these meetings.

In larger institutions with more complex administrative structures and specially appointed committees, these committees may adopt a variety of continuing review mechanisms. They may involve systematic review of projects at fixed intervals, or at intervals set by the committee commensurate with the project's risk. Thus, a project involving an untried procedure may initially require reconsideration as each subject completes his involvement. A highly routine project may need no more than annual review. Routine diagnostic service procedures, such as biopsy and autopsy, which contribute to research and demonstration activities generally require no more than annual review. Spot checks may be used to supplement scheduled reviews.

Actual review may involve interviews with the responsible staff, or

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[5] *Salgo vs. Leland Stanford Jr. University Board of Trustees* (154 C.A. 2nd 560; 317 P. 2d 1701).

[6] *Halushka vs. University of Saskatchewan,* (1965) 53 D.L.R. (2d).

review of written reports and supporting documents and forms. In any event, such review must be completed at least annually to permit certifications of review on noncompeting continuation applications.

C. *Communication of the Committee's Action, Advice, and Counsel*

If the committee's overall recommendation is favorable, it may simultaneously prescribe restrictions or conditions under which the activity may be conducted, define substantial changes in the research plans which should be brought to its attention, and determine the nature and frequency of interim review procedures to insure continued acceptable conduct of the research.

Favorable recommendations by an institutional committee are, of course, always subject to further appropriate review and rejection by institution officials.

Unfavorable recommendations, restrictions, or conditions cannot be removed except by the committee or by the action of another appropriate review group described in the assurance filed with the Department of Health, Education, and Welfare.

Staff with supervisory responsibility for investigators and program directors whose projects or activities have been disapproved or restricted, and institutional administrative and financial officers should be informed of the committee's recommendations. Responsible professional staff should be informed of the reasons for any adverse actions taken by the institutional committee.

The committee should be prepared at all times to provide advice and counsel to staff developing new projects or activities or contemplating revision of ongoing projects or disapproved proposals.

D. *Maintenance of an Active and Effective Committee*

Institutions should establish policy determining overall committee composition, including provisions for rotation of memberships and appointment of chairmen. Channels of responsibility should be established for implementation of committee recommendations as they may affect the actions of responsible professional staff, grants and contracts officers, business officers, and other responsible staff. Provisions should be made for remedial action in the event of disregard of committee recommendations.

ASSURANCES

A. *Negotiation of Assurances*

An institution applying to the DHEW for a grant or contract involving human subjects 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 or, in the case of special assurances concerned with single projects or activities, a report of initial findings and pro-

posed continuing review procedures. Institutions that have not previously filed assurances should request instructions for the preparation of an assurance from the Division of Research Grants, National Institutes of Health.

Negotiation of assurances is the responsibility of the DRG, NIH. Negotiation will be initiated on receipt of a copy of a grant application, a contract proposal, or other documentation identifying the project and the offeror or sponsoring institution.

Assurances will not be accepted from institutions or institutional components which do not have control over the expenditure of DHEW grant or contract funds unless they are an active part of a cooperative project or activity.

An assurance will be accepted only after review and approval by the DRG, NIH.

B. *Types of Assurance*

Assurances may be one of two types:

1. *General assurance.*—A general assurance describes the review and implementation procedures applicable to all DHEW-supported activities within an institution, regardless of the number, location, or types of its components (see attachment A). General assurances will be required from institutions having a significant number of concurrent DHEW projects or activities involving human subjects.

2. *Special assurance.*—A special assurance will, as a rule, describe those review and implementation procedures applicable to a single project or activity (see attachment B). Special assurances may also be approved in modified forms to meet unusual requirements either of the operating agency or of the institution receiving a grant or contract. Special assurances are not to be solicited from institutions which have accepted general assurances on file.

C. *Minimum Requirements for General Assurances*

1. *Statement of compliance.*—A formal statement of compliance with DHEW policy must be executed by an appropriate institutional official.

2. *Implementing guidelines.*—The institution must include as part of its assurance implementing guidelines that specifically provide for:

a. The statement of principles that will assist the institution in the discharge of its responsibilities for protecting the rights and welfare of subjects. This may be an appropriate existing code or declaration or one formulated by the institution itself.

b. A committee or committee structure which will conduct initial and continuing reviews. Committee members shall be identified by name, occupation or position, and by other pertinent indications of experience and competence in areas pertinent to the areas of review such as earned degrees, board certifications, licensures, memberships, etc.

c. The procedures which the institution will follow in carrying out its initial and continuing review of proposals and activities to insure that:

(1) The rights and welfare of subjects are adequately protected;
(2) The risks to subjects are outweighed by potential benefits;
(3) The informed consent of subjects will be obtained by methods that are adequate and appropriate.

d. The procedures which the committee will follow to provide advice and counsel to project and program directors with regard to the committee's actions as well as the requirement for reporting to the committee any emergent problems or proposed procedural changes.

e. The procedures which the institution will follow to maintain an active and effective committee and to implement its recommendations.

D. *Minimum Requirements for Special Assurance*

An acceptable special assurance covering a single activity consists of a properly completed statement of compliance, similar to that illustrated by attachment B. This assurance shall identify the specific grant or contract involved by its number, if known; by its full title; and by the name of the project or program director, principal investigator, fellow, or other person immediately responsible for the conduct of the activity. The assurance shall be signed by a committee of not fewer than three members and executed by an appropriate institutional official. The committee shall describe in general terms those risks to the subject that it recognizes as inherent in the activity. *Consent procedures to be used are to be described.* Any consent statement to be signed, heard, or read by the subject or responsible third parties should be attached. The assurance should outline the circumstances under which the director or investigator will be required to inform the committee of proposed changes in the activity, or of emergent problems involving human subjects. The assurance should also indicate whether the director or investigator will be required to submit written reports, appear for interview, or be visited by the committee or committees to provide for continuing review. It should also indicate the intervals at which such reviews will take place.

TIMING AND CERTIFICATION OF INSTITUTIONAL REVIEW

A. *General Assurances*

1. *Timely review.*—All proposals involving human subjects submitted by institutions with accepted general assurances should, whenever possible, be given institutional review and approval prior to submission to the DHEW. The proposal or application should be appropriately marked in the spaces provided on forms, or the following statement should be typed on the lower or right hand margin of the page bearing the name of the institutional official authorized to sign or execute applications or proposals for the institution:
"HUMAN SUBJECTS—REVIEWED AND APPROVED ON ____(date)____."
(This date should be no more than 90 days prior to the submission date, and must not be more than 12 months prior to the proposed starting date.)

2. *Pending review.*—If it will be necessary to delay the review, the

proposal is to be appropriately marked in the spaces provided on forms, or the following statement is to be typed in the lower or right hand margin of the page bearing the name of the institutional official authorized to sign or execute applications or proposals for the institution:

"HUMAN SUBJECTS—REVIEW PENDING ON ____(date)____."

(This date should be at least one month earlier than the proposed starting date of the project to avoid possible conflict with the award date.)

3. *Completion of pending review.*—Review should be initiated as soon as possible after the submission of the proposal so that final action can be completed prior to the pending review date. If this final action is disapproval, or is approval contingent on substantive changes in the proposal, the operating agency is to be notified promptly by telegram; an immediate confirmatory letter; and, where appropriate, by withdrawal of the application from further consideration by the agency.

4. *Institutional review of proposals lacking definite plans or specifications for the involvement of human subjects.*—Certain types of proposals are submitted with the knowledge that human subjects are to be involved within the project period, but definite plans for this involvement cannot properly be included in the proposal. These include (1) certain training grants where trainee projects remain to be selected, and (2) research, pilot, or developmental studies in which involvement depends upon such things as the completion of instruments, or of prior animal studies, or upon the purification of compounds.

Such proposals should be reviewed and certified in the same manner as more complete proposals. The initial certification indicates institutional approval of the applications as submitted, and commits the institution to later review of the plans when completed. Such later review should be completed prior to the beginning of the budget period during which actual involvement of human subjects is to begin.

5. *Institutional review of proposals not submitted with the intent of involving human subjects.*—If a proposal, at the time it is submitted to the DHEW, does not anticipate involving or intend to involve human subjects, no certification should be submitted. In those instances, however, where funds are awarded in response to the proposal and it later becomes appropriate to use all or parts of these funds for activities which will involve human subjects, such use must be reviewed and approved in accordance with the institutional assurance prior to the use of subjects:

a. Where support is provided by project grants or contracts, review and approval of such changes must be certified to the awarding agency or contracting agency, together with a description of the proposed change in the project plan or contract workscope. Subjects should not be used prior to receipt of approval from agency staff or from the project officer concerned.

b. Where support is provided by a mandatory grant or institutional grant, in which cases the institution determines within broad guidelines the project or activities supported, including the use of human

subjects (i.e., general research support grants, clinical research center projects), review must be carried out in accordance with the institutional assurance. Certification for individual projects need not be forwarded to the awarding agency.

Whenever the committee is uncertain as to whether a change should or should not be reported, the question should be referred to the operating agency concerned.

All certifications are subject to verfication by DHEW representatives authorized to examine institutional and committee records.

B. *Special Assurances*

When a special assurance is submitted, it provides certification for the initial grant or contract period concerned. No additional documentation is required. If the terms of the grant or contract provide for additional years of support, with annual obligation or funds, the noncompeting renewal application or proposal shall be certified in the manner described in the preceding section.

COOPERATIVE ACTIVITIES

Cooperative activities are those which involve other than the grantee or prime contractor (such as a contractor under a grantee or a subcontractor under a prime contractor). In such instances the grantee or prime contractor may obtain access to all or some of the human subjects involved through the cooperating institution. Regardless of the distances involved and the nature of the cooperative arrangement, the basic DHEW policy applies and the grantee or prime contractor remains responsible for safeguarding the rights and welfare of the subjects. The manner in which this responsibility can be discharged depends on whether the grantee or contractor holds an institutional general assurance or an institutional special assurance.

A. *Institutions with General Assurances*

1. Initial and continuing institutional review may be carried out by one or a combination of procedures:

—By the grantee's or contractor's committee;
—By the committee reviews conducted at both institutions; or
—Through cooperation of appropriate individuals or committees representing the cooperating institution.

The procedures to be followed must be made a matter of record in the institutional files for the grant or contract before funds are released by the grantee or contractor for the cooperative project. There are three relationships that may govern in reference to the cooperating institution:

a. Cooperating institutions with accepted general assurances When the cooperating institution has on file with the DHEW an accepted general assurance, the grantee or contractor may request the cooperator to conduct its own independent review and to report to the grantee's or contractor's committee the cooperating committee's recommendations on those aspects of the activity that concern indi-

viduals for whom the cooperating institution has responsibility in accordance with its own assurance. The grantee or contractor may, at its discretion, concur with or further restrict the recommendations of the cooperating institution. It is the responsibility of the grantee or contractor to maintain communication with the cooperating institutional committees. The cooperating institution should promptly notify the grantee or contracting institution whenever the cooperating institution finds the conduct of the project or activity within its purview unsatisfactory.

b. Cooperating institution with no accepted general assurance When the cooperating institution does not have an accepted assurance on file with the DHEW, the awarding agency concerned may request the DRG, NIH, to negotiate an assurance.

c. Interinstitutional joint reviews.—The grantee or contracting institution may wish to develop an agreement with cooperating institutions to provide for a review committee with representatives from cooperating institutions. Representatives of cooperating institutions may be appointed as *ad hoc* members of the grantee or contracting institution's existing review committee or, if cooperation is on a frequent or continuing basis as between a medical school and a group of affiliated hospitals, appointments may be made permanent. Under some circumstances component subcommittees may be established within cooperating institutions. All such cooperative arrangements must be accepted by the Department as part of a general assurance, ar as an amendment to a general assurance, or in unusual situations as determined by the DRG, NIH, as a special assurance.

B. *Institutions with Special Assurances*

While responsibility for initial and continuing review necessarily lies with the contractor, the DHEW will also require acceptable assurances from those cooperating institutions having immediate responsibility for subjects.

If the cooperating institution has on file with the DHEW an accepted general assurance, the contractor shall request the cooperator to conduct its own independent review of those aspects of the project or activity which will involve human subjects for which it has immediate responsibility. Such a request shall be in writing and should provide for direct notification of the contractor's committee in the event that the cooperator's committee finds the conduct of the activity unsatisfactory.

If the cooperating institution does not have an accepted general assurance on file with the DHEW, the operating agency concerned must request the DRG, NIH, to negotiate an assurance.

INSTITUTIONAL ADMINISTRATION OF ASSURANCES

A. *Institutional Responsibility*

The grantee or contracting institution's administration is accountable to the Department for effectively carrying out the provisions of the institutional assurance for the protection of human subjects as ac-

cepted and recognized by the Department. Revisions in the institutional assurance, including the implementing procedures, are to be reported to the Department prior to the date such revisions become effective. Revision without prior notification may result in withdrawal of departmental recognition of the institution's assurance.

B. *Executive Functions*

Specific executive functions to be conducted by the institutional administration include institutional policy formulation, development, promulgation, and continuing indoctrination of personnel. Appropriate administrative assistance and support must be provided for the committee's functions. Implementation of the committee's recommendations through appropriate administrative action and followup is a condition of acceptance of an assurance. Committee approvals and recommendations are, of course, subject to review and to disapproval or further restriction by institutional officials. Committee disapprovals, restrictions, or conditions cannot be rescinded or removed except by action of the committee or another appropriate review group as described and accepted in the assurance filed with the Department.

C. *Assurance Implementation*

Under no circumstances shall proposed activity plans, not approved by the committee, be implemented with Department funds. The principal investigator, program or project director, or other responsible staff must be notified as promptly as possible of committee actions, including any restrictive recommendations made by the institutional committee or the administration. They must also be informed and reminded of their continuing responsibility to bring to the attention of the committee any proposed significant changes in project or activity plans or any emergent problems that will affect human subjects. Where continuing review of projects involves the channels of administrative authority in the institution, notification of committee actions should be sent through these channels. Establishment of mechanisms for consultation and appeal by investigators and subjects may be an important condition of acceptance of an assurance by the Department.

D. *Documentation*

1. *General.*—Development of appropriate documentation and reporting procedures is an essential administrative function. The files must include copies of all documents presented or required for initial and continuing review by the institutional review committee and transmittals on actions, instructions, and conditions resulting from review committee deliberations addressed to the activity director are to be made part of the official institutional files for the supported activity. Committee meeting minutes including records of discussions of substantive issues and their resolution are to be retained by the institution and be made available upon request to representatives of the DHEW.

2. *Informed consent.*—An institution proposing to place any individual at risk is obligated to obtain and document his informed consent; the terms "at risk" and "informed consent" will apply as defined previously.

The actual procedure in obtaining informed consent and the basis for committee determinations that the procedures are adequate and appropriate are to be fully documented. The documentation will follow one of the following three forms:

a. Provision of a written consent document embodying all of the basic elements of informed consent. *This form is to be signed by the subject or his authorized representative.* A sample of the form as approved by the committee is to be retained in its records. Completed forms are to be handled in accordance with institutional practice.

b. Provision of a "short" form written consent document indicating that the basic elements of informed consent have been presented orally to the subject. Written summaries of what is to be said to the patient are to be approved by the committee. *The "short" form is to be signed by the subject or his authorized representative and an auditor-witness to the oral presentation and to the subject's or his authorized representative's signature.* A copy of the approved summary, annotated to show any additions, is to be signed by the persons obtaining the consent on behalf of the institution and by the auditor-witness. Sample copies of the consent form and of the summaries as approved by the committee are to be retained in its records. Completed forms are to be handled in accordance with institutional practice.

c. Modification of either of the above two primary procedures. *All such modifications must be approved by the committee in the minutes signed by the committee chairman.* Granting of permission to use modified procedures imposes additional responsibility upon the review committee and the institution 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.

The committee's reasons for permitting modification or elimination of any of the six basic elements of informed consent, or for altering requirements for a subject's signature, or for signature of an auditor-witness, or for substitution (i.e., debriefing), or other modification of full, complete, written prior consent, must be individually and specifically documented in the minutes and in reports of committee actions to the institutional files. Approval of any such modifications should be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation as appropriate.

3. *Reporting to DHEW.*—No routine reports to DHEW are required. Significant changes in policy, procedure, or committee structure shall, however, be promptly reported to the DRG, NIH, for review and acceptance. Review of these changes or of institutional and other records of performance under the terms and conditions of DHEW

policy, may require renegotiation of the assurance or such other action as may be appropriate.

ENFORCEMENT

The DRG, NIH, will follow up reports by reviewers, evaluators, consultants, and staff of the DHEW indicating concern for the welfare of subjects involved in approved and funded grants or contracts, and of subjects potentially involved in activities approved but not funded, and in disapproved proposals. On the basis of these reports and of other sources of information, the DRG, NIH, may, in collaboration with the operating agency concerned, correspond with or visit institutions to discuss correction of any apparent deficiencies in its implementation of the procedures described in its institutional assurance.

If, in the judgment of the Secretary, an institution has failed in a material manner to comply with the terms of this policy with respect to a particular DHEW grant or contract, he may require that it be terminated in the manner provided for in applicable grant or procurement regulations. The institution shall be promptly notified of such finding and of the reason therefor.

If, in the judgment of the Secretary, an institution fails to discharge its responsibilities for the protection of the rights and welfare of the individuals in its care, whether or not DHEW funds are involved, he may question whether the institution and the individuals concerned should remain eligible to receive future DHEW funds for activities involving human subjects. The institution and individuals concerned shall be promptly notified of this finding and of the reasons therefor.

DEPARTMENTAL REVIEW OF ASSURANCES

All assurances submitted for approval are to be forwarded to the DRG, NIH, for review and acceptance on behalf of the Department. Review will be principally concerned with the adequacy of the proposed committee in the light of the probable scope of the applicant institution's activities, and with the appropriateness of the proposed initial and continuing review in the light of the probable risks to be encountered, the types of subject populations involved, and the size and complexity of the institution's administration. Institutions submitting inadequate assurances will be informed of deficiencies. The appropriate operating agency will be kept informed, on request, of the status and acceptance of an assurance.

ATTACHMENT A

EXAMPLE OF A STATEMENT OF COMPLIANCE PART ONE OF A GENERAL INSTITUTIONAL ASSURANCE

The (name of institution) will comply with the policy for the protection of human subjects participating in activities supported directly or indirectly by grants or contracts from the Department of Health, Education, and Welfare. In fulfillment of its assurance:

This institution will establish and maintain a committee competent to review projects and activities that involve human subjects. The committee will be assigned responsibility to determine for each activity as planned and conducted that:

> The rights and welfare of subjects are adequately protected.
> The risks to subjects are outweighed by potential benefits.
> The informed consent of subjects will be obtained by methods that are adequate and appropriate.

This institution will provide for committee reviews to be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from reviews of projects or activities in which they have an active role or a conflict of interests.

This institution will encourage continuing constructive communication between the committee and the project directors as a means of safeguarding the rights and welfare of subjects.

This institution will provide for the facilities and professional attention required for subjects who may suffer physical, psychological, or other injury as a result of participation in an activity.

This institution will maintain appropriate and informative records of committee reviews of applications and active projects, of documentation of informed consent, and of other documentation that may pertain to the selection, participation, and protection of subjects and to reviews of circumstances that adversely affect the rights or welfare of individual subjects.

This institution will periodically reassure itself through appropriate administrative overview that the practices and procedures designed for the protection of the rights and welfare of subjects are being effectively applied and are consistent with its assurance as accepted by the Department of Health, Education, and Welfare.

Official signing for the Institution

Signature _____

Title _____

Date _____

Enclosure: Implementing Guidelines, Part Two of a General Institutional Assurance.

ATTACHMENT B

EXAMPLE OF A STATEMENT OF COMPLIANCE SPECIAL INSTITUTIONAL ASSURANCE IN CONNECTION WITH SINGLE PROJECTS INVOLVING HUMAN SUBJECTS

(0) The (name of institution) will comply with the policy for the protection of human subjects participating in projects or activities supported by grants and contracts made by the Department of Health, Education, and Welfare. This policy requires a review independent of the investigator or director to safeguard the rights and welfare of those subjects. An initial review of the application for a grant or contract identified as _____ submitted by this institution on behalf of _____ indicates that:

(1) In the opinion of this committee the risks to the rights and welfare of the subject in this project or activity are:

The committee states that adequate safeguards against these risks have been provided.

(2) In the opinion of the committee the potential benefits of this activity to the subjects outweigh any probable risks. This opinion is justified by the following reasons:

(3) In the opinion of the committee the following informed consent procedures will be adequate and appropriate. Documentation is attached.

(4) The committee agrees to arrange for a continuing exchange of information and advice between itself and the investigator or director, particularly to deal with proposed changes in project or activity design, or with emergent problems which may alter the investigational situation with regard to the criteria cited above. This exchange will be implemented through:

This institution will provide whatever professional attention or facilities are required to safeguard the rights and welfare of human subjects.

(5) The signatures, names, and occupations or titles of the members of the committee are listed below.

Signature	Name	Occupation or Title
Signature	Name	Occupation or Title
Signature	Name	Occupation or Title
Signature	Name	Occupation or Title

Date of Committee Approval _____

(Continued page 20)

(6) Official signing for Institution _____

Signature

_____

Name

_____

Title

_____

Address

_____

Institution

_____

_____

Telephone Number

Date _____

(see instructions)

ATTACHMENT B

INSTRUCTIONS

An acceptable special institutional assurance consists of a properly completed formal statement of compliance with Department of Health, Education, and Welfare policy (see attachment B), signed by a committee of not less than three members and by an official authorized to sign for the institution. The explanatory paragraphs which follow refer to the corresponding section of the attachment.

(0) This should identify the application for a grant, contract, or award by its identifying number, where known, or by its full title. The name should be that of the investigator, program director, fellow, or other individual immediately responsible for the conduct of the work.

(1) The committee should identify in general terms those risks that it recognizes as probable occurrences; i.e., "Aggravation of anxiety status through contact with interviewers," "Preservation of confidentiality of data," "Renal injury subsequent to multiple biopsy," "Possibility of side reactions to drugs," "Possible local hematosis and nerve injury associated with venipuncture."

(2) The committee should identify the benefits to the subject or to mankind in general that will accrue through the subject's participation in the project. This should be followed by a brief discussion, weighing the risks against the benefits.

(3) Consent procedures should be described and the minimum statement to be used should be attached. "Students responding to the attached advertisement will be interviewed." "The project outline will be submitted to the executive council of the PTA." "Individual teachers will be asked to allow an observer in the rooms chosen." "Superintendents of several State mental hospitals will be approached. The attached statement to the next of kin or guardian will be signed by the principal investigator and the superintendent." "The following special consent form will be signed by each subject and his or her spouse or next of kin before acceptance of the subject." "No prior consent will be sought. The following debriefing schedule will be followed within 30 minutes after completion of the test."

(4) This should indicate whether the investigator or director will be required to submit written reports, or to appear for interviews, or will be visited by the committee or committee representatives, and at approximately what intervals these steps will be carried out.

(5) No further explanation is necessary. (The committee must be composed of sufficient members with varying backgrounds to assure complete and adequate review of the project. The committee may be an existing one, or one especially appointed for the purpose. The institution may utilize staff, consultants, or both. The membership should possess not only broad competence to comprehend the nature of the project, but also other competencies necessary in the judgments as to acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. The com-

mittee's maturity and experience should be such as to justify respect for its advice and counsel.)

(No individual involved in the conduct of the project shall participate in its review, except to provide information to the committee.)

(Committee members should be identified in the assurance by name, positions, earned degrees, board certifications, licensures, memberships, and other indications of experience, competence, and interest.)

The completed assurance should be attached to the application, or returned directly to the office requesting its submission.

ATTACHMENT C

Codes or statements of principles which are concerned with the protection of human subjects in research, investigation, and care have been issued by:

Organization	Code; adoption date	Reference
World Medical Association 10 Columbus Circle New York, N.Y. 10019 (code available from AMA; see address listed herein)	The Declaration of Helsinki; Recommendations Guiding Doctors in Clinical Research; 1964	**J.A.M.A.**, 197(11):32, Sept. 12, 1966
Nuernberg Military Tribunals: U.S. v. Karl Brandt	Text from which the "Nuernberg Code" is derived.	**Trials of War Criminals Before the Nuernberg Military Tribunals**, vol. II, pp. 181–82; GPO 1949
American Medical Association 535 North Dearborn Street Chicago, Ill. 60610	AMA Ethical Guidelines for Clinical Investigation; Nov. 30, 1966	←
(British) Medical Research Council 20 Park Crescent London W.1, England	Responsibility in Investigations on Human Subjects; 1964	**Report of the Medical Research Council for 1962–1963**, (Cmnd. 2382), pp. 21–25
(Canadian) Medical Research Council Montreal Road Ottawa 7, Ontario, Canada	Medical Research Council; Extramural Programme; 1966	←
American Association on Mental Deficiency 20 North Street Willimantic, Conn. 06226	Statement on the Use of Human Subjects for Research; May 1969	**American Journal of Mental Deficiency**, 74 (1):157, July 1969
American Nurses' Association 10 Columbus Circle New York, N.Y. 10019	The Nurse in Research; ANA Guidelines on Ethical Values; January 1968	←
American Personnel and Guidance Association 1607 New Hampshire Avenue, N.W. Washington, D.C. 20009	American Personnel and Guidance Association; Code of Ethical Standards; no date specified	←
American Psychological Association, Inc. 1200 17th Street, N.W. Washington, D.C. 20036	Ethical Standards of Psychologists; Copyrighted January 1963	**American Psychologist**, 18 (1):56–60, January 1963
International League of Societies for the Mentally Handicapped 12 Rue Forestiere Brussels 5, Belgium	Declaration of General and Special Rights of the Mentally Retarded; Oct. 24, 1968	←

Organization	Code; adoption date	Reference
National Association of Social Workers 2 Park Avenue New York, N.Y. 10016	NASW Code of Ethics; Oct. 13, 1968	←

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