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Dr. N. Public Health Service
Division of Research Grants
Bethesda, Maryland 20014

December 12, 1966

SUBJECT: Investigations Involving Human Subjects, Including Clinical Research. Requirements for Review to Insure the Rights and Welfare of Individuals. Clarification

ACTION GROUP: All PHS Grant and Award

REFERENCE: PHS #[illegible], Revised, July 1, 1966

This report is to clarify issues raised by PHS grantees and staff regarding the meaning of the requirements of PHS #[illegible], Revised, July 1, 1966, subject: "Investigations Involving Human Subjects, Including Clinical Research: Requirements for Review to Insure the Rights and Welfare of Individuals."

This policy refers to all investigations that involve human subjects, including investigations in the behavioral and social sciences. The grantee institution is responsible for assuring that the investigations are in accord with the fact of the community in which the investigations are conducted and for giving due consideration to pertinent ethical issues. Appropriate groups of associates within the institution, and outside consultants if needed, are to be utilized to provide the necessary review. Institutions may designate separate groups in order to assure competence and independence of review for particular areas.

The principles of this policy apply most directly and comprehensively in cases instances of social, behavioral, and medical science investigations where a procedure may induce in the subject an altered state or condition potentially harmful to his personal welfare. Surgical procedures, the administration of drugs, the requirement of strenuous physical exertion, and participation in psychologically or socially harmful activities are examples of experimental arrangements which require thorough scrutiny by institutional review groups. Such procedures require continuing overview and full documentation for the record.

Aside from the above types of procedures, there is a large range of social and behavioral research in which no personal risk to the subject is involved. In these circumstances, regardless of whether the investigation is classified as behavioral, social, medical, or other, the issues of concern are the fully voluntary nature of the participation of the subject, the maintenance of confidentiality of information obtained from the subject, and the protection of the subject from misuse of the findings. For example,

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A major class of procedures in the social and behavioral sciences does no more than observe or elicit information about the subject's status, by means of administration of tests, inventories, questionnaires, or surveys of personality or background. In such instances, the ethical considerations of voluntary participation, confidentiality, and propriety in use of the findings are the most generally relevant ones. However, such procedures may in many instances not require the fully informed content of the subject or even his knowledgeable participation. In such instances full and specific documentation is necessary for the record.

Any investigation in the social and behavioral sciences involve procedures designed to alter the status of the individual as, for example, studies of human learning, sub-perception, or group effectiveness. In such research the effects, if any, on the subject may be transitory or even more or less permanent, but they must be judged clearly not to be harmful or not to involve the risk of harm.

Whatever the nature of the investigation, the concern for the protection of the subject and for the assurance of voluntary participation becomes most critical when the subject is not of age or competence to make an adequate judgment in his own behalf.

These are only some examples of issues which may arise. The fundamental point is that every project must be considered on an individual basis to clarify which, if any, such issues are present and to insure that these are adequately resolved by the specific design of its procedures. For this reason, it is essential that the grantee institution be responsible for the clarification and resolution of all ethical and other pertinent issues. The appropriate mechanism for this purpose is the utilization of groups of associates, established at the institution to provide competent, independent review. Based on its knowledgeable summary of the specifics of the investigation involved, such a review group can decide which issues are present and assert the adequacy of provisions for protecting the rights and welfare of human subjects in research, the appropriateness of the methods used to secure informed consent, and the risks and potential benefits of the investigation.

ORIGINATING OFFICE: Office of the Director, Division of Research Grants

APPROVED BY: Grants Policy Officer, OBS

Edward M. Gibbons

Date: 12/10/66

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