

U. S. Public Health Service
Division of Research Grants
Bethesda, Maryland 20014

PPO # 129
POLICY
February 8, 1966

SUBJECT : Clinical Investigations Using Human Subjects

APPLICABILITY : All PHS Research and Research Training Grants
in Support of Such Clinical Investigations
(including General Research Support Grants)

EFFECTIVE DATE: Immediately

BACKGROUND:

The National Advisory Health Council on December 3, 1965, recommended to the Surgeon General as follows:

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.

The Surgeon General accepted the recommendation of the Council and instructed the Grants Policy Officer to develop implementing procedures for research and research training grants.

STATEMENT OF POLICY:

No new, renewal, or continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application the manner in which the grantee institution will provide prior review of the judgment of the principal investigator or program director by a committee of his institutional associates. This review should assure an independent determination: (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent, and (3) of the risks and potential medical benefits of the investigation. A description of the committee of associates who will provide the review shall be included in the application.

PROCEDURE:

The above policy becomes effective immediately and will be incorporated in all PHS research and research training grant regulations and research and research training policy statements as soon as possible. In the meantime, the attached memorandum from the Surgeon General explains the policy to grantee institutions.

The PHS staff who administer the initial review of applications for clinical research and investigation involving human beings (including the administrative review for continuation applications) shall ascertain that each application includes the information required by this policy and shall obtain this information, if necessary, in a document signed by both the principal investigator or program director and the official authorized to sign for the institution.

Attachment

ORIGINATING OFFICE: The Surgeon General, Public Health Service

APPROVED BY: Grants Policy Officer, OSG

Ernest M. Allen

Date: 2/8/66

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