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[illegible] PHS policy [illegible] review [illegible] prior to the use of human beings as subjects. There are advantages to [illegible] review [illegible] conducted [illegible] support. The PHS encourages the [illegible] review [illegible] application process and [illegible] type that normally [illegible].

[illegible] ASSURANCES OF APPLICANTS AND GRANTEES

In furtherance of this policy statement, the PHS will require necessary assurances from the grantee institutions which sponsor investigations involving human subjects, including clinical research. These assurances will cover both the general principles of safeguarding human rights and welfare [illegible] and the specific points of the Surgeon General's policy. The assurances should provide explicit information on the policy and procedures [illegible] for review and decision on the propriety of plans of research involving human subjects. The descriptions will include the [illegible] represented on the committees of associates [illegible] the number of consultants (if used), the administrative mechanisms [illegible] provided for projects involving human subjects [illegible] changes in protocol or [illegible] the kinds of guidance and advice provided [illegible] and the manner in which the institution will [illegible] that the advice of the committee of associates will be followed. Copies of documents of institutional policies on these issues should be attached [illegible] assurance. An example of an acceptable assurance is attached.

Assurances [illegible] provided which apply only to individual major components of universities or other large institutions in those instances where [illegible] impracticable or [illegible].

Each assurance and its attachments shall be transmitted to the Public Health Service, [illegible] of the Chief, Division of Research Grants. When the Public Health Service has reviewed and accepted the assurance, the Chief, Division of Research Grants, shall so notify both the responsible official of the grantee [illegible] and all Public Health Service [illegible].

Each grantee institution [illegible] report [illegible] any changes in its policies, [illegible] represented on its committee of associates.

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Sieckert, William Huffman, 1954
Revised prior to Clinical Research
involving human subjects 7/1/66
R. HOLMES 10/24/94
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For each application that is not due to be likely to involve investigations involving human subjects, including clinical research, the applicant institution should have reference to the certification as follows:

> "The investigations contemplated by this application have been [illegible] approved by the committee of [illegible] of the [illegible] in accordance with the institution's assurance on clinical research dated _____."

Until an institution-wide assurance has been accepted by the PHS, the institution can fulfill requirements of this policy for individual studies by submitting an assurance with each application for PHS financial support, stating that prior to inception of investigations, the requirements of section III A of this Policy and Procedure Order will be followed. The statement must also describe the composition of the group which will conduct the review.

This interim procedure will be acceptable until November 1, 1966. After that date no new applications or renewals of continuation application for a Public Health Service grant or award to support investigations involving human subjects will be accepted for review unless the PHS has approved an institution-wide assurance.

As long as the institution-wide assurance or the interim policy procedure used in some cases until November 1, 1966, should inhibit PHS staff, advisory groups, or consultants (1) from identifying concern for the welfare of human subjects, and communicating this concern to the grantee institution, or (2) from recommending disapproval of the application if the gravity of the hazards and risks so indicate.

In the case of awards to U.S. citizens receiving fellowships for training abroad, special conditions or circumstances relating to the place at which the training is being provided may make necessary justify modification of these requirements. Requests from the sponsor for approval of such modifications must be reviewed by the Office of International Research, NIH, and approved by the PHS Bureau chief concerned.

Attachment

ORIGINATING TENSION: Office of the Surgeon General, PHS

APPROVED BY: Grants Policy Officer, DEC

[signature]

Date: July 1, 1966

Index: Clinical Research
Human Subjects, Investigations Involving
Individuals, Rights and Welfare of

[illegible] Box 10 [illegible] Regulations on clinical research involving human subjects [illegible] Holmes 10/24/14

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Example of an Acceptable Assurance

Institutional Assurance [illegible]

[illegible] Involving Human Subjects,

Including Clinical Research

[illegible] (name of institution) [illegible] agrees with the principles of the Public Health Service policy (Statement on Policy and Procedure Order [illegible] (July [illegible], 1966)) with regard to investigations involving human subjects [illegible]. This institution [illegible] that [illegible] independent of the investigator is necessary to safeguard the rights and welfare of human subjects of research investigations and assures the Public Health Service that it will establish and maintain [illegible] competent to review plans of investigation involving human subjects, prior to [illegible] of investigations, to insure [illegible] review and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved, (2) the appropriateness of the methods used to secure informed consent, and (3) the risks and potential medical benefits of the investigations.

The institution [illegible] surveillance of PHS-supported [illegible] human subjects [illegible] changes in protocol which may alter [illegible] listed above. The institution [illegible] the Public Health Service that it will provide [illegible] to investigators on matters of employing human subjects in investigation, and also that it will provide whatever [illegible] may be required to safeguard the rights and welfare of human subjects involved in investigation. Records [illegible] on the use of human subjects and of informed consent will be developed and kept by the institution.

Attached as part of this statement [illegible] policy and procedure of this institution [illegible] human subjects in investigation, as well as [illegible] of the groups utilized to review projects for [illegible] of these policies and the [illegible] in which the institution will [illegible] that the advice of the committee of associates is followed.

Signature: ______________________

Title: ______________________

Date: ______________________

Attachments

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The [illegible] of [illegible] in Berkeley policy and procedure, [illegible] Revised, July 1, 1966, [illegible] that each institution receiving support from the [illegible] for projects that include [illegible] investigation of human subjects [illegible], and have approved, an institutional statement of assurance [illegible] investigations that involve human subjects.

We shall [illegible] for your institution an institutional statement of agreement which covers [illegible] the points of the sample statement attached to the public Health Service policy issuance of July 1, 1966 (#129), [illegible] the signature of the [illegible] authorized to sign for the institution.

We shall also need an attachment to this statement a description of the following:

1. The requirements of your institution for the following:

   a. Group review and decision on the adequacy of provisions [illegible] protecting the rights and welfare of the subjects, on the appropriateness of the methods used to secure the informed consent of the subjects, and on the risks and potential medical benefits of the investigation (please see section III A on page 2 and section IV on page 3)

   b. Mangering to the [illegible] of the committee of associates [illegible] investigative proposals, which may affect the subjects, before such changes are made, and emergent problems of investigation, which may affect the subjects, when such problems occur.

   c. Conveying the advice of the committee of associates to the investigator concerned.

   d. Assuring the institution that the investigator follows the advice of the committee of associates (please see section IV on page 3)

2. The competencies represented in the committee of associates (please see section III A on page 2 and section IV on page 3)

3. The [illegible] of consultants, if employed (please see section IV on page 3)

4. Provision of facilities and professional attention necessary for the health and safety of the subjects (please see section III A on page 2)

[illegible]

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Stewart, William Hoffman pg 8/9
Berkeley Pres. On Annual Research
Travelling Human Exp, etc 7/1/66
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[illegible]

1. The applicability of your statement, i.e., whether to the institution as a whole or to a specified component of the institution (please see section IV on page 3)

[illegible] copy will help us hasten the review

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