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OFFICE OF THE  
VICE PRESIDENT OF THE UNIVERSITY

November 8, 1972

CHANCELLORS  
VICE PRESIDENT -- AGRICULTURAL SCIENCES  
VICE PRESIDENT -- EXTENDED ACADEMIC AND PUBLIC SERVICE PROGRAMS

Gentlemen:

Policy on The Protection of Human Subjects.

Subsequent to the issuance of a U.S. Public Health Service policy titled "Protection of the Individual as a Research Subject" (May 1, 1969), President Hitch issued, on June 25, 1970, a University policy concerning research involving human subjects. That University policy provided that the USPHS policy " . . . shall be applicable to all investigations involving human subjects for which the University is responsible, not just those funded by the USPHS . . ."

On April 15, 1971, the USPHS policy was superseded by a Department of Health, Education, and Welfare policy. Consequently, I issued on March 29, 1972 a revised policy statement, to supersede the University's June 25, 1970 policy. During subsequent discussions with representatives of the campuses, the Office of the President, and the Office of the General Counsel it became clear that certain modifications of the March 29 policy were needed. These have been incorporated in the attached policy which is to be effective immediately. The principal changes in the revised statement are (1) the extension of the applicability of the policy as required by DHEW to a broader scope of activities than just research, i.e., to classroom activities, demonstrations, and other activities in which human subjects may be at risk; and (2) the permissibility of obtaining consent after the fact in unusual circumstances.

As was the case with the USPHS policy, the new DHEW policy shall be applicable to all activities involving human subjects (as defined in the DHEW policy) for which the University is responsible except for those supported by other granting agencies which have their own regulations. In the case of conflict between regulations of another funding agency and DHEW, the more restrictive regulations shall prevail.

The University policy has three attachments\*: (1) a copy of DHEW Grants Administration Manual Chapter 1-40 (dated April 15, 1971) which

\*These attachments are not being circulated with this revised policy, since they are identical to the attachments sent with the March 29 policy with one correction: the title of attachment (3) should be changed from "Supplement to The Policy on Research Involving Human Subjects" to "Supplement to The Policy on The Protection of Human Subjects."

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HUMAN SUBJECTS I  
HISTORICAL 1972-1975

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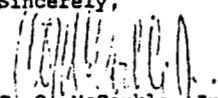
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includes a basic statement of the policy, its applicability, and implementing procedures; (2) a copy of The Institutional Guide to DHEW Policy on Protection of Human Subjects, DHEW Publication No. (NIH) 72-102, December 1, 1971, and (3) a "Supplement to the Policy on The Protection of Human Subjects," consisting of a compilation of memoranda from the campuses, the Office of the President, and the Office of the General Counsel on several issues related to the implementation of the policy.

The DHEW policy is clearly derived from the old PHS policy, with two differences which deserve special mention: (1) The DHEW policy provides for two types of assurances, a "general assurance" and a "special assurance" (Grants Administration Manual Chapter 1-40, pages 5-6) -- the University falls into the general assurance category, and (2) minor changes have been made in the "Informed Consent" provisions (ibid., pages 2, 16 and 17) and the applicable ones have been incorporated in the University's form "Consent to Act as Human Subject" (attached to the University's policy).

As was mentioned in connection with the issuance of the earlier University policy, no policy such as this can provide for all possible circumstances. Thus we recognize that, in practice, this policy will have to be interpreted with some flexibility, although this must be done with strict adherence to its spirit. For example, while this policy applies to all subjects "at risk," defined as exposure ". . . 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," there will be many instances, particularly in the social and behavioral sciences, for which it will be difficult to determine whether the applicability of this policy is indicated. As the policy states, "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" (page 2).

Sincerely,

  
C. O. McCorkle, Jr.

Attachments

cc: President Hitch  
Other Vice Presidents  
Laboratory Directors  
Special Assistant Powell  
General Counsel Cunningham  
Assistant Vice President Everett

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