STATE OF MINNESOTA

FARIBAULT STATE HOSPITAL OFFICE MEMORANDUM

TO; All Departments Date: March 16, 1967

FROM: E. J. Engberg, M.D., Superintendent

SUBJECT: Use of Human Subjects in Research

1. General

It is the policy of this hospital that research programs be conducted in such a manner and in such facilities as to safeguard the rights and welfare of patients involved, to obtain informed consent when necessary, and to preserve human dignity.

2. Research Committee

a. Since 1963, an institution Research Committee has been appointed annually by the Superintendent, its members representing various professional specialties on the staff including, but not limited to, psychiatry, medicine, social service, psychology, rehabilitation and nursing.

b. The functions of the Research Committee include:

(1) Stimulation of individual and cooperative research projects within the institution.
(2) Review, approval, and surveillance of research projects carried out by or with institution staff, subjects, or facilities. Approval for such research is given only upon the Committee's determination that:

(a) The type of research is appropriate to the functions of the institution.
(b) The research design is appropriate to the matter under investigation.
(c) The rights and welfare of individuals involved will be protected.
(d) Consent of subjects is or is not appropriate and that, where consent should be obtained appropriate methods are used to secure it.
(e) The risks and potential medical benefits of the investigation have been carefully weighed.

c. Members of the Research Committee, effective July 1, 1967, until June 30, 1967, are: Mr. Arnold Madow, Chief Psychologist, Chairman; Dr. Allen Fogerson, Dentist, Secretary; Dr. H. H. Bruhl, Chief of Pediatric Service; Dr. Thorsten Smith, Clinical Director; Miss Caroline Perkins, Social Service Supervisor; Mrs. Valeria Blomquist, Director of Nursing Program Development; Mr. Raymond Roach, Patient Programs Supervisor; and Mr. Delbert Knack, Institution School Principal.

3. Extra-Institution Research Review

a. The Mental Health Medical Policy Committee of the Minnesota Department

of Public Welfare is invested by law with the responsibility of approval and guidance of proposed clinical research in State institutions to assure, among other matters, an independent determination of:

(1) The rights and welfare of individuals involved
(2) The appropriateness of the methods used to secure informed consent, and
(3) The risks and potential medical benefits of the investigation.

b. The Mental Health Medical Policy Committee is appointed by the Commissioner of Public Welfare and is composed of five members who are experts in their various fields of medicine or related sciences. Mo more than one member is selected from any one field of medicine or related sciences, which include psychiatry, neurology, physiology, biochemistry, internal medicine, pediatrics, pharmacology and psychology.

c. Present members of the Mental Health Medical Policy Committee are: Carl Koutsky, M.D., University of Minnesota Hospitals: Lloyd Harris, M.D., Section bf Pediatrics, Kayo Clinic; Samuel K. Boyer, M.D., Duluth; V. P. Mattox, Ph.D., Mayo Clinic: William Schofield, Ph.D., Department of Psychiatry and Neurology, University of Minnesota Hospitals.

4. Review, Approval and Follow-up of Research Programs

a. Individuals desiring to conduct research at Faribault State Hospital, whether members of the staff or not, and whatever the source of the research funds, will review their plans with the Research Committee prior to undertaking any part of the research.

b. If the proposed research is approved by the Research Committee, the proposal will be submitted to the Mental Health Medical Policy Committee through the Research Consultant in the Division of Medical Services, Department of Public Welfare, for review and approval. Programs not approved with respect to the criteria outlined in Section 3.a., above, will not be initiated until they are modified and approved.

c. Following approval by the Mental Health Medical Policy Committee, any change in protocol will require a review of such changes by the institution's Research Committee and the Mental Health Medical Policy Committee.

d. Project directors will make periodic progress reports to the Research Committee and the Mental Health Medical Policy Committee to insure that they are conforming to the approved protocol.

e. Application for training grants, if they involve human subjects in any type of research, will require the same approval as described above.

f. When the nature of the research indicates that acquiring of consent is appropriate, the program will be explained to and written consent obtained from the nearest relative or guardian, as well as from the patient if he is capable of giving such consent.

SUPERINTENDENT