Rules of
Department of Mental Health
Division 60—Research
Chapter 1—Rules for Conducting Research and Program Evaluation

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 60—Research
Chapter 1—Rules for Conducting Research and Program Evaluation

9 CSR 60-1.010 Application for Client Research

PURPOSE: This rule prescribes procedures by which applications for research involving any client or patient or any individual identified by virtue of being a former client or patient of the department are submitted and reviewed for approval.

(1) The terms defined in section 630.005, RSMo are incorporated into this regulation. As used in this administrative rule the following terms mean:

(A) Archival research is the review or analysis of historical data generated by the department and kept as part of the permanent management information record;

(B) Behavioral or psychological research is the experimentation with patients, clients or residents to determine the effects of manipulation or application of environmental variables including, but not limited to, experimental use of behavior modification;

(C) Biomedical research is experimentation by intruding into a patient's, client's or resident's body to monitor the biological reaction to controlled stimuli or biological study involving experimental medical or surgical procedures, withdrawal or removal of body tissues or fluids or input of energy or manipulation of bodily processes;

(D) Deputy director is the deputy director of the Office of Departmental Affairs;

(E) Professional review committee (PRC) is the ten (10)-person committee established under section 630.192, RSMo and appointed by the director to review and recommend approval or disapproval of proposed research projects;

(F) Pharmacological research is experimentation with patients, clients or residents to determine responses to drugs or other substances;

(G) Program evaluation is an activity designed to assess or evaluate policies, procedures or programs currently in operation to determine their effectiveness or usefulness or to identify needed changes, including survey research and specifically limited to instances where no manipulation of variables or conditions is involved; and

(H) Research is experimentation or intervention with or on departmental patients, clients or residents, including behavioral or psychological research, biomedical research, pharmacological research and program evaluation. Excluded are those instances where the manipulation or application is intended solely and explicitly for individual treatment of a condition, falls within the prerogative of accepted practice and is subject to appropriate quality assurance review. Also excluded are activities limited to program evaluation conducted by staff members as a regular part of their jobs, the collection or analysis of management information system data, archival research or the use of departmental statistics.

(2) Any person may request to do research on departmental clients by requesting the application for research with clients from the Office of Departmental Affairs (DMH form 8114). It is incumbent on the individual wishing to conduct research to seek and gain approval for research before initiating the project.

(3) The person requesting to do research shall send an application and ten (10) copies to the deputy director or designee. Based on the completed application, the deputy director or designee may exempt from PRC review those projects which do not meet the criteria of research as defined in section (1). In the case of projects approved by the facility director which are exempted from review, the facility director accepts the responsibility of insuring client confidentiality, informed consent and the right to refuse to participate.

(4) For approved projects, it is incumbent on the principal investigator to ensure that execution of the project does not violate statutes.

(5) Statements provided in this regulation shall not be construed to limit client rights established by statutes, including the right to informed consent and the right to refuse to participate.

AUTHORITY: sections 630.192 to 630.198, RSMo 1994. Original rule filed March 18, 1987, effective Aug. 15, 1987. Amended: Filed July 17, 1995, effective March 30, 1996.*

Original authority: 630.192 to 630.198, see **Missouri Revised Statutes, 2000.*

STATE OF MISSOURI
DEPARTMENT OF MENTAL HEALTH

APPLICATION FOR RESEARCH WITH CLIENTS OF THE MISSOURI DEPARTMENT OF MENTAL HEALTH

NAME OF PRINCIPAL RESEARCHER	DATE
HOME ADDRESS	PHONE
CURRENT EMPLOYER	
ADDRESS	PHONE
HIGHEST ACADEMIC DEGREE	
MAJOR FIELD OF STUDY	

I. Title of Proposal _____

_____

II. Dates of Proposed Project Period _____

III. Facility or Location where Research Project will be conducted _____

_____

Who will serve to oversee the project at the facility where the research will be conducted? Unless the applicant works in a managerial capacity in the unit where the project will be conducted, a staff member in a managerial position should be enlisted to ensure that the project proceeds smoothly and does not unnecessarily disrupt the unit's operation.

Facility Overseer _____

Position Title _____

IV. Who will serve as the principal investigator for the project? Note the definition in Standard 3.1 of the Research Guidelines of scientifically qualified individuals. If the applicant does not feel he/she qualifies as per this definition, a more senior researcher should be enlisted to oversee the project. Generally, a student's professor serves as the principal investigator when the project receives academic credit.

Attach curriculum vitae of applicant and principal investigator.

Principal Investigator _____

Title _____ Affiliation _____

MO 650-0240 (5-89) DMH-8114

V. If the proposed project is to serve as a requirement for an academic program, indicate its role. Include any deadlines which are known.

☐ Master's Thesis _____ Deadline for _____
(I.E., DATA COLLECTION)

☐ Doctoral Dissertation

☐ Pilot study for thesis or dissertation research.

☐ Other academic requirement, please specify _____

Indicate the University and Department in which you are enrolled _____

_____

Indicate the faculty member who will serve as your academic advisor _____

_____

Has the project received approval by your professor/committee? ☐ YES ☐ NO

If yes, please attach a statement to that effect, signed by your professor.

If no, please indicate expected date of approval _____

VI. Please answer the following questions in a total of no more than seven pages.

1. Describe and assess the potential benefits that may come as a result of the planned work (include literature review). Describe the benefits to participants and to mental health in general.

2. Describe the relationship to other studies of this type. Include literature reviews to support your discussion.

3. **Subjects:** Briefly describe the potential subjects. Describe the characteristics of the subject population, i.e., age, sex, ethnic background, diagnosis. Include target number of subjects and sampling techniques. Explain why a DMH client sample is requested.

4. **Methods:** Discuss in detail the research design and the procedures to be used to accomplish the specific aims of the project. Describe the protocols to be used and the tentative sequence of the investigation. Include the means by which the data will be analyzed and interpreted. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

5. **Performance Sites:** Indicate where the project will be conducted. Include the potential cost and impact on the operation of the facility(ies), any assistance you will need from facility personnel, etc. Enclose letter(s) from the facility director(s) reflecting tentative approval of the project.

VII. **Human Subject Assurance Procedures:** Describe the procedure you intend to follow to assure that informed consent will be solicited and obtained, the nature of information to be provided to prospective subjects, and the method of documenting consent. Attach a copy of the letter of informed consent which you intend to use.

VIII. **Funding Source:** Briefly explain the funding source and the assurance you have that funds will be available throughout the project. Indicate who will be responsible for the incidental costs (Xerox, mail, transportation) of the project.

COMPLETE ONLY IF FUNDING IS REQUIRED IN ORDER TO COMPLETE THIS PROJECT.

DETAILED BUDGET	FROM	THROUGH

PERSONNEL (APPLICANT ORGANIZATION ONLY — SEE INSTRUCTIONS)		TIME/EFFORT		DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
NAME	TITLE OF POSITION	%	HOURS PER WEEK	SALARY	FRINGE BENEFITS	TOTALS
	PRINCIPAL INVESTIGATOR					
		SUBTOTALS				
CONSULTANT COSTS (SEE INSTRUCTIONS)						
EQUIPMENT (ITEMIZE)						
SUPPLIES (ITEMIZE BY CATEGORY)						
TRAVEL						
INSTATE						
OUTSTATE						

PLEASE SUBMIT ORIGINAL AND TEN COPIES TO:
Office of Departmental Affairs
Research & Evaluation Section
Department of Mental Health
Post Office Box 687
Jefferson City, MO 65102

MO 650-0240 (5-89) DMH-8114

9 CSR 60-1.015 Review of Research in Progress

PURPOSE: This rule prescribes the procedures by which the Professional Review Committee may review and investigate research.

(1) The terms defined in section 630.005, RSMo are incorporated into this rule. As used in this administrative rule, the following terms mean:

(A) Professional review committee (PRC) is the ten (10)-person committee established under section 630.192, RSMo and appointed by the director to review and recommend approval or disapproval of proposed research projects;

(B) Approved research is any behavioral or psychological research, biomedical research, pharmacological research or program evaluation approved by the PRC;

(C) Facility director is the chief administrator or director of a state facility, vendor facility or vendor agency which serves clients of the Department of Mental Health; and

(D) PRC coordinator is the director of Research and Evaluation or other designee of the department director.

(2) Research which has been approved by the PRC shall be reviewed at one hundred eighty (180)-day intervals or more often as determined by the PRC from the date of approval until the project is completed. The principal investigator shall submit information as specified by the PRC regarding the status of the research project.

(A) The principal investigator shall provide a report of the results to the department upon completion of the project.

(B) Based on the information obtained in a review, the PRC shall investigate the project if any harm, increased risk of harm or unapproved deviation from the research protocol occurs.

(3) Any written complaint regarding research which produced harm, increased risk of harm or which failed to conform to approved research protocol shall be investigated by the PRC.

(A) A complaint may be filed with a member of the PRC or its coordinator, or with a facility director where research is being conducted. Those receiving complaints shall provide a copy of the complaint to the coordinator.

(B) The coordinator shall notify the principal investigator and all facility directors where the project is being conducted of any complaints received.

(C) The principal investigator may respond in writing to any complaint regarding the project.

(D) The facility director shall investigate the complaint and provide recommendations to the coordinator of the PRC within ten (10) days of the filing of the complaint. The facility director may chose to suspend or halt the project after receiving notification of a complaint. The facility director shall notify the principal investigator and the coordinator of any decision to suspend or halt a research project.

(4) The PRC may investigate any research project which it has approved. The PRC shall investigate any approved research project when it has reason to believe that harm or increased risk of harm to the subjects or deviation from approved protocol has occurred.

(A) The PRC may halt the research project while it is under investigation.

(B) The principal investigator shall provide information requested by the PRC that is necessary for the investigation.

(C) Employees of the department shall provide information requested by the PRC that is necessary for the investigation.

(D) Staff of vendor agencies serving clients of the department shall provide information requested by the PRC necessary for the investigation.

(E) The PRC shall rule on projects which have been investigated.

1. The PRC may take into account information received from the facility director where the project is conducted, from the principal investigator, and from other sources having information pertaining to the project.

2. The PRC may rule to halt the project or suspend the project until deficiencies are corrected.

3. The principal investigator and the facility director shall be notified of the decision of the PRC.

(5) At the request of a facility director, the PRC may investigate research activities which have not been reviewed including archival studies and program evaluation projects.

AUTHORITY: section 630.194, RSMo 1994. Original rule filed Nov. 30, 1987, effective May 12, 1988. Rescinded: Filed Sept. 1, 1995, effective March 30, 1996. Readopted: Filed May 20, 1996, effective Dec. 30, 1996.*

**Original authority: 630.194, RSMo 1980.*

9 CSR 60-1.020 Archival and Program Evaluation Activities

(Rescinded March 30, 1996)

AUTHORITY: sections 630.192 to 630.198, RSMo 1986. Original rule filed March 18, 1987, effective Aug. 15, 1987. Rescinded: Filed July 17, 1995, effective March 30, 1996.

9 CSR 60-1.030 Research Review Committee

(Rescinded March 30, 1996)

AUTHORITY: sections 630.196 and 630.198, RSMo 1986. Original rule filed March 18, 1987, effective Aug. 15, 1987. Rescinded: Filed July 17, 1995, effective March 30, 1996.