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) Professional review committee (PRC) is the ten- (10-) person committee established under section 630.193, RSMo and appointed by the department director or designee to review and recommend approval or disapproval of proposed research projects;

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

(F) 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

(G) 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 department director or designee. 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 to the department director or designee as indicated on the application. Based on the completed application, the department 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, 630.193 to 630.198, RSMo 2016. Original rule filed March 18, 1987, effective Aug. 15, 1987. Amended: Filed July 17, 1995, effective March 30, 1996. Amended: Filed July 26, 2016, effective Feb. 28, 2017.*

Original authority: 630.192, RSMo 1980, amended 1996, 2011 and 630.193 to 630.198, RSMo 1980. See **Missouri Revised Statutes, 2016.*

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 630.193, RSMo and appointed by the department director or designee 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 appointed by the department director or designee.

(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 2016. 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. Amended: Filed July 26, 2016, effective Feb. 28, 2017.*

**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.