*Section 27.10.* Research involving human subjects.

(a) Patient participation. The understanding, prevention and amelioration of mental disability is enhanced by knowledge gained through research. Patients may participate only in research which does not come in substantial conflict with their individual service plans. Participation as a subject in any research project or activity shall not deprive any patient of the rights, privileges and protections provided to all patients by this Part. Directors of facilities shall maintain an up-to-date list of all patients who are involved in research projects and shall make the list available to the Mental Health Information Service representative on request.

(b) Informed consent of patients in research projects.

(1) Informed written consent of patients who participate as subjects must be obtained in accordance with the requirements of section 27.9(a) or (c) of this Part as applicable.

(2) If it is clear that a patient does not have sufficient mental capacity to give consent for participation, consent may be obtained from the facility director if the research project director clearly demonstrates to the institution review committee that (i) the project has overriding therapeutic importance for a condition presented by the patient in question, and (ii) that the project could not be carried out without the participation of patients such as the one in question.

(3) The informed consent required by paragraphs (1) and (2) of this subdivision must be secured in accordance with applicable policies of the department, and the regulations of Federal agencies which are applicable to such research before projects or activities may be approved.

(c) Approval by division of research. Research projects or activity involving patients are subject to department approval under the policies and procedures of the division of research. Experimental drugs or treatment procedures may be used only after the proposed procedure has been submitted to the division of research for review and specific written approval has been granted in each instance.

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