**TITLE: AUTHORIZATION TO APPROVE RESEARCH PROJECTS**

**PURPOSE:** To establish guidelines for approving Research Projects at The Center for Health Care Services. This policy supersedes the Authorization to Approve Research Projects (6.6) dated May 19, 2005.

[Key Words: Approval, Contracts, Research, Human Subject, Institutional Review Board (IRB), Research Review Committee (RRC)]

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**POLICY STATEMENT:**

The Board of Trustees recognizes that research is a complex enterprise. It is The Center for Health Care Services' (Center) policy to encourage research that is consistent with the Center's values and that benefits the Center, its consumers specifically, and society as a whole.

**POLICY ELABORATION:**

## I. DEFINITIONS

A. "Consumer" – an individual residing in Bexar County who is actively being treated for a developmental disability, a mental health, and/or a substance abuse disorder by the Center.

B. "Human Subject" – an individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private

information. IRB review and approval is required for such research.

C. "Institutional Review Board" (IRB) - any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. Any clinical investigation, which must meet the requirements for prior submission to the Food and Drug Administration (FDA) or considered in support of an application for a research or marketing permit, must have been reviewed and approved by, and remained subject to continuing review by an IRB, meeting the requirements of Title 21, Code of Federal Regulations, Part 56.

D. "Qualified Investigator" - an individual who is responsible for conducting the study (drug studies or health or supportive services interventions) involving Consumers (study subjects) or in the event of research conducted by a team of individuals, is the responsible leader of the research team.

E. "Research" (also referred to as Clinical Investigation) - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

F. "Research Review Committee" (RRC) – is the entity composed of the following Center staff or his/her designee: The Chief of Staff, Medical Services, the Center's Rights Protection Officer, the Director of Information Services, Chief Operating Officer, Chief

Financial Officer, Director of Quality Improvement Support Services, and any person(s) deemed appropriate by the Center. The Center will be responsible for reviewing all proposed research projects and making recommendations to the Executive Director.

## II. GUIDING PRINCIPLES

A. Internally and externally-generated projects that involve the Center's consumers as human subjects and that include the use of Center resources (e.g., staff, facilities) must obtain administrative approval before they begin at the Center.

B. The Center shall strive in its approval process to ensure that all research involving consumers as study subjects protects the safety, well-being, and dignity of the subject.

C. The Center recognizes and expresses a commitment to conducting research in a manner that is consistent with the best interests and protection of its consumers, respecting confidentiality and the personal rights of consumers as human subjects involved in the research. This includes conducting research in a manner that protects individuals from participating in research activities that conflict with their individual treatment goals.

D. From a continuity of care (services) perspective, it is important that Center staff and researchers develop methods to track patients participating and disengaging from research. This will require on-going communication between staff providing care to the consumer and researchers working with consumers as study subjects.

## III. REVIEW AND APPROVAL

A. The Center's Research Review Committee (RRC) is responsible for reviewing and approving research projects conducted in whole or in part at the Center.

B. The Center is responsible for assuring that investigators understand the following Center expectations:

1. That research must be pursuant to applicable local, state, and federal laws, and accepted ethical and professional guidelines.

2. That an IRB created in accordance with federal and/or state or local laws, reviews and approves the proposed research project, where applicable.

3. That the investigator must provide the Center with proof of liability coverage for the research activities.

4. That the investigator must provide periodic updates to the Center about the research.

5. That the investigator must notify the Center whenever a significant event, as defined in applicable local, state, and/or federal regulations, occurs within the project.

C. Under certain circumstances delineated in the Center's procedures and based on recommendations from the RRC, the Center may choose to withdraw from on-going research projects with concurrent notification to participating Center consumers.

D. The Center shall approve drug research pursuant to applicable Food and Drug Administration (FDA) regulations.

E. Center staff shall regularly report to the Board of Trustees on the progress of research projects administratively approved by the Center.

**REFERENCES/BIBLIOGRAPHY:**

Title 21, Code of Federal Regulations, Part 56 (Institutional Review Boards)
Title 45, Code of Federal Regulations, Part 46 (Protection of Human Subjects)

**OFFICE OF PRIMARY RESPONSIBILITY:**

Chief of Staff, Medical Services
Medical Executive Committee