

SUBJECT: RESEARCH, EXPERIMENTATION, INVESTIGATIONAL
STUDIES, AND CLINICAL TRIALS

EFFECTIVE

DATE: 02-19-10 (replaces 07-14-05)

APPROVED BY:

Reviewed (no changes): _____

Executive Director

POLICY

It is the policy of McIntosh Trail CSB that research, experimentation, and clinical trials are only used by the organization with written justification and approval. The consumer has the right to be informed of any experimental, research, or educational activities that are involved in his/her treatment. The consumer has the right to refuse to participate or withdraw consent and discontinue participation in any such activity. Investigators and others directly involved in human subject research, both in obtaining consent and in conducting research, adhere to professional standards concerning the conduct of research and are guided by the regulations of Department of Behavioral Health and Developmental Disability Services concerning the Protection of Human Subjects.

The organization, represented by the Risk Management Committee, reviews center/service proposals requesting participation in an experimental procedure. This multi-disciplinary committee approves participation based on the project's compatibility and the organization's mission, staff qualifications/competence, available resources, and positive benefits to its consumers. The consumer consent form is also reviewed before consideration of research, experimentation, investigational studies and clinical trials.

Before requesting the consumer's consent for participation, all consumers asked to participate in a research project are supplied with a description of the benefits to be expected; a description of the potential discomforts and risks; a description of alternative services that might also prove advantageous to them; a full explanation of the procedures to be followed, especially those which are experimental in nature; and assurance of their right to refuse to participate in any research project without compromising their access to the services of the organization.

Clinical records of each participant indicate this policy is followed during each project.

The principle investigator attempts to alleviate, to the extent possible, any confusion, misinformation, stress, physical discomfort, or other harmful consequences that may have arisen with respect to the participants as a result of the procedures.

Research is conducted in a manner that respects the rights and needs of individuals served. This principle is supported through efforts to minimize potential adverse effects of participation in research. The principal investigator must assume the responsibility for timely post research follow-up with participants.

All consent forms address the information specified above and indicate the name of the person who supplied the prospective participant with the information and the date the form was signed and states the participant's right to privacy, confidentiality and safety.

Reference: JCO Chapters RI, PC, IM

Attachment: Consumer Informed Consent to Research, Experimentation, and/or Clinical Trials Form

**McIntosh Trail Community Service Board
Consumer Informed Consent to Research,
Experimentation, and/or Clinical Trials Form**

Name

CID No.

Note: Before consumer consent for participation is requested, this form **MUST** be completed.

Description of benefits to be expected:

Description of potential discomforts and risks:

Description of alternative services that might also be advantageous to you.

Full explanation of procedures to be followed.

I understand I can refuse to participate in any research project without compromising my access to services at McIntosh Trail CSB and that I have the right to privacy, confidentiality, and safety.

_____ I agree to participate in the research project as stated above.

_____ I do not agree to participate in the research project as stated above.

Consumer under 18 years old legal guardian/consumer/
parent/legal guardian and/or advocate.

Date form signed

Person supplying information to prospective participant

APPROVE/DISAPPROVE: _____

Chair Risk Management Committee

Date

If approved, date sent to DBHDD for review and approval: _____

(CSB 02/10)

Date