Policy: It shall be the policy of the Division that when a program conducts or participates in research with human subjects, there shall be written policies.

Purpose: This policy is designed to ensure that rigorous review is made of the merits of each research project and of the potential effects of the research procedures on the participants.

Procedure:

I. There shall be an interdisciplinary research review committee made up of individuals qualified by training and experience to conduct reviews of research projects. This committee may be either a permanent standing committee or a committee convened on an as-needed basis and composed of individuals with appropriate experience in the research area to be reviewed.

A. A majority of the members of the review committee should be made up of individuals who are not directly associated with the research project under consideration. Some members should be selected from among individuals not formally associated with the program.

B. Prior to the authorization and beginning of each research project, the research committee shall conduct a detailed review of the project. This initial review shall form the basis for the written report that shall be submitted by the committee to the agency administrator. This review shall concern:

1. The adequacy of the research design;
2. The qualifications of the individuals responsible for coordinating the project;
3. The benefits of the research in general;
4. The benefits and risks to the participants;
5. The benefits the program will derive from the research;
6. The possible disruptive effects of the project on program operations;
7. The compliance of the research design with accepted ethical standards;
8. The process to be used in obtaining informed consent from participants; and
9. The procedures for dealing with any potentially harmful effects that may occur in the course of the research activities.

C. If the research committee approves the research project, it must then be submitted for final approval to the Department of Health and Human Services, deputy director's office for final approval by the Institutional Review Board.

II. All individuals asked to participate in a research project shall be given the following information prior to being asked to give their consent:

A. A description of alternative services that might prove equally advantageous to them;

B. A full explanation of the procedures to be followed, especially those that are experimental in nature;

C. A description of the potential discomforts and risks; and

D. A description of the benefits to be expected.

III. If the investigator does not wish to fully disclose to the participants the purpose, nature, outcome, and implications of the research prior to its commencement, the investigator shall clearly and rigorously justify to the review committee that such disclosure is inadvisable and that failure to give full disclosure is not detrimental to the participants. Under such conditions, disclosure may be deferred until the research project is completed. Upon completion of the project, full disclosures to participants will be made.

IV. All prospective participants over the age of 12 and all parents of participants under the age of 18 shall sign a written consent form (copy attached) that indicates willingness to participate in the project.

A. The consent form shall contain the full information described in Section 16, paragraph 3, sections a)-d), as well as the date the consent form was signed and the name of the individual who supplied the prospective participant with the information.

B. The consent form shall indicate the date the form was signed and the signature of a witness.

C. The participant's right to privacy and confidentiality shall be addressed by the informed consent document.

D. Neither the consent form nor any other written or oral agreement entered into by the participant shall include any language through which the program, its agents, or those responsible for conducting the research are released from liability for negligence.

V. Prospective participants age 12 or younger and all prospective participants who are legally or functionally incompetent to provide informed consent shall participate only when and if consent has been given by a person legally empowered to consent and such consent has been reviewed by an independent advocacy group, if available. Such legal guardian and/or advocate shall receive

the same information as required for the consumer in this policy and shall sign the consent form.

VI. The denial of consent to participate by any potential research subject shall not be a cause for denying or altering the indicated services to that patient.

VII. Participants shall be allowed to withdraw consent and discontinue participation in the project at any time without affecting their status in the program or of the indicated services to that patient.

VIII. Upon completion of the research procedures, the principal investigator shall attempt to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences that may arise in the participants as a result of the procedures. Investigators and others directly involved in research shall adhere to the ethical standards of their respective professions concerning the conduct of research and should be guided by the regulations of the Department of Health, Education, and Welfare on the protection of human subjects (Title 45, Part 46, 1978).

IX. Upon completion of the research, the principal investigator, whether a member of the program staff or an outside research group shall be responsible for communicating to the staff of the program, the purpose, nature, outcome, and possible practical or theoretical implications of the research.

X. Reports of all research projects shall be maintained by the program.

XI. Each agency shall develop policies and procedures regarding the provisions of the Department of Health and Human Services policy on Procedures for Research Involving Human Subject and Protocols and Guidelines adopted August 5, 1999, or shall incorporate this policy into the agency policy and procedure manual.

XII. Each Division agency shall develop specific written procedures to implement the provision of this policy or shall incorporate this policy into the agency policy manual.

Administrator

Effective Date: 4/30/98
Date Revised: 8/23/99, 5/15/02; 7/3/07

ATTACHMENT: Consent to Treatment/Evaluation

***For Department of Health and Human Services Procedures for Research Involving Human Subjects and Protocols and Guidelines (including forms), Please contact the Director's office at 775/684-4000.***

Attachment

I, _____, Consent to a treatment/evaluation plan at the Division of MHDS. I understand that the evaluation plan may include medication, interviews, psychological testing and rehabilitative care and that before the plans are put into effect I have the right to be informed as to:

1. The nature and consequence of the evaluation/treatment plans.
2. The reasonable risks, benefits and purposes of the evaluation/treatment plans.
3. Any alternative evaluation/treatment plans or procedures available.
4. I DO DO NOT, consent to the limited and supervised participation of students in the health professions (medical student, psychology interns, nursing students, social work interns, special education students or others in related fields) in my evaluation and/or treatment with the understanding that a professional staff member will have responsibility for my care.

_____ _____

Consumer's Signature Date

_____ _____

Witness Signature Date

DIVISION OF MHDS ENTER

CONSENT FOR EVALUATION AND

TREATMENT CASE #