5122-28-05 **Research activities.**

(A) The purpose of this standard is to ensure that research activities are conducted in an ethical manner, that participants' rights regarding such activities are respected and protected, and that research undertaken enhances the overall performance of the agency.

(B) The following definitions apply to this rule:

(1) "Appropriate Alternative Procedure" means a mental health treatment procedure that is ordinarily available to a research participant and is commonly applied to the condition for which the individual has been selected to participate in research.

(2) "Benefits" means any consequences with some desirable value that may accrue to a research participant as a result of participation.

(3) "Consent" means agreement to participate in a research or treatment procedure on the basis of the participant's understanding of its nature and possible risks and benefits.

(4) "Ethnic, Minority, or Cultural Group" means population groups such as African Americans, Hispanic persons, Asian persons, Native Americans, persons from the Amish culture, deaf/hard of hearing persons, or other groups that share a set of values or experiences that are important to understand in order to provide relevant mental health services.

(5) "Existing Scientific Theory" means a general explanation of a phenomenon that has achieved at least minimal acceptance among some group of researchers, as evidenced by journal articles or books dealing with the topic.

(6) "Experimental" means the introduction of new physical, psychological, or social interventions in a research process, the effectiveness and appropriateness of which have not yet become an accepted part of professional practice.

(7) "Generalizability" means the accuracy with which research results can be transferred to situations other than those originally studied.

(8) "Methodological Expertise" means having extensive training and experience in research methodology that is considered acceptable to professional scientists who conduct and publish research of a similar nature.

(9) "Methodological Standards" means rules of conduct for research that are outlined in or may be derived from methodological and statistical books and journals or that methodological experts within a particular area of research would agree are appropriate.

(10) "Minimal Risk" means risk that is no greater than that encountered in ordinary

daily activities outside of a research setting.

(11) "Negative Consequences" means undesirable results or risk of undesirable results that may occur as a result of participation in a research study. Such undesirable results may include physical or psychological harm, pain, or financial or material loss.

(12) "New Knowledge" means information that is added to or modifies existing scientific theory or facts that are accepted among a group of researchers.

(13) "Non-Threatening Information" means information that does not concern sexual behavior, drug or alcohol use, participation in criminal acts, or any other information that, if disclosed, might produce some negative consequences for the research participant.

(14) "Paper and Pencil Questionnaire" means a printed or written data collection form with items that are of a non-threatening nature, in which the information to be derived by the researcher from the items is directly apparent from the item content. This excludes psychological tests requiring special scoring procedures that cannot be easily explained to the research participant, such as intelligence or personality tests.

(15) "Participant" means a person who is an object of study as part of a research activity. Participants may include persons receiving mental health services, staff of mental health agencies, or other persons.

(16) "Research Activity" means a systematic investigation of phenomena or relationships among variables, guided by existing theory in the mental health field, and executed within a rigorous methodological design, such that the results are generalizable and have the potential to yield new knowledge about the causes and prevention of mental health problems, the mental health needs of special client populations, and the development of effective services.

(17) "Risk" means a possibility that some negative consequence might occur as a result of participation in a research study.

(C) The research design shall:

(1) Promote consideration of participant values and preferences, including the decision to discontinue participation;

(2) Recognize responsibilities under law and regulations;

(3) Inform participants of their rights and responsibilities in the research project;

(4) Undertake the process in an ethical manner;

(5) Ensure that information that identifies individuals shall be used in compliance with federal and state laws and regulations, with professional standards regarding confidentiality, and regarding client rights; and

(6) Ensure that, prior to the start of research activities in which they are being asked to participate, participants receive explanatory written and oral information about the activity(ies), its perceived value and link to better treatment.

(D) Participants in research projects have a fundamental right to care that safeguards their personal dignity and respects their cultural, psychosocial, and spiritual values.

(E) An overt refusal to participate in research activities by either the adult/child participant or the parent/guardian shall be taken as final.

(F) When an agency conducts, participates in, or is the site of research activity with human subjects, this research activity shall comply with the following requirements:

(1) If the research involves an agency, the agency's board of trustees shall be informed of the agency's participation in each research project.

(2) An agency that conducts research activity shall ensure research attention to the needs and characteristics of ethnic, minority or cultural groups, including requirements that:

(a) Research shall be conducted in a manner that provides such individuals with the opportunity of being selected for research at least in proportion to their representation in the population being studied;

(b) All research that includes ethnic, minority or cultural group representation shall include, at a minimum, a qualitative examination of potential differences in findings for such groups; and

(c) Data analysis conducted as part of research shall include tests of differences in findings and interactions pertaining to membership in ethnic, minority or cultural groups.

(3) All research activity shall be reviewed and approved by a multi-disciplinary research committee.

(a) A majority of the committee shall not be directly associated with the research activity under construction.

(b) This committee shall be composed of at least five members, including:

(i) Representatives of ethnic, minority or cultural populations in

numbers proportional to their representation in the service populations being studied, if possible;

(ii) A member who represents the client rights perspective;

(iii) Individuals who are appropriately experienced in programmatic aspects of the research; and

(iv) Individuals with methodological expertise that is relevant to the research.

(c) The research committee may be either a permanent or an ad hoc committee, a committee of the agency, or an officially constituted research committee of an academic institution with which one or more of the agency staff and researchers are affiliated.

(i) If the committee is an officially constituted research committee of an academic institution, the research activity must still comply with all provisions of this standard.

(4) Prior to the initiation of any research activity, the research committee shall conduct a detailed review and determine authorization. The review shall consider compliance with standards set forth in this rule for confidentiality and written informed consent, and adherence to all applicable state and federal laws and regulations. The committee shall review the following factors and consider them in determining authorization:

(a) Adequacy of the research design and compliance with methodological standards;

(b) Relevance to existing scientific theory;

(c) Potential to yield new knowledge;

(d) Generalizability of findings;

(e) Qualifications of the individuals conducting the research activity;

(f) Benefits and risks to the individuals involved and to the agency;

(g) Possible disruptive effects on normal routine operations of services or agencies; and

(h) Costs to the agency.

(5) Consent shall be obtained by a parent or guardian for individuals under eighteen years of age and for individuals for whom a legal guardian has been assigned

because they are deemed incompetent to consent. Such consent shall be contingent upon the voluntary participation of the research participant.

(a) If the multi-disciplinary research committee finds that there is more than "minimal risk" for individuals under eighteen years of age, consent is to be obtained from both parents unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(6) The consent of each participant shall be obtained in writing except for:

(a) Research involving the collection of existing data that are publicly available; or

(b) Information made available to the researcher without direct or indirect identifiers; or

(c) Paper and pencil questionnaire involving the solicitation of non-threatening information. In this situation, the return of the questionnaire to the researcher implies voluntary consent.

(7) The written consent from a research participant may be obtained for the duration of the research project or more frequently, if desired, and shall be kept in the ICR.

(a) The consent form shall use simple and non-coercive language and shall include the following basic elements:

(i) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the individual's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(ii) A statement concerning all other data sources that will be consulted concerning the participant, including other persons, agency records, or other service system records;

(iii) A description of any forseeable side effects, risks or discomforts to the participant;

(iv) A description of any benefits to the participant or to others that may reasonably be expected from the research;

(v) A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant;

(vi) A statement describing the extent to which confidentiality of records identifying the participant will be maintained;

(vii) For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(viii) An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights and whom to contact in the event of a research-related injury to the participant;

(ix) A statement that participation is voluntary; and

(x) A statement that the participant may refuse or may discontinue participation at any time without penalty or loss of benefits or services to which the participant is otherwise entitled.

(G) Research activity data shall, at minimum, be retained for whatever the period of the research is, plus the subsequent period of primary and secondary data analysis.

(H) Researchers shall, at minimum and upon request, make available to participants the results of the research activity(ies).

(I) Research activities shall be monitored on a quarterly basis through the agency's performance improvement processes.

Effective:

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Certification

Date

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