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Document No. 5039
DEPARTMENT OF DISABILITIES AND SPECIAL NEEDS
CHAPTER 88
Statutory Authority: 1976 Code Section 44-20-220

Article 8. Research Involving Persons Eligible for Services. (New)

Preamble:

The Department of Disabilities and Special Needs proposes to add Article 8 to provide for establishing procedures for research involving persons eligible for services through the Department of Disabilities and Special Needs. Specific sections added are Regulations 88-805, Definitions; 88-810, Review and Approval of Research Proposals; 88-815, Protection of Rights and Welfare of Research Participants; and 88-820, Publications.

Section-by-Section Discussion

88-805. Definitions. New.

88-810. Review and Approval of Research Proposals. New.

A. Describes the members and functions of the Research Review Committee

88-815. Protection of Rights and Welfare of Research Participants. New.

A. The scientific, legal, and ethical principles

B. Qualified professionals

C. No physical harm or psychological or emotional impairment

D. Avoid pain, suffering or inconvenience

E. Consent forms

F. Confidentiality statements

G. Federal Regulation 45 CFR 46

H. Concerns and complaints

88-820. Publications. New.

A. Copies of the research

B. Prior to submission for publication

C. Approval

D. Statement

A Notice of Drafting was published in the *State Register* on December 25, 2020.

Notice of Public Hearing and Opportunity for Public Comment:

Should a hearing be requested pursuant to Section 1-23-110(A)(3) of the 1976 Code, as amended, such hearing will be conducted before the Department of Disabilities and Special Needs Commission, 3440 Harden Street Extension, Columbia, South Carolina, 29240 on April 15, 2021, thirty minutes after the adjournment of the regular Commission meeting. Written comments may be directed to Mary Poole, State Director, Department of Disabilities and Special Needs, 3440 Harden Street Extension, Post Office Box 4706, Columbia, South Carolina, 29240, no later than 5:00 p.m., March 29, 2021. If a qualifying request pursuant to Section 1-23-110(A)(3) is not received, the hearing will be cancelled.

Preliminary Fiscal Impact Statement:

There will be no increased cost to the State or its political subdivisions.

Statement of Need and Reasonableness:

DESCRIPTION OF REGULATION:

Purpose: This article is added to provide the procedure establishing procedures for research involving persons eligible for services through the Department of Disabilities and Special Needs

Legal Authority: 1976 Code Section 44-20-220.

Plan for Implementation: The added regulations will take effect upon approval by the General Assembly and upon publication in the State Register. The Department will notify applicants for services of the regulation by posting it on the agency's web site.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The proposed regulations are needed to ensure that all applicants for services are aware of the process and their rights.

DETERMINATION OF COSTS AND BENEFITS:

There will be no increased cost to the State or its political subdivisions.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates concerning these regulations.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

These regulations will have no effect on the environment of this state. The public health of the State will be enhanced by public awareness of Department procedures.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will be no detrimental effects on the environment and public health if the regulations are not implemented in this State.

Statement of Rationale:

These regulations are added to clarify and state Department procedures.

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Indicates New Matter

Text:

ARTICLE 8
RESEARCH INVOLVING PERSONS ELIGIBLE FOR SERVICES

88-805. Definitions.

A. Minimal risk- means the risk of harm anticipated in the proposed research is not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

B. Research -is defined as a special observation, or data collection usually made under conditions determined by the investigator, which aims to test a hypothesis or to discover some previously unknown principle, effect, or relationship. Research is further defined as a systematic investigation designed to contribute to generalized knowledge.

C. Activities which use experiments, tests, and/or observations designed to elicit information which is not publicly available are considered types of research.

D. Research participant- is defined as persons eligible for services from The Department about whom an investigator conducting the research obtains:

(1) Data through intervention or interaction with the participant, or

(2) Identifiable private information.

E. County Disabilities and Special Needs Boards (DSN Boards): the local public body administering, planning, coordinating, or providing services within a county or combination of counties for persons with Intellectual Disability, Related Disabilities, Head Injuries, or spinal Cord Injuries and recognized by the Department.

F. Qualified Provider - A provider of services to persons eligible for services from The Department, other than a county DSN Board, that is qualified by the state to provide such services.

88-810. Review and Approval of Research Proposals.

A. Research Review Committee

(1) The Department Research Review Committee (the Committee) shall be designated and chaired by the State Director or a designee. The Committee shall include executive staff and others as appointed by the chairperson. The committee retains authority for final approval for research involving persons eligible for services from the Department.

(2)The committee will have at least three (3) members with varying backgrounds to promote the complete and appropriate review of proposed activities.

(3) The Department Research Review Committee shall review all research proposals to ascertain the acceptability of the proposed research in terms of departmental commitments and regulations, applicable laws, research participant protections and standards of professional conduct and practice.

88-815. Protection of Rights and Welfare Of Research Participants.

A. Any research conducted must conform to the scientific, legal, and ethical principles which justify all research and should emerge from a sound theoretical basis or follow previously accepted research design.

B. Any research involving routine medical examinations or behavioral intervention techniques shall be conducted only by qualified professionals in adequately equipped settings and with the appropriate liaison or supervision during which a suitably qualified clinician is used.

Where body integrity may be violated or when otherwise appropriate, medical liaison or supervision shall be included.

C. All caution in exercise of research is limited not only to physical harm, but also includes unwarranted psychological or emotional impairment to the research participant or his/her family or legal guardian.

D. All experimentation shall be planned in such a way as to avoid pain, suffering, or inconvenience to the research participant and his/her family or legal guardian.

E. A copy of the signed informed consent form, for each research participant, shall be maintained by the Department.

F. All investigators who are not employees of the Department, a DSN Board or a Qualified Provider and who are allowed access to information about individuals served shall sign a confidentiality statement which shall be maintained in a file containing the research proposal and approval at the Department.

This shall be maintained in the file containing the research proposal and approval at the Department.

G. Facilities and programs are required to meet provisions of the federal regulations 45 CRF 46 Protection of Human Subjects.

H. Any concerns or complaints regarding the research may be addressed directly to the chairperson of The Department Review Committee and shall be investigated.

88-820. Publications.

A. The investigator shall provide a copy of the final research report to the participating programs, facilities, and the chair of The Department Research Review Committee.

B. A copy shall also be forwarded to the State Director (if the chair is the designee of the State Director) prior to submission for publication.

C. All manuscripts submitted for publication which bear the facility or The Department name and sponsorship must be approved by the State Director prior to submission to a professional journal or publishing company.

D. Any published material or lectures on the particular project or study shall contain the following statement: "Research involving persons eligible for services from the South Carolina Department of Disabilities and Special Needs is acknowledged, but it is not to be construed as implying official approval of the South Carolina Department of Disabilities and Special Needs of the conclusions presented."