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- 01/11/2022 Received by Lt. Gov & Speaker 05/11/2022

H 01/11/2022 Referred to Committee

S 01/11/2022 Referred to Committee

S 04/21/2022 Committee Requested Withdrawal

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- 04/21/2022 Withdrawn and Resubmitted 05/11/2022

- 05/11/2022 Approved by: Expiration Date

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 provided for in the Regulation

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)

**Synopsis**:

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.

**Instructions:**

Print the regulation as shown below.

**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 trial, 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.

G. Informed Consent – The knowing and voluntary agreement by the research participant or an individual

authorized by law to consent on behalf of an individual, without any element of coercion or undue influence. The research participant or the legally authorized representative must be given information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. The information that is given to the research participant or legally authorized representative shall be in language understandable to the participant or legally authorized representative.

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 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. A copy of the proposal approved by an Institutional Review Board (IRB) appropriate to the employer of the investigator is required for the proposal to be reviewed by the Committee to include procedures for obtaining informed consent, obtaining more information and exiting the study. A local Human Rights Committee shall review any research proposals that involve personal contact, observation, or interaction prior to submission to the Committee to ensure that the rights and welfare of the research participants are protected; that informed consent is obtained by adequate and appropriate methods; that individuals served are not used as captive sources of research; that the research is in no way detrimental to their welfare, and are consistent with federal regulation 45 CFR 46 (6/18/91), Protection of Human Subjects.

 (4) Only research proposals approved by the Committee shall be implemented and for the designated period included in the issued written approval.

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."

**Fiscal Impact Statement**:

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

**Statement of Rationale**:

These regulations are added to clarify and state Department procedures.