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PURPOSE

This directive contains guidelines and procedures for the review and approval of research proposals which use the Department of Disabilities and Special Needs (DDSN) resources and/or use as research participants persons receiving services from or staff employed by or through contractual arrangements with DDSN. It does not apply to analysis of summary data such as those related to provision of services, since these data do not enable identification of any individual person or reveal any private information. It also does not apply to data collected on individual service recipients when these data are for the evaluation of DDSN services and/or are part of required or customary management practices.

POLICY

Research involving persons receiving services from or staff employed by a DDSN Regional Center, county DSN board, or contracted community service provider may be conducted by facility or program staff or by outside investigators. The same policy and procedures for

reviewing, approving, and conducting research are in effect whether the investigator is an employee or non-employee. Research shall be conducted only when assurance is provided that the rights, welfare and dignity of the participants are adequately protected, that appropriate methods are used to obtain informed consent where required, that the risks involved are minimal and the research directly benefits or contributes to the understanding or treatment (including provision of supports) of intellectual disability or a related disability, autism, or a head and spinal cord injury.

DEFINITIONS

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.

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

Research participant is defined as an individual about whom an investigator conducting the research obtains (1) data through intervention or interaction with the participant, or (2) identifiable private information.

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.

Categories of research

Research proposals will be divided into two categories depending upon the level of risk involved.

Category-I: Activities involving the collection or study of existing data, documents, or records, if these sources are not publicly available. Research participants are not used directly in the gathering of information. This type of research does not involve any personal contact, observation or interaction with the participants.

Category-II: Research activities in which there is minimal risk and the research participants involved have no more than customary, every day risks (e.g., interviews, data survey, general observation, routine medical, behavioral support procedures, etc.). Any research that involves personal contact, observation, or interaction falls into this category.

Review and approval of research proposals

DDSN Research Review Committee

The DDSN Research Review Committee is chaired by the DDSN State Director or a designee and includes DDSN executive staff and others as appointed by the chairman. They retain authority for final approval for research involving persons served or employed by DDSN or that involves DDSN resources. The committee will have at least three members with varying backgrounds to promote complete and appropriate review of proposed activities. Membership may include representatives from organizations such as universities or colleges in South Carolina, DDSN, provider organizations, S.C. Protection & Advocacy System, Parent/ Consumer organizations and individuals such as an attorney, physician, ethicist, consumer or family member of a consumer, etc. Other members may include ad hoc members with specific expertise and representatives of a Regional Center or County DSN board if the research proposal involves participation of two or more programs or facilities. The DDSN Research Review Committee shall review all Category-II research proposals to ascertain the acceptability of the proposed research in terms of departmental commitments and regulations, applicable laws, participant protections and standards of professional conduct and practice. Category-I proposals may be administratively reviewed by the DDSN Research Review Committee Chair without full review by the committee. The committee chair can require review by the full committee if it appears needed upon review of the proposal.

Review Process

1. Prior to the start of research project, the investigator shall submit a proposal to the DDSN Research Review Committee. The brief proposal should include information on: contact information for the person with overall responsibility for the proposed study, the purpose of the study including objectives and intended outcomes, the characteristics of the intended participants, the procedures to be used and how the participants would be involved, potential benefits and risks to participants, and how informed consent would be obtained, and how confidentiality will be maintained (in compliance with HIPAA). A copy of the approved proposal by an Institutional Review Board (IRB) appropriate to the employer of the investigator should be attached to the proposal

2. A local Human Rights Committee shall review any Category-II research proposal before it is submitted to the DDSN Research Review 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 a captive source of research not associated with intellectual disability or a related disability, autism, or a head and spinal cord injury; and that the research is in no way detrimental to their welfare.

3. Investigators shall be notified in writing of the decision to approve or disapprove the proposed research activity or modifications required to secure approval. Approval may be granted for up to five (5) years (e.g., for a five (5) year proposed project). However, approval for more than one (1) year is contingent upon submission of an annual report to the committee that assures continued compliance with committee guidelines.

4. Written approval from the DDSN Research Review Committee must be received by the investigator prior to initiating the proposed research. The investigator must also obtain written approval from this committee before deviating in any way from the procedures previously approved.

5. A local staff liaison person shall be assigned to each research project conducted by an outside investigator.

6. The principal investigator for a research project will provide a written report at the end of each 12-month period for an approved project. This is to ensure that approved procedures are followed. Research findings and reports shall be sent by the investigator to the DDSN Research Review at the conclusion of the study.

Special Exemption:

As a general rule, only Category-I and Category-II research will be endorsed by DDSN. However, DDSN recognizes that there may be rare occasions when a research opportunity may exceed minimal risk, yet offer extraordinary potential benefit to the participants. For example, the situation may arise that a medication approved for clinical trials by the Food and Drug Administration to treat an otherwise fatal or debilitating condition such as AIDS. Such a trial may represent the only potentially beneficial treatment, yet constitutes risk that is appropriate, yet greater than minimal. Other examples may arise from the tremendous recent advances in genetic diagnosis and treatment of previously untreatable diseases. In such cases, research approval can be sought using the process described in this directive with the appropriate justification.

PROTECTION OF RIGHTS AND WELFARE OF RESEARCH PARTICIPANTS

1. 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.

2. Any Category-II 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.

3. All caution in exercise of research is limited not only to physical harm, but also includes unwarranted psychological or emotional impairment to the individual or their family.

4. 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 guardian.

5. All investigators who are not employees of DDSN, a county DSN board or a provider agency and who are allowed access to information about individuals served or staff must sign a confidentiality statement. This shall be maintained in the file containing the research proposal and approval at DDSN.

6. Facilities and programs are required to meet provisions of the federal regulations 45CRF46 (6/18/91), Protection of Human Subjects.

7. Any concerns or complaints regarding the research may be addressed directly to the chairperson of the DDSN Review Committee. The name and address of the chairperson will be provided to each research participant and/or their parent or guardian. It will also be provided to the staff working with research participants. All concerns/complaints will be investigated and the DDSN Research Review Committee notified.

8. A copy of the signed informed consent form shall be placed in the permanent file of each participant (including an employee's file when appropriate).

INFORMED CONSENT

Written informed consent, obtained prior to a person's participation, is required for all Category-II research. The investigator must obtain written or documented informed consent from the parent/legal guardian if the person is under the age of 18. If the person is 18 or older and has not been adjudicated incompetent, then they may give informed consent. Continued parental involvement is desirable for persons who are 18 years of age or older or who are unable to give informed consent. Procedures for obtaining informed consent as outlined in DDSN Directive 535-07-DD: Obtaining Consent for Minor and Adults shall be followed.

Specific detailed information shall be provided to all potential research participants and/or their parents, or legal guardians when obtaining informed consent.

PUBLICATIONS

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

DDSN staff is encouraged to develop training materials and conduct research consistent with sound professional practice which advances knowledge about the prevention, causes, or treatment of intellectual disability or a related disability, autism, or a head and spinal cord injury. However, all manuscripts submitted for publication which bear the facility or DDSN name and sponsorship must be approved by the State Director
prior to submission to a professional journal or publishing company. Once the manuscript has been approved by the State Director, the employee may submit the manuscript for publication.

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(Originator)

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State Director
(Approved)