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ARKANSAS DEPARTMENT OF HUMAN SERVICES  
DIVISION OF DEVELOPMENTAL DISABILITIES SERVICES  
DDS DIRECTOR'S OFFICE POLICY MANUAL

Policy Type	Subject of Policy	Policy No.
Service	Research Involving Individuals Served	3003-I

1. Purpose. This policy establishes Developmental Disabilities Services' (DDS) responsibility to protect the human rights of individuals receiving services with respect to research proposals/projects. Projects will be in compliance with Department of Health and Human Services (DHHS) Policy for Protection of Human Research Subjects.
2. Scope. This policy affects all programs operated and/or licensed by Developmental Disabilities Services, all individuals served by those programs, and all parties interested in conducting research involving those programs and individuals.
3. Research Review. Research proposals involving individuals or programs operated and/or licensed by DDS will be reviewed by a Research Review Board as outlined in DHHS Policy - 46.104 through 46.108 constituted for that purpose and convened as needed.
  - A. Community Programs - Each licensed program shall develop and have on file procedures for protection of individuals being served. The procedures shall be in compliance with the U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects.
  - B. Human Development Centers - (1) The HDC Superintendent will approve/disapprove proposals regarding psychological, medical and/or education research upon the recommendation of the Institutional Research Review Board. All Superintendent approved proposals will be forwarded to the DDS Director for review. (2) Upon approval of the DDS Director, proposals will be reviewed by the Agency Research Review Board.

NOTE: The HDC Superintendent retains the authority to refer proposals to a Research Review Board when research criteria do not apply; however, individual interest is best served by the review.

Replacement Notation: This policy replaces 3003-I previously issued, effective November 21, 1979; June 17, 1980, September 9, 1983, January 8, 1987, and March 15, 1993.

Effective Date: December 1, 1993

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References: "Regulations for the Protection of Human Research Subjects," Code of Federal Regulations 45 CFR 46, Revised as of March 8, 1983; Intermediate Care Facilities for the Mentally Retarded, Code of Federal Regulations 45 CFR 442.416.

Administrative Rules & Regulations Sub Committee of the Arkansas Legislative Council: November 4, 1993.

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4. Research Review Boards Composition. The Agency and Institutional Research Review Boards (ARRB, IRRB) will have at least five (5) members with varying ethnic and cultural backgrounds to include at a minimum, one member not affiliated with DDS or its individuals; one member who is receiving or has received services from DDS; and one member who is primarily an advocate for people with developmental disabilities. The Board may invite persons with particular expertise to assist in reviewing complex issues. The DDS Director may serve in an ex officio capacity.
5. Board Functions. The Research Review Boards convened to consider a research proposal shall:
- A. review and have authority to approve, require modifications in (to secure approval) or disapprove the proposal.
  - B. conduct continuing review of the research at intervals depending on degree of risk, but not less than once per year.
  - C. report to the Director of Developmental Disabilities Services any serious or continuing non-compliance by investigators.
  - D. recommend suspension or termination of research not being conducted in accordance with the determination of the Board or in which there is unexpected serious harm to individuals.
6. Children as Research Subjects. DHHS will conduct or fund research in which the ARRB or the IRRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual, or by a monitoring procedure that is likely to contribute to the individuals well-being only if the ARRB or the IRRB finds that:
- A. the risk is justified by the anticipated benefit to the individual;
  - B. the relation of the anticipated benefit to the risk is at least as favorable to the individuals as that presented by available alternative approaches; and
  - C. adequate provisions are made for soliciting the assent (a child's consent or affirmative agreement to participate in research) of the children and permission of their parents or guardians, as set forth in DHHS Regulations.
- In determining whether children are capable of assenting, the ARRB or the IRRB shall take into account the ages, maturity, and psychological state of the children involved.

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7. Wards. Children who are wards of the state or any other residential program, or entity can participate in research only if such research is:
  - A. related to their status as wards; or
  - B. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.
  
8. Maintenance of Records. DDS will maintain records of Board members; identities by name and qualifications; minutes of Board meetings, research progress reports; reports of injuries to the participants; and records continuing review activities for at least five (5) years after completion of the research.
  
9. Procedural Additions. The Research Review Boards will file procedural additions with the Office of the DDS Director, in accordance with DHHS Regulations for the Protection of Human Research Subjects, 45 CFR 46.

