DIVISION CIRCULAR #27
(N/A)

DEPARTMENT OF HUMAN SERVICES
DIVISION OF DEVELOPMENTAL DISABILITIES

EFFECTIVE DATE: Immediately

DATE ISSUED: July 1, 2003

I. TITLE: Research

II. PURPOSE: To establish policy and procedures for the authorization of requests to conduct research involving the Division of Developmental Disabilities (DDD) or persons receiving services. (Rescinds Division Circular #27, "Research", issued March 23, 1998.)

III. SCOPE: This circular applies to all components of the Division as well as agencies under contract with or regulated by the Division.

IV. POLICIES:

- The Division supports research activities in order to contribute to understanding, prevention and amelioration of developmental disabilities.

- All research project proposals involving persons receiving services from the Division shall be submitted to the Division and reviewed by the Chairperson of the DDD Interdisciplinary Research Committee. Final approval will be by the Division Director prior to implementation.

- All research projects shall be designed to protect individual rights in accordance with:

  N.J.S.A. 30:4-24.3 "Confidential Nature of Reports"

  N.J.S.A. 30:6D "Rights of Developmentally Disabled"

  Division Circular #30 "Access to Records and Record Privacy" (N.J.A.C. 10:41-2)

45 CFR 46.102-113 “Statement of Assurance on Research with Human Subjects”

- Findings and conclusions of research shall be made available to the Division.

V. STANDARDS:

A. **Definitions** - For the purposes of this circular, the following terms shall have meanings defined herein:

“Accepted Clinical Practice” means treatment that includes medical, psychological, psychiatric or behavioral procedures that are recognized by professionals in a particular area of service delivery (e.g., medical personnel, psychologists, behavioral modification program technicians, social workers, etc.) as effective treatment for a particular clinical diagnosis. This may be evidenced by FDA approval, citations in textbooks or peer reviewed professional journals, recognition by professional societies or organizations as acceptable practice, or other commonly used reporting mechanisms.

“Clinical Evaluation/Screening Studies” means monitoring the effectiveness of approved procedures, medications or devices.

“DDD” means Division of Developmental Disabilities.

“Division Component” means a Developmental Center, Region of Community Service, Bureau, Office or Unit of the Division’s Central Office.

“Individual Habilitation Plan (IHP)” - Refer to Division Circular #35.

“Interdisciplinary Research Committee (IRC)” means a group of no fewer than five and no more than 15 individuals representing a variety of professions who are responsible to review research proposals submitted to the Division.

“Private Agency” means an agency regulated by or under contract with the Division of Developmental Disabilities.

“Research” means the activities described below:

Level 1 Activities - Non-Experimental Designs

These activities utilize data from existing data bases or information which is regularly collected as part of the individuals' routine programming, behavioral or medical treatment plans or involve use of techniques/procedures that represent accepted clinical practice by professionals in the field. Organized data collection or use of standardized methods of service delivery during use of accepted clinical practice methods does not constitute experimental research, but is an indication of accepted professional conduct during delivery of a service and falls under the purview of quality assurance or monitoring. Examples are listed below.

a. Clinical case studies and case reports.

b. Reports of accepted clinical/habilitative treatment practices. This could include clinical evaluation/screening studies if all techniques utilized represent accepted clinical practice. Also, there could be cases where the relative effectiveness of two or more approved and effective treatments or interventions (e.g., drugs, medical procedures, behavior programs, educational practices, etc.) wish to be compared, the potential risks or side effects of each treatment are the same for the individual(s), and the clinician knows which treatment each person is receiving.

c. Initial observation and descriptive reports (e.g., identification of previously unreported syndromes, diagnoses, response patterns, or other phenomena).

d. Descriptive reports using demographic, clinical, or program data on groups to describe a subset of the population of people with developmental disabilities. Includes program descriptions, descriptions of databases, file or record systems.

e. Projects designed to develop information on a specific segment of the population of people with developmental disabilities (e.g., assembling routine medical histories of aging people or infants at risk for developmental disabilities).

f. Questionnaire or other rating scale and survey research involving persons receiving services from the Division of Developmental Disabilities.

g. Simple pretest-posttest and static group comparisons that involve no experimental control parameters. Examples include change score analyses, cost-benefit analyses, education progress reports/studies, service utilization reports, and program evaluation research.

h. Administrative experimentation projects (e.g., comparison of two living units, programs, or case management models)

i. Correlational studies on existing clinical and service database using coded, and sometimes aggregated information.

j. Retrospective utilization and outcome studies employing existing service data, or outcome studies arising from naturally occurring experiments (e.g., closing of a facility and transfer of clients to several small sites).

k. Use of non-reactive measures. Non-reactive measures are those that do not require the performance of subjects. An example would be the application of a post hoc algorithm to existing performance data; a simple example would be counting ticket sales at an event to determine peak time of attendance.

Level 2 Activities - Prospective Outcome Designs

These activities reflect the more classical experimental design techniques, utilizing such things as prospective random assignment to control and experimental treatment groups, and blind or double blind testing and evaluation of subjects. Examples are listed below.

a. Controlled prospective outcome studies.

b. Pretest-posttest control group designs.

c. Behavioral Designs including Reversals and/or Multiple Baseline techniques for research purposes.

d. Prospective, blinded or non-blinded drug or medical treatment efficacy studies.

e. Studies in which variables or treatments are systematically varied, certain experimental conditions are induced or variables are otherwise manipulated.

B. The principal investigator seeking to conduct research is affiliated with an organization that publishes ethical standards for the conduct of research.

C. The principal investigator is affiliated with or sponsored by an organization that shares responsibility for the protection of participants in research studies.

D. The Division Director reserves the right to rescind approval of a research project at any time for good cause.

E. A Division staff member may be assigned by the administrative head of the Division component in which the project is to be conducted to provide liaison with each research project.

F. Access to an individual's records or other confidential information by persons outside the Department of Human Services shall not be permitted without prior written authorization by the competent adult or the guardian of the incompetent adult or minor unless the person (or persons) requesting access to the records is(are) under contract with the Division to conduct research or program evaluation or technical assistance requiring access to this information and there is a signed assurance by this person(s) on file with the Division attesting to his/her compliance with N.J.A.C. 10:41-2.

G. When it is determined by the Division that a guardian ad litem is required in accordance with N.J.S.A. 30:6D-5a(4), the researcher shall be responsible to pay for any associated attorney fees or court costs.

H. The participation of a person receiving services in a research project shall not unduly conflict with the provision of services recommended in his/her IHP.

I. Those members of the Interdisciplinary Research Committee who are not employees of the Division may receive reimbursement for travel expenses (i.e., mileage, tolls, parking, public transportation expenses and meals). Committee members who are affiliated with an organization under contract with DDD may receive reimbursement through their agency's contract.

VI. PROCEDURES:

A. The principal investigator shall submit a written proposal to the Division Director, which outlines the purpose, nature, potential outcome(s) and possible practical or theoretical implications of the planned research.

B. Level 1 techniques are reviewed by the chairperson of the IRC but do not constitute research that require review by the full IRC or HRC. But any proposal using Level 1 techniques may be reviewed by the appropriate human rights committee if other human rights issues are present.

C. Level 2 techniques do require review by the IRC, however, the chairperson may determine that review by the full committee is not required if there is no apparent increased risk to human subjects. In this case the chairperson, in consultation with the Division's Administrative Practice Officer, may provide an expedited review of the proposal or call on other members of the IRC to provide an expedited review.

D. The chairperson of the IRC will make the determination of whether a proposed research project is Level 1 or Level 2 research.

E. Application for Permission to do Research

1. Each proposal shall be accompanied by a cover letter on official agency stationary which contains the following information:

i. Name and mailing address of the person submitting the proposal.

ii. Affiliation of the principal investigator to the Division e.g., employee, volunteer intern, no affiliation.

iii. Name and address of the organization with whom the principal investigator is affiliated including college or university.

iv. Status of approval or reviews by affiliated organization.

v. Title of research proposal.

vi. Intended site(s) of research.

vii. Reason the research is being conducted.

2. Proposal Format (These items in the proposal may be modified at the discretion of the IRC Chairperson for Level 1 Research Proposals)

i. Summary/abstract of proposal

ii. Rationale/hypothesis

iii. Methodology

a. Subject selection

b. Research design

c. Data collection procedures

d. General analyses

e. A short review (2-3 pages) of the relevant material from the professional literature with a bibliography.

f. A current curriculum vitae of the applicant. If the applicant is a graduate student or post doctoral fellow, a curriculum vitae of the sponsor shall also be submitted.

g. A statement of the expected time frame for the project.

h. A statement of the role of Division staff at the facility where the project will be conducted.

iv. Informed consent

a. Risk factors associated with research

b. Confidentiality

c. Risk to individual

d. Voluntary nature of participation and statement that the individual can withdraw at any time without fear of reprisal.

F. Interdisciplinary Research Committee (IRC)

1. The Division Director shall appoint a chairperson and up to fourteen additional members to the committee.

2. The members of the research committee shall have diverse backgrounds and represent a variety of professions such as: medicine, psychology, education and social work.

3. At least one member shall have expertise in research design.

4. At least one member shall not be an employee of the Division.

5. If there is a conflict of interest for any member of the committee, that committee member shall not be included in determining committee consensus.

6. At its discretion, the committee may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available within the committee.

7. The committee shall meet when the chairperson schedules a meeting to review a research proposal or conduct other committee business. The committee shall only conduct business when the chairperson determines that sufficient members are present.

8. The chairperson shall appoint a temporary chairperson whenever the chairperson is unable to attend a committee meeting.

9. The committee shall consider the proposal according to the following criteria of approval:

    a. The risks to the subject(s) are within acceptable limits and reasonable efforts have been made to ensure the safety of the individual.

    b. The risks to the subject(s) are reasonable in relationship to the anticipated benefits.

    c. The selection of the subject(s) is equitable.

    d. Informed consent is obtained where appropriate.

    e. The research design makes adequate provision for monitoring data collection.

    f. The research design is adequate to achieve its intended end.

    g. The research design includes adequate provisions to protect the privacy of the individual and maintain the confidentiality of the data.

    h. The research design is in compliance with the provisions of federal and state laws and regulations and conforms with acceptable ethical standards (e.g., Belmont Report, APA, AMA, etc).

10. The recommendations of the chairperson or the full committee shall be communicated in writing by the chairperson to the Division Director. If disapproved, supporting reasons shall be included.

11. The Committee may adopt such other procedures to facilitate its functioning as the group deems necessary.

G. Application for Approval

1. The chairperson or full committee shall complete its review of the proposal within 30 days of its receipt.

2. If the Level 2 research proposal has preliminary approval by the chairperson or full committee and has not been approved by a Human Rights Committee, it shall be referred to the Human Rights Committee in the Division component(s) or

private agency where the research is to be conducted. Documentation of Human Rights Committee approval will be required before final approval is granted by the IRC.

H. Human Rights Committee (HRC)

1. The HRC shall assure that the Level 2 proposal:

   a. Protects the rights and welfare of research subjects who receive services from the Division.

   b. Includes a procedure for obtaining consent to participation in research by adequate and appropriate methods;

   c. Ensures that individuals served are not used as a captive source of research;

   d. Reviews the potential risks and benefits to the participants.

2. The HRC shall assure that any agreement entered into by individual and/or guardian does not contain any waiver, release or hold harmless agreement of any kind.

3. The HRC shall make a written recommendation to the Interdisciplinary Research Committee as soon as possible but no later than 30 days after receipt of the proposal.

I. Informed Consent

Consent shall be obtained from a competent adult or guardian for a minor or incompetent adult or guardian ad litem as applicable in accordance with Division Circular #41.

J. Implementation

1. The chairperson of the IRC shall submit a written recommendation to the Division Director.

2. The Division Director shall inform the principal investigator of his decision in writing. Copies shall be sent to the chairpersons of the IRC and the HRC as well as the Administrative Head of the component.

3. The administrative head of the component may appoint a staff member to provide liaison with each research project conducted by investigators. The staff member shall set up a schedule of routine contacts with the principal investigator for a progress report. Any matters of extraordinary concern to the staff liaison shall be communicated to the administrative head of the component and the chairperson of the HRC and IRC. Corrective action(s) shall be taken by the administrative head of the component as necessary.

4. The chairperson of the Division's IRC shall maintain a summary record of approved research projects for ready reference by the Division Director.

5. The principal investigator of each completed research project shall provide three copies of a summary of the results to the chairperson of the IRC and shall highlight in a cover letter the implications of the results.

6. The chairperson of the IRC shall recommend to the Division Director how the results of completed research may be disseminated to key personnel and to other interested professionals or professional groups.

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James W. Smith, Jr., Director
Division of Developmental Disabilities