

DEPARTMENT OF HUMAN RESOURCES
SOCIAL SERVICES ADMINISTRATION
311 WEST SARATOGA STREET
BALTIMORE, MARYLAND 21201

DATE: April 17, 2008

CIRCULAR LETTER #: SSA 08 - 25

TO: Directors, Local Departments of Social Services
Assistant Directors of Social Services
Local Department of Social Services

FROM: Cathy Mols, Executive Director

RE: Use of Human Subjects in Research and Research related activities

PROGRAMS AFFECTED: All SSA Programs

ORIGINATING OFFICE: Social Service Administration/Child Welfare and Policy

ACTION REQUIRED OF: All Local Departments

REQUIRED ACTION: Implement policy and practice regarding Use of Human Subjects in Research and Research related activities

ACTION DUE DATE: Immediately
Kevin Keegan, Director

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PURPOSE

This Circular Letter outlines and clarifies the procedures to be used when considering the use of human subjects in research or research-related activities.

For the purposes of this policy, research activity includes all forms of investigation that is designed to develop, confirm or contribute to practical or theoretical knowledge to benefit children and families. Internal program evaluations and outcomes research for purposes of evaluating services and for review of legal compliance by appropriate governmental agencies, or

educational projects performed by students or interns as part of their professional training under the supervision of agency employees are not considered to be research.

FEDERAL AND STATE RESTRICTIONS

All research involving human subjects must comply with the Annotated Code of Maryland, Health General (HG) 13-2001 through 13-2004 and Federal regulations 45 CFR Part 46 and 21 CFR parts 50 and 56, as described in “The Federal Policy for the Protection of Human Subjects”. These provisions may restrict the research that may be conducted with children who are under the custody or guardianship of the agency and who have not attained the legal age for consent to treatments or procedures involved in the research, and families receiving services from the agency.

Additionally, as the result of a Maryland Court of Appeals decision, a parent or guardian may not consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is a greater level of risk of injury or damage to the health of the subject than the minimal risks inherent in everyday life.ⁱ Nontherapeutic research presents no reasonable prospect of directly benefiting the health of the individuals utilized in the research, but is designed solely to achieve beneficial results for society through the acquisition of scientific knowledge. In contrast, therapeutic research, although primarily aimed at acquiring scientific knowledge, also presents as reasonable prospect of direct health benefits to the subjects.

PROCEDURES

External agency researchers may include, but are not limited to local, state or nationally recognized researchers, as deemed appropriate by the Local Department of Social Services (LDSS) Director.

All research involving children and families served by the Department must initially be approved by the Research Review Board (RRB) of SSA. Thereafter, the SSA Director shall have the final approval on any research proposal, and no intervention or interaction with agency customers may begin until this approval has been granted.

The functions of the RRB are to: (1) review all research proposals and make recommendations to the SSA Director as to whether DHR customers should participate in the proposed research; (2) maintain a tracking or information system of all research being done involving agency customers; and (3) monitor the compliance of the researcher with the stated provisions of the research activities.

The RRB shall be composed of five members, selected by the SSA Director from the Offices of Child Welfare Practice and Policy, Research Evaluation and Systems Development, Resource Development Placement and Support Services and the Executive Office of the Director. The RRB shall also include a representative from the Office of the Attorney General. The RRB shall be convened bi-monthly.

All requests for participation by the LDSS or LDSS's customers in any research activity must be forwarded to the LDSS Director who will then forward the request to the SSA Director. The SSA Director will review the materials provided and forward them to the RRB for their consideration at the next scheduled RRB meeting. All requests for participation must include:

1. "A Summary of Proposed Research" that addresses the following issues:
 - a. Purpose or hypotheses of study
 - b. Potential knowledge to be gained. The particular relevance of this knowledge to children and families, if any, should be specified. Any potential benefit of this research to the administrators, supervisors, or other staff of the agency may also be specified in this section.
 - c. Brief Description of study methodology and design. This description should include how subjects will be involved (through observation, completing questionnaires, use of records, etc.) and, if applicable, how cultural sensitivity issues will be addressed in interviewing and interactive data collection. Also to be included are a description of the intervention and treatment and an indication of whether experimental manipulation will be involved. Medical research should indicate any drugs and the dosage to be received by both the control and experimental groups, as well as the duration of treatment.
 - d. Description of sample. This includes the legal status of the children to be involved, recruitment procedures, and inclusion and exclusion criteria. If the majority of the children to be involved in the research are in the custody or guardianship of the agency, the reason for selecting this population for the research should be explained, particularly if the research hypotheses do not address questions specific to this population. If the ethnic and gender mix of the sample is not proportionate with the population represented by the sample, the disproportionate sample should be justified. Also any difficulties presented by the sampling procedures in the generalizing of results should be addressed.
 - e. Potential risks and benefits. This section must include an assessment of the level of risk and the type of risk (physical, psychological, legal, etc.), and any determination on these issues by the relevant Institutional Review Board. Include both objective risks and risks which might be perceived by the subjects. Describe procedures through which any objective risk might be minimized, and how perceived risks will be clarified for the subjects. If appropriate, describe alternative research methods that could have been used to minimize risk, and state why they were rejected. The special conditions or protections to be provided to children for whom the agency is legally responsible and their families should be specified. If a control group is utilized, any potential risks to these subjects should be addressed as well.

- f. Consents. Procedures to obtain and document informed legal consent and, in research involving children, informed voluntary verbal or written assent. Exact details concerning the obtaining of consent must be provided, such as how parents will be contacted in cases in which parents must provide consent. Copies of the consent forms to be used must be provided.

The content of required consents must comply with applicable laws, regulations and policies, and at a minimum, must include:

- a statement that he or she voluntarily agrees to participate
- a statement that the agency will continue to provide services whether he or she agrees to participate
- an explanation of the nature and purpose of the research
- a clear description of the possible risks or discomfort
- a guarantee of confidentiality

A sample consent form is attached as Exhibit A.

- g. Incentives. Specify any incentives given to subjects.
- h. Confidentiality. Describe the procedures planned to maintain the confidentiality of records and data.
- i. Monitoring. A statement regarding the scope and frequency of information to be provided to the agency to permit the RRB to adequately monitor the compliance of the researcher with the stated provisions of the research activities.
2. Approval letters received from other Institutional Review Boards prior to submission to the agency.
3. Research that entails greater than minimal risk, but also presents a reasonable prospect of direct benefit to the subject. A certification from a physician, not involved in the research, that the subject's participation would serve their medical interests at least as well as any alternative outside the research.

The RRB shall make its recommendations to the SSA Director on each research proposal it receives within 5 business days after completing its consideration and discussion of the proposal. Its recommendations shall be based on considerations that include, but are not limited to, the following:

1. All research that involves more risk to the health of the subject than the minimal risks that are inherent in everyday life, or no expected direct benefit to the health of the subject, is prohibited.
2. Adequate provisions are made to protect the privacy of children and their families and to maintain the confidentiality of data. Statistical analyses, reports, and summaries are compiled and presented in a manner that masks the identity of the research participants. Case examples from individual case records must be prepared, prior to dissemination, in a manner that masks the individual's identity.
3. Adequate provisions are made to prevent the overuse of any one group of children based solely upon administrative convenience, availability of a population, economic disadvantage, or racial, sex, ethnic, religious or other types of discrimination.
4. Adequate provisions are stated for monitoring the customer's participation in the research.
5. Adequate provisions are made to assure that the agency has clearance over any published work that contains research results involving children or adults for whom the agency is responsible.
6. The use of financial incentives for recruiting research participants is prohibited.

The researcher will be notified by mail of the SSA Director's decision within 10 business days after the Director receives the recommendation of the RRB.

If the research is approved, a Memorandum of Agreement (MOA) must be signed by the SSA Director and the researcher before any research involving DHR customers begins.

Customers are free to refuse to participate in any form of research. Their refusal will not affect their ability to receive services offered by this agency. Customers should not be encouraged or discouraged to participate in any research activity by agency staff.

ⁱ Grimes v. Kennedy Krieger Institute, Inc., 366 Md. 29, 782 A.2d 807 (2000).

CONSENT TO PARTICIPATE IN RESEARCH PROJECT

I, _____, voluntarily agree to participate in the _____ research project on behalf of Maryland's Department of Human Resources (DHR) for a period of _____ (days/months/years). I have been informed that the nature and purpose of the project is:

and the possible risks, if any, are:

I understand that information obtained about me and my family will be kept confidential and will only be used for this project. I have not been coerced to participate in this activity nor have I been threatened with termination of service should I refuse to participate, and that I have the right to withdraw this consent at any time.

Print Name of Participant

Signature of Participant

Address

Telephone Number

Date

If the participant is a minor or an adult incapable of providing informed consent, the signature of a parent, legal guardian or other authorized decision-maker is required.

Print Name of Parent/Guardian/Other

Signature

Relationship to Participant

Address

Telephone Number

Date