

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

DATE: July 1, 2010

POLICY DIRECTIVE #: 11-05 - Replaces Circular Letter #08-25

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

FROM: Carnitra White, Executive Director

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

PROGRAMS AFFECTED: Out-of-Home Placement Services/Foster Care/Kinship Care/ Adoption/ In-Home Services

ORIGINATING OFFICE: Social Service Administration/Executive Office

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

CONTACT PERSON: Tammy Donlan
Administrative Aide to the SSA/RRB
410-767-7149
tdonlan@dhr.state.md.us

ALTERNATE CONTACT: David Ayer
410-767-8946
dayer@dhr.state.md.us

PURPOSE

This Policy Directive outlines and clarifies the procedures to be used when considering the use of service recipients of the Department as 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 adults, children and families. The following types of research activities are not covered by this policy, thus permission for these types of research may be granted by the appropriate Appointing Authority:

(1) Internal program evaluations and outcomes research for purposes of evaluating services and for review of legal compliance by appropriate governmental agencies;

(2) Educational projects performed by students or interns as part of their professional training under the supervision of agency employees and that do not require the researcher or his/her agents to make personal contact with individual recipients of services, or to have access to identifying data relating to individual recipients of services;

(3) Requests from researchers to interview or administer surveys to individual local department or Central Office staff which can be approved by the appropriate Appointing Authority. However, such requests concerning multiple jurisdictions will require Research Review Board (RRB) review and SSA Executive Director approval with final permission granted by the local Appointing Authority.

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.¹ 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 a reasonable prospect of direct health benefits to the subjects.

REGULAR 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 adults, children and families served by the Department that does not fall with the exempted categories of research as stated above, must initially be approved by the Research Review Board (RRB) of SSA. Thereafter, the SSA Executive Director, or Deputy Executive Director in the absence of the Executive 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 on 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 and designated alternates who shall act if the regular member is unable to review an emergency request or is out of the office for an extended period of time. Four of the members shall be selected by the SSA Executive 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. The RRB shall also include a representative from the Office of the Attorney General. The RRB shall be convened monthly. Generally, the RRB meets on the first Wednesday of every month. All requests for RRB review must be received by SSA one week prior to that date in order to receive full consideration.

Requests for participation by a particular LDSS or LDSS's customers in any research activity may be forwarded to the LDSS Director in the jurisdiction providing services to the prospective participants in the study who will review the request and forward it to the SSA Executive Director. On the other hand, a request for participation by LDSS customers may be sent directly to the SSA Executive Director

All requests for statewide, individualized data or participation of more than one LDSS or LDSSs customers should be sent to the SSA Executive Director.

The SSA Executive 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 a discussion of the following items or they will not be considered. It is strongly suggested that attached format, Exhibit A, be used to discuss these items to insure they are adequately covered.

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 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 B.

- 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 Executive Director on each research proposal it receives within 10 business days after completing its consideration and discussion of the proposal which may include a request for additional information from the requestor. 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 an opportunity, prior to publication, to review and make comments on any published work that contains research results involving children or adults for whom the agency is responsible.
6. The use of reasonable and minimal financial or other incentives for recruiting research participants is allowed subject to a final determination by the RRB and upon approval by the SSA Executive Director.

The researcher and, where appropriate, the relevant LDSS Director(s) will be notified by mail of the SSA Executive Director's decision within 10 business days after the Executive Director receives the recommendation of the RRB.

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

If the research involves the participation of a local department's clients (and not, for example, data exchanges of matches which can be performed solely by SSA), the participation in and implementation of the research remains under the purview of the local department director. Additionally, in cases where the local department is the legal and/or medical guardian for a prospective participant in the research, the local department director or designee must sign the appropriate consent forms. When appropriate, the RRB may forward the research proposal to the relevant local department director prior to RRB approval in order to expedite the obtaining of consents on behalf of prospective participants.

EMERGENCY PROCEDURES

There may be occasions when the health of a services recipient would be seriously endangered unless he or she is immediately enrolled in a research study that may provide a direct health benefit to the participant, but may also pose a greater than minimal risk. In such cases, the time required to obtain approval from the RRB and the SSA Executive Director or Deputy Executive Director, as outlined above, may create a delay in treatment that significantly worsens the individual's condition. These occasions may be rare, but the agency needs to have procedures in place to expedite the normal approval process in such cases.

On these occasions, a researcher may request an emergency decision from the agency by sending an email to both SSA contact persons listed on page 1 of this Policy. The email should state why this request for participation must be considered on an expedited basis, and should include as much of the information that is normally submitted in the "Summary of Proposed Research" as is available, preferably using the attached format.

The contact person will determine the emergent nature of the request and, if found to be so, shall convene a meeting of the RRB to discuss and decide upon the request. In order to expedite the obtaining of the appropriate consents in the event the study is approved, the contact person shall also alert the relevant LDSS Director of the emergency request for participation. The RRB may meet in person, by conference call or e-mail to consider the request, and will thereafter forward the RRB recommendation to the SSA Executive Director, or designee, for final approval.

This process will be completed within 24 hours of the receipt of the request.

The only exception to this emergency policy would be where the immediate health and safety of a child would be endangered by delaying, however briefly, entry into a clinical trial and such treatment has been ordered by a court of competent jurisdiction. In this case, the RRB and the SSA Executive Director should be notified in writing about the circumstances of enrollment within 10 business days.

PARTICIPATION IS TOTALLY VOLUNTARY

Recipients of the Department's services are completely free to refuse to participate in any form of research. Their refusal will not affect their ability to receive services offered by the Department. 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).

Exhibit A

**Department of Human Resources - Social Services Administration
Research Review Board
Submission Form**

Requestor: _____

Date: _____

Brief Title of Study: _____

Purpose or hypotheses of study:

Potential knowledge to be gained:

Brief description of study methodology and design:

Description of sample:

Potential risks and benefits:

Consents:

--

Incentives:

--

Confidentiality:

--

Monitoring:

--

Exhibit B

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