DELAWARE CHILDREN'S DEPARTMENT POLICY

POLICY #117	SUBJECT: Participation of DSCYF Clients in Research
EFFECTIVE DATE: June 4, 2008 REVISED DATE: 6/19/14	PAGE 1 OF 5
AUTHORIZED SIGNATURE	

PARTICIPATION OF DSCYF CLIENTS IN RESEARCH

I. PURPOSE

The purpose of this policy is to assure the safety and the rights of children in the care and custody of the Department of Services for Children, Youth and Their Families (DSCYF) when/if there is a request for them to participate as subjects in research protocols. Such requests require the review and approval of the proposed research protocol by an Institutional Review Board (IRB).

DSCYF recognizes that research and evidence-based practice contribute to the development of safe and effective interventions for children and their families. The DSCYF population is inherently vulnerable, however, and thus warrants special protections. Research using DSCYF clients as human subjects will not be permitted without documentation of safeguards as specified in the Procedures outlined in this policy.

This policy applies to all workers employed or contracted by DSCYF and to all Contractors who are providing services to children and families under DSCYF funding.

II. DEFINITIONS

A. *Client* – Any minor child (under the age of 18) who is active with DSCYF.
B. *Institutional Review Board (IRB)* – A panel of experts in the content areas of potential research who have the education, training and experience to review research protocols pursuant to the requirements of the United States Department of Health and Human Services Office for Human Research Protections (OHRP). Most universities and hospitals have IRBs as do some large governmental agencies. In addition, there are corporate proprietary entities that are approved through OHRP which provide IRB services.
C. *Human Subjects Research* – Research meeting the definition below in which project staff obtain data from people by intervening or interacting with them.
D. *Protocol* – The procedures by which an investigator proposes to test a research hypothesis. A protocol often includes terms for recruitment of subjects (e.g. sample size, criteria for excluding or including prospective subjects); data-gathering (e.g. self-report questionnaires, physiological or biological measures); consent for participation (e.g., language in the consent forms that is at an appropriate reading level for the persons who must sign the consent forms, the terms of confidentiality, an explanation of how the data

will be used); the conditions to which subjects will be exposed (e.g. treatment); and potential risks vs. benefits of participation.

E. *Research* - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

IIII. TYPES OF RESEARCH AND RELATIVE RISK TO DSCYF CLIENTS

A. Level 1- Little or No Risk to Clients
This level of research may examine existing aggregate data or may propose to develop data-gathering processes to do outcome studies on an existing program. It does not involve identifiable confidential client information, except for aggregate reporting. There is no interaction between project staff and individual clients for purposes of gathering data upon which to draw conclusions. The following are requirements for Level 1 research:

1. Use of non-identifiable aggregate DSCYF/Division data/information by DSCYF employees may be approved for research at the level at which the data are produced within the DSCYF. Approval must be documented.
2. Release of non-identifiable aggregate DSCYF/Division data for use by researchers outside DSCYF must be documented by the Cabinet Secretary for Department data and the Division Director for Divisional data.
3. Researchers may publish their own non-identifiable aggregate data if this information is not the product of contractual reporting requirements. If the program is fully funded by DSCYF, the data must first be approved by the contracting Division(s). The name of the program, Division and Department must be acknowledged in the publication.

B. Level 2- Minimal Risk to Clients
This level of research may look at the effects of an existing or proposed program that uses methodology already accepted within mainstream practice (e.g. trauma-focused cognitive behavior therapy, functional assessment of infants or toddlers in foster care before and after foster parents receive specialized training, classroom management techniques). The following are requirements for Level 2 research:

1. If a DSCYF Program Administrator/Contract Manager receives a request from a Contractor to perform research in a DSCYF program, using DSCYF clients at any level, he/she may provide permission if the following are documented: (1) the Contractor provides a copy of the IRB review and approval for the research protocol, and (2) the proposed research is intended to support the development of evidence-based practices in the program and can be reasonably expected to improve the quality

of services to be provided, and (3) The Division Director or his/her designee is consulted and approves in writing.

2. When DFS holds parental rights for a child, a worker may sign informed consent for the child's participation in research if : (1) DFS documents receipt of a copy of IRB review and approval which acknowledges 45 CFR § 46.409: Participation of children who are wards of the state, and (2) The Division Director or his/her designee provides written approval either for a specific child to participate, or in the case of an entire program being provided under Departmental auspices, for an entire class of children to participate.

3. When DFS holds legal custody but does not hold parental rights for a child, a worker may sign informed consent for the child's participation in research if they document:
   (a) That DFS has received a copy of IRB review and approval, and
   (b) DFS has documented recent efforts to locate the person who holds parental rights without success, and that failure to sign consent would deprive the child of a service that would benefit him/her or children in similar circumstances, and (3) The Division Director or his/her designee provides written approval either for a specific child to participate, or in the case of an entire program being provided under Departmental auspices, for an entire class of children to participate.

C. <u>Level 3- Moderate Risk to Clients</u>
This level of research may use certain types of untried non-invasive diagnostic procedures or treatment techniques. It usually requires assignment of a client to a test condition or to a control-group that will not experience the test condition. There is interaction between project staff and individual clients that:

1. Has the potential for some level of physical or emotional discomfort or uneasiness
2. May assign a client to a group not receiving the expected benefit of the treatment/technique
3. May introduce a risk of harm that is greater in terms of magnitude or probability than what is usually encountered in daily life

The following are requirements for Level 3 research:

1. All requests for DSCYF client participation in research at this level must go through the Division Director who will examine the IRB review and approval and weigh the risks and benefits to clients, and seek appropriate professional advice including consultation with the Cabinet Secretary if required before making a decision.
2. The Division Director will designate in writing, what if any DSCYF worker may sign informed consent for a client's participation where parents are not available.

D. Level 4- Greater than Moderate Risk to Clients
This level of research applies to clinical trials for medication, untried diagnostic medical and surgical procedures. On very rare occasions, an individual child for whom DFS holds parental rights may have a serious medical condition in which failure to provide an experimental treatment would result in serious physical impairment or death. These are the only situations in which a DSCYF client may participate in research at this level of risk. On these occasions, only the Cabinet Secretary, or his/her designee may provide permission. This permission must be documented.

IV. PROCEDURES

A. The following are prohibited:
1. At no time will there be a direct or implied requirement for parents involved with DSCYF to be required to sign consent for their child to participate in research. Participation of clients in research must be free from coercion or the appearance of coercion.
2. At no time will there be a direct or implied requirement for any client to participate in research in exchange for positive consideration from Department staff.
3. Because information regarding HIV status, sexually transmitted diseases (STDs) and pregnancy is strictly regulated by Delaware Statute (ref: 16 Del. C §710; 711; 712 and 16 Del. C Section 120-1232) and because assuring the confidentiality of DSCYF clients is paramount (Reference DSCYF Policy #205), DSCYF will not participate in research where eligibility to participate in research is based on HIV status, pregnancy or having an STD.

B. For all levels of research beyond Level 1, whether performed internally by Department staff or externally by other researchers, DSCYF clients may not be considered for participation until the research protocol is reviewed and approved by an Institutional Review Board (IRB) that meets all the federal requirements as an IRB; approval by the IRB must be documented.

C. Participation in research must be with full informed, written consent of the legal authorized representative which has an expiration date of no more than one year and must be renewed at that time. When a child is to be the subject this is usually a parent or legal guardian. Signed consent may be revoked by the parent or legal guardian at any time. For youth in DYRS secure care, consent must be obtained from the parent or legal guardian (i.e. DYRS may not consent to participation on behalf of the parent or guardian). For youth involved with DFS:
1. When DFS holds parental rights, the DFS worker may sign the informed consent under the conditions listed within this policy
2. When DFS holds custody but not parental rights, the DFS worker may sign the informed consent under the conditions listed within this policy

D. Whenever the nature of the project and the developmental level of the youth permits, the youth should have the opportunity to assent to participation in research in addition to the consent by the legally authorized person.

E. Participation of clients in research in which individual identifiable information will be gathered and analyzed must be with the assurance that privacy and confidentiality will be maintained pursuant to Federal, State, Departmental and professional standards. No personally identifiable information regarding DSCYF clients may be shared in oral or written discussion of the research study including reporting of research findings.

F. Client participation in research should provide a reasonable expectation that the participation is likely to yield some direct benefit to the subject and/or that the knowledge generated by the project has the potential to benefit other children/adolescents.