



Administrative Policies and Procedures: 1.33

Subject:	Research Proposals
Authority:	TCA 37-5-105, TCA 37-5-106, TCA 37-5-107, TCA 37-5-112, TCA 37-5-113, TCA 37-5-115, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Standards:	ACA: 3-JTS-1F-02, 3-JTS-1F-03, 3-JTS-1F-04, 3-JTS-1F-05, 3-JTS-1F-06, 3-JTS-4C-45; COA: PA ETH 6.01, 6.02, 6.03
Application:	To All Department Children's Services Employees, youth, family/children clients, volunteers, all persons requesting research information or data not already in the public domain and all persons requesting and/or participating in the conduct of research activities within the scope of the department.

Policy Statement:

The Department of Children's Services shall adhere to State and Federal Rules and Regulations and Laws and shall provide structure to protect the confidentiality and ensure the safety of potential participants while providing support for **research** efforts.

Purpose:

The Department of Children's Services supports and cooperatively engages in research initiatives that contribute to the establishment of future goals and objectives or that contribute to more effective, efficient and economical departmental operation or services delivery. The Department is ethically and lawfully motivated to provide participation guidelines which ensure safety and confidentiality for the children/youth in its care as well as any participating staff.

A. Scope

1. The Department of Children's Services may receive requests for DCS employees and/or children/youth/families supervised by the department to participate in an external research or evaluation project.
2. Any employee or client asked to voluntarily participate in a research project shall be free to participate or decline of his/her own free will.
3. Refusing to participate in any research project shall not affect any benefits to which employees, clients or participants are otherwise entitled, and no one shall ever be required to participate in a research study.
4. In research studies where applicable law, standards, regulations, or policy would necessitate the subject's informed consent, those electing to participate shall sign DCS form **CS-0334, Request for Access to Human**

	<p>Subjects or Records Which May Involve Informed Consent, that complies with all provisions established under <i>Title 45 Part 46</i> of the Code of Federal Regulations.</p> <ol style="list-style-type: none"> 5. In accordance with <i>45 CFR 46.4.09</i> and <i>21 CFR 50.56</i>, an advocate must be appointed for each child who is DCS custody, who participates in research. Any time a child in foster care is used as a subject of clinical research, it is imperative that the rights of the child are protected through the appointment of an independent advocate and consent from a guardian. If the child already has an attorney or Guardian at Litem (GAL), that person can serve in that capacity, but they must be informed about the research and involved in the decision to include the child. 6. This policy shall apply to all research activities or proposals involving use of human subjects or access to confidential records and data (see DCS policy <u>9.5, Access and Release of Confidential Child-Specific Information</u>), archival research not requiring access to confidential records or human subjects by persons who do not have customary access to such information as part of their job duties, and requests for research data or information not already in the public domain or covered by applicable state law. 7. No proposed research or evaluation project shall interfere with a Department of Children's Services employee carrying out his/her normal and customary assigned duties, nor shall any proposed project conflict with applicable State law, Federal Regulations, American Correctional Association (ACA) or Council on Accreditation (COA) standards regarding use of human subjects for research purposes. 8. This policy shall not interfere with the Department of Children's Services or a contracted agency from conducting necessary program evaluation studies of existing or proposed programs provided the study does not conflict with applicable state law, federal regulations, or ACA standards regarding use of human subjects for research purposes. When a new external evaluation is planned, the Director of Evaluation and Monitoring will be informed and the evaluation plan submitted to the Evaluation and Monitoring division for review and approval. 9. This policy shall not interfere with the Department of Children's Services from instituting pilot programs used to determine how proposed operational changes will impact public safety or departmental operations. 10. A list of all proposal requests and on-going research or evaluation studies will be maintained by the Director of Evaluation and Monitoring.
<p>B. Research Review Committee and Proposal Review Process</p>	<ol style="list-style-type: none"> 1. The Department of Children's Services will maintain a Research Review Committee (RRC) to review research proposals and make recommendations to approve or disapprove the proposal. The members of the RRC will be as follows: <ol style="list-style-type: none"> a) Deputy Commissioner of Administration and Training/Designee (Advisor), b) Director of Evaluation and Monitoring/Designee (Chair), c) Designated Legal Staff,

	<ul style="list-style-type: none">d) Designated Data Quality Staff,e) Other appropriate staff relevant to the research subject matter, and/orf) Other members as appointed by the Commissioner. <p>2. The chair of the committee, will convene a RRC to review all research proposals which involve:</p> <ul style="list-style-type: none">a) Access to records, reports, files, or databases by individuals who would not typically have access to this information as part of their customary job duties;b) Access to confidential records (e.g., medical or mental health records) where issues such as informed consent must be considered;c) Access to use human subjects for research purposes where issues such as informed consent must be considered;d) All other requests to conduct activities considered research from individuals outside the department of children's services or from employees whose job duties do not typically involve this activity. <p>3. A decision of approval or disapproval of the request will be based on the RRC's discussion and consideration of at least following factors:</p> <ul style="list-style-type: none">a) Applicable state law, federal regulations, Council on Accreditation (COA), and American Correctional Association (ACA) standards;b) The purpose for which the information is to be used and benefits to the department;c) Ability to provide the requested information,d) Cost (time and staff resources) of providing the requested information,e) Feasibility, merit, potential outcome, and benefit of the research. <p>4. The DCS Research Review Committee (RRC):</p> <ul style="list-style-type: none">a) May also require independent approval or exemption of the research proposal by an outside Institutional Review Board (IRB) as defined in the <i>Department of Health and Human Services - Title 45 Part 46, Protection of Human Subjects</i> code of federal regulations and must require IRB review where the CFR regulations require such review (as in research which requires informed consent or presents more than "minimal risk" to participants).b) Shall ensure the research proposal complies with all applicable state laws, federal regulations, COA and ACA standards.c) Shall disseminate copies or summaries of the research proposal to all deputy commissioners, directors, superintendents, or other agency management whose duties or responsibilities would be affected by the research proposal, for purposes of review and comment.d) Shall recommend disapproval of any research proposal disapproved by the affected manager.
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	<ol style="list-style-type: none"> 5. In no case shall the DCS RRC recommend approval of research proposals that violate existing state laws, federal regulations, COA or ACA standards. Specifically prohibited from approval is any research that uses children in the custody or guardianship of DCS for medical, pharmaceutical, or cosmetic experiments, or use of medications such as stimulants, tranquilizers, or psychotropic drugs administered for purposes of program management and control or for purposes of experimentation and research. 6. The Director of Evaluation and Monitoring shall notify the Principal Investigator as to whether the proposal was approved or disapproved by the committee, and may suggest amendments or changes that would affect this decision and need for resubmission. 7. In all cases, the Commissioner shall receive the committee’s recommendation and will give the final decision regarding approval or disapproval of research proposals. 8. Not applicable to this research policy are medications prescribed when clinically indicated as one facet of a program of therapy, or in cases of necessary medical procedures which may not be generally available but are not a part of a general program of medical experimentation.
<p>C. Proposal Submission</p>	<ol style="list-style-type: none"> 1. Requests for information, data, or statistics which are not already in the public domain, do not involve use of human subjects for research purposes, and do not involve access to any records or files such as departmental or institutional files or records typically not available to the public, shall be submitted on form CS-0541, Requests For Information, and submitted to the Director of Evaluation and Monitoring or designee. 2. A research request must follow procedures developed by the RRC to obtain all necessary information required to recommend approval or disapproval of research proposals. If the research involves human subjects or existing records and data with identifying information, the Principal Investigator must complete the appropriate form CS-0334, Requests for Access to Human Subjects or Records Which may Involve Informed Consent or CS-0542, Research Involving Study of Existing Records or Data that are required for the purpose of confidentiality prior to the research activities. 3. The information required on the form(s) includes: <ol style="list-style-type: none"> a) Identifying information about the investigator(s), institutional affiliation, and research credentials; b) Purpose of the research project; c) Proposed research methodology; d) Risks and benefits to the research subjects (if applicable); e) Cost versus benefits to the department; f) Other potential benefits of the research; g) Issues impacting confidentiality of the records or data and preserving anonymity of the research participants;

	<ul style="list-style-type: none"> h) Plan for obtaining informed consent (if applicable); and i) Agreement to furnish DCS with research results for review and comment by the appropriate department heads and/or facility administrator prior to publication or dissemination as required by ACA standards.
<p>D. Research activities</p>	<ol style="list-style-type: none"> 1. If approved, the Department shall allow a research project to commence subject to informed consent of the research subjects if applicable. <ol style="list-style-type: none"> a) The Principal Investigator and all research team members are responsible for maintaining confidentiality of the research data and/or subject responses, anonymity of the research participants, conducting themselves within the boundaries of the approved research protocol, and compliance with all applicable state laws, federal regulations, COA and ACA standards, and departmental policy. b) Violation may lead to discontinuance of the current research and/or future research, or subject the violator to civil or criminal penalties. c) The Director of Evaluation and Monitoring or his/her designee must approve any changes to the approved research protocol in writing prior to implementation and the Principal Investigator shall be responsible for obtaining written approval before implementing any changes. 2. Upon completion of the research project, the Principal Investigator shall furnish the Director of Evaluation and Monitoring or his/her designee a copy of any results, findings, reports, or conclusions prior to publication or dissemination. 3. The Director of Evaluation and Monitoring or his/her designee will submit copies of all research results to the appropriate deputy commissioner, regional administrator, and facility superintendent/DCS residential facilities director for purposes of review and comment.

<p>Forms:</p>	<p><u>CS-0334, Requests for Access to Human Subjects or Records Which May Involve Informed Consent</u></p> <p><u>CS-0541, Requests For Information</u></p> <p><u>CS-0542, Research Involving Study of Existing Records or Data</u></p>
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<p>Collateral Documents:</p>	<p>Department of Health and Human Services - Title 45 Part 46 Protection of Human Subjects <u>http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm</u></p>
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