Administrative Policies and Procedures: 1.33

Subject:	**Research, Surveys, Grant Proposals**
Authority:	TCA 37-5-105 (3), 37-5-106, 37-5-107, 37-5-115, 37-1-612 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Standards:	**COA:** PA ETH 6.01, 6.02, 6.03
Application:	All persons requesting approval for research projects or data not already in the public domain; all persons requesting a letter of support or memorandum of understanding for grant applications within the scope of the department; and all persons requesting to survey DCS employees, clients, and/or stakeholders.

Policy Statement:

The Department of Children's Services (DCS) adheres to all State and Federal Rules and Laws that protect the confidentiality of clients and client records when providing support for research and funding requests for information including data and survey results. DCS supports and cooperatively engages in research, surveys and grant proposals that contribute to public policy, best practice and improved service delivery.

Purpose:

To provide guidance on how to submit proposals for approval.

Procedures:

A. Scope

1. In research studies where applicable law, standards, regulations, or policy would necessitate the subject's informed consent must comply with all provisions established under *Department of Health and Human Services* - Title 45 Part 46, Protection of Human Subjects Code of Federal Regulations.
2. In accordance with *45 CFR 46.4.09* and *21 CFR 50.56*, an advocate is appointed for each child who is in 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 ad 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.

	3. This policy applies to all research, survey, and grant activities or proposals involving use of human subjects or access to confidential records and data archival research proposals requesting information from 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. (see DCS Policy ***9.5 Access and Release of Confidential Child-Specific Information***) 4. No proposed research, survey or evaluation project will interfere with a DCS employee carrying out his/her normal and customary assigned duties, nor will any proposed project conflict with applicable State and Federal Rules and Laws or applicable accreditation standards regarding use of human subjects 5. Proposed and/or approved research, survey or evaluation projects will not interfere with DCS or a contracted agency conducting necessary program evaluation studies of existing or proposed programs provided the study does not conflict with applicable State and Federal Rules and Laws or applicable accreditation standards regarding use of human subjects for research purposes. Instead, this policy provides guidance and oversight to ensure program evaluation occurs at a quality level. 6. Proposed and/or approved research, survey or evaluation projects will not interfere with DCS instituting pilot programs used to determine how proposed operational changes impact public safety or departmental operations. 7. A list of all proposal requests, including on-going research, surveys, grants or evaluation studies is maintained by the Office of Continuous Quality Improvement. 8. Any employee or client asked to voluntarily participate in a research project or survey is free to participate or decline. 9. Refusing to participate in any research project or survey will not affect any benefits to which employees, clients or participants are otherwise entitled, and no one is ever required to participate in a research study.
B. Research, Survey and Grant Review Committee and Proposal review process	1. DCS maintains a Research, Survey and Grant Review Committee (RSGRC) to review research, survey or grant proposals. This committee makes decisions to approve or disapprove the proposal. The members of the RSGRC are: a) Assistant Commissioner of Continuous Quality Improvement /designee; b) Designated Legal staff; c) Designated Continuous Quality Improvement staff; d) Other appropriate staff relevant to the research/survey/ grant subject matter; and/or e) Other members as appointed by the Commissioner. 2. The chair of the committee convenes members of the RSGRC to review research, survey or grant proposals which involve: 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 or confidentiality agreements 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 DCS or from employees whose job duties do not typically involve this activity;

e) Surveys involving children and youth where issues such as parental consent must be considered;

f) Surveys involving DCS employees; or

g) Grant proposals requesting a letter of support or memorandum of understanding from DCS.

3. A decision of approval or disapproval of the request is based on the RSGRC's discussion and consideration of at least one of the following factors:

a) Applicable State and Federal Rules and Laws or applicable accreditation standards;

b) The purpose for which the information is to be used and benefits to DCS;

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/survey/ grant and/or results;

Note: The decision of the committee is considered discretionary and final.

4. The DCS Research, Survey and Grant Review Committee:

a) May require independent approval or exemption of the research/ survey/grant proposal by an outside Institutional Review Board (IRB) as defined in the *Department of Health and Human Services - Title 45 Part 46, Protection of Human Subjects* 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) Ensures the research/survey/ grant proposals comply with all applicable State and Federal Rules and Laws or applicable accreditation standards.

c) Disseminates copies or summaries of the research/survey/grant proposal to deputy commissioners, directors, superintendents, or other DCS management, whose duties or responsibilities are affected by the research proposal, for purposes of review and comment.

5. The DCS RSGRC does not approve research proposals that violate existing State and Federal Rules and Laws or applicable accreditation 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 Assistant Commissioner of Continuous Quality Improvement/designee notifies 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.
B. Proposal submission	1. If the request is for a grant only and does not require a letter of support or request for data, the Principal Investigator completes the appropriate DCS form ***CS-1059, Research, Survey, and Grant Request*** (Basic Information and Section A). 2. If the requestor already accessed public information and needs additional information/statistics, the Principal Investigator completes ***CS-1059, Research, Survey, and Grant Request*** (Section B, Basic information). 3. Requests for information, data, or statistics that involve use of human subjects and/or confidential records that may require informed consent are submitted on form CS-***1059, Research, Survey, and Grant Request*** *(*Basic Information and Section C)*,* and submitted to the Assistant Commissioner of Continuous Quality Improvement /designee. 4. If the research/survey/grant involves existing records and data with identifying information that does not require informed consent, the Principal Investigator completes the DCS form ***CS-1059*, *Research, Survey, Grant, and Survey Request*** Basic Information and Section D, as applicable. A signed confidentiality agreement form may also be required. 5. Persons wanting to survey DCS employees are required to provide: a) A completed ***CS-1059, Research, Survey, Grant, and Survey Request*** and may be asked to complete the additional "***Work Aid for Developing Quality Research and Surveys***" supplemental to this policy; and b) A copy of the survey.
D. Research and survey activities	1. If approved, DCS allows research and survey projects to commence subject to submission of signed confidentiality agreement forms and informed consent of the research subjects, if applicable. 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 and Federal Rules and Laws or applicable accreditation 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 Assistant Commissioner of Continuous Quality Improvement/designee approves any changes to the approved research protocol in writing prior to implementation and the Principal Investigator is responsible for obtaining written approval before implementing any changes. d) In the event an adverse effect is experienced during the research study that requires the outside IRB to be notified; the principle investigator is also responsible for notifying the DCS Assistant Commissioner of Continuous Quality Improvement/designee. 2. Upon completion of the research or survey project, the Principal Investigator furnishes the Assistant Commissioner of Continuous Quality Improvement/ designee a copy of any results, findings, reports, or conclusions prior to publication or dissemination. 3. The Assistant Commissioner of Continuous Quality Improvement/designee submits 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.

Forms:	***CS-1059 Research, Survey and Grant Request***

Collateral Documents:	***Department of Health and Human Services - Protection of Human Subjects - Title 45 Part 46*** ***Work Aid for Developing Quality Research and Surveys*** **Policy *9.5 Access and Release of Confidential Child-Specific Information***