Administrative Policies and Procedures: 1.33

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<td>COA: PA ETH 6.01, 6.02, 6.03</td>
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<td>Application:</td>
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**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 and data requests that contribute to public policy, best practice and improved service delivery.

**Purpose:**

To provide guidance on how to submit Research and Data Requests 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.

   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 and data requests 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.
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or covered by applicable state law. (see DCS Policy 9.5 Access and Release of Confidential Child-Specific Information).

4. No proposed research or data request 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 or data request 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 and data requests 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 requests, including on-going research projects is maintained on an internal tracking log.

8. Any employee or client asked to voluntarily participate in a research project is free to participate or decline.

9. Refusing to participate in any research project 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 Request Submission Process

1. Complete form CS-1059, Research Request Form and submit the form to EI_DCSResearch_and_Data_Request@tn.gov.

2. A decision of approval or disapproval of the request is based on the discussion and consideration of at least one of the following factors:
   - Applicable State and Federal Rules and Laws or applicable accreditation standards;
   - The purpose for which the information is to be used and benefits to DCS;
   - Ability to provide the requested information;
   - Cost (time and staff resources) of providing the requested information, including the frequency the data will need to be provided;
   - Feasibility, merit, potential outcome, and benefit of the research project and/or results.

Note: Requests are reviewed once a month; therefore, decision notification may take at least one month. The decision is determined by the Commissioner and/or the Commissioner’s designee and is considered discretionary and final.
3. DCS:
   - 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).
   - Ensures the research projects comply with all applicable State and Federal Rules and Laws or applicable accreditation standards;
   - Disseminates copies or summaries of the research projects 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.

4. DCS 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.

5. The Commissioner’s designee notifies the Principal Investigator as to whether the proposal was approved or disapproved and may suggest amendments or changes that would affect this decision and need for resubmission.

C. Completing Form CS-1059

1. If the requestor already accessed public information and needs additional information/statistics, the Principal Investigator completes CS-1059, Research Request Form, (Section A, Basic information).

2. 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 Request Form, (Basic Information and Section B) and submitted to the Commissioner’s designee.

3. If the research involves existing records and data with identifying information that does not require informed consent, the Principal Investigator completes the DCS form CS-1059, Research Request Form, (Basic Information and Section C) as applicable. A signed confidentiality agreement form may also be required.

D. Research Activities

1. If approved, DCS allows research 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 Commissioner’s 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 principal investigator is also responsible for notifying the Commissioner’s designee.

2. Upon completion of the research project, the Principal Investigator furnishes the Commissioner’s designee a copy of any results, findings, reports, or conclusions prior to publication or dissemination.

3. The Commissioner’s designee submits copies of all research results to the appropriate deputy commissioner, regional administrator, and facility superintendent for purposes of review and comment.

### E. Data Request Submission Process

Data requests not to be used for research purposes and available in the TFACTS system are to be completed on form **CS-4208, Data Request Synopsis**. Submit the form to: **EI_DCSResearch_and_Data_Request@tn.gov**.

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

   - Applicable State and Federal Rules and Laws or applicable accreditation standards;
   - The purpose for which the information is to be used and benefits to DCS;
   - Ability to provide the requested information;
   - Cost (time and staff resources) of providing the requested information, including the frequency the data will need to be provided;
   - Feasibility, merit, potential outcome, and benefit of the research project and/or results.

**Note:** Requests are reviewed once a month; therefore, decision notification may take at least one month. The decision is determined by the Commissioner and/or designee and is considered discretionary and final.

2. If approved, DCS routes the requested data to the STS contact person to pull the data and the data will be provided to the requestor.
| **Forms:**       | CS-1059, Research Request Form  
|                 | CS-4186, Research Request Synopsis  
|                 | CS-4208, Data Request Synopsis  |

| **Collateral Documents:** | Department of Health and Human Services - Protection of Human Subjects - Title 45 Part 46  
|                           | Policy 9.5 Access and Release of Confidential Child-Specific Information  |