STATE of NEW JERSEY
OFFICE of the STATE MEDICAL EXAMINER
SUDDEN INFANT DEATH SYNDROME and
SUDDEN UNEXPLAINED DEATH IN INFANCY and CHILDHOOD
RESEARCH TISSUE REQUEST PROTOCOL

I. Introduction

The Sudden Infant Death Syndrome and Sudden Unexplained Death in Childhood (SIDS/SUDC) Research Tissue Request Protocol has been developed by the Office of the State Medical Examiner (OSME) in consultation with the Commissioner of the Department of Health and Senior Services (DHSS) and the Sudden Child Death Autopsy Protocol Committee (SCDAPC). This protocol delineates required procedures for all medical research activities in the State of New Jersey involving medical examiners and duly approved and authorized research projects for the purpose of identifying potential causes of SIDS/SUDC.

This protocol is to be utilized in the collection and use of tissue, including FTA blood cards as may be requested in a particular project, and other identifying information on all autopsies in which the suspected cause of death of an infant under the age of one year of age (hereinafter “decedent”) is SIDS and the suspected cause of death of a child three years of age and under (hereinafter “decedent”) is not considered a violent death. However, tissue will not be collected from a decedent whose legal guardian has objected to an autopsy because it is contrary to the religious beliefs of the decedent.

According to N.J.S.A. 52:17B-88.11, the State Medical Examiner, county medical examiner, or other authorized person (hereinafter “medical examiner”) is authorized to collect tissue from a decedent and to transfer tissue to an approved research project before obtaining the consent of the parent or legal guardian (hereinafter “legal guardian”).

1. The information provided is in accordance with N.J.S.A. 52:17B-88.11, and as such, provides the legal basis of obtaining SIDS/SUDC research tissue. This act provides that the OSME, medical examiner, the SCDAPC, their employees and other persons authorized by the OSME to provide tissue samples and identifying information to the research project shall not be civilly liable for damages for complying in good faith with the act’s provisions. N.J.S.A. 52:17B-88.11e.

2. Sudden Infant Death Syndrome (SIDS) is defined as the sudden death of an infant one year or younger which is unexpected and after a thorough postmortem examination including an autopsy, death scene investigation, and review of the infant and family’s medical history, fails to identify an adequate cause of death. Sudden Unexplained Death in Childhood (SUDC) is defined as the sudden death of a child one year or older which is unexpected and after a thorough postmortem examination including an autopsy, death scene investigation, and review of the child and family’s medical history, fails to identify an adequate cause of death.

3. Violent deaths include deaths caused by apparent homicide and other suspicious deaths.

4. Authorized person is defined as a duly licensed and physician qualified and determined eligible to perform autopsies in the New Jersey medical examiner system and may include State and County Medical Examiners, deputy, assistant or associate medical examiners, designated pathologists and forensic pathology fellows.
Upon receipt of notification that the research project has obtained written consent from the legal guardian, the medical examiner is further authorized to provide to the research project relevant data including the autopsy report and other ancillary reports prepared by the medical examiner.

This protocol applies to a Principal Investigative Researcher (PI) who is making application for or has received approval from authorities delineated herein to conduct medical research on decedent tissue to potentially identify genetic, biochemical or other causes of death. Applications are considered only for research projects involving utilization of decedent tissue and not for the purpose of obtaining whole organs.

The PI in charge of the research project requesting SIDS/SUDC tissue has full responsibility for submitting a formal request to the OSME and for ensuring that N.J.S.A. 52:17B-88.11 statutory requirements are followed throughout the application process and until the completion or termination of the approved research project.

II. Application

The PI is required to provide the following documentation and information to the OSME. Only complete applications will be forwarded to the SCDAPC for review and approval, if granted.

A. Name of PI, title of research project, location of research project.

B. An overview of the research project.

C. The type and amount of tissue to be obtained.

D. Specify any additional information requested from the investigation of the death.

E. Specify the time period the collection process will include.

F. A copy of written approval of the research project by the Institutional Review Board (IRB) of the facility where the research will be conducted. As provided at N.J.S.A. 52:17B-88.11, the research project must first be approved by the IRB of the facility at which the research shall be conducted, then by the Sudden Child Death Autopsy Protocol Committee, and finally by the IRB of the New Jersey Department of Health and Senior Services. If a research project is submitted by the Department of Health and Senior Services, the final review of the project shall be conducted by an independent review board. All costs associated in obtaining and providing these approvals is the responsibility of the PI.
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G. A written plan for the release of tissue by the medical examiner to the PI. The plan must incorporate:

1. How the PI and research project will retrieve, receive, catalog, and store the tissue. The tissue catalog should contain case-specific identifiers and an inventory number;
2. The utilization of a tissue release form containing case specific identifiers including contact information for the legal guardian, the type and amount of tissue collected / released, the signature of the medical examiner and the PI or their authorized representatives, and the date of collection / release of tissue;
3. How the PI and research project will store the tissue until the PI receives the legal guardian’s written consent to use the tissue;
4. Provide reimbursement costs to the medical examiner office of record for the reasonable costs incurred in taking, storing and providing tissue samples to the research project.

H. A written plan for the process of obtaining written consent from the decedent’s legal guardians for the use of decedent tissue and other identifying information for approved research purposes consistent with this protocol. The plan includes the developing of a written consent form that will be reviewed by the OSME. The written consent form must contain:

1. The decedent’s name and medical examiner case number;
2. The legal guardian’s name, signature, and date of signature.
3. A release for the medical examiner to collect and disseminate tissue and identifying information about the tissue and decedent to the PI and research project; and
4. A release that allows the PI to use the decedent’s tissue and other identifying information for approved research purposes consistent with this protocol.

I. A written plan for the disposal of decedent tissue which contains:

1. Procedures to dispose of the tissue if written consent is not obtained from decedent’s legal guardians;
2. Procedures to dispose of decedent tissue upon completion of the research project;
3. Procedures to dispose of tissue and biohazardous materials according to applicable federal, state, and local regulations, laws and policies;
4. Making reasonable efforts to accommodate the disposal requests of the legal guardians; and
5. Providing written notice to the OSME and medical examiner when tissue is disposed.

J. An informational document to be distributed to the decedent’s legal guardians about the purpose behind the SIDS/SUDC research statute, N.J.S.A. 52:17B-88.11, the research project, and on the tissue collection, use and disposal. The document must advise that any significant results discovered from examining the tissue will be reported to the legal guardian. PI is required to submit this document to the decedent’s legal guardians with the written consent forms. Upon approval of a research project by SCDAPC, the PI must submit the informational document to OSME for review.

K. A list of the names and contact information, including telephone and e-mail address, of all individuals listed in the IRB application and all individuals involved in obtaining, storing, and testing of the tissue.

L. Written plans and procedures including any certificate, form or other documentation required by any funding source or governmental entity for maintaining the confidentiality of decedent’s tissue and identifying data, including taking adequate precautions to ensure administrative and physical security of the tissue and identifying data, and to preserve the confidentiality of the personally identifiable information. Project plans must be designed to preserve the confidentiality of the decedents and their legal guardians, including where appropriate, name stripping, coding of data or other similar procedures.

III. Process and Responsibilities

A. The OSME has the responsibility to ensure the completeness and accuracy of the tissue research application. Incomplete and/or inaccurate applications will not be processed until outstanding deficiencies have been corrected and completed.

B. OSME will send completed applications to the SCDAPC for its review and approval. SCDAPC will consider completed applications for a minimum two-week period. Thereafter, the SCDAPC will convene to vote on each application. A majority vote of the convening members will determine if the application is preliminarily approved or disapproved.

1. Criteria for approval:
   a) The research project will advance the understanding of SIDS/SUDC.
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b) The research project has a direct bearing on SIDS/SUDC.
c) The research conforms to professional standards for scientific investigation without moral or ethical improprieties.

2. Criteria for disapproval:
   a) The research does not have application to the advancement of the understanding of SIDS/SUDC.
   b) The research is unethical or does not meet professional criteria for scientific investigation.

3. SCDAPC members who have a conflict of interest with pending applications must recuse themselves from participating in the discussions or voting on the applications for which there is a conflict. All questions regarding conflicts should be referred to the OSME.

C. The SCDAPC cannot grant final approval if approval of the project is not obtained from the IRB of the New Jersey Department of Health and Senior Services (DHSS). If the research project is submitted by DHSS, the research project must receive the approval of an independent review board.

   1. Within seven (7) days of final approval of an application by the SCDAPC, the OSME will notify the PI of the approval and will advise state and county medical examiner offices to provide tissue to the PI as appropriate tissue becomes available.

D. A PI may request a meeting with the SCDAPC to review the decision not to approve a specific project. The majority of the SCDAPC will again vote and that vote will be final without further recourse by the PI.

E. The SCDAPC will submit an annual report of its research related activities to the Office of the Attorney General through the Director of the Division of Criminal Justice beginning one year from the first release of tissue by a medical examiner to the PI and on each subsequent anniversary thereafter.

IV. Conditions of Approved Research Project

A. The PI agrees to use the tissue and other identifying data received from the medical examiner only for the purposes approved of by SCDAPC and as specified by this protocol.

B. The PI agrees that the decedent’s tissue shall not be examined unless written consent is received from the decedent’s legal guardians. The PI agrees to obtain a written consent from the decedent’s legal guardians.
1. The written consent must be obtained by the PI within one year of receipt of tissue.

2. A copy of the written consent must be sent to the OSME and the medical examiner of record within five (5) days of execution.

C. The PI must arrange with the medical examiner of record for tissue type, amount and retrieval and provide an acknowledgment of receipt form for the tissue containing case-specific identifiers for all tissue samples and an inventory number. The PI, or its agent, may not interfere with the activities of the medical examiner in any fashion.

D. The PI agrees to reimburse the state or county medical examiner office of record for the reasonable costs incurred in taking and providing tissue samples and identifiable data to the PI and research project. Reasonable costs will be reviewed and approved by State Medical Examiner upon advice of the OSME financial office. The PI agrees to reimburse the medical examiner office of record within thirty (30) days of receipt of invoice.

E. The PI agrees to dispose of the tissue according to local, state and federal procedures, laws and regulations for disposal of surgical biopsies and biohazardous materials. The PI agrees to make reasonable efforts to accommodate the requests of the legal guardians. Within seven (7) business days of the disposition of the tissue, the PI agrees to provide written notice to the OSME and the medical examiner of record.

F. The medical examiners agree to release autopsy and other ancillary report(s) generated by the office concerning decedents in which the PI and research project have received a written consent.

G. The PI, its employees and subcontractors, agree to comply with all state and federal laws, regulations and policy on confidentiality concerning the collection and use of the tissue and relevant data or information.

H. The PI, its employees, subcontractors, consultants and agents, agree to comply with federal regulations according to 28 C.F.R. Part 22, including:

   1. The PI agrees data identifiable to a private person will not be used or revealed except as authorized by law.
   2. The PI agrees to limit access to the data to those employees having a need for such data and that such employees shall be advised of and agree in writing to comply with these regulations and laws.
3. The PI agrees to comply with 28 C.F.R. § 22.23 and 24 on information transfer agreements.

4. The PI, its employees, subcontractors, consultants and agents have been advised of and have agreed in writing to comply with all procedures to protect privacy and the confidentiality of personally identifiable information. The PI, its employees, subcontractors, consultants and agents agree to provide to the OSME privacy certificates according to the requirements of 28 C.F.R. Part 22 and, in particular, section 22.23.

5. The PI, its employees, subcontractors, consultants and agents agree and understand that the tissue and other personally identifiable information shall not be divulged or made public so as to disclose the identity of any decedent or legal guardian or other person to whom they relate.

I. The PI, its employees, subcontractors, consultants and agents agree and understand that the information provided to the research project is not considered a public record according to N.J.S.A. 47:1A-1 et seq. or N.J.S.A. 47:1A-5 et seq.

J. The OSME requires immediate notification of any inquiry, investigation, sanction, or adverse action or decision by any authorizing IRB during the research period. The PI agrees to provide the OSME with all relevant documentation within 5 days of said notification. The SCDAPC, in consultation with the OSME, reserves the right to terminate tissue release, for a permanent or temporary period, to a research project after review of the IRB inquiry or decision and all pertinent documentation.

K. The SCDAPC, in consultation with the OSME, reserves the right to terminate tissue release to a research project that is not in compliance with applicable federal and state law or regulation and / or procedures as contained within this protocol.

L. Complying with N.J.S.A. 52:17B-88.7 to 88.9, the PI understands that anatomical gift and organ donations will take priority over taking tissue samples for the research project.

M. The PI understands that tissue may not be obtained if the tissue is essential in determining the cause and manner of death. [The PI understands that tissue may not be obtained in suspected homicide cases unless a separate approval is granted by the county prosecutor in consultation with the medical examiner.] Delete

N. In cases of multiple requests of the same tissue, the SCDAPC shall arbitrate through a designated representative to determine the priority of the request and the extent of tissue to be obtained.
O. The PI must provide all materials and personnel required to obtain the requested tissue. The medical examiner will remove and submit the tissue to the PI and/or the PI's representative at the time and place designated by the medical examiner.

P. Prior to any modifications of the research project, the PI agrees to submit the proposed change to the SCDAPC for review and approval.

Q. The PI agrees to provide interim and annual reporting on the status of the research project to SCDAPC and OSME. The SCDAPC will review the approved research projects(s) on an ongoing basis. The SCDAPC will convene no less than every six (6) months.

1. An inventory of all tissue used and stored must be submitted to the OSME biannually throughout the duration of the project. For each research tissue specimen received, the inventory must include: case-specific identifiers, amount and type of tissue, and method of tissue disposition.

2. With the biannual inventory, the PI must also submit to the OSME and SCDAPC a narrative status report on the research project.