FATALITY REVIEW CASE REPORTING SYSTEM DATA USE AGREEMENT BETWEEN THE MICHIGAN PUBLIC HEALTH INSTITUTE AND THE COUNTY OF FRESNO, CALIFORNIA

This data use agreement is entered into upon execution between the Michigan Public Health Institute (MPHI) (known hereafter as "Receiver") and the County of Fresno, California (known hereafter as "Holder").

The purpose of this agreement is to establish the terms and conditions for the collection, storage and use of data obtained from the fatality case reviews submitted by Fatality Review (FR) teams in the County of Fresno, California and entrusted to the Receiver as the National Fatality Review Case Reporting System (NFR-CRS).

A. The Receiver

1. The Receiver is a non-profit private agency. It has a Cooperative Agreement with the Maternal and Child Health Bureau, Health Resources and Services Administration, U.S. Department of Health and Human Services, to manage the National Center for Fatality Review and Prevention (NCFRP). As part of this agreement, the Receiver is to manage a standardized, web-based reporting system for state and local fatality review teams.
2. The Receiver is responsible for the development of the NFR-CRS, training and liaison to state and/or county agencies participating in the system, technical assistance in using the system, and analysis and dissemination of national FR data generated by the system. The Receiver is responsible for the security, data storage, and data access by users of the NFR-CRS.
3. The Receiver holds a Federalwide Assurance (FWA) that is a written commitment to protect human research subjects by complying with federal regulations and maintaining adequate programs and procedures for the protection of human subjects. This FWA specifies adherence to the Code of Federal Regulations Title 45 Public Welfare Part 46 Protection of Human Subjects, and the use of the Belmont Report as an ethics guideline. The NCFRP including the NFR-CRS is reviewed annually by the Receiver's Institutional Review Board. Copies of the panel decision letters are available to the Holder.
4. The Receiver complies with the federal privacy requirements specified in the HIPAA Privacy and Security Rules (45 CFR Parts 160, 162 and 164, Standards for Privacy of Individually Identifiable Health Information). The Receiver has appointed a Privacy Officer and a Security Officer, developed and adopted HIPAA-compliant privacy and security policies and procedures, and staff receive training in these policies and procedures. The NCFRP including the NFR-CRS is reviewed annually by the Receiver's Office of Research Integrity and Compliance and decisions letters are available to the Holder. Because the NFR-CRS does not collect Protected Health Information (PHI), the NFR-CRS is not HIPAA privacy sensitive.

B. The Holder

County of Fresno, a Political Subdivision of the State of California.

C. Purpose of and Type of Data

1. The Fatality Review teams in Fresno, California are supplying data to the NCFRP in order to:
    a. Provide the state and local FR teams with a comprehensive FR case reporting system for collecting, analyzing and reporting on their reviews of fetal, infant, and child deaths.
    b. Permit comparability of FR data within and between local FR teams and states.
    c. Use data collected to promote policy, programs, services and laws to prevent fetal, infant, and child deaths at the local, state and national levels.
    d. Use data collected to better identify and address health disparities.

D. Data Entry and Transmittal

1. Data are submitted by the Holder to the Receiver only via the Internet, using the NFR-CRS, ©Michigan Public Health Institute. The Receiver will provide paper forms to the Holder upon request; however all data is obtained by the Receiver through the Internet.
2. The Holder is complying with its applicable state laws and policies in making the determination of the specific data to be entered into this system and of the persons it authorizes to enter and transmit the data. Relevant Holder state FR statutes or promulgated rules are set out in Appendix A.
3. Only persons selected by the Holder and provided with a password by the Holder or the Receiver will have access to the NFR-CRS for data entry and submission as a data entry user.
4. The Receiver will create and administer data entry user accounts upon request of the Holder, or accounts can be created and maintained by the assigned administrators of this reporting system upon request of the Holder.
5. Accounts are locked out when a user attempts but fails to log in successfully 5 times in 10 minutes; such accounts remain locked out until released by NCFRP staff or assigned Holder administrators.
6. Accounts are automatically logged out after 60 minutes when there is no transmission to the server.
7. The Receiver and/or the Holder's assigned administrator may terminate a user's access to the system at any time.

E. Data Storage

1. All data submitted via the Internet using the NFR-CRS shall be stored using appropriate safeguards to prevent the use or disclosure of confidential information.
2. The Receiver ensures that administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of data it creates, receives, maintains or transmits are implemented.
3. Data received by Receiver will be stored indefinitely unless either party terminates the data use agreement.

4. The Receiver will comply with all federal laws regarding the handling, use, storage, return, disposal and any other action related to the data provided by the Holder.
5. The Receiver is not responsible for any damage caused by viruses originating from any places not attributable to the Receiver.
6. It is strongly suggested that the Holder have consistent/comparable security practices in place for data that is downloaded from the servers back to the Holder or back to the Holder's identified users.

F. Access to the FR Data

1. Receiver staff supporting the infrastructure of the NFR-CRS will only access the data submitted by the Holder in the event that there are unforeseen problems with the database that need troubleshooting, correction or upgrading or during development of NFR-CRS releases or upgrades. Receiver staff will not amend, addend, alter or erase any information contained in data files without prior written authorization.
2. Identifiers will be removed from data downloads based on the permission levels for each of the Holder and Receiver. This removal of data elements is a software program feature of the NFR-CRS.
3. NCFRP staff will have access only to data submitted by the Holder and its authorized data entry persons that have case identifiers removed using the HIPAA standards listed in Appendix B, unless in the event of unforeseen problems with the database that require troubleshooting or during development of NFR-CRS releases or upgrades.
4. The Holder will identify the level of access to data of its authorized persons at both the state and local level. Data will be accessible to the Holder via the Internet.
5. It is strongly suggested that the Holder have signed confidentiality statements from all of its authorized users (see Appendix C as an example statement).
6. The Holder will provide the Receiver with the written names and contact information for persons with permission to access data in the event the Receiver is asked by the Holder to create logins.
7. Any breach of security or unintended disclosure known by the Receiver will be reported immediately to the appropriate Receiver supervisors, Privacy Officer, Security Officer, and Research Integrity Officer. The Holder will then be notified of the event and steps will be taken in coordination with the Holder to mitigate harm and cure the breach of security within thirty days. As stated in Section A, the privacy protocols and policies in place at the Receiver are in compliance with HIPAA and meet or exceed federal standards.
8. Any breach of security or unintended disclosure known by the Holder will be reported immediately to the Receiver, and steps will be taken in coordination with the Holder to mitigate harm.

G. Permitted Data Uses

1. Data submitted by the Holder to the Receiver are not subject to the Freedom of Information Act (FOIA) and, as such, no data submitted by the Holder will be released by the Receiver in response to any FOIA request. The Holder will address any FOIA request made to the Holder.

2. All data accessed by and released to the Holder are the responsibility of the Holder. Any subsequent breaches of security or confidentiality once the Holder obtains the data are the responsibility of the Holder.
3. The Holder will comply with its applicable state laws and policies in determining the specific data the Receiver is allowed to disclose.
4. The Receiver will not release any data that includes identifiable characteristics as defined by HIPAA (Appendix B) to any persons or organizations, except in circumstances provided in writing by the Holder.
5. The Receiver may release de-identified data only in accordance with the MPHI IRB/Privacy approved data dissemination policy (Appendix E).
6. All reports released by the Receiver and the Holder shall be developed with adequate provision for the accuracy, reliability and integrity of the data.

H. Ownership

1. The Receiver acknowledges that all fatality review data submitted by the Holder and by the Holder's designated data entry persons shall be and remain the sole property of the Holder.
2. The Holder acknowledges that the NFR-CRS and all of its software platform applications are the copyrighted property of the Receiver.

I. Agreement Terms and Termination

1. This agreement shall take effect on the date of the final signature and shall terminate pursuant to section 2 below. Upon execution, all provisions of any current or ongoing DUA between the parties are hereby superseded and replaced.
2. This agreement may be terminated by the Holder or Receiver by giving written notice under any of the following circumstances:
    a. If the Holder wishes to terminate its relationship with the Receiver for any reason.
    b. If the Holder of data can no longer participate in the Internet web system due to changes in laws or funding for FR programs.
    c. If the Receiver of data no longer receives funding to serve as the NCFRP.
3. Upon termination of this agreement, the Receiver, shall, upon request of the Holder, remove all of the Holder's fatality review case data. Fatality review data stored on backup tapes cannot be removed in the event of the Holder's termination but will never be used, reported or disseminated by the Receiver.
4. Any subcontractors or other agents hired by the Receiver or Holder must agree to the same restrictions and conditions that apply through this agreement.
5. All Receiver staff with access to the data submitted by the Holder will sign a confidentiality agreement (Appendix D).
6. The Receiver agrees to maintain an insurance rider to provide additional liability insurance, beyond that normally required for MPHI programs.

IN WITNESS WHEREOF, the parties hereto execute this agreement as follows:

Michigan Public Health Institute
Data Receiver

DocuSigned by:
Janice Kidd
181A7DDB91C34D9...

By: _____
Janice Kidd

Finance & Budget Manager

Date: 8/24/2020

Fresno County, California
Data Holder

By: _____
Ernest Buddy Mendes, Chairman of the Board of Supervisors of the County of Fresno

Date: 9-1-2020

Attest:

Bernice E. Seidel
Clerk of the Board of Supervisors
County of Fresno, State of California

By: Susan Bishop
Deputy

Appendix A
Relevant State FR Statutes or Promulgated Rules for the Collection, Analysis and Distribution of FR Data

County of Fresno
DEPARTMENT OF PUBLIC HEALTH
David Pomaville, Director
Dr. Sara Goldgraben, Health Officer

DATE: May 16, 2019

TO: To Whom It May Concern

FROM: Mercy Kagoda, MD, MPH – Deputy Health Officer

SUBJECT: Authority to Conduct Fetal and Infant Mortality Review

Under provisions of the California Health and Safety Code 100325 and 56.10(c)(7) of the California Civil Code, the local Health Officer has the authority to obtain access to medical records for the purpose of public health investigation of fetal and infant mortality.

Local authority to conduct the Fetal and Infant Mortality Review (FIMR) Project is assigned to the Public Health Nursing (PHN) Division of the Fresno County Department of Public Health. This document authorizes the FIMR Program staff and the FIMR Case Review Team members to review relevant medical and social records without obtaining a signed consent from the family.

The PHN Division has been conducting FIMR since 1991 under the direction of the California Department of Public Health. Fresno is one of many counties participating in the Statewide FIMR Project, which works in collaboration with the American College of Obstetricians and Gynecologists and the National Centers for Disease Control.

The purpose of FIMR is to identify common denominators, which contribute to fetal, neonatal and post-neonatal mortality. The primary goals are to identify gaps in service, coordinate perinatal outreach, and improve the quality of, and access to, prenatal care in an effort to reduce the infant mortality rates in Fresno County. Information is gathered from birth and death certificates, medical and social records and family interviews. The data is abstracted and de-identified under confidentiality requirements established by federal and state law and presented to a FIMR Case Review Team for interpretation, conclusions and recommendations.

For additional information regarding the FIMR Program, you may contact the FIMR Coordinator, Natalie Adolph, at (559) 600-1021.

DP:na

CALIFORNIA HEALTH AND **SAFETY CODE**
SECTION **100325-100330**

100325. The department shall cause special investigations of the sources of morbidity and mortality and the effects of localities, employments, conditions and circumstances on the public health and the department shall perform other duties as may be required in procuring information for state and federal agencies regarding the effects of these conditions on the public health.

100330. All records of interviews, written reports, and statements procured by the department or by any other person, agency, or organization acting jointly with the department, in connection with special morbidity and mortality studies shall be confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes of the study. The furnishing of this information to the department or its authorized representative, or to any other co-operating individual, agency or organization in any special study, shall not subject any person, hospital, sanitarium, rest home, nursing home, or other organization furnishing this information to any action for damages. This section shall not apply to general morbidity and mortality studies customarily and continuously conducted by the department that do not involve patient identification. Nothing in this section shall prohibit the publishing by the department of statistical compilations relating to morbidity and mortality studies that do not identify individual cases and sources of information or religious affiliations.

California Code, Civil Code- CIV CA CIVIL § 56.10(c)(7)

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in a way that would disclose the identity of a patient or violate this part.

Appendix B

HIPAA Required Elements to De-Identify Case Data*

The NFR-CRS supports two types of data downloads: identified and de-identified. NCFRP staff and researchers who have been approved by the NCFRP will receive only de-identified data. The NFR-CRS variables that will be removed in de-identified downloads are listed below.

The NFR-CRS contains many free text fields (most often in the 'specify' or 'describe' text fields). The NFR-CRS also provides users the opportunity to provide more detail surrounding the circumstances of the death in Section O: Narrative text field. **When the Narrative, 'specify,' and/or 'describe' text fields are included in a de-identified download, the Narrative, 'describe,' and 'specify' text fields SHOULD NOT contain any HIPAA Identifiers.**

HIPAA Identifiers include names; all geographical subdivisions smaller than a state; all elements of dates (except year) for dates directly related to an individual; phone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web universal resource locators; internet protocol address numbers; biometric identifiers; full face photographic images; and any other unique identifying number, characteristic or code.

Identifying information can be entered into the NFR-CRS element fields in the list below, including free text fields associated with the listed fields, because all the listed fields and their related text fields will be removed from every de-identified download. **However, users should be instructed by the Holder not to enter any identifying information in other free text fields, including Section O: Narrative text field, because these text fields may be included in de-identified downloads. NCFRP cannot review free text fields in de-identified downloads to assure that they contain no HIPAA Identifiers.**

HIPAA Required Elements to De-Identify Case Data

The NFR-CRS elements listed below will be removed for all persons accessing de-identified case data:

Introduction: Case Definition
Case number
County of review
Review team number
Sequence of review
Death certificate number
Birth certificate number

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* **Source: Code of Federal Regulations Section 164.514(b)(2)(i).**

Medical examiner/Coroner number
Date FR team notified of death

Section A: Child Information
Child first name
Child middle name
Child last name
Child name: unknown
Date of birth: month, day, and year
Date of birth: unknown
Date of death: month and day
Date of death: unknown
Residential address: unknown
Residential address: street
Residential address: apartment
Residential address: city
Residential address: county
Residential address: zip
County of death
Mother's first name
Mother's middle name
Mother's last name
Mother's maiden name
Mother's name: unknown
Father's first name
Father's middle name
Father's last name
Father's name: unknown
Mother's residence address: same as child
Mother's residence address: unknown
Mother's residence address:street
Mother's residence address: apartment
Mother's residence address city
Mother's residence address: zip
Mother's residence address: county
Mother's discharge date from hospital
Date of infant's last discharge date

Section E: Incident Information
Date of incident
Date of incident: same
Date of incident: unknown
Incident county

Section M: Review Meeting Process
Date of first FR meeting

Section N: SUID and SDY Case Registry
Date of first Advanced Review meeting
Date of SUID Case Registry data entry complete

Section P: Form Completed By
Form completed by – Person's name
Form completed by – Title
Form completed by – Agency
Form completed by – Phone

Form completed by – Phone extension
Form completed by – Email
Form completed by - Date
Date of quality assurance completed by State

My FR Outcomes
My FR Outcomes – Person's name
My FR Outcomes - Team of review

* **Source: Code of Federal Regulation Section 164.514(b)(2)(i).**

Appendix C
Holder Confidentiality Agreements

Sample Confidentiality Statement for State and Local Users of the *Fatality Review Case Reporting System*

By signing this Agreement, I agree to the following when I access any and all components of the *Fatality Review Case Reporting System*

1. I will comply with all laws, regulations, policies and procedures as set by the State of _____
2. I will safeguard the confidentiality of all confidential information to which I have access. I will not carelessly handle confidential information. I will not in any way divulge, copy, release, sell, loan, review, alter or destroy any confidential information except as within the scope of my duties.
3. I will only access confidential information for which I have a need to know and I will use that information only as needed to perform my duties.
4. I will safeguard and will not disclose my user name and password unless authorized by the state administrator of the reporting system. I understand that my user name and password allows me to access confidential information for my team on the *Fatality Review Case Reporting System*. I understand that the State administrator may revoke my access to the data system if my responsibilities change. *
5. I will promptly report activities by any individual or entity that I suspect may compromise the availability, integrity, security, or privacy of confidential information.
6. I understand that the ownership in any confidential information referred to in this Agreement is defined by State statute.
7. I understand that violating applicable laws and regulations may lead to other legal penalties imposed by the judicial system.

Signature: _____ **Date:** _____

Print Name: _____

* If your state already has confidentiality statements in place, you might consider replacing this form with your own, but adding statement four from above.

Appendix D
MPHI Confidentiality Agreement

Confidentiality Agreement for Michigan Public Health Institute Staff Assigned to Privacy-Sensitive Projects

As described in the Michigan Public Health Institute (MPHI) Employee Handbook, all MPHI employees have the responsibility to maintain the accuracy, availability, completeness, and confidentiality of the business information, trade secrets, and data to which they have access. Due to the nature of its work, MPHI has access to, stores, uses, and discloses data (including Protected Health Information as defined by the HIPAA Privacy Rule). Any or all of the following factors may require that use and disclosure of these data be restricted in various ways:

1. Federal, tribal, state and local laws and regulations. Examples include: the HIPAA and HITECH, which govern the privacy and security of health information and the Common Rule that governs Institutional Review Boards and research with human subjects.
2. MPHI policies, procedures and training, including project-specific protocols. [1]
3. Contractual agreements between MPHI and project partners and clients.

MPHI employees must annually sign this agreement to demonstrate that they are aware of their obligations to protect the confidentiality and security of the data to which they have access.

By signing this agreement, I agree to the following:

1. I will comply with all laws, regulations, contractual agreements, MPHI policies and procedures, and project-specific protocols related to my assigned duties. I understand that I may be required to complete additional training related to these obligations.
2. I will safeguard and will not disclose my work related password(s), access code(s), or any other work related authorization(s). I understand that MPHI may at any time revoke my password(s), access code(s), other authorization(s), or access.
3. At all times during my employment, I will safeguard the confidentiality of all information to which I have access. I will not carelessly handle information. I will not in any way divulge, copy, release, sell, loan, review, alter, or destroy any information except as properly authorized within the scope of my assigned duties at MPHI.
4. I will only access information for which I have a need to know and I will use that information only *as needed* to perform my legitimate duties as an employee of MPHI.
5. I will not misuse information.
6. I will promptly report activities by any individual or entity that I suspect may compromise the availability, integrity, security, or privacy of information held by MPHI. I understand that reports made in good faith about suspect activities will be held in confidence to the extent permitted.
7. I understand that I have no right or ownership interest in any information referred to in this agreement.
8. I understand that my failure to comply with this Agreement may result in disciplinary action up to and including termination of my employment. I understand that violating

applicable laws and regulations may lead to other legal penalties imposed by the judicial system, such as fines and/or imprisonment.

9. I understand and accept that signing this agreement is a condition of my employment and those obligations under this Agreement will continue after termination of my employment.

Employee Signature: _____ **Date:** _____

Print Employee Name: _____

Supervisor Signature: _____ **Date:** _____

Print Supervisor Name: _____

1 I understand that it is my responsibility to read the Privacy and Confidentiality Policy and any associated policies and understand its terms. If I have any questions concerning information contained in the policy, I will bring them to the attention of my supervisor, manager, or Privacy Officer.

Appendix E
NCFRP Data Dissemination Policy &
Guidelines for Requesting De-identified Dataset

DATA DISSEMINATION POLICY

Background

The purpose of the National Fatality Review Case Reporting System (NFR-CRS) housed by the National Center for Fatality Review and Prevention (NCFRP) is to systematically collect information on the circumstances surrounding the stillbirths and deaths of individual infants and children obtained during child death review and fetal infant mortality review programs in the US.[1] The information can then be analyzed at the local, state, or national levels and used to inform services, policy, and prevention initiatives focused on improving maternal and child health and safety and preventing additional deaths. The data collected include the following:

- Demographic information about the child and family; details about the child's supervisor and perpetrator of violence (if applicable);
- Information about the death investigation and the types of action taken during the investigation;
- Circumstances surrounding the death including information on risk and protective factors; cause and manner of death;
- Services provided or needed as a result of the death;
- The team's recommendations and other actions taken to prevent other fetal, infant, and child deaths; and
- Factors affecting the quality of the death review meeting.

The NFR-CRS is a web-based system first implemented in May 2004 in 14 pilot states as the Child Death Review Case Reporting System. Version 1 was made available for widespread use in January 2005. Since 2005, the software has been upgraded several times, including the addition of several new questions, most notably to support the Sudden Unexpected Infant Death Case Registry and the Sudden Death in the Young Case Registry. Effective with Version 5, the NFR-CRS collects detailed information about fetal and infant deaths. A print version showing the data elements and structure of NFR-CRS is available on the NFRCP website (https://www.ncfrp.org/wp-content/uploads/NCRPCD-Docs/CDR_CRS_v5.pdf) and is referred to in this document as the Case Report tool.

Information on the number of participating states and number of deaths is available from NCFRP.

Data Sources

Data entered into NFR-CRS are the result of multi-disciplinary fatality review processes that bring together professionals from state and/or community agencies for the purpose of sharing information on circumstances of maternal health, fetal, infant and child death events in an effort

[1] The NFR-CRS is supported by the Maternal and Child Health Bureau (Title V, Social Security Act) Health Resources and Services Administration, Department of Health and Human Services, (Cooperative Agreements Number UG7MC 248482 and UG7MC31831) and by the US Centers for Disease Control and Prevention (Contract 75030118CO3074).

to identify risk factors and possible prevention strategies. Data entered into NFR-CRS may be obtained from the following data sources: birth certificates, death certificates, law enforcement records, medical records, autopsy reports, child protective services reports, and Emergency Medical Services/ambulance run reports.

Fatality Review Programs in States

Fatality review programs vary by jurisdiction and state with respect to the types of deaths reviewed (e.g., all deaths, non-natural deaths, all fatal injuries, abuse and neglect deaths; the age of children whose deaths are reviewed (e.g., 0-14, 0-17, 0-25); and the average time between review and death (ranges 1 to 36 months). Due to this variability, the data are not universally consistent from site to site or state to state.

Because most states do not review or enter every fetal, infant and child fatality, NFR-CRS cannot be directly compared with vital statistics data nor should it be used to compute mortality rates. All these distinctions among sites and states and limitations must be noted in any analysis of the data that is prepared for presentation or publication. More information about fatality review programs and their criteria for selection can be found at http://www.nfrp.org.

Prior to the release of Version 5 of NFR-CRS, local FIMR programs had been using a variety of systems to collect and report their data. Typically, most FIMR information is collected from the following data sources: maternal interviews, birth and death certificates, autopsy reports, hospital records including labor and delivery, newborn, neonatal and pediatric care units, emergency department, outpatient records including prenatal care, pediatric well baby and sick baby visits, and other service providers such as WIC, public health, home visits, and department of human and social services records. FIMR data is meant to complement other population data. Collection of FIMR data in NFR-CRS did not begin until 2018.

Data Ownership

Fatality review data in NFR-CRS are owned by the individual program that reviewed the death and entered the data (per the data use agreement executed between each local program or state and MPHI/NCFRP). Requests for de-identified data on individual deaths must be submitted to the NCFRP Data Dissemination Committee, per guidelines and processed outlined in this document. For any research request that proposes to identify data by state in any published or publicly released analysis or results, local programs and states will be provided an opportunity to have their state's data excluded from the study.

Data Inclusion

The de-identified dataset will include all cases that are at least 24 months from the end of the calendar year for the preceding January-December time frame. For example, deaths that occurred in calendar year 2015 (January 1- December 31, 2015) and earlier will be made available in a researcher de-identified dataset on January 1, 2018. Deaths occurring in calendar year 2016 and earlier will be made available in a researcher de-identified dataset on January 1, 2019. Cases migrated from previous fatality review reporting systems into the NFR-CRS will not be included in a standard dataset but may be provided upon further consultation between the researcher and NCFRP.

Removal of Identifiable Data Elements for Dataset
Although states often enter HIPPA-defined personally identifiable data elements (child's name, address, date of birth, date of death, date and time of incident, and incident county) into the NFR-CRS, no data file that includes HIPAA-defined personally identifiable elements will be made available to researchers. Prior to providing data for an approved research project, all personally identifiable data elements will be removed. HIPAA-defined personally identifiable elements are listed in Attachment 1 of the Application for Access to De-identified Data (Application for Data). The "Narrative" field contained in Section O of the Case Report form is typically not available to researchers. It can be released under special circumstances and after a lengthy review process in which personally identifiable elements have been redacted.

Although no HIPAA defined personally identifiable data elements should be included in the Narrative field of Section O, should there by ANY identifying elements contained in this section, it is to be considered an inadvertent disclosure and (1) shall not be used or disclosed by researchers, (2) shall be immediately deleted by researchers and (3) be immediately reported to MPHI/NCFRP with written confirmation by the researchers that the confidential information cannot be used.

If any HIPAA personally identifying data elements are included in other free text fields in the researcher dataset, it is also considered to be an inadvertent disclosure and the confidential information (1) shall not be used or disclosed by researchers, (2) shall be immediately deleted by researchers and (3) be immediately reported to MPHI/NCFRP with written confirmation by the researchers that the confidential information cannot be used.

To protect anonymity of state-specific data, individual states are not identified in data provided for approved research. However, NCFRP will create and provide a unique state code so that researchers can evaluate variation and control for potential bias in the dataset without identifying the individual states.

Permitted Data Uses
NCFRP may use de-identified case report data for its own research and reports. NCFRP only has access to de-identified case report data; NCFRP does not have to obtain permission from the Data Dissemination Committee (see Guidelines below) in order to have access to the de-identified data. NCFRP has access to all de-identified data entered into the NFR-CRS and is not limited to only those cases in the researcher dataset. NCFRP may report aggregated, de-identified data identified by state to requesting parties such as agencies or organizations without state permission. Only data with cell counts of six or more cases can be reported in any analysis. Data with cell counts less than six must be suppressed. Requests by researchers for de-identified data must be made in accordance with the Guidelines for Requesting De-identified Dataset (Guidelines), below, and NCFRP will only release de-identified datasets in accordance with the Guidelines.

Required Fees
A fee may be charged to each applicant for preparation of the requested dataset. The amount of the fee will be determined by NCFRP staff. An estimate of any fee will be provided to the applicant upon a preliminary review of the proposal by staff. Fees will be determined based on a

price equal to the number of staffing hours estimated to prepare the dataset using the federally approved MPHI MOBUS rates. Fees must be paid in full prior to the release of the dataset to the applicant. NCFRP reserves the right to waive fees in certain situations.

Data Quality

In order to standardize the collection and interpretation of data elements, NFR-CRS contains a comprehensive Data Dictionary that is readily available online when entering data or as a standalone PDF document that can be used during fatality review team meetings. Additionally, NCFRP staff are readily available to provide technical assistance about the Case Report tool and are in constant communication with states about data and reporting questions. Since the data are owned by the participating states, they are responsible for the quality of their data. States vary in the degree to which they review data for inconsistencies, incompleteness, or inaccuracies. The NCFRP has found that data quality appears to improve with training and increased time using the System. The Case Report tool contains a number of subjective questions to engage team discussion (e.g., "Was the death preventable?" or "Did a person or persons other than the child do something that caused or contributed to the death?"). The subjective nature of these questions can, however, make data analysis more challenging. Finally, although teams record the agencies that participated in the fatality review, the primary data source for each data element is not documented in the NFR-CRS. If there is a discrepancy in information shared by the different agencies at the review meeting, it is up to the fatality review teams to determine the best answer; NCFRP has no set primacy rule for data sources.

More information about NFR-CRS and limitations on the use of the data can be found in the February 2011 Supplement to *Injury Prevention* (Covington TM. The US national child death review case reporting system. *Injury Prevention* 2011; 17 Suppl 1:i34-i37) found at https://www.ncfrp.org/wp-content/uploads/NCRPCD-Docs/InjuryPreventionSupplement2011.pdf.

GUIDELINES AND PROCESSES FOR REQUESTING DE-IDENTIFIED DATA FOR RESEARCH PURPOSES

Researchers affiliated with an eligible Receiving Institution may apply for access to a de-identified dataset. To be eligible, the Receiving Institution must be an institution of higher education, research organization, non-profit agency or government agency that either employs or contracts with the researcher. The Receiving Institution must be registered with the U.S. Office for Human Research Protections. Any release of data will be subject to a signed Contract for Access to and Use of Data (Contract for Data) between NCFRP, the principal investigator (PI) and an authorized representative of the Receiving Institution. The Contract for Data is set out after these Guidelines.

An Application for De-identified Data (Application for Data) must identify a PI. The PI serves as the primary point of contact for all communications involving the Contract for Data. The PI must sign the Contract for Data, by which the PI assumes responsibility for compliance with all terms of the Contract for Data by employees of the Receiving Institution, including the day-to-day security of the electronic data and all printed output derived from the files.

Each additional researcher who will have access to the NCFRP data must be identified on the Application for Data and must sign the Confidentiality Agreement attached (Attachment 3). The applicants may not release or permit others to release the dataset in whole or in part to any persons other than those identified in the Application for Data.

Access to the dataset is also subject to the following requirements:

1. The researchers given access to NFR-CRS data may not conduct analyses of the data for purposes other than those described in the approved Application for Data. Applicants will not alter the approved research design unless they have notified and obtained written permission for the alteration from NCFRP.
2. The PI must obtain IRB approval for the proposed research. Letters of approval must be submitted to NCFRP prior to release of data for approved analyses.
3. All data shared are and shall at all times remain the sole property of the state and local jurisdictions that conducted the fatality reviews that are the source of the data.
4. No data will be released that identifies data by state jurisdiction without the explicit approval of the state(s). States have the right of first refusal to participate in this research project if the PI plans to publish or publicly release any analysis or results that identifies individual states. It is permissible, however, to list the states included in the dataset, as long as no data are attributed to specific states, and the states have authorized this acknowledgement. States will be asked whether they wish to be specifically acknowledged in any project publication or presentation.
5. The researchers must not attempt nor permit others to attempt to use the data to learn the identity of any decedent. If the identity of a decedent should be inadvertently discovered by the PI or any other individual, the PI must make no use of this knowledge, permit others to use the knowledge, or inform anyone else of this knowledge, and must inform NCFRP of the discovery so it can prevent future discoveries of this nature.
6. Although no HIPAA defined personally identifiable data elements should be included in the free text fields or the Narrative field of Section O, should there be ANY identifying

elements in these variables, it is considered to be an inadvertent disclosure and (1) shall not be used or disclosed by researchers, (2) shall be immediately deleted by researchers and (3) be immediately reported to MPHI/NCFRP with written confirmation by the researchers that the confidential information cannot be used.

7. Only aggregated data with cell counts of six or more cases will be released and reported in any analysis. Cells less than six will be omitted or combined with other like cells.
8. All oral and written presentations or other distribution of information resulting from the use of these data must be developed with adequate provision for the accuracy, reliability and integrity of the data.
9. All oral and written presentations or other distribution of information resulting from the use of the requested data must be submitted to NCFRP for review at least two weeks prior to presentation or submission to a journal or other source of publication. The purpose of this review is to determine whether the research was completed in the manner specified in the Application and whether the analysis is in the spirit of Fatality Review and the NCFRP mission, and to permit NCFRP to have advance notice of potential issues pertaining to the analysis and/or results. Any additional or other use of these data will be considered a breach of the Contract for Data, unless agreed upon in writing by both parties beforehand.
10. NCFRP may terminate its contract with the recipient if the recipient is in violation of any condition of the contract and such violation is not remedied within 30 days after the date of written notice of the violation. Furthermore, failure to comply with the contract terms will result in the disqualification of the PI, along with any collaborators implicated in the violation, from receiving additional NCFRP data.
11. All presentations and publications making use of these data must be provided to NCFRP in a timely manner so that it is a repository of the various uses of the data.
12. All presentations or other distribution resulting from use of the requested dataset must include an acknowledgement of the participating states and NCFRP. They must include the following language: "This dataset was provided by the NCFRP, which is funded in part by Cooperative Agreement Numbers UG7MC28482 and UG7MC31831from the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) and in part by the US Centers for Disease Control and Prevention Division of Reproductive Health. The contents are solely the responsibility of the authors and do not necessarily represent the official views of NCFRP, HHS or the participating states. The following states contributed data from their fatality review: (list states)."
13. Within three years of completion of the project, all hard copies of the dataset generated by the researchers must be destroyed with a cross-cut shredder or returned to NCFRP, and all electronic data must be destroyed/deleted within the same time frame. Written confirmation that the dataset has been destroyed is required.
14. All installations of the data must have electronic security measures in place to prevent unauthorized access, by electronic or physical means, to the confidential data provided or to output from that data.

Data Inclusion

Cases included in the de-identified dataset will include all deaths that occur at least 24 months from the end of the calendar year for the preceding January-December time frame. For example,

deaths from calendar year 2015 (January 1 -December 31, 2015) and earlier will be made available in a researcher de-identified dataset on January 1, 2018. Similarly, deaths from calendar year 2016 and earlier will be made available in a researcher de-identified dataset on January 1, 2019. Cases migrated from previous fatality review reporting systems into NFR-CRS will not be included in a standard dataset but may be provided upon further consultation between the researcher and NCFRP.

Application Process

To request de-identified data from the NCFRP, the researcher must complete an Application for Data, which includes a detailed proposal describing the purpose of the data research, proposed study methods, and mechanisms that will be used to keep the data secure (see Application form). Upon receipt, the application will be reviewed by the NCFRP Data Dissemination Committee which is composed of representatives of participating states, scientists, and other relevant individuals. The Data Dissemination Committee will evaluate the application on the basis of the following criteria:

- Quality of the research question(s) and aims for use of the dataset;
- Whether the requested data elements are clearly described and whether access to those elements is necessary for the research questions;
- Applicant's understanding of the strengths and limitations of the database and analysis plan that is appropriate for this type of dataset;
- Qualifications of researchers who will have access to the dataset;
- Sufficiency of safeguards in place to maintain the data security, confidentiality, and prevent unauthorized access to data and evidence that the institution is registered with the U.S. Office for Human Research Protections;
- Extent to which the proposal is in accordance with the mission of Fatality Review, which is to better understand how and why children die and use the findings to take action that can prevent other deaths and improve the health and safety of children;
- Whether NCFRP is conducting similar research or has plans to do so; and
- Whether anticipated presentations, publications, or other dissemination of results from the research are consistent with the NCFRP mission.

At a minimum, the Committee will review applications on a quarterly basis. All applicants will be notified in writing by NCFRP of the Committee's decision. Proposals will be evaluated using the above criteria with one of three outcomes:

1. Approved
2. Revisions requested
3. Rejected for not meeting the criteria

For approved proposals, NCFRP will inform the states participating in NFR-CRS of the Committee's decision and pending research. For any research request that proposes to identify data by state in any published or publicly released analysis or results, states will be given the opportunity to have their data excluded from the study (Attachment 2). States will also be asked whether they wish to be specifically acknowledged in any project publication or presentation.

Requests for more information about the data and the process for obtaining permission to access the data should be directed to:

National Center for Fatality Review and Prevention
2395 Jolly Road, Suite 120
Okemos, MI 48864
Phone : (800) 656-2434
Email : info@ncfrp.org

NATIONAL CENTER FOR FATALITY REVIEW & PREVENTION

National Fatality Review Case Reporting System (NFR-CRS) Application for De-identified Data for Research

IMPORTANT: Please read "Data Dissemination Policies and Guidelines for Requesting Access to De-identified Data from the National Fatality Review Case Reporting System (NFR-CRS) for Research Purposes" prior to completing your application.

Please submit the completed application via e-mail to info@ncfrp.org.

A. Proposed Study

1. Project Title:

2. Principal Investigator Name:

3. Date:

4. Description of proposed research. In no more than 5 pages (excluding listing of variables), provide a detailed description of the study. This description should include:

- Clear statement of the research question(s) and/or specific study aim(s)
- A brief summary of relevant literature that provides a rationale for and documents the significance the proposed research and culminates in a succinct statement of the purpose of the research
- Detailed description of the study design and methods. Include:
    - A description of the study design;
    - Definition of your study population (e.g., infants only, children ages 10-17 with motor vehicle crash as mechanism of injury) and years of data you are requesting (e.g., 2005-2010). If you plan a comparison group, define this population also;
    - List of the variables needed to carry out the study, using the NFR-CRS as a guide. Clearly identify and define your main independent (exposure, risk factor, confounding) and dependent (outcome) variables. For example, if your main exposure is premature birth, state how you will define premature birth using these NFR-CRS data. (See Data Dissemination Policy and Guidelines -- Attachment 1 identifies the variables in the Case Report form that are removed in de-identified datasets. These variables cannot be requested for research purposes. Attachment 2 is the template used by NCFRP to request permission from states if researchers intends to publish data by state name.);

- NOTE: Sections I1 and N of the NFR-CRS were added for use by the Centers for Disease Control and Prevention's Sudden Unexpected Infant Death and Sudden Death in the Young Case Registry. As such, these data elements are not available across all years, and completion may be limited among jurisdictions that were not funded for participation in the Registry.

- A detailed analysis plan. Include the software that will be used for analysis and statistical tests (if any) planned. It is extremely helpful to include proposed tables;
- A description of how you will handle small numbers and missing/incomplete data; and
- A description of how the limitations of the NFR-CRS might affect your study and how these limitations will be addressed/mitigated.

5. A timeline for completion of your study:

6. Anticipated presentations, publications, or other dissemination of results, be specific:

B. Investigator/researchers

1. Identify the Principal Investigator (PI) who will carry out the duties described in the Guidelines. Provide name, title, institution, department, address, contact telephone and e-mail address. Provide curriculum vitae as an attachment.

2. Identify each additional researcher/collaborator/co-investigator that will have access to the data. Include name, title, institution, department, address, contact telephone and e-mail address. Provide a curriculum vitae for each.

3. Describe the specific responsibilities that the PI and each of the other investigator(s) will have in conducting and completing the proposed research. The PI and all other investigators will each need to complete a confidentiality agreement (Attachment 3).

C. Data Security

All users of the NFR-CRS data must have electronic security measures in place to prevent access to the data from unauthorized individuals.

1. Describe where the data will reside and how the data will be shared among researchers. Describe the physical transmission.

2. Security details: In the table below, provide a comprehensive list of all devices on which the data will be installed and indicate the electronic security measures that will be applied to each device. For those devices that have access to the Internet, all four of the electronic security measures must be in place for this data request to be approved. For non-Internet devices, firewall protection is not required.

If co-investigators at different institutions from the PI will also have physical control of the data, complete a table for each such co-investigator's institution.

ID	**Device type** Indicate workstation, laptop, server, portable media, or other device	**Internet** Does the device have access to the Internet?(Y/N)	**Electronic security measures**			
			Password login? (Y/N) The device requires a login ID and password at startup and after a period of inactivity.	**Restricted directory access? (Y/N)** The directories containing the data are restricted to authorized users who have logged in to the device.	**Virus protection? (Y/N?)** Anti-virus software is installed on the device.	**Firewall protection? (Y/N)** Firewall technology is in place for devices that are connected to the Internet.
1						
2						
3						
4						

3. Physical security: In addition to electronic security, the devices on which the data have been copied must be physically secured to prevent theft of the device. Describe below the physical security measure in place for each device.

   If co-investigators at different institutions from the PI will also have physical control of the data, complete the table for each such co-investigator's institution and describe how data will be securely transferred between institutions.

ID	**Location of Device** Indicate building name and office number	**Description of physical security** Examples are offices are locked when unoccupied; storage in secure cabinets when the device is not in use; and monitored access to the building where the data are stored.
1		
2		
3		
4		

D. Receiving Institution

1. Identify the Receiving Institution.
2. Describe your Institution in detail. What kind of work does it do? Include the type of organization, its profit/non-profit status, and primary sources of revenue.
3. Provide evidence in an attachment that your institution is registered with the U.S. Office for Human Research Protections.
4. Describe your plans to obtain Institutional Review Board (IRB) approval for this study using the NFR-CRS data.
5. Provide the IRB assurance number.
6. Describe your Institution's experience in overseeing the use of sensitive research data by its staff. Please give specific examples.
7. Describe any known breaches of sensitive research data by your organization and the steps taken to remedy the breach.

Application signatures:

_____ _____

Signature of Principal Investigator Date

_____ _____

Signature of Representative of Receiving Institution Date

_____

Title

TEMPLATE ONLY: CONTRACT NEED NOT BE COMPLETED OR SIGNED AT TIME OF APPLICATION

MICHIGAN PUBLIC HEALTH INSTITUTE
National Center for Fatality Review and Prevention

SAMPLE Contract for Access to and Use of Data

This contract specifies the conditions for release of National Center for Fatality Review and Prevention (NCFRP) Fatality Reporting System data, research, and reports for legitimate public health or related research. The intent of this contract is to foster such research and to prevent misrepresentation of the data. This Contract for Access to and Use of Data (Contract for Data) is between [_____] (Investigators), and Michigan Public Health Institute/National Center for Fatality Review and Prevention (NCFRP).

This Contract for Data is for the study entitled [_____], as described in the Application for De-identified Data, dated [_____], which is attached hereto and made part of this contract as Appendix A. The Investigators are responsible for ensuring that all work under this study including the work of additional researchers, collaborators, and co-investigators complies with all applicable federal, state, local and international laws and regulations; and that the work is performed in a professional manner to the highest academic standards.

Investigators agree to the following requirements for the use of the data and assure compliance with the requirements.

1. This agreement applies to all activities occurring between the date of signing and 18 months after that date.

2. No one will be permitted to use this dataset to conduct analyses other than those described in the Application for Access to and Use of Data that accompanies this statement.

3. IRB approval of the Receiving Institution will be obtained, and documentation of that approval will be provided to NCFRP prior to release of any dataset.

4. Investigators understand that all data shared are and shall at all times remain the sole property of the state and local teams that conducted the fatality reviews that are the source of the data.

5. NCFRP will seek permission from the participating states for release of the data for the project described in the Application for Data if said states are to be named in the

analysis or results. States have the right of first refusal to participate in this research project if applicant intends to identify state jurisdiction in any published or publicly released analysis or results.

6. Neither the dataset nor any part of it will be released to any persons other than those identified in the approved Application for Data.

7. Investigators and all other researchers with access to the data will not attempt nor permit others to attempt to use the data to learn the identity of any decedent. If the identity of a decedent should be inadvertently discovered, Investigators will make no use of this knowledge, nor will they permit others to use the knowledge. Investigators will inform NCFRP of the discovery so it can prevent future discoveries. Investigators will not inform anyone else of the discovery of identity.

8. Investigators understand that not all deaths of children in the states have been reviewed by fatality review teams and that not every fatality review team in the country participates in the NFR-CRS.

9. Investigators understand that data will only be reported at an aggregated level and no data will be released that identifies data by state jurisdiction without explicit state permission. Aggregated data must have cell counts of six or more in order to be reported.

10. Investigators will not alter the approved research design without written permission from NCFRP.

11. All oral and written presentations or other distribution of information resulting from the use of this dataset shall be developed with adequate provision for the accuracy, reliability and integrity of the data.

12. All oral and written presentations or other distribution of information resulting from the use of the requested dataset will be submitted to the NCFRP for review at least two weeks prior to presentation or submission to a journal or other source of publication.

13. All oral and written presentations or other distribution of information resulting from use of the requested dataset will include an acknowledgement of the participating states and NCFRP.

14. All presentations and publications will include the following language: "This dataset was provided by the NCFRP, which is funded in part by the U.S. Department of Health and Human Services (HHS), Health Resources and

TEMPLATE ONLY: CONTRACT NEED NOT BE COMPLETED OR SIGNED AT TIME OF APPLICATION

Services Administration (HRSA) and in part by the US Centers for Disease Control and Prevention Division of Reproductive Health. The contents are solely the responsibility of the authors and do not necessarily represent the official views of NCFRP, HHS or the participating states. The following states contributed data from their fatality review (list states)."

15. All presentations and publications making use of these data shall be provided to NCFRP in a timely manner so that it is a repository of the various uses of the data.

16. Investigators understand that once a proposal for use of the data is approved, NCFRP may acknowledge publicly the investigators' names, institution, and name of the study as partners working with the NFR-CRS data.

17. The sharing of these data for the purposes stated in the approved project does not imply, in whole or in part, that the topic of the approved project has not been investigated before or will not be investigated now or in the future, by other investigators interested in this topic.

18. Any additional or other use of these data except as described in Investigators' Application for Data will be considered a breach of this contract, unless agreed upon in writing by both parties beforehand.

19. Investigators will assure compliance with the security measures described in the Application for Data.

20. When the proposed analyses are completed, all copies of the dataset will be destroyed with a cross-cut shredder or returned to the NCFRP upon completion of project plus three years. All electronic versions of the dataset will be deleted. Written confirmation that the dataset has been destroyed or deleted is required.

21. By signing this document, Investigators agree to be responsible for compliance with the conditions of this agreement and agree to these conditions by their signatures below.

22. Cost-reimbursement for the time and expenses spent by MPHI staff to compile the data file requested by Investigators may be invoiced to Investigators after the work is complete. The invoice must be paid in full to Michigan Public Health Institute prior to release of the data file.

23. NCFRP may terminate the Contract for Data if the Investigator is in violation of any condition of the agreement and such violation is not remedied within 30 days after the date of written notice of the violation.

TEMPLATE ONLY: CONTRACT NEED NOT BE COMPLETED OR SIGNED AT TIME OF APPLICATION

Principal Investigator:

Name: _____ Title: _____

Organization: _____

Address: _____

Email address: _____Phone: _____

Signature: _____ Date: _____

For Receiving Institution:

Name: _____ Title: _____

Organization: _____

Address: _____

Email address: _____Phone: (_) _____

Signature: _____ Date: _____

For MPHI:

Name: _____ Title: _____

Organization: ___Michigan Public Health Institute_____

Address: __2395 Jolly Road, Suite 120, Okemos MI 48864_____

Email address: _____Phone: (_) _____

Signature: _____ Date: _____

Attachment 1

HIPAA Required Elements to De-Identify Case Data*

The NFR-CRS supports two types of data downloads: identified and de-identified. NCFRP staff and researchers who have been approved by the NCFRP will receive only de-identified data. The NFR-CRS variables that will be removed in de-identified downloads are listed below.

The NFR-CRS contains many free text fields (most often in the 'specify' or 'describe' text fields). The NFR-CRS also provides users the opportunity to provide more detail surrounding the circumstances of the death in Section O: Narrative text field. **When the Narrative, 'specify,' and/or 'describe' text fields are included in a de-identified download, the Narrative, 'describe,' and 'specify' text fields SHOULD NOT contain any HIPAA Identifiers.**

HIPAA Identifiers include names; all geographical subdivisions smaller than a state; all elements of dates (except year) for dates directly related to an individual; phone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web universal resource locators; internet protocol address numbers; biometric identifiers; full face photographic images; and any other unique identifying number, characteristic or code.

Identifying information can be entered into the NFR-CRS element fields in the list below, including free text fields associated with the listed fields, because all the listed fields and their related text fields will be removed from every de-identified download. **However, users should be instructed by the Holder not to enter any identifying information in other free text fields, including Section O: Narrative text field, because these text fields may be included in de-identified downloads. NCFRP cannot review free text fields in de-identified downloads to assure that they contain no HIPAA Identifiers.**

HIPAA Required Elements to De-Identify Case Data

The NFR-CRS elements listed below will be removed for all persons accessing de-identified case data:

Introduction: Case Definition
Case number
County of review
Review team number
Sequence of review
Death certificate number
Birth certificate number
Medical examiner/Coroner number
Date fatality review team notified of death

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* **Source: Code of Federal Regulations Section 164.514(b)(2)(i).**

Section A: Child Information
Child first name
Child middle name
Child last name
Child name: unknown
Date of birth: month, day, and year
Date of birth: unknown
Date of death: month and day
Date of death: unknown
Residential address: unknown
Residential address: street
Residential address: apartment
Residential address: city
Residential address: county
Residential address: zip
County of death
Mother's first name
Mother's middle name
Mother's last name
Mother's maiden name
Mother's name: unknown
Father's first name
Father's middle name
Father's last name
Father's name: unknown
Mother's residence address: same as child
Mother's residence address: unknown
Mother's residence address:street
Mother's residence address: apartment
Mother's residence address city
Mother's residence address: zip
Mother's residence address: county
Mother's discharge date from hospital
Date of infant's last discharge date

Section E: Incident Information
Date of incident
Date of incident: same
Date of incident: unknown
Incident county

Section M: Review Meeting Process
Date of first review meeting

Section N: SUID and SDY Case Registry
Date of first Advanced Review meeting
Date of SUID Case Registry data entry complete

Section P: Form Completed By
Form completed by – Person's name
Form completed by – Title
Form completed by – Agency
Form completed by – Phone
Form completed by – Phone extension
Form completed by – Email
Form completed by - Date
Date of quality assurance completed by State

Prevention Outcomes
Prevention Outcomes – Person's name
Prevention Outcomes - Team of review

* **Source: Code of Federal Regulation Section 164.514(b)(2)(i).**

Attachment 2

A Request for the Release of Fatality Review Case Report Data when Research Applicant Intends to Identify State(s) in Proposed Published Analysis or Results

The following template will be used by NCFRP to request written authorization from states participating with the Fatality Review Case Reporting System for permission to release individual case report data to research applicants that intend to identify state jurisdiction in published analysis or results. State permission will be sought once the Data Dissemination Committee has approved the project.

Dear State of (insert state) Data Holder:

This letter is to inform you that the National Center for Fatality Review and Prevention (NCFRP) has received a request to release de-identified individual case report data. The request was submitted by (insert name of requestor and organization) on (insert date).

The requester will be using the data for the purpose of (insert purpose). If the requester intends to use the data for a purpose other than what is stated here, they must submit a new request.

Per the National Center for Fatality Review and Prevention's Guidelines for Requesting De-identified Data, written permission is necessary from each state where the research applicant intends to identify state jurisdictions in published or publicly released analysis or results of fatality review data.

As a reminder, de-identified individual case report data released by the NCFRP will not include the list of data elements found in Appendix B of the NCFRP Data Dissemination Policy and Guidelines.

Please verify that your state is not precluded from releasing this data by any rules or statutes before signing this agreement.

If you approve this data request, please sign both copies of the attached contract. Mail both copies to the National Center for Fatality Review and Prevention for signature.

Attachment 3

Confidentiality Agreement to be Signed by All Researchers with Access to NFR-CRS Data

By signing this Agreement, I agree to the following:

1. I will safeguard the confidentiality of all confidential information contained in the NFR-CRS data to which I have been given access. I will not carelessly handle confidential information. I will not in any way divulge copy, release, sell, loan, review, or alter any confidential information except as within the scope of my duties.
2. I will only access confidential information for which I have a need to know and I will use that information only as needed to perform my duties.
3. I will not attempt nor permit others to attempt to use the data to learn the identity of any decedent. If I inadvertently discover the identity of a decedent, I will make no use of this knowledge, will not permit others to use the knowledge, will not inform anyone else of this knowledge, and will inform NCFRP of the discovery so it can prevent future discoveries.
4. I will transmit and store all electronic and hard copy data in a secure and confidential manner and location at all times.
5. Upon completion of the performance of my duties, the identifiable data will be destroyed and no opportunities will be available to access that data on the network or computer systems.
6. I will promptly report activities by any individual or entity that I suspect may compromise the availability, integrity, security, or privacy of confidential information.
7. I understand that the ownership of any confidential information referred to in this Agreement is defined by State statutes.
8. I understand that violating applicable laws and regulations may lead to other legal penalties imposed by the judicial system.

Signature: _____ **Date:** _____

Print Name: _____

Attachment 4

NATIONAL CFRP
Saving Lives Together

SELECTED JOURNAL ARTICLES AND REPORTS USING NFR-CRS DATA

Updated August 2019

Firearm Suicide among Youth in the United States, 2004-2015

Schnitzer P, Dykstra H, Trigylidas T, Lichenstein R. *J Behav Med* (2019) 42: 584. https://doi.org/10.1007/s10865-019-00037-0

Infant Deaths in Sitting Devices

Liaw P, Moon R, Han A, Colvin J. *Pediatrics* Jul 2019, 144 (1) e20182576; DOI: 10.1542/peds.2018-2576

Sleep-Related Infant Suffocation Deaths Attributable to Soft Bedding, Overlay, and Wedging

Erck AB, Parks SE, Cottengim, C, Faulkner, M, Hauck F, Shapiro-Mendoza CK. 2019. *Pediatrics* May 2019, 143 (5) e20183408; DOI: 10.1542/peds.2018-3408

The Sudden Death in the Young Case Registry: Collaborating to Understand and Reduce Mortality

Burns KM, Bienemann L, Camperlengo L, Cottengim C, Covington T, Dykstra H, Faulkner M, Kobau R, Lambert AB, MacLeod H, Parks SE, Rosenberg E, Russell M, Shapiro-Mendoza CK, Shaw E, Tian N, Whittemore V, Kaltman J Sudden Death in the Young Case Registry Steering Committee *Pediatrics* Mar 2017, 139 (3) e20162757; DOI: 10.1542/peds.2016-2757

Dangerous Waters: Profiles of Fatal Child Drowning in the U.S. 2005-2014

MacKay JM, Steel A, Dykstra H. 2016. Safe Kids Worldwide.
https://www.safekids.org/sites/default/files/dangerous_waters_research_report.pdf

Keeping Kids Safe In and Around Water: Exploring Misconceptions that Lead to Drowning

MacKay JM, Steel A, Dykstra H, Wheeler T, Samuel E, Green A. 2016. Safe Kids Worldwide.
https://www.safekids.org/sites/default/files/small_water_safety_study_2016.pdf

Death Scene Investigation and Autopsy Practices in Sudden Unexpected Infant Deaths

Erck AB, Parks SE, Camperlengo L, Cottengim C, Anderson RL, Covington TM, Shapiro-Mendoza CK. 2016. *Pediatrics* 2016; 174:84-90.

Pediatric Suicide in the United States: Analysis of the National Child Death Case Reporting System

Triglylidas T, Reynolds E, Teshome G, Dykstra H, Lichenstein R. 2016. I*njury Prevention* 2016; 0:1–6. Published first online.doi:10.1136/injuryprev-2015-041796

Crib bumpers continue to cause infant deaths: A need for a new preventive approach

Scheers N.J., Woodard D.W, Thach, B.T. 2015. *Pediatrics*, DOI: http://dx.doi.org/10.1016/j.jpeds.2015.10.050. Published online 11/24/2015.

Cause-specific mortality among children and young adults with epilepsy: Results from the U.S. National Child Death Review Case Reporting System

Tian N, Shaw EC, Zack M, Kobau R, Dykstra H, Covington TM. 2015. *Epilepsy Behav*. 2015. Apr; 45:31-4. doi: 10.1016/j.yebeh.2015.02.006.

Development of a dataset of national cardiovascular deaths in the young
Vetter VL, Dugan NP, Haley DM, Covington TM, Dykstra H, Overpeck M, Iyer VR, Shults J. 2014. *American Heart Journal.* DOI: doi: 10.1016/j.ahj.2014.06.015.

Sofas and Infant Mortality
Rechtman LR, Colvin JD, Blair PS, & Moon RY. 2014. *Pediatrics* 2014. 134:e1292.

Sleep Environment Risks for Younger and Older Infants
Colvin J, et al. 2014. *Pediatrics* 134(2):e406-e412.

Classification System for the Sudden Unexpected Infant Death Case Registry and its Application
Shapiro-Mendoza C, Camperlengo L, Ludvigsen R, Cottengim C, Anderson R, Andrew T, Covington T, Hauck F, Kemp J, MacDorman M. 2014. *Pediatrics* 2014; 134(1): 1-10.

Child maltreatment deaths in the U.S. National Child Death Review Case Reporting System
Palusci V, Covington T. 2013. *Child Abuse Neglect.* S0145-2134(13)00245-7. doi: 10.1016/j.chiabu.2013.08.014.

Sudden Unexpected Infant Deaths: Sleep Environment and Circumstances
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