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 NCFRP website **(**https://www.ncfrp.org).

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 to identify risk factors and possible prevention strategies. Data entered into NFR-CRS may be

[1] The National Center is funded in part by Cooperative Agreement Number UG728482 from the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB) as part of an award totaling $5,149,996 annually with 0 percent financed with non-governmental sources. Its contents are solely the responsibility of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

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: parental/family 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 or FIMR jurisdiction 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 2020 (January 1- December 31, 2020) and earlier will be made available in a researcher de-identified dataset on January 1, 2023. Deaths occurring in calendar year 2021 and earlier will be made available in a researcher de-identified dataset on January 1, 2024. 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 teams often enter HIPAA-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 NFR-CRS 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 be 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 data, individual states or FIMR jurisdictions are not identified in data provided for approved research. However, NCFRP will create and provide a unique code so that researchers can evaluate variation and control for potential bias in the dataset without identifying the individual states or jurisdictions.

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 the number of staffing hours estimated to prepare the dataset using MPHI hourly 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 NFR-CRS and are in constant communication with teams about data and reporting questions. Since the data are owned by the participating states and FIMR jurisdictions, they are responsible for the quality of their data. States and FIMR jurisdictions 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 NFR-CRS. The NFR-CRS 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 or jurisdiction without the explicit approval of the state(s) or jurisdiction(s). States or jurisdictions 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 or jurisdictions. It is permissible, however, to list the states or jurisdiction included in the dataset, as long as no data are attributed to specific states or jurisdiction, and the states or jurisdictions have authorized this acknowledgement. The PI will need to inform NCFRP of their desired intention to list participating states or jurisdictions in their research; NCFRP will contact states or jurisdictions for permission before public release of any results by PI.
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 distributions resulting from use of the requested dataset must include an acknowledgment 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 UG728482 from the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) and in part by the U.S. 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."
13. The PI will have three years from the time the data file has been provided by NCFRP to prepare a manuscript. If the manuscript has not been completed within three years of receipt of the data file, the PI agrees to destroy all hard copies of the dataset generated with a cross-cut shredder or return the dataset to NCFRP; all electronic data must be destroyed/deleted within the same time frame. The PI will provide written notification to NCFRP that they were unable to complete the research and will no longer be conducting any analysis on the research topic and will not be publishing any findings.
14. 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.

15. 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 2020 (January 1 - December 31, 2020) and earlier will be made available in a researcher de-identified dataset on January 1, 2023. Similarly, deaths from calendar year 2021 and earlier will be made available in a researcher de-identified dataset on January 1, 2024. 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 fetuses, infants, and 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 any research request that proposes to identify data by state or jurisdiction in any published or publicly released analysis or results, states or jurisdictions will be given the opportunity to have their data excluded from the study (Attachment 2).

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

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