Bureau of Vital Statistics
Florida Department of Health
External Procedures for Data Access and Research

Purpose

These guidelines are intended for individuals external to the Florida Department of Health (DOH) who wish to access vital statistics data (e.g., births, deaths, fetal deaths, infant deaths, maternal deaths, marriage and divorce).

Data Release Goals

- Maximize Florida vital records data availability and use for program evaluation and research
- Release meaningful vital records data while protecting individual privacy and confidentiality
- Comply with all federal and state laws and Florida Department of Health policies

Research and Data Access Overview

Because vital statistics data include medical and personal information that could identify individual respondents, these data are considered confidential under Florida Statute 382.025 (3)(d). Examples of confidential information include name, address, social security number, date of birth, census block, latitude/longitude, and cause of death. The Bureau of Vital Statistics may provide exceptions to the statute for qualified applicants for the release of certain data.

Florida Statute 382.025 (3)(d) provides the release of vital statistics data if the research meets all of the following criteria:

- Demonstrates scientific merit;
- Does not involve intrusive follow back of contacts;
- Includes an approved Vital Statistics Data Use Agreement; and,
- Receives a research determination where appropriate by the Florida Department of Health Institutional Review Board.

The Bureau of Vital Statistics conducts a detailed review of every application for access to vital statistics data and makes a determination on a case by case basis. Requests for confidential data will be granted only if the project meets the criteria above and the project cannot be reasonably completed with de-identified information. Approved applicants are held to the highest ethical standards and must agree to the stipulations detailed in the Vital Statistics Data Use Agreement. Maintaining the privacy of the individuals whose personal information is included in vital records is essential to preserving the integrity of the data sharing process.

Vital Statistics Data Use Agreement

All data shared with external applicants require an approved data use agreement. This applies whether the data are confidential or non-confidential, or an ongoing project or a one time request. The primary custodian is the person to whom data are given and who is responsible for ensuring adherence to the DOH data confidentiality and security policies. Please note that for projects spanning more than one physical location someone from each additional site must be designated as a primary data custodian. Data may be used by the primary custodian only for the purpose stated in the data use agreement and may not be used for any other purpose without direct

approval from the Bureau of Vital Statistics. The primary custodian may not link vital records data with any other source of information without the written authorization of the Bureau of Vital Statistics. All persons who have access to vital statistics data must sign a confidentiality statement.

Consistent with Florida law, applicants must make provisions for the destruction of confidential records at the conclusion of their research investigation, detailing both the manner and timeline for destruction.

No contacts of any kind can be made with any person named on a certificate or data file made without the permission of the Bureau of Vital Statistics and the IRB. Data use agreements may be rejected if the research protocol involves intrusive follow back of research subjects. **If the project requires IRB review, applicants first must have an approved data use agreement to apply for IRB review**.

Florida Department of Health Institutional Review Board Review

In addition to Florida and federal laws that govern confidential information, federal regulations protect the rights and privacy of human subjects involved either directly or indirectly in research studies. The US Department of Health and Human Services (HHS) has issued regulations (45 CFR part 46) that apply to the protection of human subjects in research studies. Human subjects encompass both living individuals about whom an investigator collects data through interaction or intervention OR about whom identifiable private information is collected. The federal regulations determine whether an activity meets the criteria for research defined as a "means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

If a study meets the criteria for research with human subjects, then compliance with 45 CFR 46 is mandated. This means that the proposed research must be reviewed and approved by the DOH IRB. No interaction with human subjects in research may begin until the DOH IRB has reviewed and approved the research protocol. Additionally, the regulations further specify when a research study requires full board review or may be expedited because the study poses no more than minimal risk to research subjects. Examples of expedited review include research activities limited to existing datasets, records review, or documents that do not require direct contact with individuals.

Meeting one or more of the following criteria requires Florida IRB review:

- The project involves human subjects and its purpose is to conduct research or an investigation that will contribute to generalizable knowledge (a publication, presentation, etc.)

- The activity involves obtaining identifiable data about living individuals who are being contacted for research purposes.

- The project deals with decedents and involves contact with their family.

If, after data are collected for non-research purposes, an applicant wants to access the data with the intent of conducting research, IRB review and approval may be required prior to accessing the data for research purposes.

If an applicant begins a non-research project and later finds that the data gathered could contribute to generalizable knowledge, the ultimate decision regarding classification lies in the

intent of the project. If the primary intent is to generate generalizable knowledge, the project is research. If the primary intent is to prevent or control disease or injury or to improve a public health program, and no research is intended at the present time, the project is non-research. The key regulatory criteria is whether, given the identifiable information obtained for research, one may "readily ascertain" the identity of participants.

Prior to initiating the IRB application process, we strongly encourage interested parties to consult with the DOH Ethics and Human Subjects Research Protection Program regarding whether their data request meets the criteria for IRB review under federal regulations. To request a consultation, please complete the form found at http://flpublichealthethics.net/index.php/eng/ethics_and_public_health_practitioners.

Confidentiality

Confidential Information refers to individually identifiable information, including, but not limited to, medical and demographic information, that:

- Reveals the identity of the data subject or is readily identified with the data subject, such as name, address, telephone number, social security number, health identification number, or date of birth; or,
- Provides a reasonable basis to believe that the information could be used, either alone or in combination with other information, to identify a data subject.

All information relating to cause of death in all death and fetal death records and the parentage, marital status, and medical information included in all fetal death records of this state are confidential and exempt from the provisions of FS 119.07(1), except for health research purposes as approved by the department.

Birth

- All fields from the birth certificate are considered confidential when personal identifiers are provided.
- Births aggregated by zip code or census tract without identifiers are non-confidential.
- Births by mother's race, mother's ethnicity, mother's age, mother's marital status, mother's education by zip code, or census tract are non-confidential.

Death

- Only probable manner and cause of death are confidential.
- Deaths by cause aggregated by zip code or census tract without special conditions or personal identifiers are non-confidential.
- Deaths by race, ethnicity, sex, age, marital status, education, and cause of death by zip code or census tract are non-confidential.

Fetal death

- Parents' personal identifiers are considered confidential.
- Aggregated counts of fetal deaths by zip code or census tract are non-confidential.
- Aggregated lists of fetal deaths by mother's race, ethnicity, age, marital status, education by zip code and/or census tract are non-confidential.

Marriage records

- None of the fields, including those with personal identifiers, are confidential.

Divorce records

- None of the fields, including those with personal identifiers, are confidential.

Destruction Schedule

Each application requesting vital statistics data must include a data destruction schedule detailing the method and timeline by which data will be destroyed after the project concludes. Acceptable methods of destruction include shredding, incineration, and electronic file deletion. If the applicant requests that the records be stored indefinitely (either at the applying agency, institution, or organization or in a Federal Records Repository), the applicant will be asked to state a definitive destruction schedule. For projects that request an indefinite schedule, case-by-case decisions regarding approval/disapproval will be made.

Permissible Uses and Disclosures of Vital Records Data

Applicants may not disclose the release of vital record data to any persons or entities other than those clearly stated in the application and data use agreement. DOH reserves the right to restrict disclosure of data to the minimum number of persons who require the data to perform the functions outlined in the data use agreement. If the applicant requires coordination or collaboration with a third party with whom identifiable data may be shared, then they must complete and notarize a Vital Statistics Data Use Agreement form and be included on the application. Once the third-party entity provides a signed, notarized form, they also enter into a direct contractual agreement with the State of Florida. If the project required IRB review, any additional persons with access to the data files must be added to the IRB protocol by submitting an amendment.

Fees

The Bureau of Vital Statistics has been given statutory authority to charge for data requests. Costs will vary based on the nature of the work to be performed. Investigators will be notified in advance of costs per hour for programming time. If the project requires IRB review, applicants must first submit signed and notarized Data Purchase and Use Agreement along with the protocol for review to Bureau of Vital Statistics. A waiver or reduction of the fees authorized by section 382.0255(1), F.S. will be considered only if the intended use of the data will have a direct health-related benefit to Florida citizens.

Publications and Presentations

Descriptive or statistical results based on the data provided by the Bureau of Vital Statistics may be released; however, DOH prohibits the release of results that may lead to the identification of individuals or be traced back to an individual record. A copy of all abstracts, presentations or papers that result from the use of the data must be sent to the Bureau of Vital Statistics (see address below), at least 30 days prior to their public release. The publication must cite the Florida DOH as the data source. A statement must also be included that any conclusions are the author's own and do not necessarily reflect the opinion of DOH.

Resources

Link to the vital records codebook:
http://www.doh.state.fl.us/Planning_eval/phstats/Codebooks/vs_coding.htm

Link to Florida CHARTS
http://www.floridacharts.com/charts/chart.aspx

Florida Institutional Review Board home page:
http://www.doh.state.fl.us/execstaff/irb/index.html

Courtesy copies of publications and presentations to:
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