Policy #002
Iowa Department of Public Health Center for Congenital and Inherited Disorders

Release of Data Policy and Procedure

I. Overview

The Iowa Newborn Screening Program (INSP) and the Iowa Maternal Prenatal Screening Program (IMPSP) are public health programs administered by the Center for Congenital and Inherited Disorders (CCID) at the Iowa Department of Public Health. The Iowa Department of Public Health (IDPH) is governed by Iowa's Open Records law and generally provides public access to all records it maintains (Iowa Code chapter 22). In addition, IDPH is committed to providing information, data, and records to the public and the media to promote and protect the health of the population.

However, Iowa law also provides that certain information, data, and records maintained by IDPH are confidential and may not be disclosed to the public. For purposes of this Policy, a "confidential public health record" includes a record, certificate, report, data, dataset, or information which is confidential under federal or state law the above-cited provisions or other provision of federal or state law.

The purpose of this policy is to outline the legal status of confidential newborn screening data, provide guidance regarding the disclosure of confidential public health information, and describe the procedure for requesting data from the INSP and IMPSP programs.

These guidelines are generally applicable to all confidential public health records within the IDPH, including newborn screening and maternal prenatal screening data.

II. Definitions

Anonymized. Permanently dissociating a specimen or data from any personally identifiable information (PII) of the index individual or their parents or relatives.

Confidentiality. Assurance that PII is accessed by authorized individuals only and is not shared without express authorization of the parent or legal guardian of the index individual.
"Confidential public health record" includes a record, certificate, report, data, dataset, or information which is confidential under federal or state law. This includes personally identifiable medical information provided for the purpose of studies to reduce morbidity or mortality. Iowa Code §§ 135.40, 135.41.

Confidential Information
As a general rule, public health records which contain personally identifiable information of a health-related nature are confidential under Iowa law.

For examples, IDPH is required by law to generally maintain the confidentiality of the following records:

1. Hospital records, medical records, and professional counselor records of the condition, diagnosis, care, or treatment of a patient. Iowa Code § 22.7(2).
2. Personally identifiable medical information provided for the purpose of studies to reduce morbidity or mortality. Iowa Code §§ 135.40, 135.41.
3. Personally identifiable information and business identity related to a reportable disease or condition. Iowa Code § 139A.3; Iowa Code §§ 139A.30 - 32.
4. Personally identifiable information contained in IDPH registries, including the Statewide Trauma Registry, Immunization Registry, Central Registry for Brain or Spinal Cord Injuries, and Congenital and Inherited Disorder Registry. Iowa Code §§ 147A.25, 147A.26; 641 IAC 136.2(5); Iowa Code section 22.7(2); 641 IAC 7.12; Iowa Code § 135.22; Iowa Code §136A.7.
5. Vital statistics records. Iowa Code § 144.43. (IDPH may release confidential records through research and data use agreements.)
6. Records which contain identifiable information related to a child's newborn hearing screening, rescreening, and diagnostic audiologic assessment. 641 IAC 3.10.
7. Perinatal program surveys and reports. Iowa Code § 135.11(28).
8. Records containing identifiable information related to a child's newborn screening, rescreening, follow-up, diagnosis and referral. Iowa Code § 136A. 641 IAC 4.

De-identified. Specimens or data that have all PII of the index individual or PII of the parents or relatives of the index individual removed and stored separately. Specimens or data alone can now neither identify nor provide a reasonable basis to identify the index individual or the parents of the individual from which the specimen was collected. A third party maintains a code that can allow for the specimen or data to be re-linked to PII if necessary.

Identified. Data which contain any information that directly or could reasonably be said to indirectly allow the linkage of a newborn screening or maternal prenatal screening specimen or data derived from the specimen back to the index individual or the parents and relatives of the index individual from which the specimen was collected.

Identifiable information (or identifiers) includes information that can be used to directly establish the identity of a person, such as a name, address, or unique identifying number. Identifiable information also includes information that can be used to indirectly establish the identity of a person by linking such information or data with external information that allows for identification of the person, such as obituaries, newspaper articles, or information on public websites.

Release of data. Provision of any data collected on behalf of the newborn screening and maternal screening public health programs to a requesting entity. May include identifiable or de-identified data.

While DNA from anonymized or de-identified newborn screening dried blood spot specimens is not considered readily identifiable information according to the "Common Rule" (Federal Policy for the Protection of Human Subjects 2008; Office of Human Research Protections, U.S. Department of Health and Human Services 2004), DNA-related information obtained through newborn or maternal prenatal screening follow up will be considered confidential information and will not be released without consent of the index patient or their guardian.

III. Release of Aggregate or Tabulated Data

As programs of IDPH, INSP and IMPSP are generally authorized to release data from a confidential public health record to the public so long as such release could not result in the identification of a person. IDPH may therefore generally release information or data in an aggregate or a tabular format. The determination of whether the release of aggregate information or tabular data would result in the identification of a person may be straightforward.

Oftentimes, the determination of whether the release of information is consistent with confidentiality restrictions is complex and may require additional analysis and consultation with these guidelines including the department's legal counsel and data use advisors.

In determining whether release of aggregate information or tabular data would result in the identification of a person, IDPH will generally follow the Centers for Disease Control and Prevention's (CDC) scientifically acceptable principles for confidentiality protection. IDPH has relied upon selected guidelines from the CDC's Staff Manual on Confidentiality, the National Center for Health Statistics Staff Manual on Confidentiality, and the CDC-CSTE Intergovernmental Data Release Guidelines Working Group Report: CDC-ATSDR Data Release Guidelines and Procedures for Re-Release of State-Provided Data, in preparing this policy. In addition, IDPH relied in part upon the Washington State Health Department's Guidelines for Working with Small Numbers in developing this policy. These sources can be found on agency specific web-sites.

In general, the following guidelines apply to the release of confidential public health records by IDPH:
Disclosure of Personal Identifiers Prohibited.

- IDPH shall not release information which directly identifies a person named in a confidential public health record, including name, address, telephone number, social security number, medical record number, exact date of subject's birth, or other direct identifiers.

- IDPH shall not knowingly release information which can be used to indirectly establish the identity of a person named in a confidential public health record by the linking of the released information or data with external information which allows for identification of such person.
  See Section V. below concerning release of data to the media.

- IDPH shall not respond to inquiries about a confidential public health record which include direct personal identifiers in a manner which confirms an inquiry.

Aggregate Data Values

- When releasing information from confidential public health records, IDPH will expand or broaden the identifier fields as needed in order to prevent identification. Common methods for preventing identification include:

- Redacting (removing) variables which directly identify a person, including name, address, telephone number, social security number, medical record number, exact date of case-patient's birth, or other direct identifiers
- Collapsing continuous/interval data (e.g., age, date of occurrence) into broad categories
- Collapsing ordinal data (e.g., location, geography) into broad categories
- Suppressing of small numbers to ensure confidentiality

Use Numerator/Cell Size Rules for Data Aggregation or Suppression

When releasing information from confidential public health records, IDPH and local boards of health and health departments should use numerator/cell size rules to either guide selection of groupings of aggregated data values, or if aggregation is insufficient, to suppress release of certain cells in a table. IDPH should not release data if the numerator cell size is five or fewer: numerator cell size counts of one, two, three, four, and five should not generally be disclosed. A count of no cases or events in the cell is not a threat to confidentiality and may be released, but a count of one, two, three, four, or five cases or events is a threat to confidentiality and should not be released.

Use Denominator/Population Size Rules for Data Aggregation or Suppression

When releasing information from confidential public health records, IDPH should use denominator/population size rules to either guide selection of groupings of aggregated data values, or if aggregation is insufficient, to suppress release of certain cells in a table. Prior to disseminating the information, IDPH should consider the size of the denominator (the population size represented in each cell of a table). Data should not be released if the total population from which the data are drawn is less than a certain size, based on the premise of a size sufficiently large enough that no subcell of the variables contained in the data would be expected to be smaller than a certain size. Generally, tabular data based on denominations greater than 300 persons per cell present minimal risk for personal identification. Caution should be exercised if the cell's population size is between 100 and 300, and release should not occur if the population is less than 100.

IV. Summary

- IDPH shall not release information which directly identifies a person named in a confidential public health record, nor respond to inquiries in a manner that confirms the identity of a person.
- IDPH should generally not report cells with counts of five or fewer.

- IDPH should be cautious when reporting rates or ratios based on denominators less than 300 and should not disclose data based on denominators less than 100.
- IDPH should be cautious when reporting a specific disease in a minority population if a high proportion of the minority population has this disease, or if the disease is primarily found in a specific population.
- When producing tables, IDPH should be careful that users cannot derive confidential information through a process of subtraction.

V. Release of Data to the Media

An important mission of public health is informing the public through the media about issues which impact the public's health. CCID staff will collaborate with the IDPH public information officers and other appropriate staff to determine the content, nature, and scope of information to be released to the media.

When releasing demographic information regarding specific case-patients to the media, if there is a question about the specificity of information which should be disclosed consultation should be sought from legal counsel prior to release of the information.

VI. Limited Exceptions Which Authorize Release of Personally Identifiable Information

In addition to those disclosures of information authorized above, Iowa law also allows IDPH to disclose confidential information under the following circumstances:

- Confidential public health records and information may be shared by and between IDPH employees and local board of health and health department employees who have a need for the information in the performance of their duties. (641 IAC 175.10(2)"a" & "e", 641 IAC 1.17(3)"a" & "b", Iowa Code 141A.9(7)). Hence, IDPH and local health department employees may share any information necessary to effectively conduct a disease investigation.
- Confidential public health records and information may be shared with public health departments in other states or the CDC or other federal agencies when necessary for the other entity to perform their duties or as necessary to conduct the investigation. (641 IAC 175.10(2)"e", 641 IAC 1.17(3)"d", Iowa Code §§ 141A.9(8)). Confidential information provided to other departments retains its confidential status and shall not be re-released by the receiving entity. In general, however, CDC and other federal agencies do not receive or retain individual identifying information.
- Public health records and information may be shared with other state governmental entities when necessary for those entities to perform their job duties. However, this information must be kept confidential by the receiving agency. In most situations, a Data Sharing Agreement may be required. Please consult the Research and Ethics Review Committee (RERC) in these situations. (641 IAC 175.10(2)"d" & "e", 641 IAC 1.17(3)"d").

- Public health records may be released to the subject of the record upon receipt of a written authorization for release from the subject or the subject's legal representative. (641 Iowa Administrative Code 175.12, Iowa Code §§ 141A.9(2)"a"). IDPH should exercise caution to ensure that other confidential information (i.e. reference to other ill individuals) contained in the report is redacted prior to release to the subject.

- Public health records may be released in response to a court order or subpoena. (641 IAC 175.9(2)"g", Iowa Code §§ 141A.9(2)"g"). Review shall be performed by the IDPH's legal counsel or local board of health and health department's legal counsel prior to release.

- IDPH may share personally identifiable information regarding diseases, health conditions, unusual clusters, or suspicious events that may be the cause of a public health disaster with the department of public safety, the homeland security and emergency management division of the department of public defense, and other appropriate federal, state, and local agencies and officials. (Iowa Code § 135.145(2)). The sharing of such information must be restricted to only that information necessary to prevent, control, and investigate the public health disaster. (Iowa Code § 135.145(3)).

VII. Penalties for Unauthorized Release of Information

A person who knowingly violates the confidentiality statutes and administrative rules cited above may be subject to criminal prosecution for a simple misdemeanor and may be subject to disciplinary action under IDPH or the relevant county's personnel policies, up to and including discharge from employment. A person who releases HIV/AIDS information is subject to criminal prosecution for an aggravated misdemeanor and is subject to civil action and civil penalties, and may be subject to disciplinary action under IDPH or the relevant county's personnel policies, up to and including discharge from employment. (Iowa Code §§ 139A.25, 141A.11).

In addition, while IDPH is not a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), local boards of health and health departments generally are covered entities, and may therefore be subject to an enforcement action under HIPAA if the local board of health or health department releases protected health information in violation of that regulation. Local boards of health and health departments should seek advice from their legal counsel to ensure their compliance with the federal law.

Procedure for Requesting Data from INSP or IMPSP Programs

I. Research to Benefit the Public Health

Research using INSP or IMPSP data shall be allowed only in instances where research would further: newborn screening activities; general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health. Products from approved research such as data or publications are not stored or maintained by the INSP.

Investigators shall submit proposals to use INSP or IMPSP data to the Executive Officer for the CCID. Any intended use of the requested data as part of the research study must be clearly delineated in the proposal. Before research can commence, proposals shall be approved by the researcher's institutional review board, the Congenital and Inherited Disorders Advisory Committee (CIDAC), and the IDPH RERC.

1. **Requests for use of INSP or IMPSP Data**

Researchers shall submit a proposal to the Executive Officer for the CCID within the IDPH. Documentation of human subjects review committee approval, a list of requested variables, resume or biosketch, and a completed Application for Access to Public Health Data for Research Agreements shall accompany the proposal.

The proposal shall:

a) Discuss project objectives, methodology, and rationale of how it will benefit the public health.
b) Identify the person or persons who will perform the study, their qualifications and organizational affiliation.
c) Describe the data needed for the study and anticipated duration of the study.
d) Describe if and how requested data will be linked to other data set(s).
e) Describe how the confidentiality and privacy of information will be assured.
f) Discuss how long the data will be kept and how the data will be discarded at the conclusion of the study.
g) Describe how the results will be disseminated.
h) Indicate that INSP/IMPSP data will be used only for the purpose stated in the proposal.

2. **Review process:**

a) The Executive Officer for CCID will distribute the proposal to the Center for Congenital and Inherited Disorders Advisory Committee (CIDAC) members and schedule a presentation of the proposal by the researcher to CIDAC members.
b) CIDAC will provide their written recommendations to the Executive Officer for CCID within two weeks of the presentation.
c) The Executive Officer for CCID will forward the CIDAC recommendations and the proposal to the RERC.
d) The RERC shall give final approval of proposals on behalf of the director of IDPH. The RERC coordinator will provide a written reply to the researcher within two months of receiving proposal from CIDAC and notify the Executive Officer of CCID. A Data Sharing Agreement may need to be completed at the discretion of the RERC. (Data sharing agreement (DSA): A legal contract between IDPH and any external entity (including other departments within state government and Regent's institutions) in which parties agree to exchange specified

variables within a dataset, or in some cases paper files, at identified intervals of time, and use of the data does not meet the conditions of initiating a research agreement.)

e) All research staff with access to the data will be required to sign a Research Agreement prior to release of the data. The Executive Officer for CCID will contact the researcher to coordinate the release of project-related data.

f) The term of the Research Agreement is two years. Upon completion of the research or within 60 days of the expiration of the Research Agreement, the researcher must submit a Confirmation of Destruction Form. If the research will extend beyond two years, a continuation application must be submitted at least 60 days prior to the expiration date of the agreement.

II. Access to INSP and IMPSP Data

Only authorized INSP and IMPSP personnel shall have access to program data. This includes authorized CCID staff, State Hygienic Laboratory staff, and screening follow up staff at The University of Iowa Department of Pediatrics, Division of Medical Genetics, and the Department of Obstetrics and Gynecology. INSP/IMPSP data shall only be released to researchers upon documentation of project approval, and description of data needed. Fees may be charged to cover costs for procurement of requested data.