Research Agreement and Research and Ethics Review Committee (RERC) Policy #CO 07-12-004

Purpose

The purpose of this policy is to outline the requirements for the review and approval of research agreements for access to confidential or implied confidential Department data for use in research as allowed by statute or Administrative Code. This policy also outlines the structure and responsibilities of the IDPH Research and Ethics Review Committee (RERC).

This policy does not apply to the review or approval of data sharing agreements where research is not the basis for the request. Non-research requests for confidential or implied confidential data must be processed according to the procedure outlined in **IDPH Policy #CO 01-16-001, Data Sharing Agreement (DSA)**. This policy also does not apply to the review or approval of Public Records requests for public data. Public records requests must be processed according to the procedures outlined in **IDPH Policy # IM 11-04-015, Public Records**.

Definitions

Confidential Public Health Information, Record or Data: A record, certificate, report, data, dataset, or information which is confidential under federal or state law. As a general rule, public health records which contain personally identifiable information of a health-related nature are confidential under Iowa law. More information about confidential public health records can be found in **IDPH Policy #CO 01-16-002, Disclosure of Confidential Public Health Information, Records, or Data.**

Data Custodian: The IDPH employee who is in the position responsible for the safe custody, transport, and storage of the data. The data custodian is also responsible for the technical environment and database structure that hosts data. The custodian for IDPH data may be indicated by statute (e.g., State Registrar of Vital Records); however, the physical custodian for the majority of IDPH data is the Bureau of Information Management and Bureau of Health Statistics.

Data Owner: The IDPH employee who is in the position that is responsible for the dataset, as designated by the director or director's designee or as indicated by statute. The data owner may authorize or deny access to certain data within IDPH, in accordance with procedures described below, and is responsible for accuracy and integrity of the data and timely response to data inquiries.

Data Requestor: The individual requesting and using confidential or implied confidential IDPH data. The requestor is the point of contact for all communication with IDPH related to the review of the application and is also responsible for non-IDPH individuals who are authorized to access data received through the research agreement.

Data Sharing Agreement (DSA): A legal contract between IDPH and any external entity (including other departments within state government and Regent's institutions), or between two internal IDPH programs in which parties agree to the exchange of specified variables within

an IDPH dataset, and use of the data does not meet the definition of research constituting a need for a Research Agreement. More information about DSAs can be found in **IDPH Policy #CO 01-16-001 Data Sharing Agreement (DSA) Policy.**

Data Steward: The IDPH employee who is in the position responsible for data content, context, and associated rules for interpretation of each data source. The data steward(s) serves as an intermediary between the data owner and data custodian. Data stewards have the responsibility of ensuring that the appropriate steps are taken to protect the data and that respective policies and guidelines are being properly implemented. The data owner and steward might be the same person.

Implied Confidential Public Health Data: Data which could 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 known external information which allows for the identification of such person. This commonly includes de-identified, row level information about an individual, and can also include some small count sizes. More information about implied confidential public health data can be found in **IDPH Policy #CO 01-16-002, Disclosure of Confidential Public Health Information, Records, or Data.**

Institutional Review Board (IRB): Also known as an independent ethics committee or ethical review board, an IRB is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans. IDPH does not have an internal IRB; therefore, an external IRB review must sought by the.

Personal Gain: Efforts by any employee that benefit an IDPH employee personally or professionally and where the "effort" is outside of the scope of normal job duties. Examples of efforts qualifying as "personal gain" include, but are not limited to using IDPH data for a dissertation or other graduate work, in consulting work, or in other supplemental employment.

Primary Investigator (PI): The individual conducting the research. The PI is responsible for the management of the research agreement. The PI is the point of contact for all communication with IDPH related to the review of the application and is also responsible for non-IDPH individuals who are authorized to access data received through the research agreement.

Research[1]: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, regardless of whether or not they are conducted or supported under a program that is considered research for other purposes. Examples of "research" are included in **Appendix A**.

[1] For the purposes of defining research within this policy, the Department has used 45 CFR § 46.102(l), which describes research activities according to the Revised Common Rule. Accessed September 2019, from https://www.ecfr.gov/.

Research Agreement: A legal contract between IDPH and any external entity (including other departments within state government and Regent's institutions) in which IDPH agrees to release specific variables within a dataset for the purposes of bona-fide research. A research agreement is required when the receiving entity intends to use the requested dataset for the purpose of research and the user is bound by the confidentiality requirements in the research agreement.

Research and Ethics Review Committee (RERC): The Research and Ethics Review Committee (RERC) is responsible for evaluating and approving or denying requests for IDPH- owned data for the purposes of research. The committee composition, roles and responsibilities are outlined in this policy.

Policy

All applications for access to confidential or implied confidential IDPH data requested for the purpose of research must be reviewed and approved by the Research and Ethics Review Committee (RERC). A research agreement must be executed prior to the release of confidential and implied confidential IDPH data for research purposes as described below. Research agreements in most cases shall be for terms of two years, and never more than a maximum of five years.

Any data released to an internal or external entity, regardless of whether or not it has been approved via this policy, must follow **IDPH Policy #CO 01-16-002, Disclosure of Confidential Public Health Information, Records, or Data**.

Data Requestors:

Those requesting IDPH data for research purposes who are external to the Iowa Department of Public Health (including other departments within state government and Regents' institutions) shall:

1. Submit an application, list of variables, notice of IRB approval or exemption, and any other information requested by the RERC or Data Management and Health Equity Program to the IDPH Data Management and Health Equity Program.
    a. Conditional project approval may be granted when IRB approval is pending; however, no data will be released until IRB approval is obtained and submitted to IDPH.
    b. A fee may be assessed for the requested data. Refer to the **Fee Schedule for Vital Records Data (Appendix C)** for more information about fees related to Vital Records.
2. Follow all terms and conditions of the research agreement if data release is approved.
3. Resubmit an application to the IDPH Data Management and Health Equity Program for continuation of a research agreement at least 60 days prior to the expiration date of the agreement if IDPH data are still required. If a research agreement is not renewed, follow all destruction terms within research agreements.

IDPH Employees:

1. IDPH employees who receive data requests shall refer requests for confidential or implied confidential IDPH data from a person or entity **outside of their program** to the Data Management and Health Equity Program. This includes requests from other internal programs or external sources.

2. IDPH employees who would like to request access to confidential or implied confidential IDPH data for research shall submit an application, list of variables, notice of IRB approval or exemption, and any other information requested by the RERC or Data Management and Health Equity Program to the IDPH Data Management and Health Equity Program in any of the below situations. IDPH employees are exempt from this process if the research is part of the employee's scope of work and the project is completed for the program for which the data were collected.

a. Data requested are being used for a research project outside of the scope of the employee's work or are not required to complete IDPH assigned duties.
b. Data requested will need to leave the program for which the data were collected.
c. Data requested are being shared with an outside person or entity for use in a research project. In this case, the IDPH Data Management and Health Equity Program may require an application from the external person or entity directly and may also require a research agreement to be executed in addition to any contract data sharing terms.
d. Data requested will be used for personal gain of any kind.

3. IDPH employees shall follow all terms and conditions of the research agreement if data release is approved.
4. IDPH employees shall resubmit an application to the IDPH Data Management and Health Equity Program for continuation of a research agreement at least 60 days prior to the expiration date of the agreement if IDPH data are still required. If a research agreement is not renewed, follow all destruction terms within research agreements.

Research and Ethics Review Committee (RERC)

Composition of the RERC

The RERC will have four permanent members designated by the IDPH Executive Team:

- Bureau Chief for the Bureau of Health Statistics (Vital Records)
- IDPH Medical Director/State Epidemiologist (Deputy State Epidemiologist may serve in the absence of the Medical Director/State Epidemiologist)
- Director of Data Management and Health Equity (Another comparable individual in a position with duties that include IDPH data management may serve in the absence of the Director of Data Management and Health Equity).
- IDPH Privacy Officer (Another comparable individual in a position with duties that include data security may serve in the absence of the Privacy Officer).

The committee may have additional members meeting the following criteria:

- Must have work experience and/or academic training in health statistics, research methodology or epidemiology of acute or chronic disease.
- A temporary subject matter expert (e.g., data owner, steward, custodian or in some cases a bureau chief or other administrator).

Duties of the RERC

Members of the RERC shall:

1. Assure all materials needed to make data release decisions have been received.
2. Review all documentation related to research projects.
3. Request more information, as necessary to evaluate the research application against the criteria outlined in **Appendix B**.
4. Make decisions regarding the approval or denial of research agreement applications based on the criteria outlined in **Appendix B**. Quorum criteria: decisions are made by consensus, when at least three permanent members must agree.

Data Management and Health Equity Program

The Data Management and Health Program shall:

1. Receive and review all requests and applications for access to confidential and implied confidential IDPH data for research purposes and determine the need for a research agreement.
2. In consultation with the requestor and the data owner, determine if the purpose of the request is for research **OR** for public health practice, surveillance, other statistical, or verification purposes.
3. Coordinate and staff the RERC.

Data Owner and Bureau Chief

The Data Owner and Bureau Chief shall:

1. Provide input on research-related requests for data within their purview.
2. Fulfill approved data requests or appoint a staff person to fulfil the data request. The data owner and data custodian will receive approval in the form of a copy of the research agreement from the Data Management and Health Equity Program.

Division Director

The Division Director shall:

1. Approve and sign research agreements. The Division Director, or when applicable the State Registrar or Deputy State Registrar for Vital Records, are the only persons authorized to obligate IDPH data through approval and execution of a research agreement.

IDPH Executive Team

The IDPH Executive Team shall:

1. Maintain oversight of the function and composition of the RERC.

Policy Violations

For IDPH employees- violations of the policy are grounds for disciplinary action, up to and including discharge.

For all persons and entities participating in a research agreement with IDPH – IDPH has the authority to employ penalties for misuse of data. Penalties for violations of the research agreement may include, but are not limited to:

- Revocation of the research agreement
- Notice to the sponsoring IRB
- Notice to the immediate supervisor of the violating party

- Notice to the IDPH Director
- Immediate revocation of data access
- Restitution of funds to the grantor agency as appropriate
- Removal of the violating party from the particular project, or special monitoring of future work
- Letter of reprimand, probation, suspension, or termination of employment for the violating party
- Withdrawal or correction of all pending or published documents emanating from the research where the misconduct was found
- Denial of future research activities involving IDPH data
- Other sanctions as authorized by federal or state law

The PI is responsible for all violations of the research agreement.

Appendix A- Policy #CO 07-12-004

Examples of Research and Non-Research Requests

The following are examples of situations when requests for access to data, either from outside IDPH or from IDPH staff, MUST be reviewed by the RERC.

Example A

A researcher is requesting access to five years' worth of birth certificate data. The data requested does not contain patient-identifying information, but is row level and will be used as part of a research project.

Explanation A

Data are being used for a research project. It does not matter whether the data will contain identifying information. All requests for confidential and implied confidential data for the purpose of research must be routed through the RERC.

Example B

A staff person at IDPH is pursuing a doctoral degree. As part of her dissertation, the staff person needs access to data from the Trauma Registry. This person has access to Trauma Registry data due to her normal job duties, but needs to extract a dataset from the registry for use on her dissertation project. The dissertation project is not part of her normal job duties and is worked on outside of IDPH hours.

Explanation B

Even though this staff person had access to the data, the dissertation project is outside of her normal scope of duties. This person must submit an application to the RERC.

Example C

The Iowa Department of Human Services (DHS) is conducting a research study to compare and describe Medicaid enrollment procedures in Iowa and other Midwestern states. DHS is requesting the list of Iowa residents enrolled in Medicaid- sponsored maternal and child health programs, including patient names and birth certificate information. DHS plans to publish the results of this study in a professional health journal with the intent to increase physician awareness of Medicaid enrollment statistics nationwide.

Explanation C

Even though the requestor of data in this example is another state agency, the agency is using the data for a research project and planning to provide generalizable knowledge. This request for data must go through the RERC.

Example D

A staff person at IDPH works routinely on situations involving infectious disease. This person began working with a statistician at a local university to determine if there were demographic patterns linked to the incidence of infectious disease. The statistician needed access to IDPH infectious disease data that had potentially-identifying information. The outcomes of the analysis for the project were submitted to a health journal for publication.

Explanation D
The work of this project is within the scope of the IDPH employee's normal job duties; however, the data is being shared with someone external to IDPH and for the purpose of research. This project and permission to share data with the statistician should be requested through the RERC. The statistician may be required to submit an application and sign a research agreement as well.

Example E
A University of Iowa graduate student is working on a research project in which they need access to data from the Iowa Registry of Congenital and Inherited Disorders.
Explanation E
Although the registry is maintained at the University of Iowa, it is still owned by IDPH. The student would need to submit an application to the RERC as well as receive a letter of agreement from the director of the registry.

The following are examples of situations when requests for access to data, either from outside IDPH or from IDPH staff, Do NOT need to be reviewed by the RERC.

Example F
The National Marrow Donor Registry has requested that IDPH match the list of eligible Iowa donors to Iowa residents who have died in the past year. The Donor Registry is making this request so that the Registry has a current list of donors.
Explanation F
This request does not involve use of the data for research; however, a data sharing agreement must be in place before data may be shared.

Example G
The Iowa Department of Human Services (DHS) is evaluating the percentage of low-income Iowa residents who are eligible for Medicaid that enroll in Medicaid either through IDPH or DHS. DHS is requesting the list of Iowa residents enrolled in Medicaid-sponsored maternal and child health programs, including patient names. The results of the evaluation are being used to assess DHS programs and will not be released outside of their department.
Explanation G
Other state agencies may request data from IDPH for use internally. A data sharing agreement is sufficient as long as the data is not released outside of the agency and is not used as part of a research project.

Example H
A statistician at a local university agreed to contract with IDPH as a consultant for non-research purposes. As part of the contract, the statistician needed access to large files of administrative program data with patient names and other identifiers.
Explanation H
A data sharing agreement should be part of the contract with the statistician, but since the work is contracted and not part of a research project, review by the RERC is not necessary.

Appendix B- Policy #CO 07-12-004

Research Agreement Application Review Criteria

The RERC shall ensure that each of the following criteria is satisfied prior to the release of any confidential or implied confidential data for research purposes:

1) The data requested will be used solely for purposes of bona fide research.
2) The research will not be conducted for personal or financial gain or for commercial purposes.
3) The research proposal includes legal and ethical considerations within the study design.
4) The research subjects will be appropriately informed and consented to their participation.
5) The research proposal includes realistic outcomes and goals.
6) IDPH possesses the legal authority to release the requested data for research purposes.
7) Knowledge gained from this research proposal will contribute to an understanding of health, or an issue related to public health and will be of intrinsic value to the people of Iowa.
8) The research proposal relies on the requested data and the data requested is the minimal amount of data necessary to meet project requirements.
9) The research proposal has received approval or exemption from an Institutional Review Board (IRB) and the application submitted to the RERC matches the information approved by the IRB.
10) A research agreement will be executed between the researcher and IDPH prior to release of any data. The research agreement shall address confidentiality, data security, publication, linkage, redisclosure, destruction, and fees.

The RERC reserves the right to request documentation outside of the parameters listed in the policy.

Appendix C- Policy #CO 07-12-004

Fee Schedule for Processing Vital Records Data Requests

Setup and estimate fee- $150 minimum (one-time)
A minimum of $150 will be charged to cover the cost of creating an export and setting up a program to extract the data. The setup fee will only be charged once for any new and recurring request resulting from a data sharing or research agreement as long as the data request does not change in successive years.

In addition to the $150 set up fee, additional fees may apply. These additional fees are outlined below.

Programming and analysis- $85/hour
If a request for data requires development of a program to extract data from an IDPH system, the requestor will be charged an hourly fee based on the current salary estimate for a database analyst. Estimates are based on the number of hours taken to develop a program for extraction of data and to perform the service.

Data access fee - $150 per month ($1,800 annually)
For each data agreement that requires routine data exports of all birth, marriage, fetal death or death records, a fee of $150 per month will be charged. For agreements that request historical data, a fee of $150 per month will be calculated based on the number of months requested. The fee will be billed on an annual basis, for the length of the agreement, and invoiced prior to the data being delivered. The fee is based on administrative costs for the vital record system and may be revised as needed. The data access fee is charged as authorized by Iowa Code section 144.46; 641 IAC 95.6(6); 641 IAC 95.6(7).

or

Per record fee- $1.00/record ($50 minimum annual charge)
A fee per record will be charged based on ongoing maintenance and support required to sustain data systems when the minimum annual fee for the data export will not exceed the annual data access charge. The per record fee is charged as authorized by Iowa Code section 144.46; 641 IAC 95.6(6); 641 IAC 95.6(7).

or

Vital records certificate requests- $20 per certificate
Each certificate requested from the Bureau of Health Statistics, Vital Records requires a fee of $20 which is collected to cover the costs of conducting the search of our records and making a copy.

For questions about this fee schedule, contact:
Melissa Bird
Chief, Bureau of Health Statistics
Melissa.bird@idph.iowa.gov
515-281-6762

Director's Signature Date