

Date of Application:
RA #

Last Revised: 1/2/2015

**Iowa Department of Public Health
Research and Ethics Review Committee (RERC)**

Application for Access to Public Health Data for Research Agreements

PROJECT TITLE: _____

RA # (to be completed by IDPH): _____

INTENDED START DATE:

INTENDED COMPLETION DATE:

IF RENEWAL, current research agreement (RA) number: _____

latest expiration date: _____

PRINCIPAL INVESTIGATOR (attach 1page biosketch)

Name:

Title/Position:

Mailing Address (principal investigator's official mailing address will be used to send a copy of the Research Agreement):

Telephone #: _____

Extension: _____

E-Mail Address: _____

Primary Employer (organization/institution name and address): _____

Grantor Organization/Institution: _____

ALTERNATE (OR ADDITIONAL) CONTACT FOR PRINCIPAL INVESTIGATOR (if student, list academic advisor)

Name: _____

Title/Position: _____

E-Mail Address: _____

Telephone #: _____

Extension: _____

AUTHORIZING CONTRACT SIGNATORY ON BEHALF OF PRIMARY EMPLOYER, if different from principal investigator

Name: _____

Title/Position: _____

Mailing Address (authorizing signatory's official mailing address will be used to send a copy of the Research Agreement):

Telephone #: _____

Extension: _____

E-Mail Address: _____

*View #14 for other individuals with access to data

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1. Provide an overview of your project (*i.e. abstract*).

2. Identify your study type (*select options that apply*):

a. Descriptive

- Case study or series
- Ecologic or cross-sectional
- Other (*list*)

OR

b. Analytic

- Ecologic or cross-sectional
- Case control
- Cohort
- Clinical trial or randomized control trial
- Other (*list*)

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3. Detail the hypothesis or purpose of your study. List the specific study aims.

4. Describe your study methods including:
a. Subject selection

b. De-identification of subjects

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c. Randomization procedures (*if applicable*)

d. Data collection and analysis techniques

5. Explain the public health importance of your project. What specific study aims address health issues affecting the health of Iowans or that of general population health?

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6. Do you intend to publish the results of this study? If yes, list the target audience and format (*check all that apply*).

- Peer-review publication
- Student presentation (*informal; closed class instructor presentation*)
- Student presentation (*graduate research project, including dissertation; open to the public*)
- Report for internal use only
- Report for public release or presentation (*including presentation at a professional conference*)
- Other (*list*)
- Results will not be published

Review and approval by IDPH is required prior to any submission for publication in accordance with the RA.

Please mark the appropriate response for each question:

7. As part of the study, will individuals be contacted?

- No, contact with individuals is not intended. (*skip to question 8*)
- Yes, contact with individuals is intended.

Are you using IDPH data to identify individuals to be contacted in the study?

- No, IDPH data will not be used to identify and contact individuals. (*skip to question 8*)
- Yes, IDPH data will be used to identify and contact individuals. Attach all documentation for contact protocols, including contact letters and/or scripts, and the informed consent form.

If the proposed research involves contact of IDPH identified individuals, the following criteria will apply:

- a. The P.I. shall provide the RERC with a detailed description of how the P.I. intends to make contact with potential subjects and conduct subsequent follow-up. Initial contact with potential subjects shall be through the issuance of a joint notification letter from the P.I. and IDPH.
- b. The P.I. will be responsible for writing the notification letter and performing mailings to potential subjects. Questions from potential subjects about the research project will be referred to the P.I.
- c. A potential subject may choose to opt out of the study (verbally or in writing) at any time, and at that point attempts to enroll the person shall cease.
- d. If approved by the RERC, IDPH will release identifiers or data items needed for the purpose of contacting the identified individuals.
- e. A list of study participants shall be maintained by the P.I. as confidential in accordance with the research agreement and shall be available for review by IDPH.

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8. Has this project/study been submitted to an Institutional Review Board (IRB)?
Please note: project/study cannot be given final approval by IDPH without IRB approval or exemption

- Yes -- Submit copy of IRB application (*if IRB application is more than 20 pages, please also submit synopsis*)
- No -- Project exempt per state statute List which statutes apply:
- No -- Project deemed exempt by Institution's Human Subjects Office (*Please attach Determination Documentation*)

Did your application for your project/study receive IRB approval?

- Yes – Submit copy of IRB approval letter in addition to the application
Date of approval: _____
Date of expiration: _____
Name of IRB _____
- No -- Approval is still pending
Date submitted for IRB approval: _____
Anticipated date of approval (if known): _____
Name of IRB: _____

9. Describe the data and variables you are requesting from IDPH:

- a. Check all data sources and/or datasets that will be used in your project. In the space next to the data source indicate date range (from: mm/yyyy to: mm/yyyy) for each set you wish to access.
Datasets listed below are the most commonly requested. If you are requesting a dataset not listed below, please specify which dataset in the "other" option so a list can be sent to you of the available variables for the requested dataset.

	<u>Date Range</u>	
<input type="checkbox"/> Behavioral Risk Factor Surveillance System (BRFSS)	From: _____	To: _____
<input type="checkbox"/> Birth Certificate Records	From: _____	To: _____
<input type="checkbox"/> Death Certificate Records	From: _____	To: _____
<input type="checkbox"/> EMS Patient Registry	From: _____	To: _____
<input type="checkbox"/> Iowa Disease Surveillance System (IDSS)	From: _____	To: _____
<input type="checkbox"/> Iowa Immunization Registry Information System (IRIS)	From: _____	To: _____
<input type="checkbox"/> State Health Registry (SEER)—"Cancer Registry"	From: _____	To: _____
<input type="checkbox"/> Other (<i>specify</i>)	From: _____	To: _____

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- b. Using the data dictionary(s), indicate the variable(s) you are requesting and specify which values are required. Please refer to data dictionary(s) to determine data availability.

- c. Indicate the geographical region or location for requested records.

- Entire state
 County(s) (*specify*) _____
 City or town(s) (*specify*) _____
 Zip Code(s) (*specify*) _____
 Other (*specify*) _____

10. Will linkage to any other dataset(s) occur? (Using data from any other source for comparison purposes, creating linked databases, or extraction of data is considered linking data, e.g. census and population data.)

- No linkage with other datasets is intended (skip to question 11).
 Linkage only of aggregate data with the following datasets is intended.
 Linkage of individual records with the following datasets is intended.
Describe each of the following in detail:

- a. Indicate what other datasets will be involved.

- b. List the specific variables and how you are planning to use them for linkage from each dataset.

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c. Describe the purpose for each linkage.

d. Include a flow chart that explains the proposed linkage process. The flow chart(s) should illustrate what datasets will be linked, what (if any) new datasets will be created, when identifiers will be stripped, etc. A flow chart should be an easy-to-understand diagram(s) showing how steps in your study fit together. It should demonstrate what happens to the data after it is obtained from IDPH until the data is destroyed. **Please see reference guide for example.**

e. If there will be linkage of IDPH dataset to another database of confidential records, attach a letter of agreement from that data owner/institution whose non-public domain dataset(s) will be linked.

Name of institution: _____

Date of letter: _____

11. Indicate the format in which you would like to receive your data:

- | | |
|---|---|
| <input type="checkbox"/> CD-ROM | <input type="checkbox"/> Computer generated hard copy |
| <input type="checkbox"/> File Transfer Protocol (FTP) | <input type="checkbox"/> Photocopies of vital records |
| <input type="checkbox"/> Secure fax | <input type="checkbox"/> Other (<i>specify</i>) _____ |

12. How will individual-record data obtained through this application be securely stored and maintained?

- | | |
|---|--|
| <input type="checkbox"/> Storage on a server | <input type="checkbox"/> Storage on work laptop |
| <input type="checkbox"/> Storage on USB | <input type="checkbox"/> Storage of hard copy documents in file cabinets |
| <input type="checkbox"/> Other (<i>specify</i>) _____ | |

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Describe mechanisms for data security making sure that they are in conjunction with security rules.

13. Describe the process you will take to ensure confidentiality of the received data, including any training of additional project personnel. Make sure transmission of data is in conjunction with security rules.

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Name: _____ Title/Position: _____
Institution: _____ E-Mail Address: _____
Telephone #: _____ Extension: _____

Please be advised that any identifying data received from IDPH is not to be shared in any public format. All individuals associated with this project must comply with the Disclosure of Confidential Public Health Records Policy.

Please submit electronically to: RERC@idph.iowa.gov
OR return the completed application materials to:

Iowa Department of Public Health
Research and Ethics Review Committee
321 East 12th Street
Des Moines, IA 50319-0075
(515) 281-7221