Illinois Department of Public Health
Institutional Review Board
Data Release and Research Committee
122 South Michigan Avenue, 7th Floor
Chicago, Illinois 60603
312-814-5173

Instructions for Extramural Investigators

I. Introduction

Investigators requesting access to confidential Illinois Department of Public Health (IDPH) records are expected to demonstrate compliance with relevant federal and state human subject regulations, including review and approval by their sponsoring or affiliated IRBs, as a prerequisite to submitting requests to obtain access to confidential IDPH data for a research project. Depending on the protocol, IDPH's Data Release and Research Committee (DRRC) and the IDPH Institutional Review Board (IRB) may be involved in the review. For protocols that only involve release of IDPH data, the IDPH IRB may be limited to determination of whether or not IDPH may release data, provided that the protocol has been approved by the DRRC and the IRB(s) of the requesting researcher(s) who will have access to the released data.

Approvals by sponsoring organizations' or investigators' IRBs do not necessarily replace review by the IDPH IRB. The approval of the request may require changes in contact procedures, consent forms, and study design. Also, the IDPH IRB may choose to conduct full reviews when the other IRBs have issued approvals based on expedited reviews or issued notifications of exemption from ongoing IRB review.

Investigators whose studies are approved are required to:

- Use the information obtained for their approved study only for the purposes of medical or scientific research as described in the approved application;
- Ensure that only the principal investigator, his/her authorized collaborators and staff have access to data provided by the IDPH or information collected for purposes of conducting the study;
- Complete training requirements specified by IDPH;
- Ensure that staff and collaborators authorized to access the confidential information understand and comply with the specified conditions for approval;
- Agree to publication specifications (e.g., notification prior to publication) required by IDPH;
- Comply with specified reporting requirements, including continuing study and completion requirements;
- Comply with any other conditions specified by IDPH.

II. Summary of Procedures

A. Extramural Investigators

1. IDPH Contacts

Prior to the submission of a request, the investigator should contact the IDPH Responsible Individual to determine if the required data are available for release and to discuss the study feasibility. A list of Responsible Individuals for different IDPH programs/databases can be found at http://www.idph.state.il.us/irb or can be obtained by contacting Harold Duckler at

Harold.Duckler@Illinois.Gov or 312-814-5173. If data from more than one IDPH program are being requested, the IRB will be notified, and one individual will be identified to act as the IDPH Responsible Individual responsible for coordinating the response to the data request prior to application submission.

The stronger the application is when first submitted, the smoother the process will be. Discussing the study project with the IDPH Responsible Individual prior to submission will result in a stronger application. If key information is exchanged prior to the investigator's submission of an application to their IRB, it may help avoid the need for the investigator to submit an amended protocol to the investigator's IRB and to the IDPH IRB.

2. Request Submission

Requests should be submitted to the appropriate IDPH Responsible Individual, who will serve as the IDPH's primary contact for the investigator. All documents must be submitted as email attachments that are 1) Microsoft® Word files or 2) Adobe® Acrobat® files that are searchable or bookmarked. The attached files shall have relevant file names and shall be paginated and listed on the *Application Coversheet.*

One of the following set of documents is required:

a. The complete IDPH IRB Application, or

b. The application documents submitted by the Principal Investigator(s) to the sponsoring or affiliated IRB(s), the IRB determination notification(s) issued, and all of the following:

   i. Sections 1-6 of the IDPH IRB *Application*, additional sections, as requested by the IDPH Responsible Individual, and the relevant appendices and addenda. Include 1) separate list(s) of data elements being requested from each IDPH program with justification for each that is correlated to hypotheses or study objectives, and 2) a detailed description of measures to ensure the confidentiality and security of the data at each site of the study, including the address of each site. See *Application* sections 15 and 19.1.);

   ii. *Curriculum vitae*, resumes or National Institutes of Health (NIH) Biographical Sketch for Principal Investigator(s) (three-page maximum), Co-Principal Investigator(s) and (for students) Sponsor(s);

   iii. Informed Consent Documents that display the approval stamp of the investigators' IRB(s) when the investigator has/have contact information outside IDPH;

   iv. Other documents that may be required.

Your application must be clear, consistent, and complete. Applications that are unclear result in delays and additional work for committee members and applicants alike.

Please request only the variables needed for your study; justifications for variable requests must be specific and should describe their use in testing hypotheses or other study objectives.

Security and storage descriptions must clearly show where all files will be maintained and how access to study data will be controlled.

A clear description of the sample or sampling methods will be required, as well as adequate power calculations for sample size.

Note: Linkages involving human subjects are typically performed by IDPH staff or by the investigator under supervision of IDPH staff. Special arrangements may be made for data linkages that require use of a national dataset (e.g., National Death Index).

The IDPH policy for follow back—contact with human subjects based on identifying information collected by IDPH—is that IDPH shall send the initial contact information (*e.g.*, cover letter, brochure, consent forms) to the potential research subject. The investigator shall submit drafts (to be signed by IDPH) of such documents after conferring with the IDPH Responsible Individual. These documents should be at a literacy level appropriate to the subjects being recruited. The investigator should also consider the need to have such documents in the primary language of the recipient.

Below are topics (when relevant) to be referenced in such documents.

1. IDPH collects confidential information;
2. IDPH is sending the recruitment letter;
3. Recipient will not be known to study unless a signed consent is submitted;
4. IDPH wants to notify recipient about the study;
5. Basis for selecting recipient;
6. Purpose of study and use of study results;
7. Study location;
8. Principal Investigator;
9. Voluntary participation;
10. Compensation;

11. Enrollment/Participation procedures;
12. Information about the collection and storage of specimens;
13. Contact information for questions about rights;
14. Contact information for questions about the study;
15. Statement that consent document was read and is fully understood;
16. Check box for enrollment and for opt out (if latter confirmation is needed);
17. Place for signature, date and printed name of enrollee;
18. Place for signature, date and printed name of guardian.

Sample text that includes some of the items above:

The Illinois Department of Public Health(IDPH) maintains records of births, deaths, and certain health conditions that are required by law to be reported to IDPH. These records are confidential, but by law, may be shared with qualified researchers conducting public health research if approved by IDPH and its Institutional Review Board (IRB) and after the researchers sign strict confidentiality agreements.

Enclosed is information regarding a study approved by IDPH, because it believes the study has an important public health purpose that could benefit the people of Illinois. However, the study is not being conducted nor sponsored by IDPH.

Your participation in the study is voluntary and your agreement to participate in this study (or recruitment activities for this study) also means that you agree to allow the Illinois Department of Public Health to share certain confidential records it maintains about you with the research team.

B. IDPH Staff

1. Application Review

   The IDPH Responsible Individual, who has the responsibility over the requested data, reviews the documents to assure that the request is complete and clearly understood. Any issues are resolved with the investigator via the IDPH Responsible Individual. The IDPH Responsible Individual completes an *Extramural Research Review* and then forwards it and the IRB *Application* to the DRRC.

The DRRC reviews the request to assess the overall scientific merit and the logical and technical soundness of the request for IDPH approval. Any issues are resolved with the IDPH Responsible Individual and the investigator.

2. *Data Use Agreement*

The IDPH Responsible Individual prepares and submits a draft of a *Data Use Agreement* to the IDPH Division of Legal Services. Any issues are resolved with the investigator via the IDPH Responsible Individual. The Division of Legal Services must approve the draft.

3. IRB Referral

The IDPH Responsible Individual or program staff prepares the IRB referral form(s), attaches the *IRB Application* and the approved *Data Use Agreement*, and submits them to the IDPH IRB. Any issues are resolved with the IDPH Responsible Individual and investigator via the IDPH Responsible Individual.

C. IRB

1. Review

The IDPH IRB reviews the documents to assure that the IDPH processing of the request for the release of its data meets federal and state requirements for the protection of the rights and welfare of human subjects involved in research activities. Any issues are resolved with the IDPH staff and investigator via the IDPH Responsible Individual.

Note: Depending on the project, IRB action may be limited (*e.g.*, to waiver of HIPAA authorization for release of data, or to approval of data release) as required by Illinois statutes, regulations, or IDPH policies based on federal regulations. Release of data does not signify that IDPH is engaged in a research project. When IDPH involvement is limited to data release to an extramural researcher, IRB decision-making will typically focus on whether or not approval is granted for the IDPH staff to release data. In such situations, the IRB will communicate approval for data release to the IDPH staff rather than to the extramural researcher.

2. Notification

The IDPH IRB notifies the IDPH staff of its determination. The notification will indicate if the determination was by expedited or full board review, if the request is approved for one year or if the review was not required. In addition the notification may indicate additional responsibilities of the IDPH staff and investigators.

D. Data Use Agreement

1. Distribution of the *Data Use Agreement*

IDPH staff email the *Data Use Agreement* approved by the Division of Legal Services with specific instructions to the investigator. (If signatures are required from individuals located at multiple sites then the signature pages for each site can be placed on separate pages and the *Data Use Agreement* will be sent to each site.)

2. Resolution of *Data Use Agreement* Issues

   The investigator notifies the IDPH Responsible Individual if s/he has concerns about the content of the agreement the investigator. If needed, the IDPH Responsible Individual confers with the IDPH Division of Legal Services.

3. Submission of the *Data Use Agreement*

   The investigator submits three complete sets of the document with each set having original signatures. (When multiple sites are involved only three sets of the signature pages need be sent by from the secondary sites. Those sets will be merged with the complete sets by the IDPH staff.)

4. Submission of Payment

   The investigator submits payment (when required) with the three sets of documents.

5. Execution of the *Data Use Agreement*

   The IDPH Responsible Individual forwards the *Data Use Agreement* sets for any required IDPH signatures to the Division of Legal Services and forwards any payment for processing to the IDPH Office of Finance and Administration.

6. Distribution of Executed *Data Use Agreement*

   The IDPH Responsible Individual mails the executed *Data Use Agreement* to investigator.

7. Fulfillment of the Data Request

   The IDPH Responsible Individual notifies IDPH program staff that the data request can be fulfilled.