Protected Data Application to the Division of Public Health (DPH)

Part A: Instructions

Purpose

All requests involving Delaware Division of Public Health (DPH) clients must be approved by the DPH Privacy Board. Requests that involve human subjects are also reviewed and must receive approval from the Delaware Department of Health and Social Service (DHSS) Human Subject Review Board (HSRB). Approval is required regardless of the funding source of the research. It is also required regardless of whether DPH clients are involved directly in the research or whether the research involves the use of DPH client data. Researchers must submit an application and receive all necessary approvals prior to initiating the research.

Application form

The application form consists of the following parts:

A. Instructions
B. Checklist
C. Project Information
D. Signatures
E. Investigator's Agreement
F. Additional Documentation

Submission and Review Processes

1. A researchers must complete and submit their application to DHSS_DPH_DataRequest@delaware.gov.
2. All questions must be answered completely unless the question does not pertain to your particular study.
3. Once the application is submitted it is sent to the members of the DPH Privacy Board for review. The board has two weeks to complete their review. At the end of two weeks the researcher will be notified if their request is approved, declined, or requires additional information for the board to reach a decision.
4. If the DPH Privacy Board approves the request, it will be sent to the Division Director for her/his approval and signature.
5. If the request involves human subjects the application will be forward to DHSS HSRB for their approval.

The DHSS HSRB must receive the request by the second Tuesday of the month to give time for the members to review the request before they meet at the end of the month. Since the protected data application is first reviewed by the DPH Privacy Board it must be submitted by the 15th of the month in order to be reviewed by the DHSS HSRB at the end of the following month.

Miscellaneous Notes

- Additional documentation can be appended to the application form or submitted as separate attachments.
- Narrative sections of the application form are expandable to allow for as much text as is needed.
- The original copy of the signed assurance page may be printed and mailed to: Delaware Health Statistics Center, Jesse Cooper Building, 417 Federal Street, Dover, DE. 19901 or signed electronically with a copy of the photo ID of the principal investigator.
- The application must be completed in compliance with DHSS Policy Memorandum #55.
- Consent forms, when required, must include contact information for the researcher as well as the DHSS HSRB. Contact information for the HSRB is as follows: Chairperson, Delaware Health and Social Services Human Subjects Review Board, Division of Management Services, Herman Holloway Sr. Campus, 1901 N. DuPont Highway, New Castle, DE 19720; (302) 255-9000, DHSS_HSRB@delaware.gov.
- Questions can be directed to: DHSS_DPH_DataRequest@delaware.gov

Part B: Checklist

REQUIRED FOR ALL APPLICATIONS

☐ Completed Checklist page

☐ Completed Project Information section

☐ Assurances Form signed by Principal Investigator

☐ Investigator Agreement signed by Principal Investigator

☐ Copy of Certificate of Completion of Training on Human Subjects Protection phrp.nihtraining.com/users/login.php

☐ A copy of the photo ID of the Principal Investigator

ADDITIONAL REQUIREMENTS FOR APPLICATIONS INVOLVING RECRUITMENT OF AND/OR CONTACT WITH HUMAN SUBJECTS

☐ Copy of an approval letter from your governing Institutional Review Board for this project, as applicable

☐ Copy of any survey and/or interview script to be used with human subjects

☐ Copy of the consent form to be used for contact with human subjects or recruitment

☐ Copy (ies) of the Notice(s) of Privacy Practices for the covered entity (ies) which maintains the protected health information (PHI) to be accessed http://dhss.delaware.gov/dhss/dph/files/notprivprac.pdf.

☐ Copy of recruitment forms/flyers to be used with human subjects

Part C: Project Information

I. Principal Investigator Information	
Project Director: Click here to enter text.	Date: Click here to enter text.
Title: Click here to enter text.	
Business/Organization: Click here to enter text.	
Business Street Address: Click here to enter text.	City: Click here to enter text.
State: Click here to enter text.	Zip: Click here to enter text.
Email Address: Click here to enter text.	
Work Phone: Click here to enter text.	Cell Phone: Click here to enter text.
Other person who may be contacted if more information is needed for the project:	
Name: Click here to enter text.	
Address (if different than project director): Click here to enter text.	
Email Address: Click here to enter text.	
Work Phone: Click here to enter text.	Cell Phone: Click here to enter text.

II. Division Contact Person	
Name: Click here to enter text.	Phone: Click here to enter text.
Division: Click here to enter text.	
Location: Click here to enter text.	
Role of divisional staff in the project: Click here to enter text.	

III. Project or Study Summary
A. Title of project or study: Click here to enter text.
B. Description of the health, medical, or other problem addressed by the proposed project or study. Click here to enter text.
C. Purpose of the study (specific aims, research question, hypotheses). Click here to enter text.
D. Does the project involve recruitment of and /or contact with human subjects? ☐ Yes ☐ No

If the project involves recruitment of and/or contact with human subjects, complete sections IV through VIII of this application. If not, proceed to Section IX, Methodology.

IV. Study Population or Subjects being recruited
A. Division whose clients/consumers will serve as research subjects: Click here to enter text.
B. Age, gender(s) and approximate number: Click here to enter text.
C. Inclusion/exclusion criteria: Click here to enter text.

D. Sampling methodology or method(s) of recruitment, including plan for determining and recording reasons for refusal to participate (Attach any information sheets or other documents used in recruitment.):

Click here to enter text.

E. Compensation /inducements to participate, if any:

Click here to enter text.

F. Process for determining eligibility for compensation /inducements, if applicable:

Click here to enter text.

G. Process for distribution of compensation/inducements, if applicable:

Click here to enter text.

H. Method(s) for ensuring participant understanding of the project and obtaining prior informed consent and HIPAA and/or 42CFR Part authorization, if applicable:

Click here to enter text.

V. Recruitment Materials

A. Are contact phone numbers provided?

☐ Yes

☐ No

B. Is the name of researcher/other contact person provided?

☐ Yes

☐ No

C. Is the name and phone number of the DHSS HSRB chairperson listed as a contact for questions participants may have about their rights as research subjects provided?

☐ Yes

☐ No

VI. Forms for recruitment of participants

A. Have the forms been edited to reduce technical terms/jargon?

☐ Yes

☐ No

If no, explain: Click here to enter text.

B. Have the forms have been translated into languages other than English?

☐ Yes

☐ No

If yes, specify: Click here to enter text.

C. Have the forms have been pretested by individuals comparable to potential participants?

☐ Yes

☐ No

If no, explain:

Click here to enter text.

D. Do the form(s) use subheadings?

☐ Yes

☐ No

If no, explain:

Click here to enter text.

E. Has the conceptual density been minimized to help reduce the amount of ambiguity in words and sentences used in materials that will be given to the research participants?

☐ Yes

☐ No

If no, explain:

Click here to enter text.

F. Is active voice used as much as possible instead of passive?

☐ Yes

☐ No

If no, explain:

Click here to enter text.

G. Readability score of forms (expressed as a grade level): Click here to enter text.

H. Readability scale or methodology used: Click here to enter text.

VII. Assistance planned to ascertain participant understanding

A. Check all that apply

☐ Participant will read the form aloud to researcher with the option of asking for clarification as the reading progresses.

☐ The participant will rephrase key aspects of the information in the form, as prompted by the researcher.

☐ The participant will respond to questions designed to elicit an understanding after going through the form independently first.

☐ A highlighted statement will be added before the signature line urging the individual to ask the researcher if he/she have any questions about the meaning of anything in the consent or authorization form.

☐ In the case of materials that are mailed to potential participants, a statement reminding the individual of the phone number to call to reach the researcher will be provided.

VIII. Withdrawal from Project

A. Method for dealing with research participants who choose to withdraw from the project and/or revoke their authorization. Include procedures for ensuring that participants understand the withdrawal and/or revocation processes and their associated rights**:**

Click here to enter text.

IX. Methodology and/or Description of Project Approach

A. Describe plans for data collection. If applicable, include copies of proposed data collection instruments.

Click here to enter text.

B. Describe plans for data analysis.

Click here to enter text.

X. Description of Protected Health Information (PHI)

A. Describe any personally identifiable information(PII) and /or protected health information (PHI) that is being requested from DHSS files (or the files of its contractor agencies) for this research project, along with the justification for needing such information in order to comply with the "minimum necessary" rule in the HIPAA regulations.

Click here to enter text.

XI. Need for PHI

A. Explain why the research could not practicably be conducted without access to and use of this PII/PHI.
Click here to enter text.

XII. Confidentiality and Use of Data

A. How will you and the research team maintain confidentiality, access to, and security of personally identifiable information(PII), protected health information (PHI), or other confidential materials obtained from the State of Delaware?
Click here to enter text.

B. Explain how copies of DHSS data or data extracted from them will be stored.
Click here to enter text.

C. Explain the plan to ensure that PII/PHI will be protected from improper use or disclosure.

Click here to enter text.

D. Delaware State regulations require you to permanently destroy electronic files in all storage media or return copies of records/computer listings upon project completion. If you are not returning the storage media or computer listing to DHSS, please describe how you will permanently destroy the files. What software will you use to permanently destroy all copies of the electronic files? When is the approximate project completion date?

Click here to enter text.

E. For the purposes of this project will any of the identifiable data obtained from the records or contact with human subjects be used by any other organization, e.g., other divisions, agencies, consultants, contractors and/or subcontractors?

☐ Yes

☐ No

If yes, indicate the name of any other organization, its role in this project, and contact information. If the organization's name is unknown at this time, indicate the type of organization. Also describe the safeguards that exist or will be implemented to ensure that the data will be used solely for the purposes of this project.

Click here to enter text.

F. Are there any health or research circumstances that would require the retention of PII/PHI after the project is completed?

☐ Yes

☐ No

If yes, please give a detailed explanation as to the need and a timeframe for retaining the PII/PHI.

Click here to enter text.

G. Is the project HIPAA-compliant?

☐ Yes

☐ No

☐ Not applicable

H. Does the project meet the criteria for exemption from HIPAA compliance allowed under 45 CFR Sec 164.512 (b) (i) (involves PHI to be used by a public health authority for a public health purpose).

☐ Yes

☐ No

I. Will access to protected health information included in this project require tracking in order to be able to comply with the HIPAA provision that individuals, upon request, must be given an accounting of certain disclosures of their protected health information (PHI)?

☐ Yes

☐ No

If yes, please provide the name and contact information of the person who will perform the tracking.

Click here to enter text.

J. Is the research covered under 42CFR Part 2(related to substance abuse confidentiality)?

☐ Yes

☐ No (skip to Section XIII Cost/Funding)

If yes, how will you comply with these regulations?

Click here to enter text.

If yes, are you requesting HSRB consideration under 42CFR Part 2 for exemption from research redisclosure?

☐Yes

☐ No

If yes, provide specific information to be considered.

Click here to enter text.

XIII. Cost/Funding

A. Funding source(s): Click here to enter text.

B. If applicable source of funding after research or pilot phase: Click here to enter text.

C. The cost of the project to DPH: Click here to enter text.

XIV. Timeframe

A. Target start date: Click here to enter text.

B. Target completion date: Click here to enter text.

XV. Benefits and Risk(s)

A. What are the anticipated benefit(s) to subjects or society?
Click here to enter text.

B. Are subjects/clients at risk for any negative impact (often referred to as "adverse event") or consequences affecting their physical, psychological, economic or social well-being as a result of participation in this project?

☐ Yes

☐ No

If yes, delineate the type of risk(s), the probability of occurrence, the anticipated level of severity, and steps to be taken to minimize such consequences.
Click here to enter text.

XVI. Results of the Project or Study

A. Describe how the results of your project or study will be released.
Click here to enter text.

XVII. Records and/or Identifiable Data Requested

A. Source of the data requested (Specify which DPH Program) :
Click here to enter text.

☐ Delaware Resident Data ☐ Delaware Occurrence Data (includes DE residents and non-DE residents who died or gave birth in Delaware)

B. File Format: (Not all formats are available in every program)

Comma delimited	Tab delimited	Excel	SPSS	SAS
☐	☐	☐	☐	☐

XVIII. Describe the cohort of records requested (specify the variables e.g. years, ages, geographic locations, etc.)

A. The years being requested:
Click here to enter text.

B. The variables or description of the variables being requested:
Click here to enter text.

XVIX If records will be selected based on matching criteria that you will provide, please specify.

A. The specific data items to be matched:
Click here to enter text.

B. The source of these data items:
Click here to enter text.

C. The manner in which you will provide the data to be matched (e.g. how will it be sent and in what format):
Click here to enter text.

Part D: Signatures

Assurances

I, the undersigned hereby agree to the following terms and conditions related to this application and the use of the information obtained from the Delaware Health and Social Services (DHSS).

A. The Project will be carried out in accordance with the principles of the Common Rule and the Privacy Rule.
B. The identifiable data obtained from DHSS will be used only for the project proposed and the purposes described in this application. Use of the information for purposes other than those described will not be undertaken until a separate application form for the project has been submitted to, and approved by, the DPH Privacy Board and the DHSS Human Subject Review Board.
C. Confidentiality and handling of the information obtained will be maintained as described in this application.
D. Copies of DHSS data, computer listings or electronic files abstracted from DHSS data obtained through this application will be returned to the DHSS or disposed following their described use in accordance with the timeline and guidelines provided in this application. A Certification of Data Disposal Form provided by DHSS will be completed and returned to DHSS certifying that the data used for the study has been disposed.
E. No information will be released to or used by any organization/agency other than the undersigned, except as shown in this application. Release of identifier information for commercial purposes is prohibited.
F. Information obtained from contact with human subjects, will be subject to the same procedures and measures of confidentiality and security after the research is completed.
G. I understand that I am responsible to oversee that those who will be assisting with this project comply with all the above terms and conditions.
H. I will indemnify, defend, and hold harmless the State of Delaware, DHSS HSRB members, DHSS and the data organizations that provide data to it from any or all claims and losses accruing to any person, organization, or other legal entity as a result of violation of this Agreement. This provision applies only to the extent permitted by federal and state law.
I. All the statements made in this application are true, complete and correct to the best of my knowledge and belief.
J. I understand that failure to comply with the above terms and conditions may result in the following:
    a. The immediate termination of access to protected DHSS data for this project and all other previously approved projects conducted by me or my organization.
    b. Prohibition from access to protected DHSS data for all future projects conducted by me or my organization.
    c. Other penalties pursuant to Delaware law.

My signature attests that I accept the terms and conditions related to this application.	
Principal Investigator's Signature: Click here to enter text.	Date: Click here to enter text.
Principal Investigator's Name: Click here to enter text.	
Title: Click here to enter text.	Organization: Click here to enter text.

Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA):	Delaware Health and Social Services
Applicable FWA #:	00005447
Principal Investigator's Name:	Click here to enter text.
Research Covered by this Agreement:	Click here to enter text.

1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; (4) the privacy regulations at 45 CFR 160 and 164, and (5) the relevant institutional policies and procedures for the protection of human subjects and their privacy.

2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights, privacy, and welfare of human subjects involved in research conducted under this Agreement.

3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Agreement.

4. The Investigator will abide by all determinations of the DHSS HSRB and will accept the final authority and decisions of this Board, including but not limited to directives to terminate participation in designated research activities.

5. The Investigator will complete any educational training required by the HSRB prior to initiating research covered under this Agreement.

6. The Investigator will report promptly to the HSRB any proposed changes in the research conducted under this Agreement. The Investigator will not initiate changes in the research without prior HSRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

7. The Investigator will report immediately to the HSRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

8. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the HSRB.

9. The Investigator acknowledges and agrees to cooperate in the HSRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the HSRB in a timely fashion.

10. In conducting research involving FDA-regulated products, the Investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812.

11. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the HSRB.

12. Emergency medical care may be delivered without HSRB review and approval to the extent permitted under applicable Federal regulations and State law.

13. This Agreement does not preclude the Investigator from taking part in research not covered under the Agreement.

14. The Investigator acknowledges that her/his primary responsibility is to safeguard the rights, privacy, and welfare of each research subject, and that the subject's rights, privacy, and welfare must take precedence over the goals and requirements of the research.

Signatures

Applicant Agency	
Principal Investigator's Signature: Click here to enter text.	Date: Click here to enter text.
Principal Investigator's Name: Click here to enter text.	
Principal Investigator's Degree(s): Click here to enter text.	
Principal Investigator's Address: Click here to enter text.	
Principal Investigator's Phone Number: Click here to enter text.	

FWA Agency	
FWA Institutional Official (or Designee) Signature:	Date:
FWA Institutional Official (or Designee) Name:	
FWA Agency's Address: DHSS, DMS, Admin. Building Rm H106, 1901 N. DuPont Highway, New Castle, DE 19720	
FWA Agency's Phone Number: 302-255-9135	

Approvals

Project or Study Title and Approval Number
Title of Project or Study:
Approval Number:

DPH Privacy Board Chairperson	
My signature attests to my approval of this project based on my understanding of the proposed research activities, including the protections that will be put into place to safeguard the rights of the research subjects.	
DPH Privacy Board Chairperson's Signature:	Date:
DPH Privacy Board Chairperson's Name:	

DPH Division Director	
My signature attests to my approval of this project based on my understanding of the proposed research activities, including the protections that will be put into place to safeguard the rights of the research subjects.	
Division Director's Signature:	Date:
Division Director's Name:	

DHSS HSRB Chairperson	
My signature attests to the fact that this project was reviewed and approved by the DHSS Human Subjects Review Board.	
HSRB Chairperson's Signature:	Date:
HSRB Chairperson's Name:	

DHSS Secretary	
My signature indicates my approval of this project.	
DHSS Secretary's Signature:	Date:
DHSS Secretary's Name:	

Part E: Additional Documentation

List the additional documentation included with this application, either appended to the application form or submitted as separate file(s):

Click here to enter text.

Please e-mail the completed application to:

DHSS_DPH_DataRequest@delaware.gov

DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health