

**DELAWARE HEALTH AND SOCIAL SERVICES (DHSS)
DIVISION OF PUBLIC HEALTH (DPH)
APPLICATION FOR PROTECTED DATA FILES
AND DHSS RESEARCH ABSTRACT**

In order to avoid delays in processing your application, please indicate on the checklist below the items included in your application. Request for DHSS Research Application inclusive of Protected Data Files will be processed after receiving the mailed original signed application and all relevant attachments.

REQUIRED FOR ALL APPLICATIONS

- All relevant sections of the enclosed application have been completed.
- A brief abstract of the project has been enclosed on a separate page that provides the information requested in the Abstract section of the application.
- A signed copy of the attached Delaware assurance page.
- A signed copy of the DHSS Human Subject Review Board's (HSRB) Investigator Agreement.
- A Certificate of Completion of Training on Human Subjects Protection. One tutorial that the Board accepts can be found on the web site of [National Institute of Health](#).
- Completed Application is in compliance with DHSS Policy Memo 55.

**ADDITIONAL REQUIREMENTS FOR APPLICATIONS INVOLVING
CONTACT WITH HUMAN SUBJECTS OR RECRUITMENT**

- A copy of an approval letter from your governing Institutional Review Board for this project. (This is a requirement for all research projects or studies involving contact with human subjects.)
- A copy of any survey to be used for contact with human subjects.
- A copy of the consent form to be used for contact with human subjects or recruitment.
- The consent form must contain the name and phone number of the DHSS HSRB Chairperson so that the subjects can call if they have any questions concerning their rights as a research subject.
- Copy(ies) of the Notice of Privacy Practices for the Covered Entity(ies) which maintains the Protected Health Information (PHI) to be accessed.

Project Descriptions; Check all that apply

- Must be HIPAA compliant: involves protected health information maintained by a 'covered entity'.
- Meets the criteria for exemption from HIPAA compliance allowed under 45 CFR Sec 164.512 (b) (i): involves protected health information (PHI) to be used by a public health authority for a public health purpose.
- Access to protected health information included in this project will require tracking on the part of _____ 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).

**Submit this completed application to:
Marianne Letavish
Jesse Cooper Building
417 Federal Street
Dover, De. 19901**

IMPORTANT

If you are requesting data for a previously approved study and the methodologies/procedures have not changed, it is not necessary to complete another application. Simply send a letter of request to the address above and identify the original approval number and title of the study.

DELAWARE HEALTH AND SOCIAL SERVICES (DHSS) DIVISION OF PUBLIC HEALTH (DPH) APPLICATION FOR PROTECTED DATA FILE AND DHSS RESEARCH ABSTRACT

The information and assurances obtained from the requester will be used by the DPH Privacy Board and the DHSS Human Subject Review Board to determine whether the proposed use of data is consistent with state and federal regulations. A copy of these regulations is available upon request.

I. Principal Investigator Information			
Project Director:		Date:	
Title:		Organization:	
Street Address:		City:	
State:	Zip:	Phone:	
Email Address:			
Other person who may be contacted if more information is needed for the project:			
Name:			
Telephone:			
Address (if different than project director):			
II. Division Contact Person			
Name:		Phone:	
Role of divisional staff in the project :			

III. Project or Study Summary
Title of project or study:
Name and address of sponsor(s), if any:
Purpose of the study (specific aims, research questions, and hypotheses)
A description of any data files that will be linked with the data provided by the State of Delaware specifying the source of these data files.
A description of how the results of your project or study will be released

IV. Human Subject Contact

Will contact with human subjects be required?

- Yes
 No

If yes has this research project or study been reviewed and approved by an Institutional Review Board for the Protection of Human Subjects. This is a requirement for all projects or studies involving contact with human subjects.

- Yes (Attach copy of approval.)
 No

V. Records and/or Identifiable Data Requested

Specify which DPH Program Records are being requested:

- Delaware Resident Data Delaware Occurrence Data (includes DE resident and non-DE resident data)

File Format: (Not all formats are available)

Comma delimited

Tab delimited

Excel

SPSS

SAS

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

VII. If you wish records to be selected based upon matching criteria which you will provide please specify.

1. The specific data items to be matched:

2. The source of these data items:

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

Please complete the following portion of the application if you will be recruiting participants. If your study does not involve recruitment please go to Section XIII.

VIII. Study Population or Subjects being recruited

Age, gender(s) an approximate number:

Inclusion/exclusion criteria:

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:

Compensation /Inducements to Participate:

Method(s) for ensuring participant understanding of the projects and obtaining prior informed consent and HIPAA authorization if applicable:

IX. Recruitment Materials

Local contact phone numbers provided:

- Yes
- No

The name and phone number of the DHSS HSRB chairperson as a contact for questions participants may have about their rights as research subjects provided:

- Yes
- No

When local contact numbers are not provided the participant is advised that they can call collect:

- Yes
- No

X. Forms for recruitment of participants

The forms have been edited to reduce of technical terms/jargon:

- Yes
- No

If No, explain :

The forms have been translated into languages other than English:

- Yes Specify: _____
- No

The forms have been pretested by individuals comparable to potential participants:

- Yes
- No

If No, explain:

The form(s) use subheadings:

- Yes
- No

If No, explain:

Conceptual density has been minimized to help reduce the amount of ambiguity in words and sentences used in materials that will be consumed by the research participants:

- Yes
- No

If No, explain:

Active voice used as much as possible instead of passive:

- Yes
- No

If No, explain:

Readability score of forms(expressed as a grade level)/scale or methodology used _____

XI. Assistance planned to ascertain participant understanding

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.

XII. Withdrawal from Project

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 these are or can be two separate steps:

XIII. Analytical Plan

Please provide a background and rationale for conducting this study.

List the study aims (objectives) to be accomplished by the data analysis and the hypotheses that is being tested.

Please give a description of plans for data collection and methods for each study aim that will be used to analyze data. The methods should include study population (inclusion/exclusion criteria), statistical methods, exposure variables (independent), outcome variables (dependent), covariates (confounders), methods used for missing data, type of analysis software, and an outline of a table or figure which will be used to present the results. If applicable include copies of proposed data collection instruments.

XIV. Description of PHI

Please describe any 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).

XV. Explain why the research could not practicably be conducted without access to and use of this PHI. Attach additional sheets if necessary.

XVI. Cost/Funding

Funding source(s):

If applicable source of funding after research or pilot phase:

The cost of the project to DHSS:

XVII. Timeframe

Target start date:

Completion date:

XVIII. Benefits

What are the anticipated benefit(s) to subjects or society:

XIX. Confidentiality and Use of Data -

A. How will you maintain confidentiality, access to, and security of identifiable data or other confidential materials obtained from the State of Delaware? Include an explanation of how copies of DHSS data or data extracted from them will be stored and the plan to ensure that PHI will be protected from improper use or disclosure. Delaware State regulations require you to destroy or return copies of records/ computer listings upon project completion. Explain how and when you plan to destroy or return copies of DHSS data/computer listings after your project is completed and the approximate project completion date. Use additional sheets of paper, if necessary.

XX. Confidentiality and Use of Data (cont'd)

B. Will you require human contact investigations to obtain additional information directly from patients, decedent's next-of-kin, physicians, hospitals, and/or other individuals or facilities mentioned on, or derived from information on the records?
Yes No

If Yes, briefly describe the following: Use additional sheets of paper, if necessary.

1. Types of respondents to be contacted:

2. Information to be obtained from respondent:

3. Methods to be used in conducting such investigations, including a copy of consent form to be signed by individuals or facilities.

4. How will you maintain the confidentiality of identifiable data obtained from contact with human subjects? Explain how such data will be stored as well as how and when you will dispose of the data.

C. For the purposes of this project, as described above, will any of the identifiable data obtained from the records or contact with human subjects be used by other organization, e.g., other divisions, agencies, consultants, contractors and/or subcontractors? Yes No

If Yes, indicate the name of any other organization and its role in this project. If the name is unknown at this time, indicate the type of organization. Also describe the safeguards that exist or will be implemented to insure that the data will be used solely for the purposes of this project. Use additional sheets of paper, if necessary.

XX. Confidentiality and Use of Data (cont'd)

D. Are there any health or research circumstances that would require the retention of 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 PHI. Use additional sheets of paper, if necessary.

XXI. Waivers

Explain why the research could not practicably be conducted without the waiver: Use additional sheets of paper, if necessary.

If a waiver is requested, will this adversely affect the subjects' rights and welfare: Use additional sheets of paper, if necessary.

- Yes
- No

Explain answer:

XXII. Assurances

The undersigned hereby agrees 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 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. 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 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 will 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.

Principal Investigator's Signature:

Date:

Printed Name:

Title:

Organization:

This section is to be completed by authorized personnel of DHSS.

DPH Privacy Board Chairperson	
Approved by: _____	Date: _____
DPH Privacy Board Chairperson	
Approval Number: _____	
My signature attests to the fact that this project was reviewed and approved by the DPH Privacy Board.	

Division Director	
Approved by: _____	Date: _____
Division Director	
My signature attests to my understanding of and agreement to any HIPAA-related obligations imposed by this project, including any necessary recordkeeping to be able to account for disclosures as mandated by HIPAA regulations.	

DHSS HSRB Chairperson	
Approved by: _____	Date: _____
Chairperson, DHSS HSRB	
My signature attests to the fact that this project was reviewed and approved by the DHSS Human Subjects Review Board/Privacy Board.	

DHSS Secretary	
Approved by: _____	Date: _____
DHSS Secretary	



DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

**Delaware Department of Health & Social Services (DHSS)
Human Subjects Review Board (HSRB)
Investigator Agreement**

Name of Institution with the Federal Wide Assurance(FWA): Delaware Health & Social Services
Applicable FWA #: 00005447

INDIVIDUAL INVESTIGATOR

Name:

Research Covered by this Agreement:

INVESTIGATOR'S AGREEMENT

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.

INVESTIGATOR'S AGREEMENT

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.

Delaware Health & Social Services (DHSS)
Human Subjects Review Board (HSRB)
Investigator Agreement
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INVESTIGATOR'S INFORMATION AND SIGNATURE		
Name:	_____	_____
	(Last)	(First) (Middle Initial)
Degree(s):	_____	
Address:	_____	Phone: _____
	(Street)	
City:	_____	State/Province: _____ Zip Code: _____
Investigator's Signature:	_____	Date: _____

Privacy Board Chairperson		
Name:	_____	_____
	(Last)	(First) (Middle Initial)
Signature:	_____	Date _____
Address:	_____	Phone: _____
	(Street)	
City:	_____	State/Province: _____ Zip Code: _____

FWA INSTITUTIONAL OFFICIAL		
Name:	_____	_____
	(Last)	(First) (Middle Initial)
Institutional Title:	_____	
Address:	_____	Phone: _____
	(Street)	
City:	_____	State/Province: _____ Zip Code: _____
FWA Institutional Official: (or Designee)	_____	Date: _____



Delaware Health and Social Services

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