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|  | Delaware Health and Social Services (DHSS)**Application to the Human Subjects Review Board (HSRB)** |

# Part A: Instructions

***Purpose***

All research involving [Delaware Health and Social Services (DHSS)](http://www.dhss.delaware.gov/dhss/index.html) clients must be approved by the [DHSS Human Subjects Review Board (HSRB)](http://www.dhss.delaware.gov/dhss/dms/epqc/hsrbservice.html). Approval is required regardless of the funding source of the research. It is also required regardless of whether clients are involved directly in the research or whether the research involves the use of DHSS client data. Researchers must submit an application and receive approval from the HSRB prior to initiating the research.

***Application form***

The application form consists of the following sections:

1. Instructions
2. Checklist
3. Project Information
4. Signatures
5. Additional Documentation

***Submission and Review Processes***

* Prior to submitting an application to the HSRB, a researcher must first submit the proposal directly to the DHSS division overseeing the subject matter and/or data involved in the proposal.
* Contact information for DHSS divisions is available on the [DHSS website](http://www.dhss.delaware.gov/dhss/main/dhssdivs.htm).
* Once a DHSS Division has reviewed the application package and the Division Director has signed it, the researcher can then submit it to the HSRB.
* Applicants requesting protected data from the Division of Public Health (DPH) must also complete a [Supplemental Application to the DPH Privacy Board for Protected Data](http://dhss.delaware.gov/dhss/dms/epqc/files/dph_privacy_board_supplement.docx).
* Completed HSRB applications should be submitted electronically to Chairperson, Human Subjects Review Board DHSS\_HSRB@delaware.gov. (Note: there is an underscore “\_” between DHSS and HSRB in the email address.)
* The HSRB Chairperson is available to answer questions about the application and/or the HSRB process.
* The HSRB meets on a monthly basis to review submitted applications.

***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 application must be completed in compliance with [DHSS Policy Memorandum #55](http://www.dhss.delaware.gov/dhss/admin/pm55.html).
* 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.

**Part B: Checklist**

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| **REQUIRED FOR ALL APPLICATIONS** |
| [ ]  Completed Checklist page[ ]  Completed Project Information section[ ]  Assurances Form signed by Principal Investigator[ ]  Investigator Agreement signed by Principal Investigator[ ]  Approval Form Signed by DHSS Division Director[ ]  Copy of Certificate of Completion of Training on Human Subjects Protection |
| **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 [ ]  Copy of recruitment forms/flyers to be used with human subjects |
| **ADDITIONAL REQUIREMENTS FOR APPLICATIONS INVOLVING PROTECTED DATA FROM THE DIVISION OF PUBLIC HEALTH (DPH)** |
| [ ]  Copy of completed [DPH Privacy Board Supplemental Application](http://dhss.delaware.gov/dhss/dms/epqc/files/dph_privacy_board_supplement.docx) |

**Part C: Project Information**

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

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| **II. Division Contact Person** |
| Name:  | Phone:  |
| Division:  |
| Location:  |
| Role of divisional staff in the project:  |

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| **III. Project Summary** |
| 1. Title of project:
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| 1. Description of the health, medical, or other problem addressed by the proposed project.
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| 1. Purpose of the project (specific aims, research question, hypotheses).
 |
| 1. 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.***

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| **IV. Study Population or Subjects being recruited** |
| 1. Division whose clients/consumers will serve as research subjects:
 |
| 1. Age, gender(s) and approximate number of subjects:
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| 1. Inclusion/exclusion criteria:
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| 1. Sampling methodology or method(s) of recruitment, including plan for determining and recording reasons for refusal to participate (Attach information sheets or other documents used in recruitment.):
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| 1. Compensation /inducements to participate, if any:
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| 1. Process for determining eligibility for compensation/inducements, if applicable:
 |
| 1. Process for distribution of compensation/inducements, if applicable:
 |
| 1. Method(s) for ensuring participant understanding of the project and obtaining prior informed consent and HIPAA and/or 42CFR Part 2 authorization, if applicable:
 |
| **V. Recruitment Materials** |
| 1. Are contact phone numbers provided?

[ ]  Yes[ ]  No |
| 1. Is the name of researcher/other contact person provided?

[ ]  Yes[ ]  No |
| 1. Is the name and phone number of the DHSS HSRB chairperson provided as a contact for questions participants may have about their rights as research subjects?

[ ]  Yes[ ]  No |

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| **VI. Forms for recruitment of participants** |
| 1. Have the forms been edited to reduce technical terms/jargon?

[ ]  Yes[ ]  NoIf no, explain : |
| 1. Have the forms been translated into languages other than English?

[ ]  Yes [ ]  NoIf yes, specify: |
| 1. Have the forms been pretested by individuals comparable to potential participants?

[ ]  Yes[ ]  NoIf no, explain: |
| 1. Do the form(s) use subheadings?

[ ]  Yes[ ]  NoIf no, explain: |
| 1. 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[ ]  NoIf no, explain: |
| 1. Is active voice used as much as possible instead of passive?

[ ]  Yes[ ]  NoIf no, explain: |
| 1. Readability score of forms (expressed as a grade level):
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| 1. Readability scale or methodology used:
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| **VII. Assistance planned to ascertain participant understanding** |
| 1. 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. |

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| **VIII. Withdrawal from Project** |
| 1. 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:
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| **IX. Methodology and/or Description of Project Approach** |
| 1. Describe plans for data collection. If applicable, include copies of proposed data collection instruments.
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| 1. Describe plans for data analysis.
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| **X. Description of Personally Identifiable Information (PII)/Protected Health Information (PHI)** |
| 1. 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.
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| **XI. Need for PII/PHI**  |
| 1. Explain why the research could not practicably be conducted without access to and use of this PII/PHI.
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| **XII. Confidentiality and Use of Data** |
| 1. How will you and the research team maintain confidentiality, access to, and security of personally identifiable information (PII), personal health information (PHI), or other confidential materials obtained from the State of Delaware?
 |
| 1. Explain how copies of DHSS data or data extracted from them will be stored.
 |
| 1. Explain the plan to ensure that PII/PHI will be protected from improper use or disclosure.
 |
| 1. 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.
 |
| 1. 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[ ]  NoIf 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 insure that the data will be used solely for the purposes of this project.  |
| 1. Are there any health or research circumstances that would require the retention of PII/PHI after the project is completed?

[ ]  Yes[ ]  No If yes, give a detailed explanation as to the need and a timeframe for retaining the PII/PHI.  |
| 1. Is the project HIPAA-compliant?

[ ]  Yes[ ]  No[ ]  Not applicable |
| 1. 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 |
| 1. 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[ ]  NoIf yes, provide the name and contact information of the person who will perform the tracking. |
| 1. 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?  |
| If yes, are you requesting HSRB consideration under 42CFR Part 2 for exemption from research re-disclosure?[ ]  Yes[ ]  NoIf yes, provide specific information to be considered. |

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| **XIII. Cost/Funding** |
| 1. Funding source(s):
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| 1. If applicable source of funding after research or pilot phase:
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| 1. The cost of the project to DHSS:
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| **XIV. Timeframe** |
| 1. Target start date:
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| 1. Target completion date:
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| **XV. Benefits and Risk(s)** |
| 1. What are the anticipated benefit(s) to subjects or society?
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| 1. 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.  |

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| **XV. Results of the Project** |
| 1. Describe how the results of the project will be released.
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**Part D: Signatures**

**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).

1. The Project will be carried out in accordance with the principles of the Common Rule and the Privacy Rule.
2. 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.
3. Confidentiality and handling of the information obtained will be maintained as described in this application.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. All the statements made in this application are true, complete and correct to the best of my knowledge and belief.
10. I understand that failure to comply with the above terms and conditions may result in the following:
	1. The immediate termination of access to protected DHSS data for this project and all other previously approved projects conducted by me or my organization.
	2. Prohibition from access to protected DHSS data for all future projects conducted by me or my organization.
	3. Other penalties pursuant to Delaware law.

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| My signature below attests to my agreement with the terms and conditions related to this application. |
| Principal Investigator’s Signature:  | Date:  |
| Principal Investigator’s Name:  |
| Title:  | Organization:  |

**Investigator Agreement**

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| Name of Institution with the Federalwide Assurance (FWA): | Delaware Health and Social Services |
| Applicable FWA #: | 00005447 |
| Principal Investigator’s Name: |  |
| Research Covered by this 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.
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**

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| **Applicant Agency** |
| Principal Investigator’s Signature:  | Date:  |
| Principal Investigator’s Name:  |
| Principal Investigator’s Degree(s): |
| Principal Investigator’s Address:  |
| Principal Investigator’s Phone Number: |

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

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| **Approvals** |
| **DHSS Division Director** |
| My signature below 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 |

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| **DHSS HSRB Chairperson** |
| My signature below 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:  |  |

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| **DHSS Secretary** |
| My signature below 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 a separate file(s):

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