**Application for Proposed Research to be Reviewed by the State of Connecticut Department of Public Health Human Investigations Committee (HIC)**



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| **Please email a PDF copy of the entire application package to:** **dph.hic@ct.gov** |
| **APPLICATION CHECKLIST. The completed application submitted to the HIC must include the following:** |
|[ ]  This form filled out in its entirety. |
|[ ]  Signed Confidentiality Pledges for all research personnel. |
|[ ]  A Data Item Inventory, Appendix A (if requesting data from DPH). A data dictionary can be obtained from the relevant DPH Program. |
|[ ]  Documentation of Human Subjects Research Training for all research personnel. Training should have been completed within the past three years. Please complete the training log (Appendix B). Acceptable training courses include: CITI Program Human Subjects Research Training: <https://www.citiprogram.org/> PHRP: <https://phrptraining.com/> OHRP: <https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html> (all 5 modules are required)**DPH Staff** can contact the HIC Chair to gain access to DPH Human Subject Research Training (CITI). |
|[ ]  Indication that this study has been reviewed by the Institutional Review Board (IRB) at the Principal Investigator’s Institution (and any other IRBs as required). Note: The HIC will not fully approve any study until it has been cleared by all other applicable institutions’ IRBs. |
|[ ]  Biosketch(es) for Principal Investigator/Co-Investigator(s). Please use NIH form, available here: <http://grants.nih.gov/grants/forms/biosketch.htm>  |
|[ ]  All other relevant documentation that will be used in the course of this study including letters, questionnaires and informed consent documents. |
|[ ]  **DPH Staff Only**All DPH staff undertaking research that receive funding from the US Public Health Service must be in compliance with the **DPH Financial Conflicts of Interest in Federally Funded Research Policy**, and must submit with their HIC application copies of their Financial Conflict of Interest Disclosure and Declaration Forms and Training Certificate. |
|[ ]  Optional: You may include *in addition* a copy of the grant application if this project is grant funded and/or a copy of the research design or proposal. **However, this does not eliminate the requirement to provide all of the information requested in this application form.** |
| **SPECIAL CLASSES OF HUMAN RESEARCH SUBJECTS. Please answer the following questions regarding research related to special classes of subjects that require additional protections. Your application will not be reviewed unless you answer these questions.** |
| Does your study involve research with **pregnant women, human fetuses and neonates**? | [ ]  Yes | [ ]  No |
| Does your study involve research with **prisoners**? | [ ]  Yes | [ ]  No |
| Does your study involve research with **children**? | [ ]  Yes | [ ]  No |
| If you answered **Yes** to any of the above, your research may require additional review according to [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/), subparts B-D. **Please contact the HIC Chair to discuss any additional review requirements.** |

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| **SECTION 1 – BASIC STUDY INFORMATION** |
|  | Application Submission Date: Click here to enter a date |
|  | Project title: Click here to enter text |
|  | Project start date: Click here to enter a date |
|  | Expected completion date: Click here to enter a date |
|  | Is this project funded by a grant or an award? [ ]  Yes [ ]  NoIf yes, please indicate the following.Is your research funded through the US Public Health Service (including Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Food and Drug Administration, and all of their constituent agencies)? [ ]  Yes [ ]  NoFunding source: Click here to enter textDuration of funding: Click here to enter textIs this study part of a multi-center research study? [ ]  Yes [ ]  NoIf yes, please list the other research centers: Click here to enter text |
|  | Has this project been reviewed by another IRB? [ ]  Yes [ ]  No [ ]  In progressIf Yes: IRB Name(s): Click here to enter textDetermination/Status: Click here to enter text*Please include a copy of the approval/determination.* |
|  | For studies that request data from a Department of Public Health (DPH) program, the researcher must discuss the study with an employee of the DPH program responsible for the data collection prior to submitting this application. Are you requesting data from DPH? [ ]  No [ ]  Yes *Please answer questions below* Type of data: [ ]  Birth data [ ]  Death data [ ]  Cancer data [ ]  Infectious disease data [ ]  Hospital discharge data  [ ]  Other *Specify:* Click here to enter textPlease provide the following:-Name of DPH Program: Click here to enter textName of DPH Program staff member with whom study has been discussed: Click here to enter text |

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| **SECTION 2– RESEARCH PERSONNEL INFORMATION**  |
|  | **Name of Principal Investigator:** | Click here to enter text |
|  | **Job title/position:** | Click here to enter text |
|  | **Institution:** | Click here to enter text |
|  | **Mailing Address:** | Click here to enter text |
|  | **Email Address:** | Click here to enter text |
|  | **Phone Number:** | Click here to enter text |
|  | **Fax Number:** | Click here to enter text |
|  | **Date of Human Subjects Research Training:**Please provide documentation. | Click here to enter text |
|  | **Name of Primary Contact:**(if not the Principal Investigator) | Click here to enter text |
|  | **Job title/position:** | Click here to enter text |
|  | **Institution:** | Click here to enter text |
|  | **Mailing Address:** | Click here to enter text |
|  | **Email Address:** | Click here to enter text |
|  | **Phone Number:** | Click here to enter text |
|  | **Other personnel (list all personnel that will have access to participants or collected data).**Please provide full names and project roles, e.g.: co-investigator; data analyst; project coordinator. (Confidentiality Pledges and Human Subjects Research Training documentation for all personnel listed here should be included in the application.)Click here to enter text |
|  | **Summarize the qualifications of the Principal Investigator and co-investigator(s) and describe why they are qualified to conduct the research.**Click here to enter text |
| **SECTION 3 – DESCRIPTION OF RESEARCH STUDY** |
| 1. **Project Summary and Background.**

Provide a summary of the study in simplified terms. Include the purpose and significance of the study, research question(s), and hypotheses. Describe what is currently known in this area of research (including a review of pertinent literature with references). Explain how the study will contribute to existing knowledge in the field. Click here to enter text |
| 1. **Research Objectives.**

List the specific aims of the study.Click here to enter text |
| 1. **Study Design.**

Summarize the data or statistical analysis method(s) to be used in the study. Include the proposed sample size, as well as a description of the procedures used to determine this study’s statistical power (if applicable).Click here to enter text |
| 1. **Provide a description of the data items that are being requested from DPH.**

Researchers should obtain the data dictionary for the dataset being requested from the DPH Program involved. Please include any restrictions (e.g., age groups or age range, gender, race/ethnicity, geographical area, time period). A full data item inventory must be provided in Appendix A.Click here to enter text |
| 1. **Include an explanation and justification for requesting DPH “identifiable health data” (as defined under the attached Regulations of Connecticut State Agencies at Section 19a-25-1 (7)) to conduct the proposed research.** Identifiable health data include, but are not limited to, individual or organization names, full dates (month/day/year), small area geographic identifiers (address, zip code, census tract, block group), medical record numbers, license numbers.

Click here to enter text |
| 1. **Does the project involve any of the following? Check all that apply.**

[ ]  **Examination of existing data, documents, or records.**[ ]  **Survey, Questionnaire, or Interview procedures**(Attach copies of all surveys/questionnaires/interview scripts).[ ]  **Collection of data from voice, video, digital, or image recordings made for research.**[ ]  **Collection of data through noninvasive procedures routinely employed in clinical practice.**(E.g., Electrocardiography, actigraphs, physical sensors, flexibility testing, etc.)[ ]  **Collection of blood samples or other biological specimens. Specify:** Click here to enter text[ ]  **Other (specify):** Click here to enter text |
| **SECTION 4 – STUDY POPULATION** |
| 1. **Describe the subject population (for example, in terms of age, sex, ethnicity, language, socioeconomic status, health status, sexual orientation, gender identity and area of residence). Include any specific inclusion/exclusion criteria.**

Click here to enter text |
| 1. **Special/vulnerable populations that are being targeted specifically in this study (check all that apply):**

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| **Fetuses/pregnant women/ human in vitro** |[ ]  **Prisoners** |[ ]  **Children** |[ ]
| **Ethnic minorities** |[ ]  **Non-English speakers** |[ ]  **Economically Disadvantaged** |[ ]
| **Decisionally impaired** |[ ]  **Elderly** |[ ]  **Terminally Ill** |[ ]
| **Institutionalized individuals** |[ ]  **Individuals seeking emergency treatment** |[ ]  **Employees/students** |[ ]
| **Other vulnerable group (describe):**Click here to enter text |[ ]  **Not specifically recruiting vulnerable subjects in this study** |[ ]

**Describe the rationale for using any special/vulnerable classes of human subjects checked above, and the safeguards in place to protect the rights and welfare of these individuals. If the study will exclude non-English speakers, provide a justification for this decision.**Click here to enter text |
| 1. **Provide a breakdown of enrollment by gender, age, and by any special/vulnerable populations checked above.**

Click here to enter text |
| 1. **Describe how participants are being identified, selected and recruited. Provide copies of any recruitment materials.** If non-English speakers are included in the study, provide copies of materials in all languages used.

Click here to enter text |
| 1. **Specify any inducements or rewards to be given to subjects for participation.**

Click here to enter text |
| 1. **Describe procedures for obtaining consent. Attach a copy of the consent form(s). Include any letters intended to introduce the study and/or obtain permission to contact an individual.** If non-English speakers are included in the study, provide copies of materials in all languages used.

Click here to enter text |
| 1. **If you are requesting a waiver of informed consent, please provide justification which addresses the following criteria (45 CFR 46.116(f)(3)):**
	1. **The research involves no more than minimal risk to the subjects;**
	2. **The research could not practicably be carried out without the waiver or alteration;**
	3. **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;**
	4. **The waiver or alteration will not adversely affect the rights and welfare of the subjects; and**
	5. **Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.**

Click here to enter text |
| **SECTION 5 – RISKS AND BENEFITS** |
| 1. **Describe the potential risks to subjects, including severity, duration and reversibility of risk. Please include, but do not limit yourself to, assessments of psychological, social and legal risks. Include details of how these risks will be monitored.**

Click here to enter text |
| 1. **Provide the details of procedures to protect against or minimize risks.**

Click here to enter text |
| 1. **What benefit, if any, may be gained by the subjects as a result of participation in this study?**

Click here to enter text |
| 1. **What benefits to society are anticipated as a result of this study?**

Click here to enter text |
| **SECTION 6 – PROTECTION OF CONFIDENTIALITY** |
| 1. **Will this study use “identifiable health data”?** [ ]  **Yes** [ ]  **No**

**All identifiable health data being requested from DPH should be listed in section 3.4 and included in the Data Item Inventory (Appendix A).** |
| 1. **List personnel that will have access to identifiable health data, and their role in the study.**

Note: all personnel listed here should be listed in Section 2.15.Click here to enter text |
| 1. **Provide details of the security measures in place to maintain confidentiality of these data, including how and where the data will be stored, and the technical safeguards employed to secure electronic data.**

Click here to enter text |
| 1. **Provide details of how the identifiable health data will be destroyed, including destruction methods and a data destruction schedule.**  This should include both electronic and paper copies of data.

Click here to enter text |
| 1. **Provide details of how data and results arising from this study will be disseminated. (**E.g., in a published paper or report, at a meeting or conference.) Please note: All plans for data sharing must be approved by the HIC.

Click here to enter text |
| 1. **Describe measures to ensure that confidentiality will not be breached in the dissemination of results from the study.** (E.g., aggregation of data, suppression of small numbers in tables.)

Click here to enter text |
| **SECTION 7 – PRINCIPAL INVESTIGATOR ASSURANCES** |
| 1. I certify that the information supplied in this form and attachments is complete and accurate, and that no other procedures will be used in this protocol. Secondary use of data obtained in this study will require a separate application to the HIC.
2. I confirm that this research study will be conducted according to the contingencies/requirements set out in the ‘Agreement to Abide’ that I will receive if this protocol is approved by the HIC.
3. I confirm that I will not commence any work described in this application until final approval has been provided by the HIC.
4. I confirm that this research study will adhere to all applicable federal, state and local laws regarding the protection of human participants in research.
5. I will request approval from the HIC for all changes to the study protocol through a request for protocol modification, and will not implement any proposed changes until I receive HIC approval.
6. I will promptly report to the HIC any research-related complaints, problems, and/or breaches of confidentiality. In addition, any significant new findings that may affect the risks and benefits to the subjects and other participants will be reported in writing to the HIC.
7. I will submit Protocol Reapproval or Study Termination paperwork one month prior to the approval expiry date, if this protocol is approved by the HIC. This submission will include an annual progress report or a final project report.
8. I confirm that any research articles based on information obtained in this study will be submitted to the HIC at least 30 days prior to submission for publication.
9. I, the PI, comply with the conflict of interest requirements mandated by [Title 42, Code of Federal Regulations, Part 50, Subpart F](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42%20-%20sp42.1.50.f#sp42.1.50.f).

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| **Signed:**  | **Date:** Click here to enter a date |
| **Print name:** Print name here |  |

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**Appendix A. DPH Data Item Inventory**

For studies requiring data from a Department of Public Health (DPH) program, the researcher must discuss the study with an employee of the DPH program responsible for the data collection prior to submitting their HIC application.

**Title of Study:**

Enter study title here

**Principal Investigator:**

Enter PI name here

**Name of DPH Program providing data:**

Enter name of DPH Program providing data

**Name of staff member with whom study has been discussed:**

Enter name of DPH Program staff member with whom study has been discussed

**Enter data variables being requested in the table below.**

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| **Data Item Name***For cancer data, please include the NAACCR item number.* [*http://datadictionary.naaccr.org/*](http://datadictionary.naaccr.org/)  | **Comment/Justification** |
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*Add additional rows as needed*

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**Appendix B. Human Subjects Research Training Log**

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| **BACKGROUND** |
| **The Department of Public Health Human Investigations Committee (HIC) requires appropriate documentation of Human Subjects Research Training for all personnel. Please complete the form below for all personnel that will have access to participants or collected data.** **The HIC accepts** [**CITI**](https://about.citiprogram.org/en/homepage/)**,** [**OHRP**](https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html) **and** [**PHRP**](https://phrptraining.com/#!/) **courses and some institutional training. Please contact the HIC Chairperson to confirm whether the HIC accepts training from your institution.** Please attach certificates of completion or documentation of training completion for all listed personnel. |

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| **SECTION 1 – STUDY INFORMATION** |
| **1.1** | **Protocol Title:** | Click here to enter text. |
| **1.2** | **Principal Investigator:** | Click here to enter text. |

| **SECTION 2 – PERSONNEL LISTING** |
| --- |
| Name | Project Role | Institution | Training Completed | Date Completed | Expiration Date |
|  | Principal Investigator |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |
|  |  |  | [ ]  CITI [ ]  PHRP [ ]  Institutional  | Click here to enter a date. | Click here to enter a date. |

*Add additional rows as needed*