|  |
| --- |
| **BACKGROUND** |
| **In order to comply with Connecticut General Statutes § 19a-25 and Regulations of Connecticut State Agencies §§ 19a-25-1 through 19a-25-4, the Connecticut Department of Public Health Human Investigations Committee (“DPH HIC”) maintains a more stringent Continuing Review policy than many academic institutions.**  The DPH HIC continues to mandate the completion of an annual continuing review for studies deemed:   1. Expedited (as described in 45 C.F.R. § 46.110); 2. Limited IRB review (as described in 45 C.F.R. § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8))   Additionally, the DPH HIC requires the completion of an annual continuing review even where the only ongoing studies include:   1. Data Analysis, including analysis of identifiable private information or identifiable biospecimens; or 2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care   Please contact the HIC Chairperson should you have any questions about these policies. |

|  |  |  |
| --- | --- | --- |
| **SECTION 1 – STUDY INFORMATION** | | |
| **1.1** | **HIC Protocol number:** | Click here to enter text. |
| **1.2** | **HIC Protocol Title:** | Click here to enter text. |
| **1.3** | **Principal Investigator:** | Click here to enter text. |
| **1.4** | **Expiration Date of the HIC approval:** | Click here to enter a date. |
| **1.5** | **Current Version Date of the approved Informed Consent Form (if applicable)\*:** | Click here to enter a date. |
| **1.6** | **Current Version Date of the approved Assent Form (if applicable)\*:** | Click here to enter a date. |

*\*Please attach copies*

|  |  |
| --- | --- |
| **SECTION 2 – STUDY STATUS** | |
| **2.1**  2.1.a  2.1.b  2.1.c  2.1.d  2.1.e  2.1.f | **What is the current status of the study? (Check where applicable)**  Remains ongoing (open to additional enrollment)  Remains ongoing (permanently closed to additional enrollment but subjects continue to  undergo research-related interactions)  Remains ongoing (permanently closed to additional enrollment and all subjects have  completed protocol-related treatments/interactions but the research remains active for  long-term follow-up of subjects)  Remains ongoing (the ONLY research activity is data analysis)  All research related activities completed. **Closure of file requested**  Study terminated (ended before planned completion)  Date Terminated: Click here to enter a date.  Reason for termination: Click here to enter text.  If you selected 2.1.e or 2.1.f, please answer:  I have complied with retention/destruction of data received as specified in the  approved protocol.  Please include a letter from your IT department confirming the date and method of data destruction. |
| **2.2** | **Do you have a signed informed consent for each subject enrolled/included?**  Yes  Waiver of Consent granted  No  N/A  If No or N/A, please explain Click here to enter text. |
| **2.3** | **Do you have a signed research subject authorization for each subject enrolled/included?**  Yes  Waiver of Authorization granted  No  N/A  If No or N/A, please explain Click here to enter text. |
| **SECTION 3 – SUBJECT INFORMATION RELATING TO THE STUDY** | |
| **3.1** | **Number of subjects accrued/included in study. This includes data received from DPH on individual subjects.**  Number accrued/included since last review: Click here to enter text.  Total number of subjects in study: Click here to enter text.  Anticipated number to be enrolled in future: Click here to enter text. |
| **3.2** | **Number of subjects withdrawn/excluded. This includes data received from DPH on individual subjects.**  Number withdrawn/excluded since last review: Click here to enter text.  Total number of subjects withdrawn/excluded: Click here to enter text.  Reason: Click here to enter text. |

|  |  |
| --- | --- |
| **SECTION 4 – ADVERSE EVENTS** | |
| **4.1** | **Were there any serious adverse events or problems?**  Yes  No  If Yes, please explain: Click here to enter text. |
| **4.2** | **Were all events, problems, withdrawals, or complaints reported promptly to the HIC?**  Yes  No  None observed  If No, please explain Click here to enter text. |
| **SECTION 5 – MODIFICATIONS** | |
| **5.1** | **Describe any problems with, or modifications to, the research since last HIC review, e.g. change in research team members; subject recruiting; advertising; inclusion/exclusion criteria; protocol; informed consent; documentation of informed consent; privacy/confidentiality protections, safety monitoring.**  Click here to enter text. |
| **5.2** | **Were all above described modifications reviewed and approved by the HIC prior to implementation?**  Yes  No  No modifications since last review  If No, please explain Click here to enter text. |
| **5.3** | **Date of Modification:** Click here to enter a date. |
| **SECTION 6 – CONCURRENT OVERSIGHT** | |
| **6.1** | **Is another IRB providing concurrent oversight over this study?**  Yes  No  If Yes, please attach a copy/copies of the most recent approval(s);  **OR**  If the IRB providing concurrent oversight does not require annual continuing review, please provide documentation showing active approval. |
| **SECTION 7 – STUDY PROGRESS** | |
| **7.1** | **Provide a narrative summary of study progress since the last approval. Include a synopsis of any new relevant scientific literature, as well as any preliminary study results, and other information that has become available since the last HIC review that may affect the HIC’s deliberations about the risks or benefits associated with the research.**  Click here to enter text. |
| **7.2** | **Have there been any published reports or journal articles, or presentations of results (slides or poster), based upon this study?**  Yes (provide details/bibliography)  No  **If Yes, was a draft copy of the manuscript, report, slides or poster sent to the HIC prior to submission/presentation?**  Yes  No  If No, please explain Click here to enter text. |

|  |
| --- |
| **PRINCIPAL INVESTIGATOR’S SIGNATURE** |
|  |
| |  |  | | --- | --- | | **Signed:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | **Print name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | |

**Appendix. Human Subjects Research Training Log**

|  |
| --- |
| **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/human-research-protection-foundational-training/index.html) **and** [**PHRP**](https://phrptraining.com/#!/) **courses and some institutional training. Please contact the HIC Chairperson to confirm if the HIC accepts training from your institution.**    *Please attach updated certificates of completion or documentation of training completion for personnel whose training expired since the last HIC review.* |

|  |  |  |
| --- | --- | --- |
| **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. |

*Add additional rows as needed*