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| **Connecticut Department of Public Health**  **Human Investigations Committee**  **PROTOCOL MODIFICATION REQUEST FORM** |
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| **SECTION 1– STUDY INFORMATION** | | | | |
|  | **Name of Principal Investigator:** | Click or tap here to enter text. | | |
|  | **HIC Protocol Number:** | Click or tap here to enter text. | | |
|  | **Protocol Title:** | Click or tap here to enter text. | | |
|  | **Current Approval Expiry Date:** | Click or tap here to enter text. | | |
| **SECTION 2 – STUDY PROGRESS** | | | | |
|  | **How many subjects have been enrolled into this study to date?** | | | Enter number. |
|  | **How many subjects are you anticipating enrolling into this study?** | | | Enter number. |
|  | **Current status of the protocol:**  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).  *Note: that the IRB considers long-term follow-up to be limited to review of medical records (i.e., information collected for clinical purposes) and checking for survival status either through contact with the subject or by a review of the National Death Index).*  Remains ongoing (the ONLY research activity is data analysis). | | | |
|  | Attach a copy of the Institutional Review Board (IRB) approval(s) for this modification from your institution and any institution(s) providing data as part of this research protocol. If this is not possible, approval would be contingent on providing the DPH HIC with all relevant IRB approval(s). | | | |
| **SECTION 3 – TYPE OF MODIFICATION (check all that apply)** | | | | |
|  | **Change in Procedure** | Describe fully in the narrative summary all changes in procedures, and attach a copy of the revised research methods/research plan, amendment, protocol, and/or investigator's brochure, as applicable. | | |
|  | **Change in Study Personnel** | **Add  Remove  Change in Role**  Provide a list of added/removed personnel including their role in the project. **Human Subjects Research (HSR) training certificates and signed HIC Confidentiality Pledges must be submitted for all new personnel.**  Click or tap here to enter text.  Acceptable HSR training courses are:  CITI Program Human Subjects Research Training:  <https://www.citiprogram.org/>  OHRP: <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html>  PHRP: <https://phrptraining.com/> | | |
|  | **Change in Principal Investigator** | Existing Principal Investigator: Click or tap here to enter text.  New Principal Investigator: Click or tap here to enter text.  Provide the following documentation for the new Principal Investigator:   * Human Subjects Research (HSR) training certification; * Signed HIC Confidentiality Pledge (Appendix A); and * Biosketch (please use the NIH form, available at <https://grants.nih.gov/grants/forms/biosketch.htm>)   Acceptable HSR training courses are:  CITI Program Human Subjects Research Training:  <https://www.citiprogram.org/>  OHRP: <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html>  PHRP: <https://phrptraining.com/> | | |
|  | **Change in Research Site** | **Add  Remove  Modify**  Provide list of added/removed sites. If adding additional sites, include a copies of IRB approvals from each new site.  Click or tap here to enter text. | | |
|  | **Change in Subject Enrollment** | **Increase by:** Enter number. | **Decrease by:** Enter number. | |
| Resulting new total to be enrolled: Enter number. | | |
|  | **Consent Change** | Attach a copy of the current approved consent document(s) and a copy of the proposed document(s) with changes highlighted. Include a version and revision date. | | |
|  | **Promotional Materials** | **Newspaper**  **Radio Announcement**  **TV Advertisement** | **Flyer or Brochure**  **Other (specify type):**  Click or tap here to enter text. | |
| Select all that apply and attach copies of the promotional material/advertisement or the text of the announcement. If an audio/video clip, please provide the recording and copy of the script. Include versions/revision dates. | | |
|  | **Other Change** | Include full details of any other type of change to the protocol.  Click or tap here to enter text. | | |
| **SECTION 4 – NARRATIVE SUMMARY** | | | | |
|  | **Provide a detailed narrative summary of all proposed modifications listed above along with a description of how the modification(s) will affect research risks and benefits. Include a description of any event or new data that precipitated the change. Provide supporting materials as appropriate.**  Click or tap here to enter text. | | | |
| **PRINCIPAL INVESTIGATOR’S SIGNATURE** | | | | |
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| |  |  | | --- | --- | | **Signed:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | **Print name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | | | | | |