## STATE OF CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH Commissioner



Ned Lamont Governor Susan Bysiewicz Lt. Governor

Human Investigations Committee

Dear Applicant:

The application package includes all the information that you need to submit your proposed research protocol to the State of Connecticut Department of Public Health Human Investigations Committee (DPH HIC) for review.

The DPH HIC usually meets the last Friday of each month, if agenda warrants. Your original proposal, two copies and one emailed PDF copy (to: <u>anna.legere@ct.gov</u>) must be received at least twenty calendar days prior to be placed on the agenda.

In addition to the specific requirements included in the application package the HIC will review research based on an assessment that the following conditions are satisfied.

- The study is in full compliance with the requirements of relevant state and federal statutes and regulations, including those listed below.<sup>‡</sup>
- The risks to subjects are minimized.
- The study is being conducted according to accepted scientific principles and is based on a thorough review of the applicable literature.
- The individuals conducting the research are scientifically qualified and are supervised by scientifically competent personnel.
- The importance of the objectives is in proportion to the inherent risks to the subject.
- The study reflects a concern for the individual subject over the interests of science and society.
- The study is designed to maximize the chance that consent by research subjects will be voluntary without coercive influence.
- Informed consent from the subject (or their legally authorized representative) is obtained in compliance with **45 CFR §46.116** and **§46.117**. Investigators should follow the guidance provided by the OHRP in their 'Informed Consent FAQs', available at: <a href="https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html</a>.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

If you have any questions, please contact Anna Legere or myself at (860) 509-7163.

Sincerely,

Lou Gonsalves, Ph.D. Chairperson, Human Investigations Committee

<sup>‡</sup> <u>Connecticut General Statute §19a-25; Regulations of CT State Agencies §§19a-25-1 through 19a-25-4; The</u> <u>Revised Common Rule (45 CFR 46)</u>



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