**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

[**CPHS@Dartmouth.edu**](mailto:CPHS@Dartmouth.edu) **• 603-646-6482**

**CPHS – PROTOCOL *PLUS***

CPHS template v. 9/09/2019

**Please complete: CPHS# PI:**

**Important Note: The CPHS Department (Chair & Scientific) Review Form is required with this application. Find the form in the RAPPORT Library or on the CPHS Website.**

* **Respond to each item, even if to indicate N/A or not applicable**
* **Attach and/or upload this form with your Sponsor or Clinical Investigator Protocol in Rapport**
* **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

1. **Risks & Benefits**

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

* 1. **Describe any potential risks which are not discussed in the protocol, their likelihood and seriousness:**
  2. **Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:**
  3. **Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:**

* 1. **It is the role of the CPHS to ensure appropriate data and safety monitoring is in place for research projects. The data and safety monitoring plan is dependent on the nature of the study and can range from an independent DSMB to PI oversight. When there is a DSMB the Membership Charter should be uploaded as a supporting document in Rapport.**

**Please request this information from the sponsor if not included in the protocol.**

1. **Placebo Use or Inconsistency with Standard of Care**

**Does any part of this study involve the use of a placebo?**

☐ No ☐ Yes

**Does any part of this study involve the use of procedures that are inconsistent with the standard of care?**

☐  No                   ☐  Yes

**If Yes, explain how the use of placebo or non-standard of care therapy may affect risks for participants, addressing the following:**

The safety and efficacy of other available therapies

The maximum total length of time a participant may receive placebo on study

The greatest potential harm that may result from not receiving or delaying effective therapy

Safeguards for the participants receiving placebo or non-standard of care therapy

1. **Genetics**

**Does any part of the study involve genetic analysis of biological specimens?**

No

Yes,the study is based on the premise that a link between a genotype or a biomarker and a specific disease or condition is clinically useful in predicting the development of that specific disease or condition. **Please complete the** [**Genetic Research Form**](http://www.dartmouth.edu/~cphs/tosubmit/forms/) **and upload it to the ‘Supporting Documents’ page in Rapport.**

***-OR -***

Yes,the study is looking for an association between a genotype or a biomarker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value. The uncertainty regarding the predictive value of the genetic marker is such that studies in this category will not involve referral of participants to genetic counseling; however, participants will be informed of genetic testing in the consent form. **Please comment:**

1. **Equitable Participant Selection**
   1. **Estimated number of participants at Dartmouth CPHS reviewed sites:**
   2. **Vulnerable populations**

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

**Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the ‘Supporting Documents’ page in Rapport.**

[Pregnant Women, Fetuses and Neonates](http://www.dartmouth.edu/~cphs/tosubmit/forms/)

[Children](http://www.dartmouth.edu/~cphs/tosubmit/forms/)

[People with impaired decision-making capacity](http://www.dartmouth.edu/~cphs/tosubmit/forms/)

**The following populations may also be considered vulnerable to coercion or other undue influence:**

* Prisoners
* People who are economically disadvantaged
* The elderly
* People who are illiterate or do not speak English
* Students and employees

**Describe any other potentially vulnerable population(s) and the additional protections provided to them:**

1. **Financial impact on participants**
   1. **List the tests, visits, and procedures performed for only research purposes and specify who will pay:**

Note: Research procedures may not be billed to a health insurance plan

* 1. **For any injury or illness related to the research, including investigational device removal**

The sponsor or funding agency will pay

The sponsor or funding agency will not pay

1. **Recruitment**

**Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the ‘Consent Forms and Recruitment Materials’ page in Rapport.**

1. **Informed Consent, Assent, and Authorization**

From both an ethical and regulatory standpoint, obtaining informed consent is an important part of subject enrollment.  We strongly recommend using the teach back method (in particular for clinical trials) to ensure subjects understand the research study.  If your research team plans to use the teach back method please indicate so below.  **If you'd like to hear a presentation to learn about teach back email** [**cphs @dartmouth.edu**](mailto:cphs.tasks@dartmouth.edu)**.**  Note the FDA requires individuals who are delegated the task of obtaining informed consent "have received adequate training”.

**All forms discussed in this section should be uploaded to the ‘Consent Forms and Recruitment Materials’ page in Rapport**

Note: The CPHS Consent Form template incorporates all the required elements of consent as well as a valid HIPAA Authorization. If submitting a sponsor's model consent form, the consent and authorization forms may be submitted separately.

* 1. **Please describe the consent and/or assent process, addressing the following:**
* Who will obtain consent/assent from participants
* Where the consent/assent process will take place
* The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
* Any precautions taken to minimize the possibility of coercion or undue influence
* The forms which will be used, as well as any aids used to simplify scientific or technical information
* How comprehension will be ensured.
  1. **Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.**

**Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the** [**Waivers and Alterations Request Form**](http://www.dartmouth.edu/~cphs/tosubmit/forms/) **and upload it to the ‘Consent Forms and Recruitment Materials’ page in Rapport.**

For the informed consent *process*

For the *documentation* of informed consent (participant signature)

For the HIPAA Authorization to use and/or disclose PHI

For a waiver of the requirement for medical record documentation

1. **Compensation or Gifts**

**Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:**

1. **Privacy of Participants**

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

* Consent discussions or interviews held in public which concern sensitive subjects or behaviors
* Observations of behavior, especially illicit behavior, in quasi-public settings

**Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:**

1. **Confidentiality of Data**

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a [Certificate of Confidentiality](http://grants.nih.gov/grants/policy/coc/). Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

* 1. **If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?**

No  Yes

**If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:**

* 1. **Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:**
* Administrative, ie. coding of participant data
* Physical, ie. use of locked file cabinets
* Technical, ie. encrypted data systems
  1. **Describe whether identifiers will be destroyed or maintained upon study conclusion, and the plan for doing so:**