**Dartmouth College • Dartmouth-Hitchcock Medical Center**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN**

**Please complete: CPHS# PI:**

* **Respond to each item, even if to indicate N/A or not applicable**
* **Attach and/or upload this form as your ‘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. **Introduction and Background**
2. **Objectives and Hypotheses**
3. **Study Design**

**Describe all study procedures, materials, and methods of data collection:**

1. **Analysis**

**Describe any qualitative tests and measures as well as quantitative methods:**

1. **Study Progress Monitoring**

Note: appropriate monitoring may include periodic assessment of the following:

* data quality
* timelines
* recruitment and enrollment

**Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:**

1. **Risks & Benefits**

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

* 1. **Describe any potential risks, 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. **Unexpected Events or Incidental Findings**

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

* finding an anomaly in a MRI
* discovering child abuse
* causing distress in interviews of a sensitive nature

**Describe potential events and provide a plan of action:**

1. **Deception**

**Does any part of this study involve deception or withholding of information from participants?**

**Yes  No**

**If Yes, provide an explanation which addresses the following:**

* A description of the deception being used
* Why the deception is necessary
* A plan for debriefing, or providing subjects with the pertinent information after participation

1. **Equitable Participant Selection**
   1. **Estimated number of participants at Dartmouth CPHS reviewed sites:**
   2. **Provide a justification of the proposed sample size**
   3. **Define the target population:**
   4. **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/docs/pregnant_women_form.docx)

[Children](http://www.dartmouth.edu/~cphs/docs/children_form.docx)

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

**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. **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**

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

* 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/docs/waiver_alteration_form.docx) **and upload it to the ‘Consent Forms and Recruitment Materials’ page in Rapport.**

For the informed consent *process*

For the *documentation* of informed consent

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 about illegal conduct may apply for a [Certificate of Confidentiality](http://grants.nih.gov/grants/policy/coc/) from the National Institute of Health.

* 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 the plan for storage or destruction of data upon study completion:**