**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**CPHS – RESEARCH INVOLVING CHILDREN**

Form version 02/16/2023

**Please complete: CPHS# PI:**

* For minors (individuals under the age of 18), parental (or guardian) permission generally must be obtained. Depending on the risk and benefit relationship offered in the study, the permission of one or both parents is required.
* When appropriate, the CPHS expects that assent from the minor will also be obtained. When assent is sought, it is important to include each minor in the discussion of the research as appropriate for their age, maturity level and psychological state.

**Complete sections I, II and III below.**

**I. Age range of minors who will be involved in this study:**

**II. Risks & Benefits**

**Select one of the risk categories numbered 1 – 4 below:**

1. **This research involves no greater than minimal risk. (45CFR46.404)**
   1. Parental permission of at least one parent is required, unless a waiver is granted
      1. Permission will be obtained
      2. Requesting a waiver of parental permission (include the Waiver Request Form)
   2. Assent from the minor
      1. Assent will be obtained and documented by a signature
      2. Assent will be obtained verbally and documented by the researcher
      3. Assent will not be obtained. If assent will not be obtained, provide a rationale below

Additional information, including a consideration of the age of the minor:

1. **This research involves greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (45CFR46.405)**
   1. Parental permission of at least one parent is required, unless a waiver is granted
      1. Permission will be obtained
      2. Requesting a waiver of parental permission (include the Waiver Request Form)
   2. Assent from the minor
      1. Assent will be obtained and documented by a signature
      2. Assent will be obtained verbally and documented by the researcher
      3. Assent will not be obtained. If assent will not be obtained, provide a rationale below

Additional information, including a consideration of the age of the minor:

**Address the following:**

* Risks must be justified by anticipated benefit
* Anticipated benefit is at least as favorable as any alternatives

1. **This research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition. (45CFR46.406)**
   1. Parental permission of both parents is required‡, unless a waiver is granted
      1. Permission will be obtained
      2. Requesting a waiver of parental permission (include the Waiver Request Form)
   2. Assent from the minor is required, unless a waiver is granted or the minor is incapable of assenting
      1. Assent will be obtained and documented by a signature
      2. Assent will be obtained verbally and documented by the researcher
      3. Assent will not be obtained. If assent will not be obtained, provide a rationale below

Additional information, including a consideration of the age of the minor:

**Address the following:**

* The risk is minor increase over minimal risk
* The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
* The anticipated knowledge that will be gained is of vital importance for the understanding or amelioration of the subjects' disorder or condition

1. **This research is not otherwise approvable, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.(45CFR46.407)**
   1. Parental permission of both parents is required‡, unless a waiver is granted
      1. Permission will be obtained
      2. Requesting a waiver of parental permission (include the Waiver Request Form)
   2. Assent from the minor is required, unless a waiver is granted or the minor is incapable of assenting
      1. Assent will be obtained and documented by a signature
      2. Assent will be obtained verbally and documented by the researcher
      3. Assent will not be obtained. If assent will not be obtained, provide a rationale below

Additional information, including a consideration of the age of the minor:

Note: in addition to this research being reviewed by the CPHS, research that falls into this category will also be referred to and reviewed by a National Advisory Board as well as made available for public review and comment prior to approval.

**III. Do you plan to recruit and enroll children who are wards of the State, or any other institution for this study?**

**No  Yes**

**If Yes, provide a description of the following:**

* Who will act as an advocate for the child(ren)
* Their background and experience to act in the best interest of the child(ren).
* Upload a letter of support or agreement from this advocate to the ‘Supporting Documents’ page in Rapport.

‡ For research in categories 3 and 4, permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.