**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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**CPHS – RESEARCH INVOLVING INDIVIDUALS LACKING DECISION-MAKING CAPACITY v. 01172024**

**Please complete: CPHS# PI:**

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Dartmouth College CPHS has established the following guidance for research studies that may involve adult subjects who lack capacity to provide informed consent to participation in a research study. **Please carefully review all items.**

**Introductory Information:**

1. When a potential participant (or patient in clinical studies) lacks capacity to provide informed consent, the investigator should obtain written permission from a legally authorized representative prior to enrolling the subject in a research study.

2.    Federal Regulations define legally authorized representative as an “individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure’s involved in the research.

3. As of July 1, 2021 New Hampshire law states **both agents and surrogates may consent to enrollment in trials or experimental treatments as long as certain protocols are in place**. The trial or experimental treatment must be overseen and authorized by an institutional review board and be consistent with state and federal regulations. Further, the consent must be consistent with any existing directives in a durable power of attorney for health care. If an existing durable power of attorney for health care is silent on enrollment, then a surrogate or agent may only consent to a trial or experimental treatment if the proposed treatment is for an immediately life-threatening disease or condition, if there are no alternative treatment options that would provide an equal or greater likelihood of saving the patient’s life, and the trial or treatment “is intended to be beneficial to the patient in terms of increasing mobility or reducing pain, distress, or discomfort.” See NH Rev. Stat. §137-J:5

4.  CPHS has defined experimental treatment as follows: A treatment that is unproven or not yet scientifically validated with respect to safety and efficacy. A treatment is defined as a drug, device or procedure intended to alleviate a disease or disorder.

**For All Requests: Complete Sections I, II, and III.**

1. **Experimental Treatment**

Does this study involve “experimental treatment” as defined in #5 above ?

[ ] Yes [ ] No

Explain:

1. **Benefit Analysis:**

Even with the permission of a surrogate decision maker, the CPHS will not permit a subject who lacks capacity to give informed consent to participate in a research study that offers little chance of **direct benefit** to the research subject over what they could receive outside the research setting and involves a meaningful increase in the risk of harm or discomfort, regardless of the potential gain to future subjects or society in general.

**Please complete a) and b):**

1. Does participating in this study offer the subject a chance of direct benefit over what they could receive outside the research setting?

1. Is there an increase in the risk of harm or discomfort for the subject over what they would experience outside the research setting?

When there is a meaningful chance of DIRECT BENEFIT to the research subject over what they could receive outside the research setting, the CPHS will make a judgment decision about who may consent to participation in the study, within the parameters of applicable laws.

1. **Please indicate the option(s) requested to allow for consent if a subject lacks decision-making capacity (refer to the introductory information for guidance):**

Durable power of attorney for health care (DPAHC)

Court appointed legal guardian

Next-of-kin

**Decision by the CPHS:**

The CPHS decision will be relayed to the investigator via the CPHS approval letter.

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**Signature section of the consent form:**

Below is the signature line to use when individuals lacking decision-making capacity may be enrolled into a research study. As described above, all options requires special CPHS approval:

Participant Signature and Date Printed Name

If participant lacks capacity to provide informed consent, sign below as appropriate:

Durable Power of Attorney for Health Care and Date Printed Name

or

Court Appointed Legal Guardian and Date Printed Name

or

Next-of-kin and Date Printed Name