**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

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

**CPHS – WAIVERS & ALTERATIONS REQUEST FORM**

* **Provide a response to each item selected as applicable:**
  + **Section 1: For a waiver or alteration of the informed consent *process***
  + **Section 2: For a waiver or alteration of the *documentation* of informed consent**
  + **Section 3: For a waiver or alteration of the HIPAA Authorization to use PHI**
* **Upload this completed form to the ‘Consent Forms and Recruitment Materials’ page in Rapport.**

1. **☐ Waiver of the entire consent process: consent will not be obtained**

**-or-**

**☐ Alteration of consent: consent will be obtained but not all** [**required elements**](http://www.hhs.gov/ohrp/policy/consentckls.html) **are present**

**Provide the justification for your above request. The justification must address all of the following:**

* A description of why the waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
* A description of why the research could not practicably be carried out without the waiver or alteration of consent
* A description of whether the subjects will be provided with additional pertinent information after participation

1. **☐ Waiver of consent documentation: no signature will be obtained,**

**a script will be used to inform participants of the research and obtain consent**

**an information sheet will be provided**

**Provide the justification for requesting a waiver or authorization of consent documentation. The justification must address *at least one* of the following:**

* The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants any documentation linking the subject with the research, and the subject's wishes will govern.
* The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

1. **☐ Waiver of HIPAA Authorization for recruitment**

**☐ Waiver of HIPAA Authorization for study activities**

**-or-**

**☐ Alteration of HIPAA Authorization; not all** [**required elements**](http://privacyruleandresearch.nih.gov/authorization.asp) **or** [**statements**](http://privacyruleandresearch.nih.gov/authorization.asp) **are present**

**Provide a justification for requesting a waiver or authorization of authorization. The justification must address the following:**

* The research could not practicably be conducted without access to and use of the PHI, nor without the alteration or waiver
* A description of why the privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
* A description of the whether identifiers will be destroyed or maintained upon conclusion of the research, and the plan for doing so
* An assurance that the PHI will not be reused or disclosed to any other person or entity, except as required or permitted by law.