**Dartmouth College**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

**CPHS @Dartmouth.edu** **• 603-646-6482**

**NOT HUMAN SUBJECTS RESEARCH APPLICATION**

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ CPHS#**

**Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Projects that do not meet the regulatory definition of research involving human subjects are not under the purview of the IRB. The following questions step through the process of determining whether your project is under the purview of the IRB. For example: A project may involve research but not involve human subjects.**

1. [ ]  **Meets the definition of research:**

45 CFR 46.102(l) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**-OR -**

[ ]  **Does not meet the definition of research.** Here are some other activities that may not meet the regulatory definition of research:

[ ]  45 CFR 46.102(l)(1) **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

[ ] 45 CFR 46.102(l)(2) **Public health surveillance activities,** including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

[ ]  Case studies do not meet the regulatory definition of human subjects research.

[ ]  By checking this box the investigator confirms consideration to obtain permission from the individuals involved

[ ]  By checking this box the investigator confirms all data presented or published will be de-identified.

[ ]  This project is program evaluation without a research component.

[ ]  This project is a quality improvement activity without a research component.

1. [ ]  **Involves human subjects**

+ 45 CFR 46.102 (e)(1) Human subject means a **living individual** about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**.

**-OR -**

[ ]  **Does not involve human subjects.**

[ ]  This project involves the analysis of deidentified data provided to the researcher by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. There is a data use agreement in place stating that the researcher will not attempt to identify or reveal the identity of individuals who are sources of the data or their family members.

[ ]  Proposed project does not involve living individuals and may use protected health information of decedents under the research exception in the HIPAA Privacy Rule, per 45 CFR 164.512(i)(1)(iii).

**For your project to be under the purview of the IRB, it must meet the definition of research, AND involve human subjects.**

**If you would like to receive a letter with a determination that your project is Not Human Subjects Research, complete this form and submit to CPHS via Rapport. In RAPPORT you will be asked to provide a brief description of the project and upload this form.**