For IRB Office Use Only

Date Received: _____ Date of IRB Modification Approval: _____

IRB Approval Valid Thru: _____

Request for Modification of an Existing Approved Project

University of Hartford
Institutional Review Board

Instructions: It is the responsibility of the investigator to submit this application in a timely manner. Investigators cannot proceed with study modifications of any kind without IRB approval. Submit one copy (hard copy or electronic PDF) of complete application to:

Jessica Pawlik-York
Chair, Institutional Review Board
Office of the Provost
University of Hartford
200 Bloomfield Ave
West Hartford, CT 06117
irb@hartford.edu

In order to obtain approval for any change in the research procedures involving human participants or in the consent form, the principal investigator must submit (a) a complete application, outlining the proposed change and rationale for the change; (b) the consent form; and (c) other documents that have been modified or added, such as recruitment materials or documentation of approval from other institutions. ***Submit proposed modifications*** **of the project description with proposed changes highlighted or clearly marked. If requesting modifications include changes to the consent form or other materials, or the addition of new materials, please attach a copy of your modified or added materials with changes highlighted or clearly indicated.**

I. General Information

Date of request: Feb 10 2020 Date of IRB Approval: _____

Project ID #: _____ (if assigned a number)

Title of Project: _____

Funding agency/ sponsor: _____

Principal Investigator: _____ Advisor (if student): _____

Department and program or research agency/ university (if not U of H): _____

Address: _____

PI Phone: _____ PI Email: _____

Co-investigator(s): _____

Department and program or research agency/ university (if not U of H): _____

Address: _____

Has this addendum/modification been reviewed and approved by another IRB? _____ Yes _____ No

- *If yes, attach a copy of that IRB approval.*

II. Study Information:

Total number of subjects enrolled in study: _____

Total number of subjects you expect to enroll: _____

Have there been any adverse events related to this study? _____

Is the modification requested in response to any adverse events? _____

If there have been any adverse events, please describe:

III. Addendum/Modification

Place an X after the box or boxes that describe the type of addendum/modification being requested:

Type of Modification		Type of Modification	
Change in recruitment procedures		**Change in nature of sample**	
Change in recruitment materials (attach new or revised materials)		**Other documents changed/added**	
Change in/ additional researchers (Proof of CITI training must be provided)		**Change to HIPAA authorization**	
Change in informed consent (attach new Informed consent)		**Change in measures (attach new measures)**	
Change in research methods/ measures (attach revised proposal with marked up changes)		**Change in sponsor/funding source**	

Describe below of the proposed changes and implications, particularly regarding likelihood for increased risks to study subjects. Specify whether modification(s) are administrative, procedural with no increased risk to subjects, or procedural with increased risk to subjects.

I certify that the approved protocol and the approved method for obtaining informed consent have been followed during the period covered by this report.

Signature: _____ Date: _____
Principal Investigator

Signature: _____ Date: _____
Co-Investigator(s) (if any)

Signature: _____ Date: _____
Major Advisor (if student project)