**Text

Description automatically generated**

**Agency of Human Services Institutional Review Board**

**Request for Modification/Amendment to Approved Research Application**

Study modifications may not be instituted until you have received written approval from the Committee. If any questions call or email Ashley Roy at 802-241-0440 or [Ashley.roy@vermont.gov](mailto:Ashley.roy@vermont.gov)

|  |  |
| --- | --- |
| AHS IRB Project Number: |  |
| Principal Investigator (PI): |  |
| Project Title: |  |

1. Date of application amendment:
2. Provide a description and justification of the requested change(s)

*\* If the description/justification is either suspension or closure fill in Section 6.*

*\* \*List any new personnel in Section 7. All new personnel is required to complete the Training in Protection of Human Subjects in Research Tutorial.*

1. Does the proposed change affect the risk to subjects, by either increasing or decreasing the risk?

YES  NO

**If yes**, please explain:

1. After review of the proposed change, in the opinion of the Investigator, does the currently approved consent form require revision to adequately convey the potential risks of study participation?

YES  NO  NA

**If yes,** please explain andattach a highlighted and clean copy of the consent form.

1. If there is a consent form and it has been revised, do you recommend providing currently enrolled participants with the information in the new consent form?

YES  NO  NA

**If yes**, describe the plan to do so:

**If no**, please explain why not:

1. Final Summary of Study Activities (if applicable)
2. Additional comments:

*Note: if you are taking a person off key personnel and that person is currently listed as a contact for this application, please identify a new contact person here.*

**­­­­­­­­­­THIS SECTION FOR AHS IRB USE ONLY**

This amendment has been reviewed and approved.

Level of review  Exempt  Expedited  Full Other Action (*specify*)

If exempt or expedited, under what conditions:



Printed name and Title of Board Official