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**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

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| --- | --- |
| 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