

AHS Case Tracking # _____

Date Rec'd at AHS _____

**Agency of Human Services Institutional Review Board
Project/Research Proposal Application Form: Revised June 2004**

The Vermont Agency of Human Services, pursuant to [policy 9.03 revised 2004](#), and the Federal [Department of Health and Human Services, pursuant to 45 CFR](#) Part 46, requires that research conducted by any component of the agency involving human subjects, their health related information and/or any potential risk to human subjects, be approved **before the research is begun**. The Agency Institutional Review Board (IRB) reviews applications concerning research on human subjects or their protected health information when the subjects are Agency clients or recipients of public services or benefits furnished by the Agency AND when the research is proposed by, affiliated with, conducted at the request of, or involves an Agency department, division, program or office. In order to assure that your project is reviewed in a timely manner, please complete this form and send to:

IRB, Agency of Human Services Secretary's Office
1st Floor Osgood
103 South Main St
Waterbury Vermont 05671 -0201

If you have questions about how to complete this form or who to send it to, please contact Laurie Hurlburt in the AHS Secretary's Office at 802-871-3008 or email her at laurie.hurlburt@state.vt.us.

Contact Information

A principal investigator or project leader refers to the person who will be responsible for assuring that the proposed project adheres to the stated methods, carries out intended protections and has responsibility for oversight of the project staff and data. This person will be responsible for assuring that the IRB is apprised of any changes to the procedures as presented and other IRB reporting and record keeping as indicated in AHS policy 9.03 revised 2004.

Name(s) of Principal Investigator/Project Leader: Susan Coburn

Address: VDH, 108 Cherry St, Burlington, VT 05402

E-mail: Scoburn@vdh.state.vt.us

Telephone: 802-951-5151

Name(s) of Co-Principal Investigator/Project Leader: (if non-applicable, please mark n/a)

Address: Jane Kolodinsky

E-mail: jane.kolodinsky@uvm.edu

Telephone: 802-656-3021

Date Proposal Submitted to Vermont AHS IRB:

Has this proposal been reviewed by or submitted to another IRB? NO Yes

If yes, please identify the other IRB _____

Outcome of Other IRB review (please attach documentation from other IRB review)_____

Agency of Human Services (AHS) Affiliation

1. AHS Department/Division/Office Affiliated with Research: Health Department, Division of Health Improvement

2. AHS Contact Person: __Susan Coburn__ Phone: __951-5151__

3. Funding Source for project: Federal State Private Other (please specify) _____

4. If investigator is not affiliated with an AHS member department of office, what AHS affiliated contractor(s) or community organization(s) are involved in this project.

Purpose & Methods

1. Purpose & Brief Description of Project

The purpose of this project is to gather opinions and ideas regarding various aspects of getting and staying healthy, particularly regarding physical activity. A series of 2 to 3 discussion groups will be conducted around the state. Each group will have between 4 to 10 participants. The information gathered from these groups will be used to plan interventions for VDH's Obesity Prevention Program.

2. Anticipated Dates of Research Project (start and end dates)

October 2005

3. Research Methods (e.g., questionnaire, interview, focus groups, record review, analysis of administrative data, application of new or experimental procedures or services, observation of behavior, etc.) Please attached copies of relevant instruments, interview or focus group protocols

Research method: discussion groups. Script attached.

Data Elements and Analysis

1. Please describe the data to be collected and analyzed.

The data to be collected and analyzed is information about what people do to be and stay healthy particularly regarding physical activity and nutrition (see attached questions).

2. What type of data analysis will be done?

A content analysis will be performed on transcripts of the discussion groups. Data will be reported in aggregate form to determine common themes regarding knowledge attitudes and beliefs around healthy behaviors.

3. Who will conduct the analysis? If other than principal investigator, please explain the relationship to

the project.

Staff at Center for Rural Studies will conduct the analysis. VDH has a contract with the Center for Rural Studies for them to lead the groups, conduct the analysis, and create a report for VDH on the findings.

4. *How will the results be presented?*

The results will be presented in a written report.

5. *To whom will results be presented?*

Results will be presented to the Obesity Prevention Program staff at VDH.

6. *What will happen to the data at the completion of the study?*

At the completion of the study, the data will be used to plan the Obesity Prevention Program interventions. A summary of the report will be shared with the Centers for Disease Control and Prevention, one of the Obesity Prevention programs' funding sources and a summary may be shared with Obesity Prevention Program's community partners in Vermont who will assist with program planning.

Participants

1. *Who will be asked to participate?*

We are planning to recruit low income women from VDH's Ladies First program.

2. *Do you anticipate using members of any vulnerable population as subjects? This includes, but is not limited to, fetuses, pregnant women, children, prisoners, persons who are in institutions, people with physical or mental disabilities. If so, identify the group and describe their participation.*

No

a. If you plan on using members of any vulnerable population as subjects, explain why this population is appropriate and necessary for this research.

3. *How will participants be recruited & selected?*

Low income women will be recruited from a mailing to women on VDH's Ladies First program. All potential participants will be asked to contact the Center for Rural Studies. Staff there will make sure the respondents meet the desired requirements for each group and monitor the number of participants.

4. *How many participants will be involved in the project?*

Approximately 10 to 20 participants will be involved in the project.

5. *Will participants be offered compensation for participation? If so, what amount?*

Participants are offered compensation of \$25.00 each for participation in a one and a half hour group.

Food will also be provided to all of the groups.

Consent and Authorization Procedures

1. *How will you obtain informed consent from participants and/or parents, guardians, or other legally authorized parties? Please attach a copy of your [lay summary and consent form](#).*

Informed Consent will be obtained from participants at the beginning of each group.

2. *If you are using protected health information, please attach a copy of your [HIPAA authorization](#). If you wish to request a partial waiver of HIPAA authorization for recruitment purposes, please attach a request to your application.*

NA

Risks to Participants

1. *Please identify all possible risks to participants.*

There are no known risks associated with participation.

2. *What steps will be taken to protect participants and minimize risk?*

N/A

3. *What steps will be taken to protect confidentiality and any health related information collected?*

All the data that is collect from the discussion groups will be kept private and confidential.

Participants will be informed that there are no right or wrong answers and that any information they say will only be reported in the aggregate.

Add consent form to bid info

4. *What will happen to confidential materials at the conclusion of the research project?*

Confidential materials will be stored for ten years by the Center for Rural Studies in a locked facility. At the end of this period of time, all records will be shredded and disposed of. Any electronic information will be stored on a password protected server.

No information on the identities of the participants will be stored with the data. Any information collected by the Center for Rural Studies for the purpose of reimbursing participants for their time will be kept separate from the data and will be stored of and disposed of in the aforementioned manner.

Benefits

1. Outline benefits to: (a) participants, (b) the Agency of Human Services, and (c) society:

Participants may benefit from hearing others speak about health related issues, learning from others in the group.

Information gathered from these discussion groups will help to inform VDH for program planning for obesity prevention. It will drive the development of key messages for behavior change that can be used in multiple programs to increase physical activity and healthy eating. These messages can be used

within VDH programs as well as other agency and community partners working to increase healthy behaviors related to nutrition and activity.

The long term benefits of these groups for participants, AHS, and society will be the prevention of obesity among Vermonters resulting in a healthier, more productive, and less costly population. The problem of obesity is becoming a national epidemic and Vermont is not immune. Data for Vermont show that in 2003, 56% of adult Vermonters were overweight or obese, 26% of youth in grades 8-12 were above a healthy weight and 29% of 2 to 5 year olds in the WIC program were above a healthy weight (>85th percentile BMI). In a healthy population this should be less than 15%. Obesity increases prevalence of at least 15 chronic diseases including: type 2 diabetes, osteoarthritis, heart disease, stroke, high blood pressure, gallbladder disease and certain cancers. Vermont data show 55 % of adults in the state have a chronic disease which is very costly: 83% of our total health care spending is related to chronic diseases and the state's annual medical expenses attributable to obesity is approximately \$141 million.

Please attach:

- ✓ **A copy of the lay summary and form you plan to use to obtain informed consent & if applicable, authorization to use protected health information from participants (See [AHS Policy number 9.03A](#) or 45 CFR 46 on instructions on the preparation of consent forms.)**
- ✓ **Assent forms for teen-age minors (12-17 years of age).**
- ✓ **A copy of any survey instrument that you intend to use.**
- ✓ **The resume of the principal investigator and other project leaders**
- ✓ **Certificate of completion of the online tutorial for IRB researchers at www.uvm.edu/irb/tutorial for all research staff involved in this project**
- ✓ **A statement that clearly indicates that the project leader/principal investigator understands their responsibilities and will assure IRB commitments are followed.**

This Section for Agency of Human Services IRB USE:

Date AHS Received _____

Level of review _____ exempt _____ expedited _____ full review _____ Other Action (specify)

If exempt or expedited, under what conditions:

IRB 1st Review Date: _____ Subsequent Dates of review (if needed) _____

Date Final Action Taken: _____

Date Continuing Review Due (if applicable): _____

Primary Reviewer: _____

Secondary Reviewer: _____

Signature of Chair: _____