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**Agency of Human Services Institutional Review Board**

**Project/Research Proposal Application Form**

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. To assure that your project is reviewed in a timely manner, please complete this form, and send to:

Institutional Review Board

Agency of Human Services, Office of the Secretary

Attn: Ashley Roy

280 State Drive – Building E

Waterbury, VT 05671

Or email it to: [ashley.roy@vermont.gov](mailto:ashley.roy@vermont.gov)

If you have questions about how to complete this form, please contact Ashley Roy in the AHS Secretary’s Office by phone at (802) 241-0440, or via email.

**APPLICATION INSTRUCTIONS**

1. Complete the application in its entirety.
2. 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.)
3. If applicable, attach Assent forms for teen-age minors (12-17 years of age).
4. Attach a copy of any survey instrument that you intend to use.
5. Attach the resume of the principal investigator and other project leaders.
6. Attach certificates of completion of a training program or course designed to prepare investigators to understand their ethical obligations to protect the rights and welfare of subjects in research for all research staff involved in this project.
7. Attach a statement that clearly indicates that the project leader/principal investigator understands their responsibilities and will assure IRB commitments are followed.

**APPLICATION FORM**

|  |  |
| --- | --- |
| Proposal Title: |  |

**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 of Principal Investigator/Project Leader:** |  |
| Address: |  |
| Email: |  |
| Telephone: |  |

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

1. The date proposal was submitted to Vermont AHS IRB:
2. Has this proposal been reviewed by or submitted to another IRB?  Yes  No

***If yes****, please identify the other IRB*:

What was the outcome of the other IRB review? (*Please attach any documentation*)

**AGENCY OF HUMAN SERVICES (AHS) AFFILIATION:**

1. AHS Department/Division/Office Affiliated with Research

2. AHS Contact Person: Phone:

3. Funding Source for the project:

Federal  State  Private  Other (*please specify*)

1. 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. Please describe the purpose and give a brief description of this project:
2. Anticipated dates of research

Start date:

End date:

1. 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 attach copies of relevant instruments, interviews, or focus group protocols.

**DATA ELEMENTS AND ANALYSIS**

1. Please describe the data to be collected and analyzed:
2. What type of data analysis will be done?
3. Who will conduct the analysis? If other than the principal investigator, please explain the relationship to the project.
4. How will the results be presented?
5. To whom will results be presented?
6. What will happen to the data at the completion of the study?

**PARTICIPANTS**

1. Who will be asked to participate?
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, and people with physical or mental disabilities. If so, identify the group and describe their participation.
3. If you plan on using members of any vulnerable population as subjects, explain why this population is appropriate and necessary for this research.
4. How will participants be recruited & selected?
5. How many participants will be involved in the project?
6. Will participants be offered compensation for participation? If so, what amount

**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.
2. If you are using protected health information, please attach a copy of your HIPAA authorization. If you wish to request a waiver of HIPAA authorization, please attach a request to your application.

**RISKS TO PARTICIPANTS**

1. Please identify all possible risks to participants:
2. What steps will be taken to protect participants and minimize risk?
3. What steps will be taken to protect confidentiality and any health-related information collected?
4. What will happen to confidential materials at the conclusion of the research project?

**BENEFITS**

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

**THIS SECTION FOR AHS IRB USE ONLY**

Date AHS Received:

IRB Number assigned:

Level of review: Exempt Expediated Full Other Action: (specify)

If exempt or expedited, under what conditions:

IRB 1st Review Date:

Subsequent Dates of review: (*if needed*)

Date final action is taken:

Date Continuing Review Due (*if applicable*):

Primary Reviewer:

Secondary reviewer:

