**Human Subjects Research**

**Qualitative Research Protocol**

*Answer the following questions to the best of your ability. The reviewers understand that qualitative research is often emergent and you may not know all of the answers at this time; however, the reviewers need enough information to be able to independently assess whether the potential benefits of the research are reasonable in relation to the potential risks to participants and whether your research meets the ethical and regulatory standards for human research as set by federal regulations. Refer to Section 7.F. in the Research Manual for additional information on Review of Qualitative Research.*

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| **1. Should I Be Using This Form?** | | | | | | |
|  | 1.a. Is this study qualitative (or primarily qualitative)? | | Yes |  | No |  |
|  | If No, stop! You should be completing the Committee on Human Research Protocol Form and the Common Protocol Cover Form. If Yes, continue. | | | | | |
|  | 1.b. Does this qualitative/primarily qualitative project include any medical procedures or include the use of protected health information? | Yes | |  | No |  |
|  |  |
|  | *The collection or use of private health information for research purposes constitutes medical research.*  If Yes, stop! You should be completing the Committee on Human Research Protocol Form and the Common Protocol Cover Form. If No, continue to Section II. | | | | | |

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| **2.** | | | | **Protocol/Project Title, Investigator and Contact Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | 2.a. Protocol/Project Title | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.b. | | | | \*Principal Investigator | | | | | | |  | | | | | | | | | | Degree: | |  | | | | | |
|  | | | | Department | | |  | | | | | | | | | Subspecialty | | | |  | | | | | | | | |
|  | | | | Phone | | |  | | | | | | | | | E-Mail: | | | |  | | | | | | | | |
|  | | | | Campus Address | | | | |  | | | | | | | | | | | | | | | | | | | |
|  | | | | Department Chair | | | | |  | | | | | | | | | | | | | | | | | | | |
|  | | | | Identify the PI’s role(s) | | | | | | | | | | | | | | | | | | | | | | | | |
|  | UVM Faculty | | | | | | | | | | | | | | | | | | | | | | |
|  | UVMMC Employee or Medical Staff | | | | | | | | | | | | | | | | | | | | | | |
|  | UVM Employee *(not faculty)* | | | | | | | | | | | | | | | | | | | | | | |
|  | Student *(check applicable status)* | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  |  | Fellow | |  | | Resident | | |  | | Graduate | |  | Undergraduate | | | | | | | | | | |
|  | | | | | List Faculty Sponsor Name | | | | | | | | |  | | | | | | | | | | | | | | |
|  | | | | | Faculty Sponsor Department | | | | | | | | |  | | | | | | | | | | | | | | |
|  | | | | | *\*NOTE: Under normal circumstances only UVM or UVM Medical Center individuals can be PI. If you are not affiliated with either institution, you must stop here and contact the RPO office for guidance.* | | | | | | | | | | | | | | | | | | | | | | |
|  | | 2.c. Do You want to Appoint a Primary Contact Other than the PI? | | | | | | | | | | | | | | | | | | | | | | | Yes |  | No |  | | |
|  | | | | | *Investigators wishing to appoint a contact for all IRB communications should complete the contact information requested below. Primary contacts are considered “key personnel” and must complete required human subjects training.* | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | Contact Full Name | | | | | | | |  | | | | | | | Email: | | |  | | | | | | | |
|  | | | | | Department /Address | | | | | | | |  | | | | | | |
|  | | | | | Campus Phone Number/ Pager | | | | | | | |  | | | | | | |

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| **3.** | | **Qualitative Study Design** | |
|  | | *If ANY of the information below is not known ahead of time, PLEASE include the strategy you intend to utilize to the best of your ability (if you find you need to alter the strategy or add information after the protocol has been approved, then an amendment must be submitted and approved).* | |
| 3.a. Lay Language Summary | | | |
|  | | *Please use non-technical language that can be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) a brief statement of the research aim and related theory supporting the intent of the study, and (2) a brief but specific description of the procedure(s) involving the human subjects. Please do not exceed one single-spaced 8 ½ X 11” page.* | |
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| 3.b. Purpose | |
|  | *State the reason for the study and the goals of the proposed study as related to the research question(s). Give background information.* |
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| 3.c. References | |
|  | *Include key references to prior human research and references that are relevant to the design and conduct of the study in order for the reviewers to assess whether the benefits of the study are reasonable in relation to the risks.* |
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| 3.d. Study Design/Procedures | |
|  | *Describe the topics or research domains you will be covering to give the reviewers a sense of what you plan to learn about or from the subjects in your research. As qualitative research is often emergent, it is understood that your description and attachments may not yet be in their final complete form. Please outline your research techniques and describe what participants will be asked to do. For example, if you plan participant observation(s), include descriptions of what will be observed (behaviors, quotes, or identities), interviews, surveys, focus groups, the use of public, private, governmental or other records, administration of tests, etc.*  *Describe what information you will use to conduct this study and how the information collected will be analyzed. Please submit copies of any questionnaires, surveys/interview questions or provide samples of the types of questions to be asked.* |
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| 3.d.i. Research Locale | |
|  | *Describe research locale, and how you (the researcher) chose this particular setting. If there are any cultural or linguistic issues relevant to the research, complete section* ***6.*** |
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| **4.** | **Source of Support** | | | | | | | | | | | | | | | | | | | | |
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|  | | | 4.a. What is the source of support for this project? *This information is important as the source of support must be included in the subject consent form.* | | | | | | | | | | | | | | | | | | |
|  | |  | | Internal (Department, Pilot funds) | | Specify Dept(s) or Pilot fund: | | | | |  | | | | | | | | | | |
|  | |
|  | |  | | Sponsored project processed through Sponsored Project Administration (SPA) at UVM | | | | | | | | | | | | | | | | | |
|  | |  | | *(e.g. NIH, DOD, cooperative groups, other state or local ,private foundations, etc.)* | | | | | | | | | | | | | | | | | |
|  | |  | | Name of Funding Agency | | | |  | | | | | | | | | | | | | |
|  | |  | | InfoEd Proposal # | | | |  | | | | | | | | | | | | | |
|  | |  | | Funding Agency Grant Number | | | |  | | | | | | | | | | | | | |
|  | |  | | Is this a Program Project grant? | | | | |  | Yes | | | |  | No | | | | | | |
|  | |  | | If yes, list PI on the Program Project grant | | | | |  | | | | | | | | | | | | |
|  | |  | | What is the status of the grant? | | |  | Awarded | | | |  | Pending | | |  | | Just in Time | | | |
|  | |  | | If the award is Pending or Just-In-Time, do you intend to begin research activities prior to obtaining the funding? | | | | | | | | | | | | |  | | Yes |  | No |
|  | |  |  |  |
|  | |  | | | *If yes, the consent form, if applicable, cannot include the funding agency. Once the funding has been received, you must submit an amendment to provide the final awarded grant document and to update the consent form with the funding agency’s name.* | | | | | | | | | | | | | | | | |
|  | |  | | Attach corresponding grant proposal. | | | | | | | | | | | | | | | | | |

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| **5. Human Subjects** | | | | | | | |
| 5.a. | Number of Subjects: *Explain approximately how many participants will be enrolled and how this number was determined. If an exact number is unknown, provide a range. If you are enrolling more than one population describe the anticipated total enrollment for each group or subset.* | | | | | |
|  |  | | | | | |
| 5.b. | Inclusion/Exclusion Criteria: *Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom.* | | | | | |
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| 5.c. | Subject Demographics: *Describe characteristics of the participant population(s), including gender, ethnicity, age range, education-level and economic status, etc.* | | | | | |
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| 5.d. | Potentially Vulnerable or Special Populations: | | | | | |
|  | *Does the proposed research involve any potentially vulnerable populations (i.e., individuals or groups of individuals whose status puts them in a position potentially susceptible to coercion or undue influence, or to possible harm, such as through a lack of capacity to provide informed consent)?* | | | | | |
|  | | Yes |  | No |  |  |
|  | If Yes, please indicate the population(s) and any additional protections that you think should be provided below. The IRB must assess whether any additional protections are necessary and this information will assist in that evaluation. If you have any questions, please do not hesitate to contact the RPO staff. | | | | | |
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| Check **all** that apply: (Place an “X” in the column next to the name of the special population.) |  | Minors |  | Economically Disadvantaged |
|  | Prisoners |  | Non-English Speaking  Illiterate |
|  | Wards of the State |  |
|  | Pregnant Women/Neonates |  |  |
|  |  |
|  | Decisionally or Cognitively Impaired |  | Other (Please specify): |
|  | Students |  |  |
|  | Employees under researcher’s supervision | |  |

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| 5.d.i. | Explain the rationale for involvement of special classes of subjects, if any. |
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| 5.d.ii. | Discuss what procedures or practices will be used to minimize their susceptibility to coercion and unnecessary risk (physical, psychological, etc.). |
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| **6. Cultural/Linguistic Considerations** | | | | | | | |
| 6.a. | Are you aware of any cultural/linguistic norms within your study population that are likely to create vulnerability among subjects and/or affect the way in which you recruit and/or obtain consent from participants (e.g., participants speak a language that does not have a written format e.g. Mai Mai, participants are unfamiliar with research processes, etc.)? | | | | | |
|  | | Yes |  | No |  |  |
|  | If No, skip to VII. | | | | | |
| 6.b. | Provide context of cultural norms and considerations with respect to research autonomy, informed consent, recruitment, etc. (Attach documentation if necessary) | | | | | |
|  |  | | | | | |
| 6.c. | Explain how it was determined that the tasks, instruments, surveys, or interview questions are culturally appropriate. *NOTE: For this qualitative research, these may be themes, topics, sample questions, probes. The reviewers are most interested in how these will be suitable for this population.* | | | | | |
|  |  | | | | | |
| 6.d. | Does the researcher or someone listed as key personnel proficiently speak/read/write the language of the Non-English speaking subjects? | | | | | |
|  | | Yes |  | No |  |  |
|  | If yes, describe experience and/or qualifications below.  If No, explain provisions for recruitment, consent accommodations, and research procedures throughout their participation in the study. | | | | | |
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| 6.e. | Will specific research materials (e.g., surveys, forms, etc.) be translated into another language? | | | | | |
|  | | Yes |  | No |  |  |
|  | If Yes, please describe process for translation. If No, explain how you will communicate with subjects. | | | | | |
|  |  | | | | | |
| 6.f. | Does the researcher or research team have an understanding of the local community attitudes and cultural norms, i.e., knowledgeable about cultural barriers you might encounter? | | | | | |
|  | | Yes |  | No |  |  |
|  | If no, explain how this will be handled: | | | | | |
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| **7. Recruitment**  *To the best of your ability, describe the recruitment procedures or strategy. If applicable, attach copies of all advertisement/recruitment materials for IRB review. Include all of the following:* | | | | | |
| 7.a | How will you recruit potential participants (e.g. announcements/notice, word-of-mouth, snowball/chain sampling, etc.). | | | |
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| 7.b. | Who will contact potential participants and how will they be contacted, (phone script, letter, e-mail, public setting, class room setting, etc.); | | | |
|  |  | | | |
| 7.c. | If you do not have a direct relationship with the potential participants, how will you (the researcher) gain access to the potential participants, e.g. through collaborators, community organizations, schools, or leaders, etc.? If recruiting at off-campus sites (for example a high school), written permission from the school’s principal/administrator will be required and should be submitted for IRB review. Institutional Support Letter template can be found on our forms page under [Miscellaneous Templates](http://www.uvm.edu/irb/?Page=forms_all.html&SM=initial_submenu.html). | | | |
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| 7.d. | Do you plan to use the SONA Psychology Pool? We ask this question so that we may track all protocols that utilize the pool. | | | |
|  |  | Yes |  | No |

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| **8. Withdrawal Procedures**  *Define the criteria for PI withdrawing a subject from the study (may not be in the subject’s best interest, disruptive to the others, if applicable). Include a description of study requirements for when a subject withdraws him or herself from the study (i.e. should contact PI, etc)* |
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| **9. Consent**  *Federal regulations and ethical principles governing human subject research require: legally effective written informed consent from each prospective research subject* ***OR*** *if regulatory criteria are met, the IRB may grant a waiver or alteration of informed consent.* | | | | | | | | | | | | | | | | | | | | | | | |
| **Note: Only the PI or those individuals listed as key personnel and designated to conduct the consent process may sign the consent form confirming the prospective participant has been provided the necessary information and that any questions have been addressed.** | | | | | | | | | | | | | | | | | | | | | | | |
| 9.a. | Explain how you will introduce yourself or be introduced (as a researcher) to potential subjects. If you already know them, please explain the circumstances. | | | | | | | | | | | | | | | | | | | | | |
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| 9.b. | How will you obtain their consent to participate (verbal, written, etc.)? | | | | | | | | | | | | | | | | | | | | | |
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| 9.c. | Address any social/cultural norms impacting the consent process (i.e. obtaining permission from group leaders, etc…) | | | | | | | | | | | | | | | | | | | | | |
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| 9.d. | Type of Consent that will be used | | | | | | | | | | | | | | | | | |  | | | |
|  | 9.d.i. | |  | I will be obtaining **written consent** | | | | | | | | | | | | | | | | | | |
|  | | |  | | I will use written consent for adults and/or parental permission for minors | | | | | | | | | | | | | | | | |
|  | | |  | | I will use written assent for minors (age 11-17) | | | | | | | | | | | | | | | | |
|  | | |  | | English version(s) attached | | | | | | | | | | | | | | | | |
|  | | |  | | Non-English versions will be sent after English version is approved. | | | | | | | | | | | | | | | | |
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| 9.d.i.a. | | |  | | I am requesting use of the **short form option for Non-English speaking participants** | | | | | | | | | | | | | | | |
|  | | | |  | | *This permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. See Research Manual, Section* ***8.B..*** *for details regarding proper consent signatures in this case.*  *The IRB must receive all foreign language versions of the short form document.* | | | | | | | | | | | | | | | |
|  | | | |  | | Describe the process and attach a copy of the short form and the summary. | | | | | | | | | | | | | | | |
|  | | | |  | |  | | | | | | | | | | | | | | | |
| 9.d.ii. | |  | I am requesting a **waiver of the documentation** of informed consent (no signature) | | | | | | | | | | | | | | | | | | | | |
|  | 9.d.ii.a. Check applicable requirement | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. | | | | | | | | | | | | | | |
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|  | | |  | | | | **OR** | | | | | | | | | | | | | | |
|  | | |  | | | | The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. | | | | | | | | | | | | | | |
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|  | 9.d.ii.b. **Describe process** | | | | | | | | | | | | | | | | | | | |
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| 9.d.iii. | |  | I am requesting a **waiver of informed consent** no written or verbal consent is obtained **or an alteration of consent procedures** (consent procedures are altered) | | | | | | | | | | | | | | | | | | |
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|  | |  | 9.d.iii.a Which process are you requesting? | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | Waiver | | | |  | Alteration | | | |  |  | |
|  | | | 9.d.iii.b Provide justification for your request.For an alteration, describe how this deviates from normal consent procedures.  *For example: When research requires deception, some but not all of the elements of informed consent are met. Information typically withheld may be necessary for the research methodology, and generally subjects are debriefed after research is complete.* | | | | | | | | | | | | | | | | | | |
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|  | | | 9.d.iii.c Does this request apply to the entire subject population? | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | Yes | | |  | | No | |  |  | | | | |
|  | | | | | | | | | If No, describe for which populations the waiver or alteration is being requested below. | | | | | | | | | | | | |
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|  | | | 9.d.iii.d Criteria for Waiver or Alteration (complete all four items) | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | 1. Describe why the research involves no more than minimal risk\* to the individual. | | | | | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | | | | | |
|  | | | | | | | | | *\*The probability and magnitude of harm is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests of the general population.* | | | | | | | | | | | | |
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|  | | | | | | | | | 2. Describe why the research will not adversely affect the rights and welfare of subjects. | | | | | | | | | | | | |
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|  | | | | | | | | | 3. Describe why the research would not be possible to conduct without a waiver or alteration of consent. | | | | | | | | | | | | |
|  | | | | | | | | |  | | | | | | | | | | | | |
|  | | | | | | | | | 4. Will information be provided to the subject once the research is complete, when appropriate? | | | | | | | | | | | | |
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| 9.e. | Linguistic/Cultural Considerations for Consent | | | | | | | | | | | | | | | | | | | | | |
| 9.e.i. | | Is the population you will be working with generally literate and able to read the consent form? | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | |  | | | No | | |  | |  | | | | | | | | |
|  | | If No, what is your procedure for making sure that each participant understands the consent form and what is involved in this study? | | | | | | | | | | | | | | | | | | | |
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| 9.e.ii. | | Is the individual research subject responsible for his/her own consent? | | | | | | | | | | | | | | | | | | | |
|  | | Yes | | |  | | | No | | |  | |  | | | | | | | | |
|  | | If No, who is responsible for giving consent for the types of procedures proposed in your research within this setting or culture, if different from the individual participant (e.g., tribe elder, government leader, etc.)? | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | | |
| 9.e.iii. | | How will people in this setting let you know if they do not want to be in the research project and/or they do not want to talk with you? | | | | | | | | | | | | | | | | | | | |
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| 9.e.iv. | | How will you manage situations in which group consent is provided but an individual(s) does not want to participate, or situations in which individual consent is given but group leaders have not given consent for the community to take part in the study? | | | | | | | | | | | | | | | | | | | |
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| **10. Risks/Benefits** | | | | | | | | | |
| 10.a. | Benefits: *Are there any potential direct benefits to individual subjects or their community?* | | | | | | | |
|  | | | Yes |  | No |  |  |
|  | | If Yes, describe any direct benefits that individual subjects can reasonably expect from taking part in this study: | | | | | | |
|  | |  | | | | | | |
|  | If yes, describe the anticipated benefits of this research for the community you will study or for society in general, and explain how the benefits outweigh the risks of harm to participants: | | | | | | |
|  |  | | | | | | |
| 10.b. | Risks of Harm: *Harm in ethnographic research is usually limited to what may result from invasion of privacy, or breach of confidentiality. Harms may happen to individuals and to the groups or communities to which they belong.* | | | | | | | |
| 10.b.i. | | Does the proposed research pose more than minimal risk of harm to participants or their communities? | | | | | |
|  | | | Yes |  | No |  |  |
|  | | If Yes, explain how the benefits outweigh the risks of harm to participants and their communities. If there are different risks for different groups of subjects, please identify those risks per group and how the benefits outweigh the risks for each group. | | | | | |
|  | |  | | | | | |
| 10.b.ii. | | Identify the potential risks of harm that may result from the study, steps you will take to minimize these risks, and plans you have to manage these harms if they do occur. | | | | | |
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| **11.** | | **Research Data Management Plan**  *Please reference the Research Manual for Guidance on Research Data Management.* | | | | | | | | | | | | | | | | | | | |
| 11.a. | | Is the research team collecting the research data? | | | | | | | | | |  | Yes | | |  | | No | | |
| 11.b. | | How will the research team record the research data? | | | | | | | | | | | | | | | | | | |
|  | |  | | with full identifiers | | | | | | | | | | | | | | | | |
|  | |  | | Describe how the directly identified data will be protected. | | | | | | | | | | | | | | | | |
|  | |  | |  | | | | | | | | | | | | | | | | |
|  | |  | | with a code number *(a master key to the code numbers (used to identify subjects) will be kept separate)* | | | | | | | | | | | | | | | | |
|  | |  | | | Describe the process you will use to code the data and confirm that the key will be kept separate from the coded data. Include who has access to the key. | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | | | | | | | | | | | |
|  | |  | | without any identifiers *(no one will be able to match the data to the person)* | | | | | | | | | | | | | | | | |
| 11.c. | | Are you being provided with a research data set from elsewhere? | | | | | | | | | | | | |  | | Yes | |  | No |
|  | | | | | If yes, describe how the data are coded. | | | | | | | | | | | | | | | |
|  | | | | |  | | | | | | | | | | | | | | | |
| 11.d. | | Describe any sensitive research data that will be collected. (*See Appendix 0 of the Research Manual for definition of “highly sensitive”.)* | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | |
| 11.e. | | How are the research data being stored? | | | | | | | | | | | | | | | | | | |
|  | | For hardcopy data: | | | | | | |  | For electronic data: | | | | | | | | | | |
|  | |  | | Locked office | | | | | |  | Local computer hard drive *(will require encryption if data contains sensitive, directly identifiable private information)* | | | | | | | | | |
|  | |  | | Locked file cabinet | | | | | |  | Password protected | | | | | | | | | |
|  | |  | |  | | | | | |  | Secure network/server list: | | |  | | | | | | |
|  | |  | |  | | | | | |  | Other types of storage *(e.g. thumbdrives, media, external hard drive)* *(will require encryption if data contains highly sensitive, directly identifiable private information)* | | | | | | | | | |
|  |
|  |
|  | |  | | Other explain or comments: | | | | | |  | Online data (i.e. forms, surveys) | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | |
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| e. i. | | | If the research data are being collected via an online survey, explain below how the subjects’ identities will be protected. | | | | | | | | | | | | | | |
|  | | |  | NA |  | | | | | | | | | | | | |

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| 11.f. | | Will sensitive, directly identifiable private research data be moved or transferred? | | | | | | | |
|  | Yes |  | No |  | | |
|  | | If yes, the media which is used to transfer the data must be encrypted. Has this been done for all media? *(encrypted thumb drives can be purchased with a PIN pad right on the device and are not dependent on software being installed)* | | | | | | |
|  | |  | Yes |  | No | |  |  |
| 11.g. | | Will sensitive, directly identifiable private research data be transferred via email? *(will require encryption of the file(s))* | | | | | | | |
|  | |  | Yes |  | No | | | |
|  | | If yes, explain why it is necessary to include identifiable information in an email. | | | | | | |
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|  | | Explain the process for encrypting the files that will be sent via email. | | | | | | |
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| 11.h. | Will the research data be shared? | |  | Yes |  | No If no, skip to i. |
|  | *NOTE: If you intend to share research data sets with other colleagues, you must obtain local IRB approval as well as the colleague’s IRB approval. The IRB typically requests that all individual identifiers be stripped prior to release. Justification for maintaining identifiers, even if coded, will be required. UVM investigators sending research data outside of the institution should contact Sponsored Projects Administration at 656-3360 to speak with the AVP for Research to determine if an agreement defining the respective institutional responsibilities is warranted.* | | | | | |
|  | | Describe the process for ensuring that the research data are protected. Include the process for obtaining appropriate IRB approvals, stripping of individual identifiers, and/or justification to maintain identifiers, even if coded. | | | | |
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| 11.i. | | | Will the research data be retained outside of a banking protocol, once the protocol is closed? | | | | | | | | | |
|
|  |  | | | Yes, continue | | |  | No, continue to section 11.g. | | | | | |
|  | | How will the data continue to be maintained? | | | | | | | | | | |
|  | |  | | | | | | | | | | |
|  | | Will you keep identifiers of any kind, direct or coded? | | | | | | |  | Yes |  | No |
|  | | If yes, explain how you will maintain security around the identifiers. | | | | | | | | | | |
|  | |  | | | | | | | | | | |
|  | | If you intend to maintain identifiers, any subsequent secondary analysis after protocol closure requires prior IRB review and approval. Please acknowledge this requirement by checking below. | | | | | | | | | | |
|  | | | | |  | I understand subsequent data analysis requires prior IRB review and approval. | | | | | | |

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| **12. Data Safety and Monitoring** | | |
| The specific design of a Data and Safety Monitoring Plan (DSMP) for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For a minimal risk study, a DSMP could be as simple as a description of the Principal Investigator’s plan for monitoring the data and performance of safety reviews or it could be as complex as the initiation of an external review. | |
| Describe the Data Safety and Monitoring Plan |
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| **13. Compensation** | | | | | | | |
| 13.a. | Are you planning to provide compensation to subjects? | | | | | |
|  | Yes |  | No |  |  |
| If Yes, describe all plans to pay subjects, either in cash, a gift or gift certificate. Describe the remuneration in both US and local currency. Include a description of payment in relative terms (i.e. payment equates to a day’s work, hourly salary, or another local reference). If you anticipate the compensation may be in the form of gifts or goods, include a description in relative terms, as described above. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study that offers a lump sum payment at the end of the study, because this can be considered coercive. *Note: The PI is not allowed to compensate participants from personal funds.* | | | | | |
|  | | | | | |
| 13.b. | Justify why the level of compensation is appropriate. The IRB needs to ensure that compensation is neither coercive nor exerts undue influence: | | | | | |
|  |  | | | | | |
| *NOTE: If the study takes place in the United States and the funds flow through UVM, the research subjects’ Social Security number must be collected if the amount exceeds $100. This information must be indicated in the consent form (see the informed consent template/confidentiality section for suggested wording).* | | | | | | |

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| **14. Collaborating Institutions** | | | | | | | | | |
|  | Will this research be conducted in collaboration with other sites at other locations? | | | | Yes |  | No |  |  |
|  | If so, complete the following for all collaborating institutions: | | | | | | | | |
| Institution Name | | Describe Involvement | Is there an IRB? If yes, attach approval or explanation | Are other permissions required? If yes, attach approval or explanation | | | | | |
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| **15. International Regulatory Issues** | | | | | | | | | | | | | | | | | | | | | |
|  | *International research conducted by UVM investigators falls under the purview and guidelines of the UVM IRB even when conducted elsewhere. International research projects must be approved by the local equivalent of an IRB prior to final approval from the UVM IRB.* | | | | | | | | | | | | | | | | | | | | |
| 15.a. Will any aspect of the study take place outside of the United States? | | | | | | | | | | | Yes | |  | No | |  | If No, skip to Section 16. | | |
|  |  |
|  | If Yes, indicate below from which country or countries participants will be recruited | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | |
| 15.b. | Does the country involved require local IRB (or the equivalent) review? | | | | | | | | | | | Yes | | |  | No | |  |  |
|  |  |
|  | If Yes, indicate the type of review (e.g. Expedited, Full), and the current status of this review. | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | |
| 15.c. | Is any other permission or approval required from authorities, institutions, and/or organizations in the specific location where the research will be conducted? | | | | | | | | | | | | | | | | | | |
| Yes | |  | | No | |  | If Yes, please complete table below | | | | | | | | | | |
|  | | | | | | |  | | | | |  | | | | | | | | | |
| List specific location(s) where research will take place | | | | | | | | | Does this location have a research review process? If yes, attach approval or explanation | | | Are other permissions required? If yes, attach approval or explanation | | | | | | | | | |
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| *NOTE: If ANY of the information below is not known ahead of time, please include the strategy you intend to use to obtain the information, to the best of your ability.* ***(If you find you must alter the strategy or add information after the protocol has been approved, then an amendment must be submitted and approved)****.* | | | | | | | | | | | | | | | | | | | | | |
| 15.d. | Who are your contacts in the host country, i.e., is it through an academic institution, a government agency, a community organization, etc.? | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | |
| 15.d.i | | What relationship do you have with these contacts, i.e., contract or agreement, research colleague, prior research relationship, etc.? | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | |
| 15.d.ii. | | Have the contacts or collaborators in the host country been involved in planning this research? Please indicate in your response whether any local “permissions” are necessary prior to the research, i.e. local leaders, community, government, etc., and if so, how this will be done. | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | |
| 15.e. | The IRB may need to obtain consultation regarding the culture of the host country. Do you have any suggestions for contacts within UVM or other local individuals (not involved in your project) who can provide insight and advise the IRB? | | | | | | | | | | | | | | | | | | |
|  | Provide names and contact information or please indicate unknown: | | | | | | | | | | | | | | | | | | |
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| **16.** | | **Disclosure of Financial Interest** | | | | | | | | | | | | | |
|  | | If yes, to any of the questions below, disclosure in the consent may be required by the Institutional Review Board (IRB) and you must also complete number 17 below. Refer to the Research Manual for the IRB policy and the consent form language. | | | | | | | | | | | | | |
|  | | 16.a. Do any members of the investigative team or members of their immediate families receive from the sponsoring entity salaries, consulting fees, or other compensation for services that exceed $5,000 in any twelve month period? | | | | | | | | | | | | | |
|  | | | |  | | Yes | | |  | | | No | | | |
|  | | | |  | | | | | | | | | | | |
|  | | 16.b. Do any members of the investigative team or members of their immediate families have an equity interest that exceeds $5,000 in value or represents more than 2% ownership interest in the sponsoring entity? | | | | | | | | | | | | | |
|  | | | |  | | Yes | | |  | | | No | | | |
|  | |  | | | | | | | | | | | | | |
|  | | 16.c. Do any members of the investigative team or members of their immediate families have any intellectual property rights (inventorship, patents, copyrights, royalties) in any article(s), product(s), drug(s), device(s), or other material(s) that will be involved in this research? | | | | | | | | | | | | | |
|  | | | |  | | Yes | | |  | | | No |  |
|  | |  | | | | | | | | | | | | | |
|  | | 16.d. Do any members of the investigative team or members of their immediate families have any financial interests similar to those described in a.,b.,c., above in an entity other than the sponsor that would, to a reasonable objective observer familiar with such issues, appear to affect or be affected by the research being undertaken? | | | | | | | | | | | | | |
|  | | | |  | | Yes | | |  | | | No | | |  |
|  | |  | | | | | | | | | | | | | |
| **17.** | | **If you answered “yes” to any question in above, answer the following additional questions. Otherwise skip to question 18.** | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | |
|  | | 17.a. Is an FDA Financial Disclosure Form (3455) required for the principal investigator or key personnel? | | | | | | | | | | | | | |
|  | | |  | | Yes | |  | | | No | | | | | | | |
|  | | | If yes, attach a copy. If disclosure is required and not attached, your approval will be withheld until this is provided. | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | |
|  | | 17.b. For UVM sponsored projects processed through SPA, is disclosure to UVM of a financial interest for this project required for the principal investigator or key personnel? | | | | | | | | | | | | | |
|  | | |  | | Yes | | |  | | | No | | | | | |
|  | | | If yes, attach a copy. If disclosure is required and not attached, your approval will be withheld until this is provided. | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | |
|  | | 17.c. Provide the names of all individuals with potential conflicts with a description of their roles and activities in this project, e.g., determine eligibility, recruitment, obtain consent, data analyses, conduct study procedures (describe), etc. | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
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|  | | 17.d. What is the amount (dollar value) and nature of the conflict (consulting fees, serving as director or on advisory board, intellectual property royalties, etc.)?, conduct study procedures (describe), etc. | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
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|  | | 17.e. Describe how the project outcome may or may not affect this financial interest, e.g., a good result would lead to more consulting or a product that I have invested in may appear more effective and have higher sales. | | | | | | | | | | | | | |
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|  | | 17.f. What actions do you think are appropriate to reduce or manage any potential harmful effects on human subjects arising from the potential conflict? Consider actions to preserve scientific objectivity, guard against coercive recruiting, objectively determine subject eligibility, etc. | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | |
|  | | 17.g. Please provide any additional information that may be helpful to the IRB in reviewing the potential conflict. | | | | | | | | | | | | | |
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| **18. AGREEMENTS** | | | | | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR**  **As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true**:  The information that is provided in this form is correct. I will seek and obtain prior written approval from the IRB for any modifications in the proposal, including changes in procedures, co-investigators, etc. All of the members of the research team have completed the applicable required training to conduct this research. I will promptly forward any reportable adverse events and unanticipated problems to subjects or others that may occur in the course of this study. I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to participation. I will not begin my research until I have received written notification of IRB approval. I will comply with all IRB requests to report on the status of the study.  If at any time I want to reuse the research data for other purposes or disclose the data to other individuals or entities, I will seek prior IRB approval. I will maintain records of this research according to applicable guidelines. If I am seeking IRB approval for a sponsored project, I hereby certify that the application that I have submitted to my funding agency accurately and completely reflects what is contained in this application. | | | | | | | | | | | | | | | | | | |
| x | | | | |  | |  | | | | | | | | | |  | |
| Original Signature of PI | | | | |  | | Date | | | | | | | | | | | |
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| **FACULTY SPONSOR (if applicable and referenced on page one, section 2, of this form)** | | | | | | | | | | | | | | | | | | |
|  | | | | |  | |  | | | | | | | | | | | |
| Advisor’s Name: |  | | | | | Telephone Number: | | | | | | | | |  | | | |
|  | | | | | |  | |  | | | | | | | | | | |
| Department/Address: | |  | | | | E-mail: | | | | |  | | | | | | | |
|  | | | | |  | | | |  | | | | | | | | | |
| Date of Human Subjects Tutorial Completion | | | | |  | | | | | | | | |  | | | | |
| ***Policy Statement from the Research Manual:*** *“As the responsible investigator, the faculty sponsor or course instructor is required to complete the Human Subjects in Research tutorial. Protocol approvals will not be released until that requirement has been met.” Completion of this requirement is every three years. The training can be found at* [*http://www.uvm.edu/irb/tutorial/index.html*](http://www.uvm.edu/irb/tutorial/index.html) | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| Is there is a thesis or dissertation committee reviewing this research? | | | | | | | | | | Yes | |  | No | | |  | |  |
| If yes, date of approval: | | |  |  | | | | | | | | | | | | | | |
| **As the faculty sponsor for this protocol,** I certify that the student will conduct this research under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this protocol in accordance with all University of Vermont and Federal Regulations relating to human research as outlined above and in the Human Subjects Research Manual. | | | | | | | | | | | | | | | | | | |
|  | | | | |  | | | |  | | | | | | | | | |
| x | | | | |  | | | |  | | | | | | | | | |
| Original Signature of Faculty Sponsor | | | | |  | | | | Date | | | | | | | | | |
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| Printed Name | | | | |  | | | |  | | | | | | | | | |

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| **19.** | **PERSONNEL ROSTER** | |  | |  | | |
|  | | **All key personnel are required to complete the** [**Training in Protection of Human Subjects in Research Tutorial**](http://www.uvm.edu/irb/tutorial/index.html)**.** | | | |
|  | | **PLEASE DO NOT INCLUDE INDIVIDUALS WHO HAVE NOT COMPLETED THE**  **REQUIRED TRAINING**  **Check tutorial completions at** [**http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm**](http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm) | | | |
|  | | **Personnel Name** | | **Email Address** | | |
| 1. | | PI: | |  | | |
| 2. | | Contact Person: | |  | | |
| 3. | | Faculty Sponsor: | |  | | |
| 4. | |  | |  | | |
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| **20. Required Documents for Committee Review** |

Please attach the following documents to this protocol:

* Full grant application, including budget information and/or any contract or draft contract associated with this application;
* Consent form(s) or request for waiver or alteration of consent;
* Survey instruments, or questionnaires, as applicable:
* Any material used for recruitment purposes, as applicable.

All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the [InfoEd Resource Materials](http://www.uvm.edu/~irb/?Page=infoed.html) page for more information.