**Human Subjects Research**

**Qualitative Research Protocol**

|  |
| --- |
| **Protocol Version Date (updated at each protocol modification):** |

*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.*

|  |
| --- |
| **1. Should I Be Using This Form?** |
|  | Is this study qualitative (or primarily qualitative)?  | Yes  |  | No |  |
|  | If No, stop! You should be completing the Human Subjects Research ProtocolIf Yes, continue. |
|  | Does this qualitative/primarily qualitative protocol include any medical procedures or include the use of [protected health information](https://www.uvm.edu/compliance/hipaa_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 Human Subjects Research Protocol. If No, continue. |
|  | Are your research procedures considered to be less than minimal risk? (probability and magnitude of harm or discomfort anticipated in **the research are not greater in and of themselves** than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) If Yes, please refer to our [Exemption forms](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) as your study may not require you to complete this form. |

|  |  |
| --- | --- |
| **2.** | **Protocol Title** |
|  |  |
| **3.** | **Principal Investigator**  |
|  |

|  |  |
| --- | --- |
| **4.** | **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).* |

|  |
| --- |
| 4.a. Purpose |
|  | *State the reason for the study and the goals of the proposed study as related to the research question(s). Give background information.* |
|  |  |

|  |
| --- |
| 4.b. 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.* |
|  |  |

|  |
| --- |
| 4.c. 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 data you will collect for this study and how the data collected will be analyzed. Please submit copies of any questionnaires, surveys/interview questions or provide samples of the types of questions to be asked.*  |
|  |  |

|  |
| --- |
| **5. Human Subjects** |
| 5.a. | Inclusion/Exclusion Criteria: *Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom.*  |
|  |  |
| 5.b.  | Subject Demographics: *Describe characteristics of the participant population(s), including gender, ethnicity, age range, education-level and economic status, etc.* |
|  |  |
| 5.c. | [Subjects Vulnerable to Coercion or Undue Influence](https://www.uvm.edu/rpo/irb-policies-and-procedures#vul_II):  |
|  | *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 you think should be provided below. The IRB must assess whether any additional protections are necessary, and this information will assist in that evaluation.  |
|  |  |

|  |  |
| --- | --- |
| 5.d.i. | Explain the rationale for involvement of special classes of subjects, if any.  |
|  |  |
| 5.d.ii. | Discuss what procedures or practices will be used to minimize their susceptibility to coercion and unnecessary risk (physical, psychological, etc.). |
|  |  |

|  |
| --- |
| **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 i.e., Mai Mai)?  |
|  | Yes |  | No |  |  |
|  | If No, skip to 7.  |
| 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? Please refer to our policy on [Informed Consent and HIPAA Authorization Process for Non-English Speaking Individuals](https://www.uvm.edu/rpo/irb-policies-and-procedures#hipaa_IIdown) |
|  | 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. |
|  |  |
| 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 managed: |
|  |  |

|  |
| --- |
| **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.).  |
|  |  |
| 7.b.  | Who will contact potential participants and how will they be contacted, (phone script, letter, e-mail, public setting, classroom 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](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) under Miscellaneous Templates. |
|  |  |
| 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. Include documentation indicating permission to use this recruiting tool. |
|  |  | Yes |  | No  |

|  |
| --- |
| **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.)*  |
|  |

|  |
| --- |
| **9. Consent Process***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. The consenting process description and application for waives or alteration of informed consent can be completed in UVMClick.*  |

|  |
| --- |
| **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 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:  |
|  |  |
|  | 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. | 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 distinct groups of subjects, please identify those risks per group and how the benefits outweigh the risks for each group. |
|  |  |
| 10.b.i | Identify the potential risk of harm that may result from the study. Describe steps you will take to minimize these risks, and plans you have to manage these harms if they do occur. |
|  |  |
| 10.c. | Research Data Management Security Plan form must be completed. The form, along with guidance, can be found in our [forms library](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) and must be submitted with your initial application. |

|  |
| --- |
| **11. Data Safety and Monitoring Plan** |
| *Please note this is different from the required Data Management and Security Plan uploaded as a separate document.* The Data Safety and Monitoring Plan (DSMP) should detail how the PI and/or study team will conduct a regular review of accrued research data ensuring the validity and integrity of the data. The scheduled review will assess if changes to the anticipated benefit-to-risk ratio of study participation has occurred. In addition, there should be an ongoing review of study procedures to ensure the privacy of research subjects and the confidentiality of research data has been maintained. The specific design of a DSMP for a protocol may vary extensively depending on the potential risks, size, and complexity of the research study. For an expedited protocol review, 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 -  |
|  |
| **12. 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 protocols must be approved by the local equivalent of an IRB prior to final approval from the UVM IRB.*  |
| 12.a. Will any aspect of the study take place outside of the United States? | Yes |  | No |  |  |
|  | If Yes, indicate below from which country or countries participants will be recruited |
|  |  |
| 12.b. | Does the country involved require local IRB (or the equivalent) review? | Yes |  | No |  |  |
|  | If Yes, indicate the type of review (i.e. Expedited or Full) and the current status of this review. |
|  |  |
| 12.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 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| *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)****.* |
| 12.d. | Who are your contacts in the host country, i.e., is it through an academic institution, a government agency, a community organization, etc.? |
|  |  |
| 12.d.i | What relationship do you have with these contacts, i.e., contract or agreement, research colleague, prior research relationship, etc.? |
|  |  |
| 12.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. |
|  |  |
| 12.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 protocol) who can provide insight and advise the IRB? |
|  | Provide names and contact information or please indicate unknown: |