**Human Subjects Research**

**Qualitative Research Protocol**

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|  | **Protocol Version Date (required for 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.*

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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 Human Subjects Research Protocol  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 |  |
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|  | *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. | | | | | |
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| **2.** | | | | **Protocol/Project Title, Investigator Name** | | | |
|  | | 2.a. Protocol/Project Title | | | | | |
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| 2.b. | | | | \*Principal Investigator |  |

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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).* |

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| 3.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.* |
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| 3.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.* |
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| 3.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 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* ***5.*** |
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| **4. Human Subjects** | | | | | | | |
| 4.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.* | | | | | |
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| 4.b. | Inclusion/Exclusion Criteria: *Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined and by whom.* | | | | | |
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| 4.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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| 4.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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| 4.d.i. | Explain the rationale for involvement of special classes of subjects, if any. |
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| 4.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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| **5. Cultural/Linguistic Considerations** | | | | | | | |
| 5.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. | | | | | |
| 5.b. | Provide context of cultural norms and considerations with respect to research autonomy, informed consent, recruitment, etc. (Attach documentation if necessary) | | | | | |
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| 5.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.* | | | | | |
|  |  | | | | | |
| 5.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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| 5.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. | | | | | |
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| 5.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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| **6. 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:* | | | | | |
| 6.a | How will you recruit potential participants (e.g. announcements/notice, word-of-mouth, snowball/chain sampling, etc.). | | | |
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| 6.b. | Who will contact potential participants and how will they be contacted, (phone script, letter, e-mail, public setting, class room setting, etc.); | | | |
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| 6.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. | | | |
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| 6.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 |

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| **7. 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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| **8. 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. Waiver or alteration forms can be completed in UVMClick.* | | | | | | | | | | | | |
| **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.** | | | | | | | | | | | | |
| 8.a. | Explain the setting and 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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| 8.b. | How will you obtain their consent to participate (verbal, written, etc.)? | | | | | | | | | | |
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| 8.c. | Address any social/cultural norms impacting the consent process (i.e. obtaining permission from group leaders, etc…) | | | | | | | | | | |
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| 8.d. | Type of Consent that will be used | | | | | | | | | |  |
|  | 8.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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| 8.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. 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. | | | | |
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| 8.d.ii. | |  | I am requesting a **waiver of the documentation** of informed consent (no signature) *Waiver or alteration forms can be completed in UVMClick.* | | | | | | | | |
| 8.e. | Linguistic/Cultural Considerations for Consent | | | | | | | | | | |
| 8.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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| 8.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.)? | | | | | | | | |
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| 8.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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| 8.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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| **9. Risks/Benefits** | | | | | | | | | | | | | | |
| 9.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: | | | | | | | |
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|  | 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: | | | | | | | |
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| 9.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.* | | | | | | | | |
| 9.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. | | | | | | |
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| 9.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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| 9.c. | | Research Data Management Plan | | | | | | | | | | |
|  | | | The Research Data Management and 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. | | | | | | | | | |

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| **10. 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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| **11. Compensation** | | | | | | | |
| 11.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.* | | | | | |
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| 11.b. | Justify why the level of compensation is appropriate. The IRB needs to ensure that compensation is neither coercive nor exerts undue influence: | | | | | |
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| *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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| **12. 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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| **13. 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.* | | | | | | | | | | | | | | | | | | | | |
| 13.a. Will any aspect of the study take place outside of the United States? | | | | | | | | | | | Yes | |  | No | |  |  | | |
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|  | If Yes, indicate below from which country or countries participants will be recruited | | | | | | | | | | | | | | | | | | |
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| 13.b. | Does the country involved require local IRB (or the equivalent) review? | | | | | | | | | | | Yes | | |  | No | |  |  |
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|  | If Yes, indicate the type of review (e.g. Expedited, Full), and the current status of this review. | | | | | | | | | | | | | | | | | | |
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| 13.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 | | | | | | | | | | |
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| 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)****.* | | | | | | | | | | | | | | | | | | | | | |
| 13.d. | Who are your contacts in the host country, i.e., is it through an academic institution, a government agency, a community organization, etc.? | | | | | | | | | | | | | | | | | | |
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| 13.d.i | | What relationship do you have with these contacts, i.e., contract or agreement, research colleague, prior research relationship, etc.? | | | | | | | | | | | | | | | | |
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| 13.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. | | | | | | | | | | | | | | | | |
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| 13.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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