**Human Subjects Research Protocol**

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| **Project Title:** | **Protocol Version Date (required for each protocol modification):** |
| **Principal Investigator:** |  |
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| Check the type of the review: |
|  | Full convened meeting - The IRBs employ the convened meeting review process for review and approval of studies that are more than minimal risk.  |
|  | Expedited review - The IRBs employ the expedited review process for approval of studies that are determined to be minimal risk and only involves activities such as prospective collection of biological specimens for research purposes by noninvasive means (blood collection, salvia, nail clippings), collection of data through noninvasive procedures (ultrasounds, MRI, physical sensors) and research on behavior such as perception, cognition, motivation, identity, language and communication.  |

**Federal regulations mandate that changes cannot occur until after IRB review and approval “except when necessary to eliminate apparent immediate hazards to the subject."**

**ALL modifications to the approved study materials (including Click forms) must be submitted to the IRB prior to implementation, regardless of the magnitude of change or effect on risk level.**

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| **PURPOSE AND OBJECTIVES** |

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| **Purpose:** The importance of the research and the potential knowledge to be gained should be explained in detail. Give background information. |
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| **References:** Include references to prior human or animal research and references that are relevant to the design and conduct of the study. |
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| **Objectives:** Clearly state the primary and secondary objective(s) of the study. |
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| **SUBJECT CHARACTERISTICS, IDENTIFICATION AND RECRUITMENT** |

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| **Subject Selection**: Provide rationale for subject selection in terms of the scientific objectives and proposed study design. |
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| **Vulnerable Populations**: Explain the rationale for involvement of subjects (e.g., cognitively impaired, non-English speaking, prisoners, students). Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.). |
|  | Not applicable |  |
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| **Inclusion/Exclusion Criteria:** Eligibility and ineligibility criteria should be specific. Describe how eligibility will be determined, by whom and how it will be documented in the research record. Please note: Inclusion and exclusion criteria must be documented for all criteria (e.g., EPIC notes, eligibility checklist with associated source documents, notes to file). Participant reported information must be documented in the research record; a lack of documentation does not prove absence of a criteria.  |
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| **Inclusion of Minorities and Women:** Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion. |
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| **Inclusion of Children:** Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. Provide target accrual for this population. Identify whether children are wards of the state. **If children are excluded** then provide appropriate justification. |
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| For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification. |
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| If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included. |
|  | Not applicable |  |
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| **Will the SONA Psychology Pool be utilized?** *Include documentation indicating permission to use this recruiting tool*  | Yes |  | No |  |
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| **METHODS AND PROCEDURES** |

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| **Study Design:** Describe the research design, including a description of any new methodology and its advantage over existing methodologies. |
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| **Procedures and Methods:** Describe all procedures (sequentially) to which human participants will be subjected. Describe required screening procedures performed before enrollment and while on study. Identify all procedures that are considered experimental and/or procedures performed exclusively for research purposes. Describe the types, frequency and duration of tests, study visits, interviews, questionnaires, etc. Note: A clinical research protocol may involve interventions that are strictly experimental, or it may involve some aspect of research (e.g., randomization among standard treatments for collection and analysis of routine clinical data for research purposes). It is important for this section to distinguish between interventions that are experimental and/or carried out for research purposes versus those procedures that are considered standard therapy. In addition, routine procedures performed solely for research purposes (e.g., additional diagnostic/follow-up tests) should be identified. |
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|  | **TYPES OF PROCEDURES** (Please do not use the “other” option unless the procedure is not listed.) |
|  | **Check all that apply** |
|  | Survey (mail, telephone, in-person, on-line) |  | Blood drawing: | Vol. |  | Over days, weeks? |  |
|  | Medical exams/history |  |  | Type & Amt. |  |
|  | Deception **\*see below** |  | Surgery |  | Collection of Urine and/or Feces |
|  | Observation |  | Drug Administration  |  | Communicable Disease Testing |
|  | Photographs |  | Device Use  |  | Ultrasound (e.g., echocardiogram) |
|  | Audio Recording |  | Exercise |  | Imaging (e.g., CT scan, DEXA, mammogram, PET scans, SPECT) |
|  | Video Recording |  | Diet |  | Use of Radiation treatment |
|  | Interviews in person or by phone |  | Pathology Specimens (retrospective) |  | Use of Radioactive substances (e.g., radiolabeled antibodies, drugs, or contrasts) |
|  | Focus Groups |  | Genetic Materials (DNA)\*\* **see below** |  | MRI (for treatment studies) |
|  | Review of prospective data |  | Questionnaires |  | MRI (not for treatment studies) |
|  | Review of retrospective data |  | Diaries |  | Tissue (obtained for clinical purposes) |
|  | Recording of Identifiable DataElectrocardiograms |  | Pregnancy Tests |  | Tissue (obtained solely for research) |
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|  | Sensitive Data (criminal or sexual conduct, drug or alcohol conduct or use) | (specify): |  |
|  | **\*\*If genetic information is being collected, GINA language must be added to the consent form.****\***Deception typically involves withholding information from the potential subject and would require an alteration to the consent process.**If you are requesting Radiology services (equipment and professional needs) you will need to contact the Radiology Research Coordinator John.Little@uvmhealth.org and complete this [form](https://commons.med.uvm.edu/dean/comclntril/SiteAssets/SitePages/Regulatory%20Documents%20and%20Resources/Radiology%20Research%20Study%20Survey%203.24.2021.doc).** |

**Statistical Considerations:** Delineate the precise outcomes to be measured and analyzed. Describe how these results will be measured and statistically analyzed. Delineate methods used to estimate the required number of subjects. Describe power calculations if the study involves comparisons. Perform this analysis on each of the primary and secondary objectives, if possible. |
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| **Risks:** Describe any potential or known risks. This includes physical, psychological, social, legal or other risks (including breach of confidentiality, which is always a risk when collecting identifiable information). Estimate the probability that given risk may occur, its severity and potential reversibility. If the study involves a placebo or washout period, the risks related to these must be addressed in both the protocol and consent. Describe the planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.  |
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| **Benefits:** Discuss the potential benefits of the research to the subjects and others. Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits to subjects and others. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research and why the risks are reasonable in relation to the knowledge that reasonably may result. If there are no benefits state so.**Therapeutic Alternatives:** List the therapeutic alternatives that are reasonably available that may be of benefit to the potential subject and include in the consent form as well. |
|  | Not Applicable |
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| **Data Safety and Monitoring:** *Please note that this is not the same as the Data Management and Security Plan that will be uploaded as a separate document.* Describe the data and safety monitoring plan (DSMP). This should provide for a regular review of accrued research data and other relevant information to ensure the validity and integrity of the data and that there is no change to the anticipated benefit-to-risk ratio of study participation. In addition, there should be an ongoing review of study procedures to ensure that the privacy of research subjects and the confidentiality of research data has not been violated. 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 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, independent Data Safety and Monitoring Board (DSMB). The UVM/UVM Medical Center process for review of adverse events should be included in the DSMP. |
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| Define criteria to be used for decision making regarding continuation, modification, or termination of the entire study (not individual participation) (i.e. “stopping rules). |
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| **What will be the frequency of the review?** Please note that the frequency of reviews should be commensurate with the risk of the study. At a minimum, a review of the data should be conducted annually at time of continuing review. These reviews must be conducted at the frequency indicated below and must be documented in the regulatory binder or files. **Forward copies of data and safety monitoring board reports to the IRB via a modification.** |
|  |  | Monthly |  | Annually |
|  |  | Quarterly |  | Other (e.g., by dosing level, no. of subjects enrolled): |
|  |  | Bi-annually |
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| **Will the sponsor be conducting data monitoring visits for this study?** |
|  |  | Yes |  | No |  | NA |
|  | If yes, how often? |
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**Adverse Event, Unanticipated Problem (UAP), Reportable New Information (RNI):** Describe how events and UAPs will be evaluated and reported to the IRB. All protocols should specify that, in the absence of more stringent reporting requirements, the guidelines established in “Section 18: Reportable New Information” of the IRB Policies and Procedures will be followed.  |
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| **Withdrawal Procedures:** Define the precise criteria for PI withdrawal of subjects from the study. Include a description of study procedures for when a subject withdraws themself from the study. |
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| **Drug Information** |

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| Investigators are encouraged to consult the UVM Medical Center Investigational Pharmacy Drug Service (847-4863) prior to finalizing study drug/substance procedures. |
| **Drug (s)** |  | **Not applicable** |
| Drug name – generic followed by brand name and common abbreviations. Availability – Source and pharmacology; vial or product sizes and supplier. If a placebo will be used, identify its contents and source.  |
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| Preparation: Reconstitution instructions; preparation of a sterile product, compounded dosage form; mixing guidelines, including fluid and volume required. Identify who will prepare. |
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| Storage and stability – for both intact and mixed products. |
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| Administration – Describe acceptable routes and methods of administration and any associated risks of administration. |
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| Toxicity – Accurate but concise listings of major toxicities. Rare toxicities, which may be severe, should be included by indicated incidence. Also, adverse interactions with other drugs used in the protocol regimen as well as specific foods should be noted. Address significant drug or drug/food interactions in the consent form as well. List all with above details. |
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| Is it FDA approved: (include FDA IND Number) |
| 1. in the dosage form specified? If no, provide justification for proposed use and source of the study drug in that form. |
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| 2. for the route of administration specified? If no, provide justification for route and describe the method to accomplish. |
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| 3. for the intended action? |
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| **FINANCIAL CONSIDERATIONS**  |

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| **Describe all potential research related expenses to subjects:**  |
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| **Compensation for participation:** Describe all plans to pay subjects, either in cash, a gift or gift certificate. Please note that all payments must be prorated throughout the life of the study. The IRB will not approve a study where there is only a lump sum payment at the end of the study because this can be considered coercive. The amount of payment must be justified. Clarify if subjects will be reimbursed for travel or other expenses. |
|  | Not applicable |  |
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| **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. |