**Human Subjects Research Protocol**

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| **PROTOCOL SUMMARY** |

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| **Project Title:** | **Protocol Version Date (required for each protocol modification):** |
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| **Principal Investigator:** |  |
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| TYPE OF REVIEW |
| **Which type of IRB review are you requesting?** | Full |  | Expedited |  | Complete category. |
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| Your research may be expeditable if the research activities (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories: (CHECK THE CATEGORY(IES) THAT APPLY. |
|  | (1) **Clinical studies of drugs and medical devices only when conditio**n **(a) or (b) is met.** |
|  | (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
|  | (2) **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh |
|  | at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week: or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |
|  | (3) Prospective **collection of biological specimens** for research purposes by noninvasive means. |
|  | (4) **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed |
|  | in clinical practice, excluding procedures involving x-rays or microwaves. |
|  | (5) Research involving **materials** (data, documents, records, or specimens) that have been collected, or will be **collected** |
|  | **solely for nonresearch purposes** (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 .CFR 46.101 (b)(4). This listing refers only to research that is not exempt.) |
|  | (6) **Collection of data from voice, video, digital, or image recordings** made for research purposes. |
|  | (7) **Research on individual or group characteristics or behavior or research employing survey, interview, oral** |
|  | **history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3)). |

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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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| **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:** Describe all procedures (sequentially) to which human participants will be subjected. 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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| Describe required screening procedures performed before enrollment and while on study. |
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| **For research involving survey, questionnaires, etc.:** Describe the setting and the mode of administering the instrument and the provisions for maintaining privacy and confidentiality. Include the duration, intervals of administration, and overall length of participation.  |
|  | **Not applicable** |  |
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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  |  | HIV 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)\* |  | 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. |

**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/Benefits:** Describe any potential or known risks. This includes physical, psychological, social, legal or other risks. 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. 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. |
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| **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:** 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, 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. **Forward copies of the data and safety monitoring reports to the 1) IRB, 2) CRC (if applicable), and/or 3) UVMCC (if applicable).** |
|  |  | 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 the “Adverse Event and Unanticipated Problems Reporting Policy” will be followed. The UVM/UVM Medical Center process for review of adverse events and UAPs to subjects or others should be included in the DSMP. |
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| **Withdrawal Procedures:** Define the precise criteria for withdrawing subjects from the study. Include a description of study requirements for when a subject withdraws him or herself from the study (if applicable). |
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| **Sources of Materials:** Identify sources of research material obtained from individually identifiable human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data. |
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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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| **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 and by whom. Changes to the eligibility criteria at a later phase of the research have the potential to invalidate the research. |
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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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| **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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| **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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| **INFORMED CONSENT**  |

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| **a. Type of Consent** |
| Are you obtaining Written Consent? |  | Yes |  | No |
| **If yes**, will there be more than one consent document? |  | Yes |  | No |
|  **If yes**, how many consent documents and for what populations. |
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| **ii.** Are you requesting a Waiver of Informed Consent? |  | Yes |  | No |
| This request means that you will not be obtaining verbal nor written consent. **If yes**, complete the form Request for a Waiver of Informed Consent/Authorization/Documentation in UVMClick. |
| **iii.** Are you requesting an Alteration of Informed Consent Procedures? |  | Yes |  | No |
| This is a request to alter an individual’s informed consent or elements of informed consent. Deception in research would be one example when consent would be altered. See [Policies and Procedures Manual](https://www.uvm.edu/rpo/irb-policies-and-procedures) for more information about when a subject’s consent may be altered.  **If yes**, complete the smart form Request for a Waiver of Informed Consent/ Authorization/ Documentation in UVMClick. |
| **iv.** Are you requesting a Waiver of Documentation of Informed Consent? |  | Yes |  | No |
| This request means you are obtaining verbal or implied consent without obtaining the subject’s signature on a consent form. See manual for the criteria required to obtain this type of waiver.**If yes**, complete the form Request for a Waiver of Informed Consent/Authorization/Documentation in UVMClick. |
| **v.** Do you intend to obtain consent from a legally authorized representative?**If yes**, describe the process. |  |  Yes |  |  No |
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| **vi.** |  Are you requesting a short form consent process for non-English speaking subjects? Yes No **If yes**, please describe. Guidance available in the [Policies and Procedures Manual](https://www.uvm.edu/rpo/irb-policies-and-procedures). |
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| **b.** | **Consent Process**  |
| **i.** | Once a prospective subject is identified, who initiates the informed consent discussion and answers questions presented by the subject or the subject’s family?  |
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| **ii.** | Where (in what setting) is the informed consent process initiated? How much time is the subject given to decide? |
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| **iii.** | Is the principal investigator present for the initial and subsequent informed consent discussions with the subject? |
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| **iv.** | What other method of documentation is used to record the informed consent process, in addition to the executed consent form? See an [example of documentation](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) of the informed consent **process** under consent templates on our forms page. *(This separate documentation is required to document the consent process with the research subject)* |
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| **Information Withheld From Subjects:** Will any information about the research purpose and design be withheld from potential or participating subjects? If so, explain and justify the non-disclosure and describe plans for post-study debriefing.  |
|  | **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. |