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| FO 301-A | 1/7/2025 |

**study summary**

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|  | **Protocol Title:** | **Important:****Please Note** |
| **1.** | **Principal Investigator:**  |  |
|  | Name: | **Attach CV** |
|  |  |  |
|  |  |  |
| **2.** | **SPONSOR / Funding information** |  |
|  | Will this protocol be supported by a federal funding agency?Provide the funding source: | [ ]  No [ ]  Yes |  |
|  |  |  |
| **3.** | **LOCATION OF RESEARCH**:  |  |
|  | **Where will the study take place1?** | **1** Include all locations for study related activities |
|  | **Address:** |
|  |  |
|  | Will the PI be conducting and/or supervising study related activity at any sites not under the jurisdiction of this institution’s IRB?If yes, complete an **Additional Study Location Form** for each location | [ ]  No [ ]  Yes |  |
|  | **Number of clinical research staff available to work on this project2:**Name(s):Email(s): | **2** Include CVs of all  |
|  |  |  |
| **4.** | **Subject INFORMATION** |  |
| **A** | **Will subjects who do not understand English be enrolled?**If yes: Describe your resources to communicate with these subjects: **3**  | [ ]  No [ ]  Yes | **3** Describe in your protocol. |
|  |  | Page #: |
|  | Into what language(s) will the consent form need to be translated:  |  |
|  | ☐ Spanish | [ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
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| **B** | **Potentially Vulnerable Populations4** | **4** Describe additional protections for these populations in your protocol. Page #: |
|  | [ ]  Children | [ ]  Investigator's patients | [ ]  Prisoners |
|  | [ ]  Fetuses / fetal material | [ ]  Investigator's staff members  | [ ]  Student or employee |
|  | [ ]  Pregnant women | [ ]  Racial or ethnic minority | [ ]  Homeless |
|  | [ ]  Socially disadvantaged  | [ ]  Economically disadvantaged | [ ]  Physical disabilities |
|  | [ ]  Mentally or cognitively impaired | [ ]  Institutionalized (correctional or mental health facility or nursing home) | [ ]  Other (describe) |
|  | Describe additional protections for potentially vulnerable subjects in protocol: |  |
|  | If you are recruiting children in this study, indicate the age range: **5** | **5** Include copy of Assent. |
| **C** | **Are there community attitudes that may affect subjects in this study?** If yes, describe attitudes and how they may affect subjects. | [ ] No [ ] Yes | Describe assent process in your protocol. Page #: |
|  |  |  |
| **5.** | **Recruitment** |  |
| **A** | **How will subjects be identified?** |  |
|  | [ ]  By chart/ database review (see below) | [ ]  Course participants |
|  | [ ]  From the Investigator's own patients  | [ ]  Circumstance (i.e., homelessness)  |
|  | [ ]  Referrals | [ ]  Living conditions (street, nursing home) |
|  | [ ]  Describe any other sources: | [ ]  Direct advertising (complete section 5E) |
| **B** | **How will subjects be recruited for participation? (Check appropriate box(es))** |  |
|  | [ ]  By chart/ database review and investigator contact by  | [ ]  During class |  |
| [ ]  email  | [ ]  At a scheduled visit by the Investigator [ ]  letter [ ]  phone (complete section 5C) [ ]  social media | [ ]  Referral (complete section 5D) **6** | **6** Initial contact must be made by the custodian of the record, (ie primary care provider, therapist, school official.) & written per-mission from the holder / custodian of the records must be includedPage #:  |
| **C** | **Chart/database review** |
|  | Who gave approval for the use of the records? |
|  |  |
|  | Describe who will make initial contact and how.**6** |
|  |  |
|  | If records are "private" medical or student records, provide the protocol, consent forms, letters, etc., for securing consent of the subjects for the records. **6** |
| **D** | **If by referral, detail the procedures and submit letters to be sent to referrers.** |
| **E** | **Direct subject advertising** | **7** Submit all advertising (proofs, scripts, letters, etc) for approval prior to use.  |
|  | Media for subject recruitment includes I: (check all that apply) |
|  | [ ]  Radio | [ ]  Television | [ ]  Letters to patients |
|  | [ ]  Newspaper | [ ]  Bulletin board/flyer | [ ]  Letters to providers |
|  | [ ]  Internet | [ ]  Other |  |
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|  | Will a centrally coordinated advertisement program be used? | [ ]  No [ ]  Yes |  |
|  | Will a central 800# facility be used for recruitment? If yes, submit the script and identify calling company. | [ ]  No [ ]  Yes |
|  |  |  |
| **6.** | **PAYMENT TO SUBJECTS** |  |
|  | Are subjects being paid for participation? If yes, indicate total amount, **8** (dollars or equivalent):  | [ ]  No [ ]  Yes | **8** Payment includes all types of reimburse-ment, such as fares, parking fees, etc. |
|  | Form of Payment: |
|  | [ ]  Reimbursement only | [ ]  Gift certificate | [ ]  Cash: [ ]  Currency [ ]  Check |
|  | Will subject be required to submit proof of expenses? [ ]  No [ ]  Yes | [ ]  Voucher | Will a 1099 be issued?[ ]  No [ ]  Yes |
| [ ]  Other: | If yes, describe procedures to protect confidentiality |
|  | Will payment be prorated? If no, explain | [ ]  No [ ]  Yes |  |
|  | When will subject be paid? | [ ]  Each visit | [ ]  Study completion | [ ]  Other:  |  |
|  |
| **7.** | **Costs to subjects** |  |
| **A** | **Study procedures and products** |  |
|  | Will subjects or their health care providers be required to pay for any study related procedures or products? If yes, explain: | [ ]  No [ ]  Yes |  |
| **B** | **Compensation for injury** |  |
|  | Who is responsible for costs incurred due to injury? |  |
|  |
| **8.** | **Description of the RESEARCH** |  |
| **A** | Does the project involve the administration of personality tests, inventories, or questionnaires? If *yes,* provide name of the standard tests/questionnaire or 3 copies of the proposed tests.  | [ ]  No [ ]  Yes |  |
| **B** | Does the project involve administration of ionizing radiation to subjects for other than clinical purposes? If *yes* contact the (CUSTOM NAME) and Radiation Safety Office.  | [ ]  No [ ]  Yes |  |
| **C** | Does the project involve gene therapy (administration of recombinant vectors) to human subjects for other than clinical purposes? If yes, contact the Biosafety Officer. | [ ]  No [ ]  Yes |  |
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| **9.** | **Are any of the test articles regulated by FDA?** | [ ]  No [ ]  Yes |  |
|  | If yes, complete this section | Submit the 1572 & Investigator Brochure |
| **A** | [ ]  This study involves a drug or biologic: IND #, if applicable: \_\_\_\_\_\_\_\_\_\_\_\_This study is: Phase 1 [ ]  Phase 2 [ ]  Phase 3 [ ]  Phase 4 [ ]  Treatment [ ]  |
| **B** | [ ]  This study involves a device:This device is [ ]  Investigational [ ]  Marketed This is a [ ]  Significant Risk Device Study [ ]  Non-Significant Risk Device | Sponsor must Include justification of Non-Significant Risk per 21 CFR 812. 66 |
| **C** | Who is the Sponsor of the IND/IDE? |  |
|  |  |  |
| **10.** | **Synopsis of the protocol – List the page number of the protocol for all of the following components** |  |
| **A** | State the objective of the research. | Page #: |
|  |  |
| **B** | Discuss the present knowledge and appropriate literature relevant to it. | Page #: |
|  |  |
| **C** | Discuss the rational for the use of the selected subject population. | Page #: |
|  |  |
| **D** | Discuss the statistical / quantitative methodology. | Page #: |
|  |  |
| **E** | List the inclusion criteria. | Page #: |
|  |  |
| **F** | List the exclusion criteria. | Page #: |
|  |  |
| **G** | How will the inclusion/exclusion criteria be assessed and by whom? | Page #: |
|  |  |  |
| **H** | What are the subjects' alternatives to participation in the study? | Page #: |
|  |  |  |
| **I** | Describe the recruitment method. | Page #: |
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| **11.** | **risks to subjects:** Consider all risks: physical psychological, social, legal economic. Attach chart or grid if available | Page #: |
| **A** | Identify the risks (current and potential).  |
|  |  |
| **B** | Describe the expected frequency, degree of severity, and reversibility.  | [ ]  NA | Page #: |
|  |  |
| **C** | Describe possible late effects.  | [ ]  NA | Page #: |
|  |  |  |
| **D** | Risks from study article: | [ ]  NA | Page #: |
|  |  |  |
| **E** | Risks from research procedures (i.e., washout risks, placebo assignment, etc.)  | [ ]  NA | Page #: |
|  |  |  |
| **F** | How will subjects be assessed for the occurrence of adverse events described in section \_\_\_\_? | [ ]  NA | Page #: |
|  |  |  |
| **G** | For studies with more than minimal risk, or FDA regulated products/ studies, who will monitor the study data? | [ ]  NA | Page #: |
|  |  |  |
| **H** | Describe your monitoring plan. | [ ]  NA | Page #: |
|  |  |  |
|  |  |  |
| **12.** | **BENEFITS** |  |
| **A** | Is there a possibility that subjects could benefit directly from taking part in this study? If yes, list the page number | [ ]  No [ ]  Yes | Page #: |
|  |  |  |
| **B** | Describe potential benefits to the group or class from which the subjects are recruited. | Page #: |
|  |  |  |
| **C** | Describe potential benefits to society. |  |
|  |  |  |
|  |  |  |
| **13.** | **Risk/Benefit Assessment** |  |
|  | Briefly assess the risk/benefit ratio of the subject's participation, include consideration of alternative therapy, benefit to the class of patients, and benefits to society.  | Page #: |
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| **14.** | **procedures** |  |
| **A** | What will be the duration of subjects' active participation? | Page #: |
| **B** | Will subjects be followed after their active participation ends? If yes, describe:  | [ ]  No [ ]  Yes | Page #: |
| **C** | Discuss the number, duration, and nature of visits/encounters (attach flowchart if available). | Page #: |
| **D** | Procedures being performed solely for the purposes of the research study (i.e. extra blood work, pregnancy testing, questionnaires, etc.) | Page #: |
| **E** | Describe all procedures that will be performed to generate data for the research. | Page #: |
|  |  |  |
| **15.** | **Informed Consent** |  |
| **A** | An IRB may approve a consent document that does not include, or alters, some or all of the elements of informed consent. Provide justifications for the following questions for requesting a waiver of written informed consent. |  |
|  |  |  |
| **B** | Are you requesting Waiver or Alteration of Informed Consent? If no, skip to G?  | [ ]  No [ ]  Yes |  |
|  |  |  |
| **C** | Why will a waiver of informed consent not adversely affect the rights and welfare of subjects? | Page #: |
|  |  |  |
| **D** | Why is it impracticable to carry out the research without a waiver or alteration of informed consent? | Page #: |
|  |  |  |
| **E** | How will pertinent information be provided to the subjects, if appropriate, at a later date? Attach your debriefing plan. | Page #: |
|  |  |  |
| **F** | Why does the proposed research present no more than minimal risk to the subjects? | Page #: |
| **G** | Who will explain the study to the potential subject?  | Page #: |
|  |  |  |
|  | Is this person an Investigator or Sub-investigator? If No, include the Delegation of Authority Form | [ ]  No [ ]  Yes |  |
| **H** | Describe your process to obtain informed consent. | Page #: |
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| **I** | Attach your informed consent document(s) for IRB review. If there is/are a Sponsor consent documents(s) include a reference copy and prepare the informed consent document by editing the Sponsor prepared forms to include the IRB’s standard language. | See consent document template. |
|  |  |  |
|  |  |  |
| **16.** | **CONFIDENTIALITY** |  |
| **A** | Are the subject’s social security number, hospital record number, or any identifier (other than study number & initials) being sent off site? If yes, describe and explain reasons. | [ ]  No [ ]  Yes | Page #: |
| **B** | Will any external entity other than the investigative staff have access or be provided to confidential medical or health related information about the subject. | [ ]  No [ ]  Yes | Page #: |
| **C** | Describe provisions made to maintain confidentiality of data. Include:Who will have access to raw data?  | Page #: |
| **D** | Will raw data be made available to anyone other than the PI and immediate study personnel (e.g., school officials, medical personnel)? If yes, describe the procedure for sharing data. Include, with whom it will be shared, how, and why.  | [ ]  No [ ]  Yes | Page #: |
|  |  |  |  |

*I certify that the information contained above is accurate. I agree to provide the IRB with the information it requires to conduct initial and continuing review of this study including serious or unexpected adverse events on a timely basis and that if the information is not provided, the IRB may suspend the study.*

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator |  | Date |  |
| Sub-investigator(s) |  | Date |  |
|  |  |  |  |
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