**FORM 3.1B STUDY SUMMARY FORM**

Study Summary

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| **1** | **Protocol Title:**  **Principal Investigator:** Name: Phone:  Email:  Fax:  The study will  will not be conducted at this address  Does the PI or any sub-investigator have a financial interest (other than payment) in this study? (IDI REC will contact either the sponsor or PI for additional information.)  No Yes  Does the PI or any sub-investigator have an interest, other than financial, in the outcome of this study? (IDI REC may contact either the sponsor or PI for additional information.)  No Yes  Other interest could be close personal or professional association with the sponsor, direct participation in the research (e.g., protocol development, or any significant professional association, such as consulting work, with the sponsoring company). | | | | | | **Important: Please Note**  **Attach CV** |
| **2** | **SPONSOR / FUNDING INFORMATION** | | | | | |  |
| Will this protocol be supported by a government funding agency?  If yes, provide details on the funding agency | | | | No  Yes | |
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| **3** | **LOCATION OF RESEARCH**: | | | | | |  |
|  | **Where will the study take place?** Only at the above address | | | | | | Include all locations for study related activities |
|  | Will the PI be conducting and/or supervising study related activity at any sites outside of Uganda? Yes  No  If yes, complete an *Additional Study Location Form*for each location  Number of clinical research staff available to work on this project: | | | | | |  |
| **4** | **PARTICIPANT INFORMATION** | | | | | |  |
| A | **Will participants who do not understand English be enrolled?**  No Yes  If yes: Describe your resources to communicate with these participants:  Into what language(s) will the consent form need to be translated: | | | | | | Attach an additional sheet if needed. |
| B | **Potentially Vulnerable Populations**  Children  Nursing home residents  Foetuses / foetal material  Mentally impaired  Students  Economically disadvantaged  Pregnant women  Investigator's staff  Homeless members  Prisoners  Investigator's patients  Other (describe)  Describe additional protections for potentially vulnerable participants:  If you are recruiting children in this study, indicate the age range: | | | | | | Describe additional protections for these populations on separate page. |
| **C** | **Are there community attitudes that may affect participants in this study?** If yes, describe attitudes and how they may affect participants.  No  Yes | | | | | |  |
| **5** | **RECRUITMENT** | | | | | |  |
| **A** | **How will participants be identified?** | | | | | |
|  | By chart/ database review (see below)  From the Investigator's own patients  Referrals  Describe any other sources: | | Course participants  Circumstance (i.e., homelessness)  Living conditions (street, nursing home)  Direct advertising (complete  section 5E) | | | |
| **B** | **How will participants be recruited for participation? (Check appropriate box(es)**  At a scheduled visit by the Investigator  During class  By chart/ database review and investigator contact  By ReferralIf by referral, detail the procedures and submit letters to be sent to referrers.  letter  phone (complete section 5C)  Chart/database review | | | | | |  |
| **C** | Who gave approval for the use of the records? Describe who will make initial contact and how.  If records are "private" medical or student records, provide the protocol, consent forms, letters, etc., for securing consent of the participants for the records. | | | | | | Initial contact  must be made  by the  custodian of  the record, (i.e. primary care  provider,  therapist,  school  official) and  written per-  mission from  the holder /  custodian of  the records  must be  included |
| **D** | **Direct participant advertising**  Media for participant recruitment includes: (check all that apply)  Radio  Television  Newspaper  Bulletin board/flyer  Internet  Letters to patients  Letters to providers  Others  Will a centrally coordinated advertisement program be used? Yes No | | | | | | Submit all  advertising  (Proofs, scripts, letters, e.t.c) For approval prior to use. |
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| **6.** | **PAYMENT TO PARTICIPANTS** | | | | | |  |
|  | Are participants being paid for participation? If yes, indicate total  No Yes amount, (shilling or equivalent): | | | | | | Payment includes all types of reimburse-ment, such as fares, parking fees, etc. |
|  | Form of Payment:  Reimbursement only. Will participant be required to submit proof of expenses?No Yes  Voucher  Cash  Check  Other: | | | | | |
|  | When will participant be paid? | Each visit | | Study completion | | Other: |
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| **7** | **COSTS TO PARTICIPANTS** | |  | |
| **A** | **Study procedures and products**  Will participants 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? | |  | |
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| **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 participants 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 participants for other than clinical purposes?  If yes, contact the Biosafety Officer. | No  Yes |  | |
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| **9.** | **TEST ARTICLES**  Are any of the test articles regulated by NDA? If yes, complete this section  No Yes | |  | |
|  |  | | Submit the Investigator Brochure | |
| This study involves a drug or biologic: IND #, if applicable:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
|  | This study is: Phase 1 Phase 2 Phase 3 Phase 4  Treatment | |  | |
|  | This study involves a device: Yes  No  This device is  Investigational Marketed  This is aSignificant Risk Device Study Non-Significant Risk Device  Who is the Sponsor of the IND/IDE? | | Sponsor must Include justification of Non-Significant  Risk per 21 CFR 812. 66 | |
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| **10.** | **SYNOPSIS OF THE PROTOCOL** | |  | |
| A | State the objective of the research. | |  | |
| B | Discuss the present knowledge and appropriate literature relevant to it. | |  | |
| C | Discuss the rational for the use of the selected participant population. | |  | |
| D | Discuss the statistical / quantitative methodology | |  | |
| **E** | List the inclusion criteria. | |  | |
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| **F** | List the exclusion criteria. | |
| **G** | How will the inclusion/exclusion criteria be assessed and by whom? | |  | |
| **H** | What are the participants' alternatives to participation in the study? | |  | |
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| **11.** | **RISKS TO PARTICIPANTS** | |  |  |
| **A** | Identify the risks (current and potential).  N/A | |  | Consider all risks: physical psychological, social, legal economic |
| **B** | Describe the expected frequency, degree of severity, and reversibility.  N/A | |  |
| **C** | Describe possible late effects.  N/A  . | |  |
| **D** | Risks from study article:  N/A | |  |
| **E** | Risks from research procedures (i.e., washout risks, placebo assignment, etc.)  N/A | |  |
| **F** | How will participants be assessed for the occurrence of adverse events described in section ?  N/A | |  |
| **G** | For studies with more than minimal risk, or NDA/FDA regulated products/ studies, who will monitor the study data?  N/A | |  |
| **H** | Describe your monitoring plan  N/A | |  |
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| **12.** | **BENEFITS** | |  | |
| **A** | Is there a possibility that participants could benefit directly from taking part in this study? If yes, describe: No Yes | |  | |
|  | Describe potential benefits to the group or class from which the participants are recruited.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | |

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| **C** | Describe potential benefits to society.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  |
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| **13.** | **RISK/BENEFIT ASSESSMENT** | | |  |
|  | Briefly assess the risk/benefit ratio of the participant's participation, include consideration of alternative therapy, benefit to the class of patients, and benefits to society. | | |  |
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| **14.** | **PROCEDURES** | | |  |
| **A** | What will be the duration of participants' active participation? | | |  |
| **B**  **C** | Will participants be followed after their active participation ends? If yes, describe: | | No  Yes |  |
| Discuss the number, duration, and nature of visits/encounters (attach flowchart if available). | | |  |
| **D** | Procedures being performed solely for the purposes of the research study (i.e.  extra blood work, pregnancy testing, questionnaires, etc.) | | |  |
| **E** | Describe all procedures that will be performed to generate data for the research. | | |  |
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| **15.** | **INFORMED CONSENT** | | |  |
| **A** | IDI REC 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. | | |  |
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| **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 participants? | | |  |
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| **D** | Why is it impracticable to carry out the research without a waiver or alteration of informed consent? | | |  |
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| **E** | How will pertinent information be provided to the participants, if appropriate, at a later date? Attach your debriefing plan. | | |  |
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| **F** | Why does the proposed research present no more than minimal risk to the participants? | | |  |
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| **G** | Who will explain the study to the potential participant? | | |  |
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| Is this person an Investigator or Sub-investigator? If No, include the Delegation of Authority Form | No Yes | |  |

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| **H** | Describe your process to obtain informed consent. | |  |
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| **I** | Attach your informed consent document(s) for IDI REC review. If there is/are Sponsor consent documents(s) include a reference copy and prepare the informed consent document by editing the Sponsor prepared forms to include the IDI REC’s standard language. | | See consent document template. |
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| **16.** | **CONFIDENTIALITY** | |  |
| **A** | Are the hospital record number, or any identifier (other than study number & initials) being sent off site? If yes, describe and explain reasons. | No  Yes |  |
| **B** | Will any external entity other than the investigative staff have access or be provided to confidential medical or health related information about the participant. | No  Yes |  |
| **C** | Describe provisions made to maintain confidentiality of data. Include: Who will have access to raw data? | |  |
| **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 |  |

*I certify that the information contained above is accurate. I agree to provide the IDI REC 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 IDI REC may suspend the study.*

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| Principal Investigator’s name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |