***PRINT ON UVA Letterhead***

INSERT DATE

INSERT NAME and ADDRESS OF SUPERINTENDENT/DIRECTOR OF CORRECTIONAL FACILITY

I am writing to inform you of a research study being conducted at the University of Virginia, for which one of your prisoners, who is also a patient at UVA Health, may qualify to enroll.

This research study provides an investigational treatment for (INSERT DIAGNOSIS/DISEASE NAME).

I have enclosed the research study plan (Protocol), the research consent form and the consent addendum for the prisoner population.

This study has been approved by the Institutional Review Board for Health Sciences Research (IRB-HSR) at the University of Virginia and will enroll subjects who are and are not prisoners. For subjects who are prisoners, the IRB members, including a prisoner representative determined the study met the following criteria required by federal regulations:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2). For studies providing an investigational treatment the study must meet Category 4:

*4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research the study may only proceed after: 1. the Secretary of DHHS (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and 2. the Secretary has published notice, in the Federal Register, of his intent to approve such research Note: Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation, nor do they require certification to OHRP.*

1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
2. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers; procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
3. The information is presented in language which is understandable to the subject population;
4. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
5. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Prior to enrolling a person in this study, who is also a prisoner, the IRB-HSR requires an agreement of cooperation from the prison/jail to confirm the prison/jail administration is willing to allow the prisoner to enroll, complete required procedures after returning to the correctional facility and when applicable are able to bring the prisoner back to UVA Health for any required follow up visits.

Please contact me directly, so that I can answer your questions.

If you agree to provide an agreement of cooperation for the prisoner to enroll in the study please complete page 3 of this letter and return it to me via email to me at (INSERT HSC EMAIL ADDRESS).

Sincerely,

(INSERT NAME, TITLE AND CONTACT INFORMATION OF INDIVIDUAL SENDING LETTER)

**Agreement of Cooperation for a Prisoner to Enroll in a Research Study**

**Research Study Title:** (INSERT STUDY TITLE)

**IRB-HSR# /UVA Study Tracking #:** (INSERT NUMBER)

I have reviewed the research study plan, consent form and consent addendum for prisoners for this study and provide an Agreement of Cooperation for (INSERT NAME of PRISONER)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to enroll in this study at UVA Health, complete required procedures after returning to the correctional facility and if required, agree to provide transportation for the prisoner to return to UVA Health for follow up visits.

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Name/Title PRINTED Signature Date