Version Date of this Document: 8/13/2026

Principal Investigator:

Study Title:

Institution/Hospital:

PRINCIPAL INVESTIGATOR ASSURANCE STATEMENT

I certify that the information provided in this application is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to the study protocol and any stipulations imposed by the Vanderbilt University Medical Center Institutional Review Board.

I understand that, should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s), is consistent in principle, to that contained in this application. I will submit modifications and/or changes to the IRB as necessary, in the form of an amendment, to ensure these are consistent.

If children are included in research activities, I agree to follow the Vanderbilt University and Vanderbilt University Medical Center Protection of Minors policy, as applicable, which includes appropriate provisions for background clearance checks, training and education, Standards of Conduct, external and mandatory reporting. For more information, please see the policy links above.

I agree to comply with all VUMC and VUMC HRPP policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants in research, including, but not limited to:

- Ensuring all investigators and key study personnel have completed and will maintain the required human subjects training certification;
- Maintaining a current key study personnel list;
- Ensuring the project is conducted by qualified personnel who will adhere to the approved IRB application and study protocol;
- Implementing no changes in the approved IRB application, study protocol, or informed consent document(s) without prior IRB approval in accordance with VUMC HRPP policy (except in an emergency, if necessary to safeguard the well-being of a human participant, and will report to the IRB within 7 days of such change);
- Obtaining the legally effective informed consent from human participants or their healthcare decision-maker, using only the currently approved date-stamped informed consent documents, and providing a copy to the participant, if applicable.
- Promptly reporting to the IRB, Data Safety and Monitoring Boards, sponsors and appropriate federal agencies any adverse experiences and all unanticipated problems involving risks to human subjects or

others that occur in the course of the research in accordance with Vanderbilt University Medical Center HRPP Policies and Procedures.

- If unavailable to conduct this research personally, as when on sabbatical, leave, or vacation, I will arrange for another investigator to assume direct responsibility for the study via an amendment submission to the IRB. In cases where a temporary leave will be less than 4 weeks and I am unable to provide oversight during that time, I will either cease study activities or ensure oversight of these activities is delegated to a qualified member of the study team. Promptly providing the IRB with any information requested related to the project;
- Promptly and completely complying with an IRB decision to suspend or withdraw approval for the project;
- Obtaining Continuing Review approval, if applicable, prior to the date the approval for the study expires. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all study activity must cease until IRB approval is granted;
- Entering the required annual study update information for studies that do not require Continuing Review, if applicable;
- Reporting any Conflict of Interest to the HRPP/IRB and appropriate institutional entity at time of awareness;
- Maintaining accurate and complete research records, including, but not limited to, all informed consent documents for 3 years from the date of study completion;
- Maintaining any authorization documents to use or disclose PHI for 6 years from the date authorization is obtained;
- Fully informing the VUMC IRB of all locations in which human participants will be recruited for this project and being responsible for obtaining and maintaining current IRB approvals/letters of cooperation when applicable;
- Notifying the HRPP/IRB as soon as possible of any planned departure from the institution and assist with needs to transition studies to other investigators or submit study closures;
- Ensuring that my Division Chief and/or Department Chair are aware that study record retention is the responsibility of the division or department when I leave the institution and/or the study is closed.

PI Signature/Date: