NIH NATIONAL CANCER INSTITUTE

Form Approved: OMB No. 0925-0613
Expiration Date: 03-31-2022

Collection of this information is for credentialing of investigators for participation in National Cancer Institute protocols. This information may be disclosed to sponsors of clinical trials (if applicable) or responsible organization, the applicable Institutional Review Board (IRB)/Independent Ethics Committee (IEC), National Cancer Institute, Food and Drug Administration's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, and the Department of Health and Human Services. Submission of this information is voluntary, however, in order to qualify for participation on NCI protocols, you must complete all fields

International Investigator Statement

Instructions:This form is used for Non-US investigators to attest that the study(ies) will be conducted according to International Conference on Harmonisation (ICH) Good Clinical Practice (GCP).
NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed International Investigator Statement Form.

1. NAME AND ADDRESS OF PRINCIPAL INVESTIGATOR.

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFIES THE INVESTIGATOR. ONE OF THE FOLLOWING IS ATTACHED.

☐ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED.

CTEP Site Code	Site Name	Site Address

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY.

CLIA/CAP Number	Lab Name	Lab Address

5. NAME AND ADDRESS OF THE RESPONSIBLE INSTITUTIONAL REVIEW BOARD(IRB)/ INDEPENDENT ETHICS COMMITTEE(IEC)

IRB Number	IRB Name	IRB Address

6. NAMES OF THE CO-INVESTIGATORS WHO WILL BE ASSISTING THE PRINCIPAL INVESTIGATOR IN THE CONDUCT OF THE PROTOCOL(S):

7. PROTOCOL NUMBER AND TITLE:

8. COMMITMENTS:

☒ I agree to conduct the protocol(s) in accordance with the relevant documents and will only make changes in a protocol after notifying the sponsor or responsible organization, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes (if applicable) and I will ensure that the requirements relating to obtaining informed consent and Independent Ethics Committee(IEC) review and approval in ICH E6, national and regional legislation, and the Declaration of Helsinki are met.

I agree to report to the sponsor or responsible organization any adverse experiences that occur in the course of the investigation(s) in accordance with ICH E6, national and regional legislation, and the Declaration of Helsinki. I have read and understand the information in the investigator's brochure (if an investigational agent is being used), including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records and to make those records available for inspection in accordance with ICH E6, national and regional legislation, and the Declaration of Helsinki.

I will ensure that an IEC that complies with the requirements of ICH E6, national and regional legislation, and the Declaration of Helsinki will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly repo it to the IEC all changes on the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IEC approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements, regarding obligations of clinical investigators and all other pertinent requirements in ICH E6, national and regional legislation, and the Declaration of Helsinki.	
9. SIGNATURE OF INVESTIGATOR *This is an electronic signature and is the legally binding equivalent to a handwritten signature.*	10. DATE