

Collection of this information is authorized under 21 CFR: ~~Part 54 [sections 2 and 4] and Part 312 [sections 53(c)(4) and 64(d)] 312.53.~~ The ~~primary use is to identify qualified investigators to participate in clinical investigations at the National Cancer Institute~~ of this information is to disclose or certify information concerning the financial interests of the clinical investigators associated with clinical studies. This information may be disclosed to ~~researchers for research purposes~~, sponsors of clinical trials, the applicable Institutional Review Board, 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 to conduct studies in accordance with the relevant regulatory requirements, you must complete all fields.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

CONFIDENTIAL FINANCIAL DISCLOSURE FORM

The following confidential financial disclosure information is being collected for all investigators in accordance with 21 CFR: part 54 and Part 312 [sections 53(c)(4) and 64(d)]. Any pharmaceutical or medical device company that submits a marketing application for any drug, biologic product, or device is required to submit certain information concerning the compensation to, and financial interests of, any clinical investigator participating in any clinical study submitted in the marketing application. The Cancer Therapy Evaluation Program (CTEP) is collecting this confidential information annually for all CTEP-registered investigators and sub-investigators.

*Please ~~indicate below if~~ note that 'You' below refers to you, your spouse, or dependent children ~~have~~ regarding any of the following disclosable financial arrangements.

Yes ___ No ___ Do ~~y~~**You*** currently have or have you at any time in the past year had any financial arrangement with a pharmaceutical, biologic, or medical device company whereby the value of the compensation could be influenced by ~~the outcome of the study~~ **outcomes?**

Yes ___ No ___ ~~Have~~ Do ~~y~~**You*** currently have or have you at any time in the past year had any ~~significant~~ **payments of other sorts totaling \$25,000 or more made on or after February 2, 1999, as defined in 21 CFR 54.2(f), made to you or to your institution** from a pharmaceutical, biologic, or medical device company, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria?

Yes ___ No ___ Do ~~y~~**You*** currently have or have you at any time in the past year had any proprietary interest in any drug, biologic product, or ~~medical~~ **device?**

Yes ___ No ___ Do ~~y~~**You*** currently have or have you at any time in the past year had any significant equity interest, as defined in 21 CFR 54.2(b), in a pharmaceutical, biologic, or medical device company?

If you answered "Yes" to any of the questions above, please provide the name of the pharmaceutical, biologic, or medical device company or companies with whom the financial arrangement exists.

PHARMACEUTICAL, BIOLOGIC, OR MEDICAL DEVICE COMPANY OR COMPANIES

| CTEP Company Code | Company Name | Company Address |
|-------------------|--------------|-----------------|
| | | |

ACKNOWLEDGEMENT

AGREEMENT: By signing this Electronic Signature Acknowledgment Form, I attest to the accuracy and integrity of this document and agree that my electronic signature is the legally binding equivalent to my handwritten signature. Whenever I execute an electronic signature, it has the same validity and meaning as my handwritten signature. I will not, at any time in the future, repudiate the meaning of my electronic signature or claim that my electronic signature is not legally binding.

The complete NCI registration documents will be maintained by the Pharmaceutical Management Branch, CTEP as part of your confidential investigator registration file and will be kept private, under the Privacy Act. ~~This~~ Information collected on this form will only be provided (1) to a ~~pharmaceutical~~ company which has an agreement (e.g., a Clinical Trials Agreement [CTA] or a Cooperative Research and Development Agreement [CRADA]) with CTEP if CTEP is notified that a licensing application is being prepared by that company, (2) to a Network or Group of which you are a member if CTEP is notified that a clinical trial is being developed by that Network or Group and a ~~pharmaceutical~~ company with whom you have indicated a financial arrangement, or (3) the Food and Drug Administration. You may be contacted in the future by a pharmaceutical company representative or by your Network or Group administrative staff for additional information.

SIGNATURE

DATE

This is an electronic signature and is the legally binding equivalent to a handwritten signature.

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec.1001.)