



Collection of this information is authorized under 21 CFR 54.4. The use 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 sponsors of clinical trials, 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 for us to qualify you to conduct a study in accordance with the relevant, current protocol(s), 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 or 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-xxxx). Do not return the completed form to this address.

CONFIDENTIAL FINANCIAL DISCLOSURE FORM

The FDA requires that the following confidential financial disclosure information be collected for all investigators (see 21CFR 54.4). Any pharmaceutical 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 NCI-registered investigators.

Please indicate below if you, your spouse, or dependent children have any of the following disclosable financial arrangements.

Yes ___ No ___ Do you currently have or have you at any time in the past year had any compensation made to you by a pharmaceutical company in which the value of the compensation could be affected by the study outcome?

Yes ___ No ___ Do you currently have or have you at any time in the past year had a proprietary interest in any drug, biologic product, or device, including, but not limited to, a patent, trademark, copyright, or licensing agreement?

Yes ___ No ___ Do you currently have or have you at any time in the past year had any equity interest in a pharmaceutical company that exceeds \$50,000 in value?

Yes ___ No ___ Do you currently have or have you at any time in the past year had significant payments of other sorts totaling \$25,000 or more from any single pharmaceutical company to you or to your institution to support activities exclusive of the costs of conducting clinical studies, such as a grant to fund your ongoing research, compensation in the form of any equipment not directly related to the conduct of the clinical trial, or retainers to you for ongoing consultation or honoraria?

If you answered "Yes" to any of the questions above, please provide the name of the pharmaceutical company or companies with whom the financial arrangement exists (add an attachment if needed).

Pharmaceutical Company(ies) _____

This form must be signed (original signature required) and dated and submitted with your signed FDA Form 1572 (original signature required) and Supplemental Investigator Data Form as part of your annual NCI investigator registration packet. Completed forms will be maintained by the Pharmaceutical Management Branch, CTEP as part of your confidential investigator registration file. This information 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 or (2) to a Cooperative Group of which you are a member if CTEP is notified that a clinical trial is being developed by that Group and a pharmaceutical company with whom you have indicated a financial arrangement. You may be contacted in the future by a pharmaceutical company representative or by your Cooperative Group administrative staff for additional information.

Signature

Date

Printed Name