06.3 HHS PIA Summary for Posting (Form) / NIH NCI Investigator Registration Filing Process

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Requested

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Requested

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NIH NCI Cancer Therapy Evaluation Program (CTEP) Investigator Registration Filing Process

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Charles. L. Hall, Jr.

10. Provide an overview of the system: The purpose of the CTEP Investigator Registration Filing Process is to manually collect, store, and manage data about registered investigators who are eligible to receive NCI supplied investigational agents from the Pharmaceutical Management Branch (PMB) of CTEP. The data collected is stored in hardcopy format in secure filing systems as well as secure Electronic Filing Systems operated by NCI.

CTEP contractors managing the Investigator Registration Process.

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is shared with the FDA and pharmaceutical companies for the purposes of exchanging clinical trials data.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected as part of the Investigator Registration Filing Process is that contained in the following documents collectively termed the IR packet. The information collected in the IR packet is used for the purposes of conducting clinical research. Some of the information provided in the IR packet is mandatory while some of it is voluntary.

1) DHHS FDA 1572 Form which collects FDA required attributes such as Investigator name, education and training experience, name and address of medical school, hospital or research facility where clinical investigation will be conducted, name and address of clinical laboratory facilities to be used in the study, name and address of Institutional Review Board responsible for review and approval, and Investigator Signature.

2) Supplemental Investigator Data Form which collects information such as Investigator name, Degrees, NCI Investigator Number, Month and Year of Birth, Provider number, Primary Specialties, Investigator related Training Information, Office Address for official correspondence with the Investigator, Address for Agent shipments, Shipping and Ordering Designee information and Investigator Signature.

3) Financial Disclosure Form which collects FDA required financial disclosure information based on four generic questions related to the Investigator's relationship to any pharmaceutical company or sponsor to the extent that the investigator has received any compensation from pharmaceutical companies, or the investigator may have any proprietary interest in any of the studies not limited to patent, trademark or licensing, or if the investigator has any equity interest in any pharmaceutical company or if the investigator or his/her institution has received any large payments in the form of funds, grants or equipment from pharmaceutical companies exclusive of the costs of supporting conducting clinical studies.

4) The Investigators are also required to submit an updated copy of their resume / CV.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NCI Investigators who wish to participate in NCI sponsored clinical trials submit their information to CTEP Investigator Registration Process in a signed Investigator Registration (IR) packet. This investigator registration packet, along with additional cover letter, informs the investigators about intended purpose and usage of their information.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

37. Does the website have any information or pages directed at children under the age of thirteen?:

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Policies and procedures exist to securing and providing access to IR packet information. For the hard copies of the Investigator Registration (IR) packet that are filed in the secure filing systems, the filing cabinets are secured behind double locked doors with restricted access to the facilities. Only select authorized staffs are allowed to access the hard copies. Access logs to hard copy documents are maintained. Access to data stored in the Electronic Filing System is through password protection account. The Server on which the Electronic Filing System is hosted is maintained in secure Key control based facilities. Audit Trails are kept regarding the Electronic Filing System to track data access.

Since the same hard copy documents are scanned and filed into the Electronic Filing System, no backups are maintained for the hard copy documentation. Contingency plans exist for the Electronic Filing System. Backups of tapes are not stored offsite.

The system falls under the Privacy Act System of Records Notice 09-25-0200

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzy Milliard

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012
