# Attachment 6: Privacy Impact Assessment (PIA)

## 06.3 HHS PIA Summary for Posting (Form) / NIH NCI PLCO Research Database (PLCO)

**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:** 7/30/2010

**2. OPDIV Name:** NIH

**3. Unique Project Identifier (UPI) Number:** Not Applicable

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** No

**5. OMB Information Collection Approval Number:** No

**6. Other Identifying Number(s):** NCI-59

**7. System Name (Align with system Item name):** NIH NCI PLCO Research Database (PLCO)

**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:** Dorothy Sullivan

**10. Provide an overview of the system:** The system is used for monitoring, quality control, and analysis of the PLCO trial.

**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?):** No

**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):** No

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):** No IIF in the system

**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:** This sytem is used to store and monitor data from the participants in the PLCO and NLST prevention trials. Such data consists of results of screening tests such as chest x-rays, serum PSA and CA-125, sigmoisoscopy, etc. Medical history and other questionaire information is also stored. To protect confidentially, the data in this system is referenced by a randomly assigned participant ID code only. The actual identity of the participant is known only to the screening center at which these tests were conducted. Since these participants are treated as clinical patients at these centers, their true identity is considered confidential, as with any patient, and is protected in accordance

with HIPPA regulations to which all of these screening centers must adhere.
**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.])** No IIF.
**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?:** No
**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):** No
**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.
***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:** 9/28/2010
**Approved for Web Publishing:** Yes
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