06.3 HHS PIA Summary for Posting (Form) / NIH NCI Clinical Research Information Exchange Federal Investigator Registry (CRIX FIREBIRD)

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: Not Applicable (this is a minor application)

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: Not Applicable

6. Other Identifying Number(s): NCI-75

7. System Name (Align with system Item name): Clinical Research Exchange Federal Investigator Registry CRIX FIREBIRD

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: Jose Galvez, MD

10. Provide an overview of the system: The Federal Investigator Registry of Biomedical Informatics Research Data (FIREBIRD) is a software application that supports electronic submission of clinical trial investigator information to trial sponsors and regulatory bodies. It is the first module realized from the vision of the Interagency Oncology Task Force (IOTF), a partnership of the National Cancer Institute (NCI) and the Food and Drug Administration (FDA), to create an electronic infrastructure for the submission of regulatory data. Through a single web-based platform, investigators will be able to maintain a secure profile of the most common information required when participating in drug trials.

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): The IIF may be shared with Pharmaceutical companies and the Food and Drug Administration

via an Oracle link. The IIF is under SOR 09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD

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: The agency collects voluntarily given data on researcher's name, birth date, mailing address, phone numbers, e-mail address, Medical license number and the State in which it was issued, and the researcher's Unique Physical ID number (UPIN) in order to identify the researcher to authorized viewers and provide contact information and credential information to authorized users. The National Cancer Institute authorizes all users.

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.]) Researchers give only their own personal information and do so voluntarily. The Firebird web site will disclose any changes to how IIF is used or shared on the website itself.

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): Yes

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): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The IIF will be secured by management, operational, and technical controls. Some of these controls include user identification and authentication, public key encryption (PKI) certificates, the concept of least privilege, and firewalls. The PKI certificates will be validated by NCI. Infrastructure product, username and password, annual risk assessments, background checks on administrative employees, and key locks, cipher locks and keycards necessary to enter server rooms.

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