

SF 115: Human Research Protection Program (HRPP) Oversight Review System Files

BACKGROUND: The records outlined in this schedule document the functions of the Assistant Secretary of Defense for Health Affairs (ASD HA), Force Health Protection and Readiness. These records provide evidence of the oversight function of HRPP in the area of human research. The mission of the HRPP is to oversee Research and Development (R&D) activities planned by components of Office of the Under Secretary of Defense for Personnel and Readiness (OUSD (P&R)). They promote policies and procedures that facilitate timely and effective reviews of research ensuring that approved research is conducted in accordance with applicable rules and effective guidelines to protect the rights and welfare of the participants.

The records of this program are collected to maintain case files for OUSD (P&R) management concerning protocols for research undertaken by or for OUSD (P&R) components. Research protocols include information on the type of research to be done, type of data to be collected, and the collection process (i.e. questionnaire, video tape, audio tape, etc.). The protocols also include documentation used by the researcher such as consent forms, data management plans, copies of posters, ads, or additional information related to their research protocol. This system also contains HRPP training taken by the researchers and allows searches based on personal information (i.e. name, course name, course date, certification date and certification expiration date). Once the research protocol information is collected, the protocol is reviewed by the Exemption Determination Official (EDO) using a checklist in the system based on guidance from 32 CFR 219.115. If additional review is required, protocols are sent to the Institutional Review Board (IRB).

From 2004-2008, the recordkeeping system for research protocols was hard copy and decentralized in each local institution. Beginning in 2008, all protocol information is collected by the HRPP Oversight Review System (HRPP ORS) and centralized within the Force Health Protection and Readiness office. The dispositions on this schedule cover both the hard copy and electronic records of this program. The inputs, outputs and system documentation for the HRPP ORS System are covered under GRS 20, Items 2(b), 4, and 11(a)(1).

ITEM 1

FILE TITLE: Human Research Protection Program Oversight Review System Files

FILE DESCRIPTION: The system includes personal information related to the researcher such as name, address, phone number and investigator role (i.e. Principal or Co-Principal); Protocol title and description; Data collection information (i.e. type of information to be collected and methods of collection); Documents used to advertise research or collect data; Human Subjects Training certificates; EDO Checklists.

DISPOSITION: Delete/Destroy 10 years after completion or termination of the research protocol (coincides with the term of the research)