

## **Federal Adverse Event Task Force (FAET)**

### **Charge**

#### **Background**

The Secretary's Advisory Committee on Human Research Protections (SACHRP) includes among its members representatives of federal agencies who serve in an *ex officio* capacity. These members meet periodically to discuss the range of concerns in human subjects protections that are being taken up by the SACHRP.

Adverse event reporting is a prominent and recurrent issue that is a clear priority for the SACHRP. In particular, SACHRP members and the public they represent have roundly called on the federal agencies to streamline and coordinate the currently diverse federal agency requirements for the reporting and review of adverse events.

To maintain the priority of this issue and to enable timely and concrete progress in responding to these concerns, OHRP director Dr. Berne Schwetz has established a Federal Adverse Event Task Force (FAET).

#### **Members**

Appointed to the group are Amy Patterson (*chair* – NIH), Michael Carome (OHRP), David Lepay (FDA), Francis Chesley (EPA), Lynn Cates (VA), and Patty DeCot (DoD). Agencies may involve other staff as necessary.

#### **Purpose and Tasks**

The FAET will work to propose specific means for promoting greater harmonization among federal agency requirements for AE reporting. To fulfill this purpose, the FEAT will:

- Study existing requirements for the reporting of adverse events among federal agencies
- Discern how agencies collect and use these data in promoting the safety and integrity of their clinical research activities
- Identify opportunities for greater interagency harmonization
- Develop proposals for consideration by relevant agencies
- Report periodically to the SACHRP on its activities

In conducting these tasks, a guiding principle is to achieve policies that satisfy the requirements and oversight needs of both agencies, while facilitating the ability of investigators, institutional review boards, and sponsors to fulfill critically important reporting and oversight responsibilities.

**Process**

The FEAT will be convened either by conference call or in person approximately twice a month. Additional meetings may be scheduled as needed. Findings, conclusions, and proposals from the FEAT activities will be shared with the full membership of the SACHRP *ex officios*, who collectively will determine necessary next steps and the appropriate manner in which to involve the SACHRP.