

Department: UAMS Human Research Advisory Committee
Policy Number: 2.6
Section: Relationships
Effective Date: July 31, 2002
Revision Date: November 18, 2002

SUBJECT: To Regulatory Agencies

The HRAC reports any unanticipated problems involving risks to human subjects or others; any instance of serious or continuing noncompliance with the HRAC regulations, requirements, or determinations; and any suspension or termination of HRAC approval to the Food and Drug Administration (FDA), the Office of Human Research Protection (OHRP), and the Office of Research Compliance and Assurance (ORCA) [21CFR56.108(b); 45CFR]. The HRAC reports any suspected misconduct to the VCAA. Once a written allegation of research misconduct has been received by the VCAA from the HRAC, the VCAA will conduct an inquiry to determine if an investigation is indicated.

Each institution engaged in research that is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federal-wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an HRAC provided for in the assurance and will be subject to continuing review by the HRAC. Assurances applicable to federally supported or conducted research shall at a minimum include:

A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under 38CFR16.101 (b) or (i).