

**Department:** UAMS Human Research Advisory Committee  
**Policy Number:** 1.3  
**Section:** Principles and Authority  
**Effective Date:** July 31, 2002  
**Revision Date:** November 18, 2002

**SUBJECT: Federal Wide Assurances**

Each institution engaged in research which is covered by this policy and which 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, National Institutes Health, DHHS, and approved for Federal wide use by that office. When the existence of an DHHS-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, National Institutes of Health, DHHS.

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:

1. **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 §45 CFR 45 CFR 46.101 (b) or (i).
2. **Designation of one or more HRACs** established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the HRAC's review and record keeping duties.
3. **A list of HRAC members** identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to HRAC deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in HRAC membership shall be reported to the Department or Agency head, unless in accord with §46.103(a) of this policy, the existence of a DHHS-approved assurance is accepted. In this case, change in HRAC membership shall be reported to the Office for Protection from Research Risks, National Institutes of Health, DHHS.
4. **Written procedures which the HRAC will follow** (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous HRAC review; and (iii) for ensuring prompt reporting to the HRAC of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which HRAC approval has already been given, may not be initiated without HRAC review and approval except

when necessary to eliminate apparent immediate hazards to the subject.

5. **Written procedures for ensuring prompt reporting to the HRAC**, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the HRAC; and (ii) any suspension or termination of HRAC approval.

The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the Department or Agency head prescribes.

The Department or Agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the Department or Agency and such experts or consultants engaged for this purpose as the Department or Agency head determines to be appropriate. The Department or Agency head's evaluation will take into consideration the adequacy of the proposed HRAC in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks and benefits, and the size and complexity of the institution.

On the basis of this evaluation, the Department or Agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Department or Agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

Certification is required when the research is supported by a Federal Department or Agency and not otherwise exempted or waived under 45CFR 45CFR46.101(b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by 45CFR46.103 of this policy has been reviewed and approved by the HRAC. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the Department or Agency to which the application or proposal is submitted. Under no condition shall research covered by 45CFR46.103 of the policy be supported prior to receipt of the certification that the research has been reviewed and approved by the HRAC. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the Department or Agency, that the application or proposal has been approved by the HRAC. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.