

**Department:** UAMS Institutional Review Board  
**Policy Number:** 12.3  
**Section:** Quality Assurances  
**Effective Date:** July 31, 2002  
**Revision Date:** June 10, 2004

**SUBJECT: Food and Drug Administration Monitoring or Reviews of the IRB - Information for the Reviewer and Investigator**

### **The Food and Drug Administration**

The FDA periodically may inspect the IRB records. These inspections may involve a single investigator's study or be for the purpose of evaluating the IRB's compliance with federal regulations regarding human research. The FDA may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection (21 CFR 56.115;). For all inspections and audits of UAMS, the UAMS Office of Research Compliance must be notified to coordinate the audit.

During an FDA inspection the inspector may present orally or in writing a summary of observation (FDA Form 483) of noncompliance on the part of the IRB. Such observations require a response by the IRB (21 CFR 56.120).

On the basis of the IRB's or the institution's response, FDA may schedule a re-inspection to confirm the adequacy of corrective actions. In addition, until the IRB or the institution takes appropriate corrective action, the FDA may:

1. Withhold approval of new studies conducted at UAMS or reviewed by the IRB
2. Direct that no new subjects be added to ongoing studies under FDA oversight
3. Terminate ongoing studies subject to when doing so would not harm subjects or
4. When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects or
5. Notify relevant State and Federal regulatory agencies such as Office of Human Research Protection (OHRP) or Office of Research Oversight (ORO) and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB

UAMS is presumed to be responsible for the operation of the IRB, and the Food and Drug Administration will ordinarily direct any administrative action against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to the component of UAMS determined to be responsible for formal designation of the IRB .

**FDA's Disqualification of the IRB or an institution.** Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the FDA, and the Commissioner of the FDA determines that this noncompliance may justify the disqualification of the IRB or the institution, the FDA Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing.

**The Commissioner may disqualify (21 CFR 56.121) an IRB or the parent if the Commissioner determines that:**

- The IRB has refused or repeatedly failed to comply with regulatory guidelines and;
- The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

If the FDA Commissioner determines that disqualification is appropriate, the FDA Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The FDA will send notice of the disqualification to the IRB and UAMS. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the FDA may elect to publish a notice of its action in the Federal Register.

The FDA will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution unless the IRB or the parent institution is reinstated as provided in 21 CFR56.123;).

**Public disclosure of information regarding revocation.** A determination that the FDA has disqualified an institution and the administrative record regarding that determination are disclosable to the public.

**Reinstatement of an IRB or an institution.** An IRB or an institution may be reinstated if the Commissioner determines upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under 21CFR56.121(c); 45CFR).

**Actions alternative or additional to disqualification.** Disqualification of an IRB or of an institution is independent of, and neither *in lieu* of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The FDA may also refer pertinent matters to another Federal State, or local government Agency for any action that Agency determines to be appropriate.