Department: **UAMS Institutional Review Board**
Policy Number: **13.4**
Section: **Confidentiality**
Effective Date: **September 10, 2004**
Revision Date:

SUBJECT: Criteria for the Release of an FDA 483

The following policy applies to the release of information contained in an FDA 483 (Inspectional Observations), issued to any investigator conducting research at the University of Arkansas for Medical Sciences (UAMS).

Introduction

A copy of all FDA 482s (Notice of Inspection) and 483s will be held in the UAMS Office of Research Compliance (ORC). Any FDA correspondence including the investigator's response to the 483 and any FDA Warning Letters or other correspondence, if issued, as well as the investigator's response, will also be retained by the UAMS ORC.

An FDA 483 technically is releasable by the FDA through the Freedom of Information Act at the time it is issued and information may or may not be redacted. The requestor must specify the location and date relevant to the 483. A blanket request by site will not be honored. Any response to a 483 may not be disclosed until the file is closed by the FDA. Information contained in a response to a 483 may or may not be redacted by the FDA.

FDA warning letters can be disclosed under Freedom of Information (FOIA) but certain information may be redacted such as privacy issues and proprietary information among others. A response to a warning letter is not available under FOIA.

Procedure

Any request by an industry sponsor regarding a 483 issued to a UAMS investigator must be referred to the ORC. Information about the existence of a 483 should not be disclosed

A request to see a 483 that has been issued to a UAMS investigator must be handled in the following manner:

1. The requestor must make an appointment with the ORC to see the 483(s).
2. They must specify which 483 they wish to see in regard to study number and/or title, or date.
3. They will not be privy to any 483 that was issued to any studies not under their company's jurisdiction.
4. A confidentiality agreement must be signed and individuals will be required to sign a log at the ORC.
5. They will be allowed to read the 483, in the presence of an ORC employee.
6. 483's will not be copied.
7. They will not be allowed to take notes on the 483.
8. They will not be allowed to read any responses made by the UAMS investigator.

The ORC reserves the right to redact any information they consider confidential prior to review by the requestor. A redacted copy will be retained in the file.

The ORC will discuss the UAMS Human Subject Protection Plan and the ORC Research Compliance Plan with the Sponsor's representative to assure that the Sponsor adequately understands the University's commitment to Human Subject Protection.