

Department: UAMS Institutional Review Board

Policy Number: 20.1

Section: Questions, Concerns, Suggestions and Complaints

Effective Date: September 1, 2007

Revision Dates:

Purpose: This policy provides guidelines for individuals and offices on campus to present questions, concerns, and suggestions/complaints regarding the human subjects' protection program on campus.

Policy: As a general rule, the IRB Office Staff, IRB Chair, IRB Director, Office of Research Compliance, IRB Executive Committee, and the Vice Chancellors for Academic Affairs/Research Administration and Institutional Compliance are appropriate members for addressing issues concerning the human subjects' protection program.

Procedure:

General Questions, Suggestions, and Concerns:

No specific order for addressing an issue is required; however, the following outline is a suggested path to follow until the issue is addressed. Response should be within two weeks to general questions, suggestions and concerns. If the question is not addressed within two weeks, move to the next level until you have reached one of the Vice Chancellors listed. Responses from the members can be written or verbal; however, this method is not an alternative method or substitute for the IRB approval process outlined in these policies. Phone numbers can be found on the IRB website:

1. IRB Office Staff
2. IRB Chair
3. IRB Director
4. Office of Research Compliance
5. IRB Executive Committee
6. Vice Chancellor for Academic Affairs/Research Administration or Institutional Compliance

Specific, Significant Concerns or Issues that potentially involve risk

Some situations or concerns may require immediate action or a response from the institution. Examples are situations that involve one of the following: potential harm (physical or other) to subjects and/or study staff; potential high regulatory risk; potential high risk to institutional resources or operations; potential civil or criminal violations; indications that study disorganization may potentially jeopardize data integrity or subject safety. Initial reports of this kind of situation or concern should be made simultaneously to the IRB Chair, IRB Director, and the Office of Research Compliance. If the IRB or the ORC is a party to the concern in question, the office that is not involved should be notified, along with a simultaneous notification to the appropriate Vice Chancellor.