Department:	**UAMS Institutional Review Board**
Policy Number:	**20.1**
Section:	**Questions, Concerns, Suggestions and Complaints**
Effective Date:	**September 1, 2007**
Revision Date:	**January 24, 2011; February 15, 2016; August 24, 2020**

SUBJECT: Questions, Concerns, Suggestions and Complaints

POLICY

The IRB Office Staff, IRB Chair, IRB Director, Office of Research Compliance, IRB Advisory Committee, the Vice Chancellor for Research and Innovation and the Vice Chancellor for Compliance/Managing Associate General Counsel are appropriate to be involved to address any comments or concerns about the human subjects' protection program. Others may also be involved, such as study teams, the Translational Research Institute, or the Cancer Clinical Trials and Regulatory Affairs office, when appropriate.

PROCEDURE

A. General Questions, Suggestions, and Concerns:
   1. No specific order for addressing an issue is required; however, the following outline is a suggested path to follow until the issue is addressed.
      a. IRB Office Staff
      b. IRB Chair
      c. IRB Director
      d. Office of Research Compliance
      e. IRB Advisory Committee (see IRB Policy 1.7)
      f. Vice Chancellor for Research and Innovation and/or the Vice Chancellor of Compliance/Managing Associate General Counsel
   2. General questions, suggestions, and concerns should be addressed within 10 working days.
   3. If the question is not addressed within 10 working days, move to the next level until you have reached one of the Vice Chancellors listed.
   4. Responses may be written or oral; however, this method is not an alternative method or substitute for the IRB approval process outlined in these policies.
   5. Any communication from subjects or other members of the public to the IRB office shall be handled as described in IRB Policy 4.7, Participant Contact.
   6. The entities on the above list may consult each other as needed when addressing question, suggestion, or concern.

B. Specific, Significant Concerns or Issues that potentially involve risk
   1. 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.
   2. 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.
      a. If the IRB or the ORC is a party to the concern in question, the office that is not involved should be notified, as well as the appropriate vice chancellor.

REFERENCES

AAHRPP Element III.1.G
UAMS IRB Policy 1.7, *IRB Advisory Committee*
UAMS IRB Policy 4.7, *Participant Contact*