POLICY

1.1 Background.

1.1.1 The management of participant questions, complaints, and concerns by the principal investigator and research staff is integral to truly informed and legally effective informed consent, protection of the rights of research participants, the good will of the public toward research, and the improvement of the University of Alabama Human Research Protections Program.

1.1.2 A “serious” question, complaint or concern is defined as but not limited to charges of misrepresentation of the study’s purpose, nature, and burden; failure to provide promised incentives; failure to ensure safety during risky treatments; violation of privacy or confidentiality assurances; and persistent unavailability or unresponsiveness from the investigator.

1.1.3 This policy deals only with investigator and research staff responsibilities for responding to participants’ questions and complaints and a brief description of IRB’s responsibilities in dealing with them, if and once the Director of Research Compliance brings them to the attention of the IRBs. For information about how to file suggestions, questions, complaints, or concern with HRPP and how the Office for Research Compliance (ORC) manages them, see POLICY Participant and Community Questions, Suggestions, Complaints, and Concerns About Research Studies.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that principal investigators and their staff will encourage and respond to questions, complaints, and concerns from participants and report the nature and management of questions and complaints to the IRB and, if necessary, to study sponsors.

1.2.1.1 Research staff training for those who have contact with research participants shall include the importance of prompt response to questions and complaints and the need to inform the principal investigator about participant concerns.

1.2.1.2 The training of research staff shall include information that they are obligated to report major or persistent violations of the protocol and investigator failure to address participant questions and complaints to the Director of Research Compliance.
1.2.1.3 At a minimum, investigators shall invite prospective participants to ask questions during the consent process, and welcome questions and provide information about how to contact the Research Compliance Office on the informed consent document.

1.2.1.4 Investigators and/or research staff shall monitor the number and nature of participant questions and complaints to promote participants' welfare both within the study and by IRB.

1.2.1.5 Participant complaints that the investigator and research staff cannot resolve to the participant's satisfaction are a reportable event.

1.2.2 The Research Compliance staff and IRB will monitor investigator information about participant questions and complaints as part of quality control and for improvement of HRPP.

1.2.3 Complaints from participants that investigators have not responded to their questions or have deviated from the study as explained in the consent form and process may be grounds for the IRB to monitor the study for cause. The investigator shall then cooperate with the IRB as requested.

1.2.4 Objective

1.2.4.1 Adherence to this policy will promote informed consent, protection of the rights of research participants, the good will of the public toward research, and the improvement of the University of Alabama Human Research Protection Program.

1.3 Responsibility.

1.3.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Director of Research Compliance and staff, the IRB chairs and members, and principal investigators and research staff.

2.0 PROCEDURE

2.1 Investigator Responsibilities for Participants’ Questions and Complaints on the IRB Application

2.1.1 Explain provisions for responding to participants' questions and complaints. This description should include:

2.1.1.1 Study-specific staff training (See GUIDANCE: General Responsibilities of Investigators) including the obligation of staff members to report major or persistent violations of the protocol and investigator failure to address serious participant questions and complaints to the Director of Research Compliance.

2.1.1.2 A description of the consent process that makes it clear that the investigator understands the difference between consent process and consent documentation.
(See POLICY: Investigator Responsibilities for Informed Consent Process and Documentation).

2.1.1.3 (If appropriate) a statement that a log or field notes will be kept on the number, nature or, and response to participants’ questions and complaints.

2.1.1.4 Consent documents providing contact information for the investigator if the participant has questions about the study and for the Director of Research Compliance if the participant has questions about his rights in the study. (SEE GUIDANCE: Template for Informed Consent.)

2.1.1.5 How participants will be informed about channels for raising questions, suggestions, complaints or concerns about the study to the Research Compliance Office. For example, the informed consent template requires telling participants about the forms for complaints or concerns on the outreach website, the availability of the Survey for Participants in UA-Sponsored Research online at http://osp.ua.edu/site/PRCO_Welcome.html, or the investigator may give participants a brochure or paper copies of the Survey for Participants.

2.2 Investigator Responsibilities for Continuing Review, Modification of Approved Applications, and Unscheduled Reporting of Complaints

2.2.1 The investigator will describe the number, nature of, and response to participants’ questions and complaints on FORM: IRB Renewal Application when seeking Continuing Review and approval.

2.2.2 If the investigator notes questions or complaints that suggest the need for a change in the presentation of the study or of the consent documents, file FORM: Modification of an Approved Protocol as soon as the need is apparent.

2.2.3 Report any serious question, concern, or complaint to the Director of Research Compliance as soon as it is received.

2.2.4 Report any serious concern or complaint that has not been resolved to the participant’s satisfaction to the IRB.

2.2.5 Report any reportable event to the study sponsor.

2.3 IRB Responsibilities

2.3.1 Review initial and continuing review applications and applications for modifications of approved protocols using FORM: IRB Checklist for Reviewers and Investigators and inform investigators of its decision and recommendations.

2.3.2 Respond to questions, complaints, and concerns forwarded to it by the Director of Research Compliance, including decisions to investigate a study for cause.
2.3.3 Identify and discuss investigators and studies with an unusually high frequency of complaints or those investigators who may be considered in serious or continuing noncompliance with IRB.

2.3.4 Identify implications of questions and complaints for improved IRB and investigator education or changes in current policies and procedures.

3.0 REFERENCES

3.1 DHHS: 45 CFR 46.116(a) (6)-(7)
3.2 FDA: 21 CFR 50.25 (a) (6)-(7)
3.3 FDA Information Sheets: A Guide to Informed Consent

4.0 RELATED SECTIONS

4.1 POLICY: Investigator Responsibilities for Informed Consent Process and Documentation
4.2 GUIDANCE: General Responsibilities of Investigators
4.3 FORM: IRB Renewal Application
4.4 FORM: Modification of an Approved Protocol
4.5 FORM: IRB Checklist for Reviewers and Investigators
4.6 GUIDANCE: Informed Consent Template
4.7 POLICY: Participant and Community Questions, Suggestions, Complaints, and Concerns
4.8 FORM: Report of Complaint or Concern About a Research Study
4.9 FORM: Question/Suggestion for IRB/Human Research Protections Program
4.10 FORM: Survey for Participants in UA-Sponsored Research
4.11 POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events Involving Risks to Participants and Others.
4.12 GUIDANCE: IRB Application Guide