1.0 POLICY

1.1 Background.

1.1.1 Adequate protection of research participants and improvement of the Human Research Protections Program needs not only requirements for principal investigators but opportunities for participants or their legally authorized representatives to ask questions, make suggestions, or raise complaints or concerns about a research study to which the Office for Research Compliance (whose staff are unaffiliated with particular research studies) will respond in a timely manner.

1.1.2 A Serious 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.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that the Office for Research Compliance will establish and maintain a safe, confidential and reliable channel for current, prospective, or past research participants (including students) or their designated representatives and research staff members to ask questions, make suggestions, or raise complaints and concerns about a research study or an investigator with an informed individual who is unaffiliated with the specific research protocol. All complaints and concerns will then be investigated. This policy also applies to IRB chairs and members who report that they have been subjected to attempts at undue influence on their decisions.

1.2.1.1 Investigators must encourage participants to ask questions and provide them with contact information for themselves and the Director of Research Compliance (DRC) on consent documents or study information sheets. (See GUIDANCE: General Responsibilities of Investigators; Template for Informed Consent; POLICY: Investigator and Staff Response to Participants’ Questions and Complaints.)

1.2.1.2 The Office for Research Compliance shall prepare pamphlets or other educational information about research that includes information about how to
ask questions, make suggestions, or raise complaints or concerns about a research study.

1.2.1.3 The Office for Research Compliance website shall describe the University’s commitment to the protection of research participants and provide information about how to ask a question, make a suggestion, or raise a complaint or concern. An online or downloadable form, an e-mail address, and a hotline with a dedicated phone number will be provided but participant communications will be accepted by any medium.

1.2.1.4 The job descriptions and orientations of IRB chairs and members shall include their obligation and right to report attempts at undue influence upon their decisions.

1.2.1.5 Questions, suggestions, complaints and concerns may be raised anonymously.

1.2.1.6 If contributors identify themselves, their issues shall be treated with the maximum possible confidentiality.

1.2.1.7 Participants’ communications shall be dealt with in a timely fashion.

1.2.1.8 The Director of Research Compliance is authorized to identify, supervise, delegate, or lead investigations of complaints and concerns and corrective actions for serious complaints (those that cannot be answered by the provision of information or that involve possible noncompliance by an investigator or unanticipated problems that place participants or others at increased risk of harm).

1.2.1.9 The Director of Research Compliance will prepare an annual summary of the number, nature, and resolution of questions, complaints, and concerns raised by research participants or their representatives and a summary of participants’ responses to the Survey of Participants in UA-Sponsored Research that raise questions, complaints, or concerns. This report shall be used for quality improvement of the Human Research Protections Program. This does not preclude immediate changes in policy or procedure if a serious or persistent problem is identified from questions, complaints, and concerns.

1.2.2 Objective

1.2.2.1 Compliance with this policy will ensure better protection of human research participants and quality improvement for the Human Research Protections 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, Research Compliance staff, IRB chairs and members, investigators, and past, present, or prospective research participants or their representatives.
2.0 PROCEDURE

2.1 Questions and Suggestions to HRPP/IRB

2.1.1 Questions and suggestions are welcome via any medium and may contain identifiers or be anonymous.

2.1.2 Each day Research Compliance Specialists, Managers of Compliance, and the Director of Research Compliance will check their own telephone messages, e-mail, and U.S. Mail for questions or suggestions and will meet with any person who visits the Research Compliance Office to ask questions or make suggestions. Also, newly completed copies of the Survey for Participants in UA-Sponsored Research will be reviewed in case respondents have raised questions, complaints, or concerns on that form. Any other persons who receive questions or suggestions about IRB (the office receptionist or a grants specialist) will forward them to the appropriate Research Compliance Specialist (medical or non-medical IRBs).

2.1.2.1 If the question or suggestion cannot be answered by the Research Compliance Specialists or Managers, they will refer it to the Director of Research Compliance, if that person was not the original recipient. Similarly, if the Research Compliance Specialist or manager feels that a personal visit would best be handled by the Director of Research Compliance, s/he will arrange for that visit.

2.1.2.2 The recipient of the question or suggestion will enter it on the computer file “Log of Questions and Suggestions”, assigning it a consecutive number and recording the date.

2.1.2.2.1 Determine whether the question or suggestion actually raises an issue of noncompliance or unanticipated events that qualify it as a complaint or concern. If so, process under Section 2.2 of this procedure.

2.1.2.3 If the contributor of a question is identified, thank him/her for the question. If the answer is known, please answer it or inform the contributor that an answer will be sought and provided within three working days.

2.1.2.4 If the contributor of a suggestion is identified, acknowledge the suggestion and state that it will be relayed to the appropriate person. If possible, ascertain whether the person wishes to know if the suggestion is adopted.

2.1.2.5 Update the FORM: Log of Questions, and Suggestions with the date when a question was answered or a suggestion was presented to the appropriate people and if it was acted upon.

2.2 Complaints and Concerns

2.2.1 Complaints and concerns may be received by any medium or in person.
2.2.2 The Director of Research Compliance or designee will check the hotline, website, e-mail, and U.S. Mail daily for complaints and concerns and will meet with any person who visits the Research Compliance Office to raise a complaint or concern. Any other persons who receive complaints or concerns about IRB or specific studies shall refer them to the Director of Research Compliance or designee.

2.2.2.1 If the Director of Research Compliance is not available when a visitor arrives, a manager of research compliance will be contacted. If a manager of research compliance is not available, a Research Compliance Specialist will meet with the visitor.

2.2.3 The recipient of a complaint or concern will read or listen to it, enter it on the FORM: Log of Complaints and Concerns, and assign it a consecutive number.

2.2.4 If the complaint/concern was submitted using the online FORM: Report of Complaint or Concern about a Research Study, the necessary contextual information should be present unless the complainant has chosen to be anonymous. Otherwise, gather all available contextual information from the communication: Contributor's/Complainant's name, address, and phone number (unless person chooses to remain anonymous); the study title and/or IRB protocol number, the name of the principal investigator, the person's role in the study, whether a consent document was received; and the person's desired resolution of a complaint or concern.

2.2.5 If a complainant wishes to remain anonymous but can be contacted (for instance, during an anonymous "live" telephone call), inform him that this may mean the complaint cannot be investigated as thoroughly as possible and that feedback about the resolution of the complaint may not be possible.

2.2.6 Assure the complainant that you will inquire into the circumstances and that the IRB or Office for Research Compliance will take appropriate measures to address the issue, explain the degree of confidentiality that will be possible for him or her and will respond to him as soon as possible (within three weeks of the complaint) if contact information is provided.

2.2.7 Start FORM: Response to Complain or Concern About a Research Study and update it as the investigation proceeds. Be sure to indicate date on which complaint is considered resolved. If complainant's contact information is available, notify him/her of the resolution of the complaint and determine degree of satisfaction if possible.

2.2.8 Consider whether the complaint or concern involves (a) an allegation or finding of noncompliance (process according to POLICY: Allegations and Findings of Noncompliance or (b) an unanticipated problem with increased risk of harm to others (Process according to POLICY: Reportable Events, Protocol Deviations, Unanticipated Problems and Adverse Events; POLICY: Monitoring of Previous Approved Research for Cause: Suspension and Termination).

2.2.8.1 A complaint or concern may also raise questions of academic or scientific misconduct. If so, the University of Alabama Policy on academic or scientific misconduct (currently under revision) will be followed.
2.2.9 Notify the Principal Investigator of the study and the IRB Chair of the nature of a complaint or concern in a timely manner, which may be immediately or at most within two working days of receipt of the complaint.

2.2.10 Treat the complaint confidentially. This means that information about the complaint should be given only to employees with responsibilities that require knowledge of the complaint.

2.2.11 Investigate complaints or concerns NOT involving noncompliance or unanticipated events on a case-by-case basis, making every effort to correct the issue at the administrative level, that is, without involving the IRB. An investigative committee of IRB members or other faculty or University staff such as Legal Counsel may be created as needed.

2.2.12 The Director of Research Compliance or designee manages the inquiry, preparing related correspondence, preparing or obtaining reports from whomever led the investigation, and maintaining documentation of the complaint review for up to six years from completion of the inquiry or close-out of the investigator's IRB file, whichever is longer.

2.3 Quality Improvement of HRPP/IRB

2.3.1 The DRC may bring any question, suggestion, or complaint or concern to the attention of the Vice President for Research, the IRB Chairs and members, or the Research Compliance staff for review and action at any time if it appears that a change would improve the functioning of IRB and the treatment of human research participants or if a serious problem in need of immediate attention is identified.

2.3.2 The DRC will prepare an annual summary of the number, nature, and resolution of questions, complaints, and concerns raised by research participants or their representatives and present this report to the Vice President for Research, who may approve its distribution to others. This report shall be used for quality improvement of the Human Research Protections Program/IRB.

3.0 REFERENCES

3.1 45 CFR §46.116 (a)(6)-(7)

3.2 21 CFR §50.25 (a) (6)-(7)


4.0 RELATED SECTIONS

4.1 GUIDANCE: General Responsibilities of Investigators
4.2 POLICY: Investigator and Staff Response to Participants’ Questions and Complaints
4.3 Template: Informed Consent for Medical or Health-Related Studies
4.4 Template: Informed Consent for Non-Medical Study
4.5 FORM: Log of Questions, Complaints, and Concerns by Participants
4.6 FORM: Report of Complaint or Concern About a Research Study
4.7 FORM: Survey for Participants in UA-Sponsored Research
4.8 FORM: Report of Attempt to Exert Undue Influence
4.9 FORM: Response to Complain or Concern About a Research Study
4.10 POLICY: Monitoring of Previously Approved Research for Cause: Suspension and Termination
4.11 POLICY: Allegations and Findings of Noncompliance