1.0 POLICY

1.1 Background.

1.1.1 The Human Research Protection Program (HRPP) values open communications with investigators under its oversight and responsiveness to their questions, concerns, and suggestions in order to protect human research participants and improve the effectiveness of the HRPP and the IRBs.

1.1.2 This policy applies only to investigators and other study staff. Input from participants, other university stakeholders, and the non-university community is described in other policies.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that the Human Research Protection Program (HRPP) and the IRB shall maintain open communications with investigators under its oversight as part of their mission to protect the rights, safety, and welfare of human research participants and to improve the effectiveness of the HRPP and of IRB processes. “Communication” includes questions, complaints, requests for information, reports of concerns, and suggestions relating to specific proposals, types of research, IRB processes, and research education for the University or the external community from investigators or members of their research teams.

1.2.2 Investigators shall be informed in multiple ways and on multiple occasions that it is their right and responsibility to seek answers to questions about the HRPP or IRB, to express complaints or concerns about the HRPP or IRB, and to offer suggestions for their improvement in order to uphold ethical standards and practices in research and to improve human research protections.

1.2.3 Investigators shall be informed how to obtain answers to questions about the HRPP or IRB, how to express concerns about the HRPP or IRB, and how to offer suggestions for the improvement of the HRPP and IRB.

1.2.4 A system shall be established to document the content of investigator questions, concerns, and suggestions and the HRPP or IRB response to them.

1.2.5 Steps shall be taken to determine whether investigators find the HRPP and IRB responsive to their questions, concerns, or suggestions. Evidence of responsiveness shall include but is not limited to HRPP or IRB written response to investigators, the rationale presented for changes in HRPP or IRB policies and
procedures (when stimulated by investigator input), the addition of templates or online guidance for investigators in response to investigator concerns or suggestions, and investigators' responses to surveys of satisfaction with the HRPP/IRB.

1.2.6 Investigator questions, complaints and concerns, and suggestions shall be considered when planning the next quality improvement plan for HRPP. See POLICY: Evaluation and Improvement of the Human Research Protection Program.

1.3 Objective.

1.3.1 Implementation of this policy and procedure will enable investigators to obtain timely needed information about protecting human subjects or IRB practices for their research, to report concerns about the HRPP or IRB processes, and to aid in the improvement of the HRPP and the IRB, with subsequent benefits to investigators, research participants, the HRPP, and the IRB.

1.4 Responsibility.

1.4.1 The ultimate responsibility for this policy rests with the Vice President for Research. Enabling parties include the Director of Research Compliance, Research Compliance staff (specialists and managers), the chairs and members of IRB, the Council of Associate Deans/Directors for Research, and investigators and key members of their research staffs.

2.0 PROCEDURE

2.1 Procedure for Raising Questions, Suggestions, Concerns or Complaints

2.1.1 Investigators with a question, suggestion, concern or complaint may contact the DRC, an IRB chair or member, a Research Compliance Specialist (RCS), or a Research Compliance Manager by telephone, e-mail, campus mail, or in person. Telephone, e-mail, and campus mail information for IRB chairs and members is provided on the IRB website and in the Campus Directory. Contact information for the DRC and Research Compliance Specialists is found on the Research Compliance website under "Contact Information".

2.1.2 Investigators may also ask questions or file concerns or complaints using the forms for questions (FORM: Questions Or Suggestions for IRB/Human Research Protection Program) or for concerns or complaints (FORM: Report of Complaint or Concern About Research Study) on the website.

2.1.3 Investigators are free to identify themselves or not, depending on the nature of the contact and their preference for being known. For example, questions about a specific protocol probably need to identify the investigator for timely response, but general questions about IRB processes or suggestions for improvement need not.

2.1.4 The HRPP/IRB maintains a tollfree telephone line (877-820-3066) that can be used to report issues or concerns about research activities. If callers identify themselves,
the call will be confidential. If callers do not identify themselves, the call will be anonymous, as caller ID is not used.

2.1.5 Callers who identify themselves may also request anonymity, and this request will be honored.

2.2 Responses to Questions, Concerns, Complaints, and Suggestions

2.2.1 The Research Compliance Specialists (RCSs) will check telephone messages, FAXes, e-mail, campus mail, and the website daily for questions, suggestions, concerns, and complaints. The Director of Research Compliance (DRC) or his/her designee will check the hotline and outreach website daily.

2.2.2 All persons receiving questions or suggestions will enter them on FORM: Log of Questions and Suggestions. All persons receiving complaints and concerns will enter them on FORM: Log of Complaints and Concerns. Messages dealing with simple requests for information (e.g., directions to the IRB meeting, university phone number requests, “Where can I find X”, etc.) will be answered immediately or no later than the close of the next business day. Users’ suggestions for IRB improvement will be collected or recorded and their receipt acknowledged by telephone or e-mail if not made orally to the recipient. Concerns or complaints, if not made on FORM: Report of Complaint or Concern about a Research Study, will be recorded on that form. (This form is available to participants or people from outside UA from the Research Compliance Office or on the Outreach website. ) Responses to the concern or complaint will be tracked using FORM: Response to Concern or Complaint about a Research Study.

2.2.3 Any input containing allegations of conduct that may affect adversely the rights, safety, or welfare of human research participants shall be forwarded immediately to the DRC (if s/he was not the original recipient). If necessary the DRC will contact the IRB chair and the institutional official. Allegations of serious harm to participants or misconduct receive priority for investigation.

2.2.4 The IRB chairs may respond to the investigator directly, raise the issue for discussion at an IRB meeting (where discussion and decisions will be recorded on the meeting minutes), or seek additional input from a RCS or the DRC. The response to the investigator input will be recorded on FORM: Response to Concern or Complaint about a Research Study.

2.2.5 All recipients of investigator input shall treat the input confidentially. Unless investigators identify themselves and give permission to be identified, all discussions and records will identify the source only as “the/an investigator”.

2.2.6 Investigators’ satisfaction with the response to their input will be assessed through brief surveys conducted by e-mail or telephone and in the annual user evaluation of IRB.

2.3 Use of Investigator Input for Quality Improvement

2.3.1 A Research Compliance Specialist will prepare a summary table of the content of investigator input at least annually and provide this information to the Quality
Institutional Review Board designated by the Vice President For Research (POLICY: Evaluation of the Human Research Protection Program).

2.3.2 The DRC and the IRB Chairs will review the FORMS: Log of Questions and Suggestions and Log of Complaints and Concerns each semester to look for trends and patterns in input that suggests a need to revisit policies and prepare or revise educational guidance for investigators.

2.3.3 Responses to the annual survey of user satisfaction with HRPP/IRB (FORM: User Evaluation of HRPP/IRB) item dealing with satisfactory and timely response to investigator input to HRPP/IRB will be tallied and become part of plans for quality improvement.

3.0 REFERENCES

3.1 No regulatory or guidance references for this standard

4.0 RELATED SECTIONS

4.1 GUIDANCE: General Responsibilities of Investigators

4.2 POLICY: Evaluation and Improvement of the Human Research Protection Program

4.3 FORM: Questions Or Suggestions for IRB/Human Research Protection Program

4.4 FORM: Report of Complaint or Concern About Research Study