1.0 POLICY

1.1 Background

1.1.1 It is recognized that IRBs may occasionally need additional expertise beyond that represented on the IRBs to ensure competent review of all applications.

1.1.2 Recognition of the need for additional expertise or consultation may arise at any state of the review process. It may manifest when applications are being assigned to reviewers by the Director of Research Compliance (DRC) and the IRB Chairs, when the application is being reviewed by a reviewer in advance of the board meeting, or during the board meeting discussion.

1.1.3 The frequent need for particular kinds of consultants is one factor that may be considered when the Office for Research and the Office of Research Compliance are appraising the adequacy of the number of IRBs or their membership.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that the IRBs shall obtain additional expertise or consultation as needed to assure knowledgeable review of and protection of human research participants in all submitted applications.

1.2.2 Consultants may come from within or outside of the University of Alabama.

1.2.3 Requests for additional expertise or consultation may arise from the Research Compliance Office (DRC), the IRB chairs, or IRB members.

1.2.4 Persons requesting consultations may suggest consultants by name if any are known to them, provided that they have no relations with the consultant that pose potential conflicts of interest. However, reviewers may not contact consultants directly. This is to be done by the DRC.

1.2.5 The Office of Research Compliance (ORC) shall maintain a list of consultants for the DRC and IRB Chairs and members to use in identifying potential consultants.

1.2.6 Consultants to IRB do not vote on applications. IRB members take consultants’ opinions into consideration before casting their votes.

1.3 Objective.
1.3.1 Implementation of this policy will ensure that the needed expertise to review proposals using human research participants is present and that the policy and procedures are evaluated and revised as needed to meet the needs of the IRB and the goal of total quality improvement of the Human Research Protections Program (HRPP).

1.4 Responsibility.

1.4.1 The ultimate responsibility for this policy rests with the Vice President for Research. Enabling parties are the Director of Research Compliance, and the IRB chairs and members. Assistance may be sought from others as needed.

2.0 PROCEDURE

2.1 IRB Recognition Of The Need for Additional Expertise or Consultation

2.1.1 Reasons for requesting consultation include but are not limited to:

2.1.1.1 Protocols using a novel design, recruitment strategy, or research methods;

2.1.1.2 Protocols using an unfamiliar or atypical sample, including standard or novel vulnerable populations;

2.1.1.3 Research done in a foreign country where customs or human research protection standards may be very different or unknown;

2.1.1.4 Research studies collecting data online that use new or unfamiliar security programs;

2.1.1.5 Studies where the need exists to verify the adequacy of translated study documents or the skills of interpreters;

2.1.1.6 Studies where review of the adequacy of a data safety plan or data safety monitoring board is considered desirable;

2.1.1.7 Studies that evoke unusual difficulty or marked disagreement among board members in determining the degree of risk represented by the research;

2.1.1.8 Reviews in which the Director of Research Compliance, the Manager of Research Compliance, the IRB chair or a majority of the board members conclude that the needed expertise is not present on the board or that an external opinion would be beneficial to the protection of human research participants.

2.1.2 Regardless of the step at which the request for consultation arises, the requester shall complete FORM: Request for Consultation on IRB Application and submit it to the Director of Research Compliance. (The Director of Research Compliance will complete it if the request originates from him/her.)

2.1.3 Decisions about consultation:
2.1.3.1 The DRC or the DRC and IRB chair may decide to seek consultation in advance of assigning applications to reviewers if their appraisal suggests this is desirable.

2.1.3.2 Requests for consultation coming from assigned reviewers in advance of the meeting will be discussed by the DRC, the IRB chair, and the requestor. Two of the three must agree that consultation is needed.

2.1.3.3 Requests for consultation arising from board discussion of an application shall be granted if a simple majority of those present (including nonvoting members) vote to obtain consultation. In the event of a tie, the Vice President for Research shall decide whether consultation is indicated.

2.2 Obtaining the Consultant

2.2.1 The Director of Research Compliance and the IRB Chair will review the expertise of IRB members to verify that the needed expertise is not present on either IRB. This may involve additional assessment of member expertise beyond that listed on the expanded membership roster.

2.2.2 The Director of Research Compliance and the IRB Chair will review the List of Consultants to determine whether an appropriate consultant is known to the Research Compliance Office. If none are identified, associate deans for research, center directors, department chairs, funding agencies, IRB members, and other sources on or off campus may be contacted for suggestions.

2.2.3 When a prospective consultant has been identified, the Director of Research Compliance contacts the prospect and determines if s/he is available and willing to review a protocol within a specified time and whether the prospect can identify any potential conflict of interest with the investigator or the University of Alabama. If the prospect is available and apparently free of conflict of interest, the DRC provides a brief explanation of the study and the needed consultation and determines with the consultant that that s/he does have expertise on the topic. The DRC then emphasizes that the application to be reviewed is a privileged communication and must be treated confidentially.

2.2.4 If no conflict of interest is apparent, the expertise matches, and the person is willing, the DRC forwards:

2.2.4.1 The application;

2.2.4.2 A copy of POLICY: Conflict of Interest for IRB Members, Chairs, and Consultants;

2.2.4.3 A copy of FORM: Agreement to Serve as Consultant with due dates, remuneration, assurances of confidentiality, and a statement that conflicts of interest exist do not exist or have been discussed with the Director of Research Compliance;

2.2.5 At the discretion of the Director of Research Compliance, an institutionally-determined honorarium may be paid to the consultant.
2.2.6 If the person is unwilling, unavailable, or has a conflict of interest, the process will be repeated until a qualified consultant is found.

2.2.7 The Director of Research Compliance or the IRB chair shall inform reviewers and board members when information has been obtained from a consultant, and provide a written copy and oral summary of the consultant’s opinion following discussion by the board and before the application is voted upon.

2.3 Maintaining and Improving the List of Consultants

2.3.1 Each time a consultant is used, the IRB members will be asked if they found the consultant’s input helpful.

2.3.2 The DRC may periodically post an announcement to faculty (Dialog, e-mail list of investigators, IRB Notes) asking about topics on which faculty could consult. This information will be used to enlarge the list of consultants and to identify expertise that may be need on the IRBs.

3.0 REFERENCES

3.1 45 CFR § 46.107 (f)

3.2 21 CFR § 56.107 (f)

4.0 RELATED SECTIONS

4.1 POLICY: Conflict of Interest for IRB Members, Chairs, and Consultants

4.2 FORM: Request for Consultation

4.3 FORM: Agreement to Serve as IRB Consultant