1.0 POLICY

1.1 Background.

1.1.1 According to the University Of Alabama Statement Of Principles Protecting Human Research Participants, the principle of respect for persons incorporates two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. In most cases of research with human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information.

1.1.2 Adequate information involves not only a comprehensive explanation of the proposed study but efforts by the investigator and research staff to assess the prospective participants’ comprehension of the study procedures, risks, and benefits both before and after informed consent has been obtained.

1.1.3 This policy deals only with strategies investigators may use to assess participant comprehension. Other policies provide additional guidance for specific vulnerable populations, information about consent process and documentation, and IRB requirements and authorizations.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama that investigators and research staff shall routinely assess participant comprehension of study procedures, risks, and benefits in applications to the IRB, when obtaining informed consent from prospective participants, and when interacting with them once informed consent has been given and that the IRBs shall evaluate the existence, assessment, and management of participant comprehension issues.

1.2.2 Investigators shall report the nature and frequency of problems with participant comprehension when seeking modifications to studies or continuing renewal.

1.2.3 Investigators and research staff shall involve the Office of Research Compliance and the IRB in response to participants’ complaints about the research process or requests for information, both of which may indicate problems with participant comprehension.

1.2.4 The IRBs are authorized to observe investigators’ consent processes for cause or for routine auditing of research.
1.2.5 The Human Research Protections Program (HRPP) may survey research participants directly to assess problems with comprehension as part of quality improvement.

1.2.6 The HRPP encourages investigators to perform research on issues in participant comprehension of research studies and to conduct pilot studies of their consent documents with members of the target population when difficulties with comprehension are possible.

1.3 Objective.

1.3.1 Adherence to this policy will help ensure that the principle of respect for persons and the obligation to obtain fully informed legally effective consent from participants or their legally authorized representatives (LARs) will be met for research participants in research studies at the University of Alabama and that investigators and research staff follow regulatory and IRB requirements.

1.4.1 Responsibility

1.4.2 The ultimate responsibility for this policy rests with the Vice President for Research. Enabling parties include the Director of Research Compliance, investigators and research staff, the IRB chairs and members, and associate deans and directors of research.

2.0 PROCEDURE

2.1 Investigator Plan for Initial Assessment of Prospective Participants’ Comprehension

2.1.1 On the IRB application the principal investigator (PI):

2.1.1.1 Describes sample characteristics and criteria completely enough to identify anticipated threats to prospective participants’ comprehension, including but not limited to degree of cognitive impairment, physical barriers such as deafness or blindness, low educational status, limited proficiency in English, or non-Western cultural background. (It is understood that many studies are unlikely to involve threats to participant comprehension that simple answering of prospects’ questions cannot address; however, PIs must estimate the existence of threats).

2.1.1.2 Identifies initial exclusion criteria or participant circumstances that will justify removal from the study once a participant has given consent.

2.1.1.3 Describes efforts to overcome possible threats to participant comprehension, including but not limited to:

2.1.1.3.1 Setting cut-off scores for eligibility on measures of cognitive status;

2.1.1.3.2 Identification of legally authorized representatives for some or all participants;
2.1.1.3.3 Conforming to or lowering the IRB standard of a maximum of an 8th grade reading level for consent documents;

2.1.1.3.4 Using large print for informed consent documents;

2.1.1.3.5 Speaking loudly;

2.1.1.3.6 Using translated documents or an interpreter. NOTE: Translators must complete FORM: Translator's Declaration to attest to the adequacy of the translation. If they also serve as interviewers, they must complete investigator training and submit certificates.

2.1.1.3.7 Provision of a staff member or assistant from the same cultural group as the prospective participant;

2.1.1.3.8 Providing enough or additional time for prospects to consider information presented or to raise questions

2.1.1.3.9 Obtaining expert opinion about the competence of prospective participants from a physician, psychologist, or other qualified person;

2.1.1.3.10 Using repeated or staged competence assessments (such as a short cognitive screen followed by a longer instrument in case of suspicious screening scores) to determine stability or probability of participants' comprehension.

2.1.1.4 In all applications, whether or not threats to comprehension are anticipated, the PI should state in the protocol and consent documents that the participant or LAR is invited to ask questions.

2.1.1.5 If an LAR is involved, describe plans for determining who that LAR may be. This is not specified in Alabama law, but UA uses this list in descending order of priority: A legally appointed guardian, a health care proxy or person authorized to make medical decisions in conjunction with a durable power of attorney, a spouse, adult child, a parent, next of kin, or a person or agency acting in loco parentis.

2.2 Investigator Plan for Ongoing Assessment of Participant Comprehension

2.2.1 The PI and research staff will:

2.2.1.1 Observe participants to see if their behavior suggests that some aspect of the study was not understood. For example, a participant may refuse a blood drawing, saying "I didn't know you were going to do that" or refuse to allow an investigator to visit him at home although the investigator had explained this study feature.

2.2.1.2 Observe participants' level of functioning to detect deterioration or a need for referral. For example, a participant who suddenly becomes very confused as to time, place, or person should be referred for further evaluation and/or removed from the study.
2.2.1.3 Take note of participants’ questions or other evidence of problems with comprehension. Conclusions from these notes should be included in requests for continuing approval (see FORM: Continuing Review of Approved Protocols) or may justify a request for modification of the study procedures (see FORM: Modification and Closure of Approved Protocols).

2.2.1.4 Assess participants’ responses to translated documents to ascertain the adequacy of translations in the research and, if necessary, modifications to the translation.

2.3 IRB Review of Applications for Issues of Participant Comprehension

2.3.1 The IRB will review the application using FORM: IRB Checklist for Reviewers and Investigators and GUIDANCE: IRB Application Guide and determine whether the study protocol involves the use of subjects with possible cognitive impairment or other comprehension issues and deals with them adequately.

3.0 REFERENCES

3.1 The Belmont Report

3.2 45 CFR §46.116, 45 CFR §46.116(a)(7), 45 CFR §117(a), 21 CFR §50.20, 21 CFR §50.25(a) (7), 21 CFR §50.27 (a), 21 CFR 50.27 (b) (2).

4.0 RELATED SECTIONS

4.1 POLICY: Identifying and Minimizing Risk to Research Participants

4.2 POLICY: Protection of the Cognitively Impaired in Research

4.3 FORM: Decision-Making Capacity Assessment Tool

4.4 GUIDANCE: Alabama Law on Children, Minors, Consent and Other Research-Related Topics

4.5 GUIDANCE: Investigators and Legally Authorized Representatives

4.4 FORM: Checklist for IRB Reviewers and Investigators

4.5 FORM: Translator’s Declaration