1.0 POLICY

1.1 Background.

1.1.1 The principle of respect for persons and the obligation to obtain the voluntary informed consent of participants or their legally authorized representatives (LARs) are key aspects of the protection of human research participants for both investigators and IRBs.

1.1.2 Legally effective informed consent is the voluntary agreement to participate in research given by a person who is able to understand the facts of a study, appreciate the implications of the decision, and who possesses the ability to decide and to communicate a decision.

1.1.3 In the event that prospective participants are unable to provide legally effective informed consent because of age (children) or diminished capacity, permission must be provided by their parents or legally authorized representatives (LARs).

1.1.4 Participants’ assent, regardless of age, may also be necessary for participants with LARs.

1.1.5 Informed consent involves both an ongoing process and the documentation of that process. Consent process refers to explaining the study purpose, procedures, costs, risks, and benefits before prospects agree to participate; responding to prospects’ or participants’ questions; verification of prospects’ comprehension of study procedures, risks, and benefits; providing contact information for the investigator and the Director of Research Compliance in case of later questions or complaints; sharing scientific news that may affect participants’ willingness to continue in a study, and, if appropriate, providing repeated opportunities for participants to reaffirm or refuse study participation throughout the study. Consent documentation refers to securing participants’ or LARs’ signatures on a consent form before start of the study or, if appropriate, at intervals throughout a study, unless the IRB has given permission to waive or alter written documentation of consent.

1.1.6 It is UA policy that all consent documents shall be dated.

1.1.7 An IRB has the right and responsibility to observe/monitor the consent process. Reasons for observation include but are not limited to studies with high risks to participants, studies with complicated procedures or interventions, studies using...
vulnerable populations such as children or the cognitively impaired; studies with staff with minimal experience in administering consent to potential participants; complaints from research staff or research participants, previous or current investigator noncompliance with IRB, or as part of routine monitoring of research studies for quality control and investigator education.

1.1.8 The Human Research Protection Program (HRPP) may survey research participants directly to evaluate their experiences with consent process and documentation in response to participant complaints or as part of the evaluation of the HRPP and quality improvement plans.

1.1.9 This policy deals with the general nature of consent process and documentation using written consent forms. Assent, waivers, and other alterations of consent are described in other policies and documents.

1.1.10 Investigators should also consult other policies or guidance relevant to consent such as those for research with vulnerable populations, assuring participant comprehension of studies, responding to complaints about studies, and who may serve as a LAR under Alabama law. Some federal agencies or sponsors such as the Department of Defense and Department of Justice also have special requirements for consent.

1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama that investigators and research staff shall understand the difference between the consent process and consent documentation.

1.2.2 Investigators and research staff shall understand that consent is an ongoing process throughout the participants' involvement in the research and that opportunities may be needed for participants to renew or refuse their continued participation.

1.2.3 Investigators and research staff are responsible for:

1.2.3.1 Recognizing and obtaining the legally effective consent of the participants or their legally authorized representatives (LARS) and assent from child or adult participants if appropriate;

1.2.3.2 Providing study information in language that is understandable to prospective participants or their LARS;

1.2.3.3 Allowing prospective participants or their LARS sufficient time to consider whether or not to participate;

1.2.3.4 Minimizing the possibility of coercion or undue influence from the conditions of the research, such as prestige of the institution or researcher or unduly attractive incentives;

1.2.3.5 Avoiding the use of exculpatory language in oral or written study presentations or consent documents in which participants are asked to waive their rights;
1.2.3.6 Following regulatory and IRB regulations for use of either long or short forms of consent documentation;

1.2.3.7 Determining the need for and nature of additional assessments of prospective participants’ or LARS’ comprehension of the study procedures and risks;

1.2.3.8 Assessing the voluntariness of the consent whether from prospective participants or LARS.

1.2.3.9 Determining the need for providing opportunities to participants to renew or verify their willingness to continue participation;

1.2.3.10 Responding to prospective participants’ or LARS’ questions throughout the study.

1.2.3.11 Providing participants or LAR(s) with contact information for the investigator and the Director of Research Compliance on the consent document in case they have questions, complaints, or concerns about the study.

1.3 Objective.

1.3.1 Adherence to this policy will ensure that prospective research participants and their LARS are treated with respect, that every effort is made to assess prospective participants’ and LARS’ comprehension and voluntary consent, that the consent process is ongoing throughout the participants’ involvement, and that investigators follow regulatory and IRB requirements.

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, the IRB chairs and members, associate deans and directors of research, investigators and research staff, and faculty supervising student research.

2.0 PROCEDURE

2.1 In the IRB application investigators should:

2.1.1.1 Include all elements of informed consent and any of the additional elements of consent that are relevant to the research, and address special requirements of any agency or sponsor such as the Department of Defense or the Department of Justice;

2.1.1.2 Describe sample criteria that may affect prospects’ comprehension or create the need to work through LARs;

2.1.1.3 Include FORM: Application for Research with Children or FORM: Application for Research With Cognitively Impaired Persons if the sample includes such persons.
2.1.1.4 Describe any plans for specific or more detailed assessment of prospects’ or LARs’ comprehension of the study if necessary.

2.1.1.4.1 Educate the LAR about the reason for contacting him/her about this study and the responsibilities involved if he does approve the prospect’s participation in the study.

2.1.1.4.1.1 It may be necessary for the investigator to assess—or have a medical professional assess—the ability of the LAR to provide effective permission for the prospective participant to take part in the study. SEE GUIDANCE: Investigators and Legally Authorized Representatives for details about identifying, educating, and evaluating LARs.

2.1.1.5 Document the reading level or understandability of the informed consent document by use of a readability formula, previous use with comparable research participants, or results from piloting the study presentation and consent process with persons from the target population;

2.1.1.6 State whether prospects or their LARs are likely to need additional time to consider participation and if so, how much time will be allowed;

2.1.1.7 Identify any possible sources of coercion and steps taken to minimize them. The use of incentives must be explained and justified. The minimum measure to be taken is the inclusion of language in the consent form to the effect that “This study has been explained to me. I have had a chance to ask questions, and I freely agree to participate. Investigators may also state that they will ask prospects or LARS if anyone is attempting to influence them to participate or to state that they are making an independent voluntary decision to participate.

2.1.1.8 Describe what signs other than clear verbal refusals constitute dissent or unwillingness of either the prospect or the LAR to consent to the study.

2.1.1.9 Describe any need for providing prospects or their LARs with opportunities to reaffirm or refuse their consent once the study is underway. Studies involving multiple sessions, interviews over time, fatiguing or stressful activities, or a focus on highly sensitive or emotional matters may mean that participants experience changes in their circumstances or willingness to continue that should be assessed. If these conditions apply, consider a brief reorienting and reconsenting of the participant or LAR. For example, the data collector might say, “We are studying A-B-C. Last month we talked about D. Today you will be asked to talk about X/perform Y; are you willing to continue with the study?” Neither a complete re-presentation of the study or signing of another entire consent form is necessary if the approved protocol has not been changed. A sheet listing the dates of the various sessions could be provided for participants or LARs to sign or initial or extra lines for reaffirming consent can be provided on the original consent form itself. (It is UA policy that all consent forms and decisions to continue must be dated.)
2.1.1.10 State (if relevant) that new information that might affect participants’ willingness to continue will be shared with them and describe a reconsenting opportunity and documentation procedure if this should happen.

2.1.1.11 State in the consent form that participants or their LARs will be given a copy of the consent form to keep for their records, and do so.

2.1.1.12 State that prospects or their LARs will read the consent form or have it read to them before either signs it.

2.1.1.13 If the study collects data by telephone interview, describe efforts to introduce the study, screen participants, and address the eight elements of informed consent. Append the script. See Investigator Guidance: Telephone Consent for a model.

2.1.1.14 The regular (long form) informed consent should be patterned after the latest template on line for Informed Consent for a Research Study.

2.1.1.15 If a short form written consent document is used,

2.1.1.15.1 Justify the need for its use or its adequacy under the research circumstances.

2.1.1.15.2 Present the study orally to the prospects or their LARs and ask them to sign and date the short form if they consent.

2.1.1.15.3 The oral presentation must be witnessed by a third party, who signs and dates both the short form and a copy of the summary as presented to the prospects of LARs. (If the participant does not speak English, the witness must speak both English and the language of the participant.)

2.1.1.15.4 The person obtaining consent shall sign and date a copy of the summary and give a copy of the summary and the short form to the prospect, parent, or LAR.

2.2 The IRB is responsible for:

2.2.1 Reviewing the application and consent form using FORM: Checklist for IRB Reviewers and Investigators and the latest template for Informed Consent for a Research Study and for Assent, if appropriate.

2.2.2 Determining whether plans for initial and ongoing consent process and documentation are adequate and whether observation of the consent process is desirable.

2.2.3 For applications for Continuing Review or for modifications, the IRB will consider such factors as increases in risk and complaints or concerns about the study or the investigator in determining whether observation of the consent process is needed.

3.0 REFERENCES
3.1.1 45 CFR 46.109(b), (e); 45 CFR 46, 111 (a) (4); 45 CFR §46.116, 45 CFR §46.116(a)(7), 45 CFR §117

3.1.2 OHRP Guidance on Exculpatory Language in Informed Consent; OHRP Guidance on Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English

3.1.3 21 CFR §50.20, 21 CFR §50.25(a) (7), 21 CFR §50.27 (a), 21 CFR 50.27 (b) (2); 21 CFR 56.109(b)(f); 21 CFR 56.111 (a)(5).


3.1.5 DoD: DoDD 3216.2, para.5.3.4; SECNAVINST 3900.39D, para.6a(5)

3.1.6 DOJ: 28 CFR 512.16

4.0 RELATED SECTIONS

4.1 POLICY: Investigator Assurance of Participant Comprehension

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

4.3 GUIDANCE: Template: Informed Consent for a Research Study

4.4 GUIDANCE: A Pediatric Research “Assent” Decision Matrix

4.5 GUIDANCE: Examples of Assent Forms

4.6 GUIDANCE: Model Telephone Consent

4.7 FORM: Checklist for IRB Reviewers and Investigators

4.8 FORM: Application for Research with Cognitively Impaired Persons

4.9 FORM: Application for Research With Children

4.10 GUIDANCE: Investigators and Legally Authorized Representatives