$1.0 \text{ POLICY}$

1.1 Background

1.1.1 Informed Consent is a person’s voluntary agreement, based on adequate knowledge and understanding, to participate in human subjects research or to undergo a medical procedure. See 21 CFR §50.20, §50.25 for detailed description.

1.1.2 The IRB may waive or alter the consent process by determining that the criteria for waivers or alterations are met.

- When following FDA regulations, waivers or alterations follow FDA regulations.
- When following both DHHS and FDA regulations, waivers or alterations are consistent with both regulations.

**Criteria for waiver or alteration of consent procedures under DHHS and FDA regulations are the following:**

1.1.2.1 The research involves no more than minimal risk to the subjects. (“Minimal risk” means that the likelihood or magnitude of harm/discomfort is not greater than what subjects would ordinarily encounter in daily life or during routine clinical care.)

1.1.2.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects.

1.1.2.3 The research could not practicably be carried out without the waiver or alteration of informed consent.

1.1.2.4 When appropriate, the subjects will be provided with additional pertinent information after participation (for example, in research involving deception or concealment. (This may not be needed in other studies involving waiver or alteration of consent or may not be possible if the data were collected without identifiers and the identity of the subjects is unknown.)
1.1.3 The IRB is allowed to waive the requirement to document the consent process by determining that the regulatory criteria for waivers are met.

1.1.3.1 When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants.

1.1.3.2 When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers requiring the investigator to provide participants with a written statement regarding the research.

1.1.4 The IRB is allowed to waive parental permission by determining that the criteria for waivers or alterations are met.

1.1.5 The IRB documents its findings justifying the waiver or alteration.

1.1.6 Investigators are responsible for knowing and following rules about waivers or alterations of consent and its documentation by other federal departments such as the Department of Defense and Department of Education.

1.1.7 **Options available for investigators covered by this policy are (a) waiver of informed consent from the prospective participant or a parent, (b) a waiver of written documentation of informed consent, (c) use of a short form of consent document, and, (4) in research using deception, alteration of the consent process using a consent document that does not fully disclose the nature of the research.**

1.1.7.1 Such terms as “passive consent”, “deferred consent”, or “implied consent” all refer to consent processes that do not follow one or more of the requirements for the consent process. Therefore, each of these cases represents a waiver or an alteration of the consent process. Research proposing these procedures cannot be conducted until the IRB approves a waiver or alteration of the consent process.

1.1.8 This policy does not apply to waivers for release of Protected Health Information (PHI). See POLICY: Protection of Human Research Participants’ Privacy and Confidentiality.

1.1.9 Waiver of Consent Process/Parental Permission for Public Demonstration Project

1.1.9.1 The research is conducted by or subject to the approval of state or local government officials.

1.1.9.2 The research or demonstration protocol is designed to study, evaluate, or otherwise examine:

1.1.9.2.1 Public benefit or service programs.

1.1.9.2.2 Procedures for obtaining benefits or services under those programs.

1.1.9.2.3 Possible changes in or alternatives to those programs or procedures.
1.1.9.2.4 Possible changes in methods or levels of payment for benefits or services under those programs.

1.1.9.3 The research cannot be practicably carried out without the waiver or alteration

1.1.9.4 The research is not FDA-regulated.

1.1.8 Waiver of Consent Process When Permission Is Not a Reasonable Requirement

1.1.8.1 The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants.

1.1.8.2 An appropriate mechanism for protecting the children who will participate as participants in the research is substituted.

1.1.8.3 The research is not FDA-regulated.

1.1.9 Waiver of Documentation of the Consent Process – Based on Harm

1.1.9.1 The only record linking the participant and the research is the consent document.

1.1.9.2 The principal risk is potential harm resulting from a breach of confidentiality.

1.1.9.3 Each participant will be asked whether he or she wants documentation linking the participant with the research, and the participant’s wishes will govern.

1.1.9.4 The research is not FDA-regulated.

1.1.10 Waiver of Documentation of the Consent Process – Based on Minimal Risk

1.1.10.1 The research presents no more than minimal risk of harm to participants.

1.1.10.2 The research involves no procedures for which written documentation of the consent process is normally required outside of the research context.
1.2 Policy Statement

1.2.1 It is the policy of the UA IRB that all requests for waiver or alteration of the informed consent process or consent documentation must undergo appropriate IRB review, and when waivers or alterations are granted, they are given based on DHHS regulatory criteria at 45 CFR §46.111(a) (4) and (5), and 45 CFR §46.116(a) to (e), 45 CFR §46.117(a) to (c).

1.2.1.1 The research must be of no more than minimal risk to participants,

1.2.1.2 The waiver or alteration will not adversely affect the rights and welfare of the participants;

1.2.1.3 The research could not be practicably be carried out without waiver or alteration (NOTE: This is commonly the most difficult criterion to justify.);

1.2.1.4 Whenever appropriate the participants will be provided with additional pertinent information after participation (45 CFR 46.116(d)).

1.2.2 The IRB, for some or all participants, may waive the requirement that the participant or the participant’s legally authorized representative sign a written consent document per 45 CFR §46.117(c) if it finds that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or involves no procedures for which written consent is normally required outside of the research context.

1.2.3 Investigators funded by other federal units (e.g., Department of Education, Department of Defense) must be aware of and conform to special consent requirements of those departments. SEE GUIDANCE: Family Educational Rights And Privacy Act (FERPA), GUIDANCE: Legislation on School-Based Surveys and Passive Consent: “No Child Left Behind” (Public Law 107-110), and GUIDANCE: Department of Defense Regulations for Human Subjects Research.

1.3 Objective

1.3.1 Implementation of this policy will enable the IRBs to ensure protection of human research participants’ rights to give informed consent and to comply with federal regulations on informed consent.

1.4 Responsibility

1.4.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties are the Director of Research Compliance (DRC), Research Compliance Specialists (RCS), IRB chairs and members, and principal investigators.

2.0 PROCEDURE

2.1 Applications Requesting Waiver of Informed Consent
2.1.1 Investigators state in their applications that they are requesting a waiver of informed consent.

2.1.1.1 A common local reason for this request is when investigators wish to waive consent from parents of UA students less than 18 years of age.

2.1.2 Investigators fill out FORM: Request for Waiver/Alteration of Informed Consent, justifying the request by addressing each criterion for waiver, and attach it to the application. (NOTE: All forms are available on the Office for Research Compliance website.)

2.1.3 Investigators describe their procedures for obtaining participants without obtaining consent.

2.2 Applications Requesting **Waiver of WRITTEN Informed Consent**

2.2.1 Investigators state in their applications that they are requesting a waiver of written informed consent.

2.2.1.1 This is appropriate when the consent document would be the only record linking the subject and the research and the chief risk would be potential harm resulting from a breach of confidentiality or in mailed survey research when return of a completed questionnaire is obvious evidence of consent to participate.

2.2.1.2 Investigators fill out FORM: Request for Waiver of Written Documentation of Informed Consent, justifying the request by describing how each criterion for this waiver is met.

2.2.1.3 Investigators describe procedure for obtaining participants without use of written informed consent. The IRB expects to see some means of providing information about the study to prospective participants such as an information sheet or a consent document similar to that to be used if written were being obtained, and in the case of mailed or internet surveys, a statement to the effect that "Return of the completed questionnaire will be taken as evidence of your informed consent to participate."

2.2.1.3.1 The IRB reviews a written description of the information that will be provided to participants.

2.2.1.3.2 Even in cases where the IRB approves the request to waive written consent, participants have the right to request written documentation of consent. The information sheet or sample consent document can serve this purpose.

2.3 Applications Requesting **Alteration of Informed Consent**

2.3.1 Applications using deception or concealment:

2.3.1.1 Investigators state in their applications that they are using deception or concealment and are requesting an alteration in the informed consent procedure and/or content. See GUIDANCE: Use of Deception/Concealment in Research.

2.3.1.2 Investigators complete FORM: Request for Waiver/Alteration of Informed Consent and attach it to the application.

2.3.1.3 Investigators describe alterations in the consent procedure and/or content in the procedure section of the application and plans for debriefing of participants.

2.3.2 Applications requesting use of a short form of consent:
2.3.2.1 Investigators state in their applications that they wish to use the short form of a consent document.

2.3.2.2 Investigators complete FORM: Request for Waiver/Alteration of Informed Consent and attach it to the application.

2.3.2.3 Investigators provide a justification of the use and adequacy of a short form consent document under the research circumstances and attach copies of the information sheet and the short consent document to be used. These documents must be written in appropriate language and reading level for the participants.

2.3.2.4 Investigators describe how they will present the study orally and in writing (an information sheet) to prospective participants and obtain the needed signatures.

2.3.2.5 The prospect must sign and date the short consent form if s/he consents.

2.3.2.6 A third party must witness the oral consent procedure and must sign and date both the short consent form and the information sheet. If the prospect does not speak English, the third party must speak both English and the language of the participant.

2.3.2.7 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.

3.0 REFERENCES

3.1 DHHS: 45 CFR §46.116(a) to (e); 45 CFR §46.117(a) to (c); OHRP Guidance on Informed Consent—Legally Effective and Prospectively Obtained

3.2 FDA: 21 CFR 56.109(c) (1) 21 CFR 56.109 (d)

3.3 DoD: DoD Directive 3216.2 E2.1.1,10 USC 980 (a,b)

3.4 ED: 343 CFR 99

4.0 RELATED SECTIONS

4.1 FORM: Request for Waiver/Alteration of Informed Consent

4.2 FORM: Request for Waiver of Written Documentation of Informed Consent

4.3 GUIDANCE: Use of Deception/Concealment in Research

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

4.5 GUIDANCE: Family Educational Rights and Privacy Act (FERPA)

4.6 GUIDANCE: Legislation on School-Based Surveys and Passive Consent: No Child Left Behind (Public Law 107-110)

4.7 GUIDANCE: Department of Defense Regulations for Human Participants Research

4.8 POLICY: Protection of Human Research Participants’ Privacy and Confidentiality