SOP 703: WAIVER OR ALTERATION OF CONSENT

PURPOSE

The University of Utah Institutional Review Board (IRB) may waive the regulatory requirement to obtain consent or may approve a consent procedure that alters elements of informed consent. This SOP outlines how the University of Utah IRB determines that a waiver or alteration of consent is granted.

SCOPE

This policy applies to non-exempt human subject research conducted at the University of Utah. This policy applies to consent and parental permission, as described. This policy does not describe the waiver of informed consent for planned emergency research or exceptions from informed consent (see SOP 506: Emergency Use of a Test Article and Planned Emergency Use).

POLICY

The University of Utah IRB may approve a consent procedure that does not include, or which alters, some or all the elements of informed consent (see SOP 701: General Requirements of Informed Consent) if the IRB finds and documents that the research meets specific criteria outlined in 45 CFR 46.116(f).

The waiver or alteration of consent for public benefit or service programs is generally not used at the University of Utah. However, the IRB may waive the requirement to obtain informed consent if it meets the specific criteria outlined in 45 CFR 46.116(e).

The University of Utah IRB does not utilize the option for broad consent.

The University of Utah IRB requires that investigators submit a request for alteration of consent for research involving deception in addition to an informed consent document.

If the University of Utah IRB determines that a research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and provided that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

In general, no Department of Defense department may conduct or use appropriated funds to support research involving a human being as an experimental subject[1] without the prior informed consent of the

[1] An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject's environment, the withholding of an intervention that would have been

subject. However, a waiver of consent may be granted for research involving a human being as an experimental subject if a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering. If the research participant does not meet the definition of an "experimental subject", the IRB may waive the consent process as described in this policy.

PROCEDURES

1. Waiver or Alteration of Informed Consent

1.1. Investigators may request that the IRB waive informed consent or alter elements of informed consent by completing the appropriate request(s) in the IRB application in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA). The investigator provides protocol-specific justification for the waiver or alteration of consent.

1.2. The convened IRB or a designated IRB reviewer (for studies reviewed using the expedited procedure) reviews this information and concurs or requires changes and/or clarification before final approval. The reviewer checklist is used to determine and document whether the waiver can be granted. Alternatively, determinations may be documented in IRB meeting minutes.

1.3. Research which involves deception or is designed in such a way that providing a complete disclosure of information during the consent process will invalidate the study, requires an informed consent document and a request for an alteration of informed consent. The investigator must complete the appropriate section of the IRB application in ERICA and must meet the criteria for waiver or alteration of informed consent. The IRB may require a debriefing or disclosure of the missing consent information after the participant has completed the study.

undertaken if not for the research purpose. This does not include: (1) Activities carried out for purposes of diagnosis, treatment, or prevention of injury and disease in members of the armed Forces and other mission essential personnel under Force Health Protection programs of the Department of Defense. (2) Authorized health and medical activities as part of the reasonable practice of medicine or other health professions. (3) Monitoring for compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units. This includes such activities as drug testing, occupational health and safety monitoring, and security clearance reviews. *(Department of Defense Directive 3216.02 section E2.1.3.)*

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.