



SOP 703: WAIVER OR ALTERATION OF CONSENT

POLICY

The University of Utah IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (see SOP 701) if the IRB finds and documents that the research meets specific criteria. **Please note that this policy does not describe the waiver of informed consent for planned emergency research or exceptions from informed consent (see SOP 506).**

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

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

In addition to the requirements outlined in this policy, if the 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 (i.e. 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 component may conduct or use appropriated funds to support research involving a human being as an experimental subject¹ without the prior informed consent of the 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 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 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.



- 1.1. The investigator requests that the IRB waive or alter some or all of the elements of informed consent by completing the appropriate request(s) in the IRB application (within the ERICA system). The Investigator provides protocol-specific justification for the waiver or alteration of consent.
- 1.2. The convened IRB or a designated IRB reviewer using the expedited procedure reviews this information and concurs or requires changes and/or clarification before final approval. The IRB or designated IRB reviewer uses the appropriate Reviewer Checklist 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 complete information during the consent process will invalidate the study, requires an informed consent document and a request for a Waiver or Alteration of Informed Consent. The investigator must complete the appropriate section of the IRB application within the ERICA system and must meet the criteria for waiver or alteration of informed consent.

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