



TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™
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Office of Research

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Regulatory Lite



A hint of research compliance tips for your everyday life

Informed Consent: To document or not, that is the question?

Informed consent is a major component of conducting human subject research. The process of conducting informed consent, along with each of its components has evolved over the progression of time in order to prevent historical atrocities from repeating themselves. Why then do waivers of documentation of informed consent and waivers of informed consent exist in research?

First, note that per the FDA and the DHHS obtaining a subject's signature is *only part* of the whole consent process. To clarify:

Documentation of Informed Consent:

- According to HHS (45CFR46.117) and FDA (21CFR50.27(a)) - "Informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form."
- *Documentation of informed consent is normally seen in greater than minimal risk research. This research may include drugs, devices, biologics, interventions or more.*

Waiver or alteration of the requirements for obtaining informed consent from adult subjects can occur under any of the following:

- HHS (45CFR46.116(f))
 - The research could not practicably be carried out without the waiver or alteration;
 - The research involves no more than minimal risk to the subjects;
 - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
 - The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
 - Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- FDA (21CFR50.24) Exception from informed consent requirements for emergency research

Waiver of Documentation of Informed Consent:

- According to HHS (45CFR46.117(c)(1)(i,ii,or iii)) and FDA (21CFR56.109(d)) - "In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research."
- *The waiver of documentation of informed consent can be seen in studies that are deemed minimal risk and may be exempt. These studies still require that the elements of informed consent be reviewed verbally with the subject or the subject's legally authorized representative. The researcher may even be asked to provide subjects with a written statement regarding the clinical investigation. In addition, the FDA recommends that when an IRB waives the documentation requirement for informed consent, the consent process and discussion be described and noted in the records relating to the clinical investigation.*

For more information on these items and more you can submit questions to the [Research Compliance Unit](#).