

Guidance- Food and Drug Administration (FDA) Requirements

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- x **Human Subject** an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Additionally, FDA definitions per 21CFR 312.62 apply to all clinical investigations **with** subject(s). The PI should consider these definitions during the development of the protocol (if applicable) and during the conduct of the clinical investigation, and educate all research **staff** of these definitions. These definitions will be considered by UNLV official and the IRB **over**seeing and/or reviewing clinical investigation.

Requirements/Best Practices

Policies and procedures describe the reporting of serious or continuing **non**compliance to FDA (SOP 11.02 Researcher Noncompliance Investigation Reporting and Corrective Action)

Consent

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P5.10.001 Tc -0.001 Tw 0.31563Td [(c)577,8 (t)19.5)1.8 (a)4.7 (i)1.7 (i)1.7

Emergency Use

Under FDA regulations, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant, and the FDA may require data from an emergency use to be reported in a marketing application.

In order to use a test article in a life-threatening situation without prior IRB or EC review, the following criteria must be met:

- x The participant is in a life-threatening or severely debilitating situation.
- x No standard acceptable treatment is available
- x There is not sufficient time to obtain IRB or EC approval.
- x The use is reported to the IRB

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- The Researcher will give either the participant or the legally authorized representative adequate opportunity to read the consent document before signing it.
- For the use of the short form of consent documentation
 - f The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant's legally authorized representative.
 - f A written summary embodies the basic and required additional elements of disclosure.
 - f There will be a witness to the oral presentation.
 - f For participants who do not speak English, the witness is conversant in both English and the language of the participant.
 - f The participant or the participant's legally authorized representative will sign the consent document.
 - f The witness will sign both the short form and a copy of the summary.
 - f The person actually obtaining consent will sign a copy of the summary.
 - f A copy of the signed short form will be given to the participant or the legal authorized representative.
 - f A copy of the signed summary will be given to the participant or the legally authorized representative.
- With regard to data retention when participants withdraw from a clinical trial
 - f When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of data removed.
 - f A Researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between related interventions (and their associated risks) and the information, such as medical course or laboratory results obtained through a chart review.

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- When granting waivers of the requirement to obtain written documentation of the consent process, the IRB will consider requiring the Researcher to provide participants with a written statement regarding the research.

Research Involving Children

- x The IRB or EC follow the requirements specified in Subpart D for research involving children.
- x When research involves children, the IRB follows the requirements in Subpart D pertaining to obtaining assent of children and permission of the parents or guardian.
- x For research that

Resources

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