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Subject: Informed Consent Process Selections for Human Subject Research
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Dear Research Community,

The principal investigator of each study utilizing human subjects has the responsibility for developing and overseeing informed consent procedures consistent with federal regulations and institutional requirements. More than one method may apply depending on the research procedures involved.

Informed consent is the process of telling potential research participants about the key elements of a research study and what their participation will involve. Consent is typically documented by obtaining a signature from the participants. However, if certain criteria are met, the study team has the option to request for alterations of the consent process. Please note that regardless of the method of consent, all approval criteria for the consent process must be met.

Documented Consent-

The consent templates contain key information, the eight required elements, and additional elements of informed consent as required by the DHHS and the FDA, and additional IRB requirements for TTUHSC El Paso research involving human subjects. Legal documentation of informed consent requires participants or their legally authorized representative's signature and date on the IRB approved consent document. To be accepted as a valid informed consent, the document must also be signed and dated by IRB approved research personnel who conducted the informed consent discussion. The consent form should be written in simple non-scientific language and as close to a 7th grade reading level as possible. A copy of the signed and dated consent form is to be provided to each subject.

Waiver or alteration of consent (in the case of a waiver, the participant is not aware that he/she is participating in a research study)-

A waiver means no consent is required. An alteration is a consent in which some of the elements of full regulatory consent are altered. This waiver applies in special circumstances when the IRB determines that it is not necessary to obtain the participants' consent to conduct the research. The IRB may approve research where investigators leave out or alter elements of informed consent, provided the research meets all applicable regulations. This method is sometimes used when the research methodology involves deception. The IRB must determine that the use of deception does not violate the rights or welfare of subjects. This is sometimes requested in planned research in an emergency setting where there is more than minimal risk to participants, provided there is a prospect of direct benefit to participants and a number of other conditions are met.

Waiver of documentation of consent (participant is aware that he/she is participating in a research study).

Potential participants, or the parents of children who are potential participants, are presented (either verbally or in writing) with the same information required in a written consent document (required elements of consent), but documentation of the process (signing of the consent form) has been waived by the IRB. This process is often used in minimal risk research involving the administration of surveys (in person, online, or mailed), interviews (in person, online, or mailed), or

when anonymous sensitive information is collected and there is a desire to not have written documentation that links the participant to the research study. An introductory paragraph or information sheet may be used with this type of request and will depend on the type of research being conducted.

For additional information, as well as informed consent templates/information sheet, please review the [IRB Website](#).

Thank you,

TTUHSC El Paso Institutional Review Board