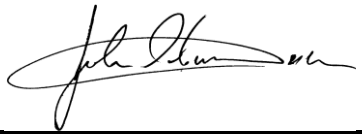
KESSLER FOUNDATION

Policies and Procedures Manual
IRB

SUBJECT: Obtaining Informed Consent from Human Subjects	**POLICY # 5035**
APPROVED: **Richard J. Greene, M.D., Ph.D.** **IRB Chair**  **John DeLuca, Ph.D.** **Senior Vice President for Research** 	**EFFECTIVE DATE:** **March 29, 2006** **REVISED DATE:** **April 10, 2014**

PURPOSE

To promulgate procedures for obtaining informed consent from all human research subjects from whom informed consent is mandated by Federal Regulations (45 CFR 46.116 and 46.117)

POLICY

It is the policy of the Kessler Foundation that no one may involve a human being as a participant in research or in a clinical investigation unless the investigator has obtained IRB approval and, when required by the IRB, that person's legally effective informed consent. The Kessler Foundation Research Center IRB may alter or waive the requirement of informed consent under the Department of Health and Human Services (DHHS) regulations governing human subject research [46.116(c)], but may not waive consent for studies regulated by the Food and Drug Administration (FDA) unless the subject is in a life-threatening condition and criteria under 21 CFR 50.23 or 50.24 are met. If the participant is an adult who is unable to consent for him/herself, the investigator must describe the process of evaluation the individual's capacity to provide consent, and if that capacity is lacking in a subject, must obtain informed consent from a legally authorized representative in accordance with state law. If the participant is a minor, the investigator must describe the consent/assent process in accordance with Federal and state law.

PROCEDURE

The Kessler Foundation IRB must judge the information to be presented to a potential participant in a written or oral form to be understandable to the participant or the participant's legally authorized representative. The consent form should be written at or below the level of 8th grade English. The informed consent may not include any language which waives, or appears to waive, any of the participant's legal rights, or release or appears to release the parties to the research from liability or negligence.

1. Informed Consent Documentation

   The content of the written information provided to the potential participant must include the elements outlined in 45 CFR 46.116(a) and, if subject to FDA regulations, 21 CFR 50.25(a), and when appropriate, the additional elements provided in 45 CFR 46.116(b) and 21 CFR 50.25 (b). The IRB will review all documents that are part of the informed consent process. If a standard informed consent document is used, the IRB requires use of the standard template language in consent forms (see attachment). The standard template language includes:

   - The purpose of the research study
   - The duration of the study
   - The procedures to be performed in the study
   - The number of participants in the study
   - Inclusion criteria
   - Exclusion criteria
   - A description of any risks and discomforts to the participants
   - A description of benefits, if any, to the participants
   - Alternatives to participating in the study
   - How new findings of the study will be communicated to participants
   - A statement about the confidentiality of study records
   - Financial costs to participants
   - Payment, if any, to participants
   - How and if medical therapy will be provided an paid for study-related injuries
   - Participants right to refuse or withdraw from the study
   - Individuals to contact concerning the study procedures

Changes proposed to the template language must be approved by the IRB. The informed consent document approved by the IRB will contain an expiration date noted prominently on the form. Only copies of IRB approved documents may be presented to participants.

2. Short Form Documentation of Informed Consent

   The Federal regulations under 45 CFR 46.117(b)(2) and 21 CFR 50.27 (b)(2) permit the use of a short form consent document stating that the required informed consent elements have been presented orally to the subject or the subject's legally authorized representative, with a witness present. For short form consent the investigator must prepare:

- A written short form consent document
- A written summary of what is to be said to the participant or the representative following the standard consent template
- The IRB must approve both the consent form and the summary
- There must be a witness to the oral presentation. For participants who do not speak English, the witness should be fluent in both English and the language of the participant.
- The participant or the participant's legally authorized representative must sign and date the consent form
- The witness must sign and date both the consent form and the summary
- The person actually obtaining consent must sign and date the summary
- The person obtaining consent must give to the participant or the representative a copy of the consent form and a copy of the summary

3. Waiver or Alteration of Informed Consent or Documentation of Informed Consent

   The IRB may approve a waiver or alteration for the consent procedure, or waive the requirement to obtain informed consent, if the IRB makes all of the following determinations, below, and documents them with protocol specific findings which justify those determinations:

   - The research involves no more than minimal risk to the subjects
   - The waiver or alteration will not adversely affect the rights and welfare of the subjects
   - The research could not practicably be carried out without the waiver or alteration
   - Whenever appropriate, the subjects will be provided with additional pertinent information after participation
   - The research is not subject to FDA regulation