University of Kentucky

DOCUMENTATION OF INFORMED CONSENT
Based on 45 CFR PART 46.117

I. Informed consent will be documented using:

A. A written form approved by the IRB

   1. University of Kentucky’s (UK) IRBs provide an “IRB Approval” stamp containing approval dates which identifies the currently approved consent/assent document;

   2. Subjects can only be enrolled using consent/assent forms which have a valid “IRB Approval” stamp unless special waiver has been obtained from the IRB.

B. Signatures from appropriate individuals - UK signature requirements for informed consent include:

   1. Subject signature or his/her legal representative signature and date informed consent is obtained;

   2. Name of the person explaining the study to the subject (this individual should be listed as study personnel with the approved protocol), and

   3. If applicable, signature of the Investigator.

II. A copy of the signed consent document must be given to the person signing the form.

III. UK’s IRBs have adapted a standardized informed consent format which includes all of the federally mandated elements of informed consent. This format is described in the “Instructions for Documentation of Informed Consent” and laid out in the consent form template available as “Form C” in the IRB Application [http://www.research.uky.edu/ori/human/HumanResearchForms.htm].

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- For additional information or handouts, please contact the Office of Research Integrity at (859) 257-9428.