Attachment A10

Penn Med Letter About Type of Consent

NIDA's STUDY OF SUBSTANCE ABUSE DOC.COM MODULE PROJECT

April 2011

Penn
University of Pennsylvania

Office of Regulatory Affairs

March 25, 2011

Elisabeth Davis, MPH
Project Officer
Office of Science Policy and Communications
National Institute on Drug Abuse
Email: davise2@nida.nih.gov
Phone: 301-594-6317

Re: Protocol 812983 - Evaluation of NIDA Substance Abuse doc.com Module

Dear Ms. Davis:

Under the regulations at 45 CFR 46.117(c)(2), an IRB may waive the requirement for the investigator to obtain a signed consent form when the IRB determines that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The purpose of the proposed study is to evaluate the efficacy of a novel online educational tool. The basic hypothesis to be tested is that health care providers (resident physicians or medical students) who complete this educational module will have more knowledge of about substance use disorders, more positive attitudes towards patients with substance use disorders, and more confidence in their communication skills with patients with substance use disorders compared with a group of health care providers who do not complete the module.

The IRB determined that this study does not pose more than minimal risks to the health care providers participating in the study and the IRB also determined that this study is eligible for a waiver of documentation of informed consent under 46 CFR 47.117.

In cases in which the documentation requirement is waived, 45 CFR 46.117 also states that the IRB may require the investigator to provide subjects with a written statement regarding the research. We think that a written statement is appropriate for this study. A consent form without a signature line may serve as the written statement regarding the research. The IRB will need to review and approve the written statement prior to approval.

I am available by telephone or e-mail if you have additional questions about the regulatory requirements for a waiver of document provisions of the regulations or the Penn IRB's practices and policies regarding waivers. My e-mail address is yhiggins@upenn.edu. My cell phone number is 215-520-1121.

Respectfully,

Yvonne K. Higgins, CIP