

Attachment A8

Penn Med and DUCOM IRB Letter

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

April 2011

University of Pennsylvania (Institution A)
Federalwide Assurance Number: FWA00004028
IRB Registration Number(s): IRB00000041

Office: University of Pennsylvania, Office of Regulatory Affairs
Address: 3624 Market Street, Suite 301 South
City, State Zip: Philadelphia, PA 19104-6006
Phone: 215-573-1206
Fax: 215-573-9438

Drexel University (Institution B):
Federalwide Assurance Number: FWA00001852
IRB Registration Number(s): IRB0000696

Office: Drexel University College, Office of Regulatory Compliance
Address: 3 Parkway Building - 1601 Cherry Street, Suite 10444
City, State Zip: Philadelphia, PA 19102-1192
Phone: 215-255-7858
Fax: 215-255-7874

The Officials signing below agree that Drexel University (Institution A) may rely on the designated IRB of the University of Pennsylvania (Institution B) for review and continuing oversight of its human subjects research described below:


This agreement is limited to the following specific protocol:

Name of Research Project: Evaluation of NIDA Substance Abuse doc.com Module
Name of Principal Investigator, University of Pennsylvania: Paul N. Lanken, MD
Name of Principal Investigator, Drexel University: Barbara A. Schindler, MD
IRB Protocol #: 812983
Sponsor or Funding Agency: National Institutes of Health
Award Number, if any: HHSN271200900021C

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA.

*This document must be kept on file by both parties and provided to OHRP upon request.

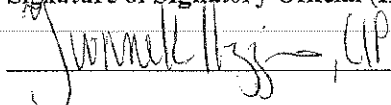
NOTIFICATION REQUIREMENTS

 University of Pennsylvania • Institutional Review Board
IRB Authorization Form

(Institution B) Drexel University shall promptly disclose to the University of Pennsylvania all material information pertinent to the terms of this Agreement and the obligations of the disclosing party hereunder. Without limiting the generality of the foregoing, (Institution B) Drexel University shall agree to notify the University of all communications to and from the FDA, Office of Human Research Protection (OHRP) and other applicable federal and state regulatory agencies regarding the research activities to which this Agreement applies and related IRB matters, including communication concerning investigators who have research activities governed by this agreement. Institution further agrees to notify the other when forwarding notification letters described below relating to research activities to which this Agreement applies:

1. any unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with 45 CFR Part 46 or University policies and procedures governing human research protections;
3. any suspension or terminations of the research by the sponsor; and,
4. any reports that require forwarding to OHRP, FDA or any Department or Agency head.

Signature of Signatory Official (Institution/Organization A):

 Yvonne K. Higgins, CIP

Date:

7 March 2011

Print Full Name: Yvonne K. Higgins, CIP

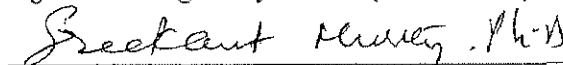
Institutional Title: Executive Director, Human Research Protections

Address: University of Pennsylvania, 3624 Market Street, Suite 301 S, Philadelphia, PA 19104

Email: yhiggins@upenn.edu

Phone number: 215-573-1206

Signature of Signatory Official (Institution B):

 Sreekant Murthy, Ph.D.

Date:

3/4/2011

Print Full Name: Sreekant Murthy, Ph.D.

Institutional Title: Vice Provost for Research Compliance

Address: 3 Parkway - 1601 Cherry Street, Suite 10444, Philadelphia, PA 19102

Email: sm53drexel.edu

Phone number: 215-255-7858