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 Regultory 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 <u>Drexel University (Institution A)</u> may rely on the designated IRB of the <u>University of Pennsylvania (Institution B)</u> 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

(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.

Signa	ture of Sign:	atory Official	(Institution/O	rganization A):	بسر			
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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

Date: 3/4/2011

Email: yhiggins@upenn.edu Phone number: 215-573-1206

Signature of Signatory Official (Institution B):

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

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