Attachment A11

DUCOM Letter About Type of Consent

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

April 2011

DREXEL UNIVERSITY COLLEGE OF MEDICINE

Office of Regulatory Research Compliance

APPROVAL NOTICE WITHOUT CONSENT

TO: Barbara A. Schindler , M.D.
SOM Faculty Group Practice / Total Psychiatry
Mailstop: QL

FROM: Frank Linnehan

Francis Linnehan , Ph.D. , Chair
Institutional Review Board (IRB #3)
Drexel University College of Medicine
1601 Cherry Street, Suite 10444, 3-Parkway, Philadelphia, Pa 19102
Tel: 215-255-7864 Fax: 215-255-7874

SUBJECT: Evaluation of NIDA Substance Abuse doc.com Module
SPONSOR: Internal
PROJECT No: 1044381, PROTOCOL No: 19630 , ACTION No: 57291 Type: New Period: 1 Seq: 1 , DETAIL No: 273524
CURRENT APPROVAL PERIOD: 03/31/2011, EXPIRES: 03/29/2012

RE: 03/31/11 – According to 45 CRF 46.110, this study is Approved Expedited Category 7.

Please Note: The Drexel University IRB has a reliance on the IRB of the University of Pennsylvania. The protocol has been approved by University of Pennsylvania IRB, along with the consent form to be used. All continuing reviews should be handled by University of Pennsylvania with copies of all correspondence being submitted to Drexel University.

Date: 4/6/2011

On behalf of the Committee, I am pleased to inform you that the subject protocol has been reviewed and approved for the period indicated above. We operate under many Government requirements. As a result, this approval is granted with the following understandings:

1. If this is a sponsored project, then the study may not be activated until the Contract is fully executed by the Clinical Research Group. If this is not a sponsored study (designated "internal"), the costs of the project must be identified and a cost center designated. Please call 215-255-7857 if you have any questions regarding these procedures.

2. You must advise the IRB of the activation date. "Activation" for the purposes of this notice is the enrollment of the first human subject or the performance of the first experimental procedure on or after the above approval date. Please use the ACTIVATION NOTICE for this purpose.
3. Any change to the protocol must be submitted in writing and approved by the IRB in advance.
4. Any adverse reaction must be reported to the IRB as soon as it occurs.
5. Should the IRB decide to monitor your project directly, please cooperate fully. Failure to do so may result in withdrawal of this approval and notification to the sponsor and/or Federal agencies. Specific information regarding monitoring appears in **GUIDELINES FOR BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN SUBJECTS**, and **GUIDELINES FOR NON-MEDICAL** obtainable through this office or the website http://research.drexel.edu.
6. Whether or not this protocol is activated, the IRB will conduct Continuing Review at least annually. Should you fail to respond to this Federally-required continuing review and progress report, the project may become ineligible for re-approval and the IRB may choose not to consider other projects for approval.
7. A final progress report must be submitted to the IRB in format similar to that of a periodic report.

The IRB welcomes your research project into the list of approved protocols. Your compliance with the above conditions will help to protect the continuation of all research activity at the University. With your project and others like it, we look forward to additions to knowledge of human health and benefits to science, our patients, and society.

cc: IRB Chair, Dept Chair, Tenet, Drexel

MEMORANDUM
Institutional Review Board (IRB #3)

ACTIVATION NOTICE

TO: Institutional Review Board (IRB #3)
1601 Cherry Street, Suite 10444, 3-Parkway, Philadelphia, Pa 19102
Tel: 215-255-7864 Fax: 215-255-7874

FROM: Barbara A. Schindler , M.D.
SOM Faculty Group Practice / Total Psychiatry

SUBJECT: ACTIVATION OF HUMAN RESEARCH PROTOCOL ENTITLED:
Evaluation of NIDA Substance Abuse doc.com Module
PROJECT No: 1044381, PROTOCOL No: 19630, ACTION No: 57291 Type: New Period: 1 Seq: 1 , DETAIL No: 273524
DATE OF APPROVAL: 03/31/2011, EXPIRES: 03/29/2012

Date: 4/6/2011

This is to inform the IRB that the subject protocol was activated* on __/__/____. I understand that a Periodic Report for Continuing Review or Final Summary is due on or before the above Expiration Date.

[ ] Yes
[ ] No

I have a copy of the University's Human Subjects Guidelines and Federal Wide Assurance (FWA) to the OHRP, as required in 45 CFR Part 46.

NOTE:
The University Guidelines for Biomedical and Behavioral Research for the protection of human subjects have been posted on the Office of Research website.
There are two sets of Guidelines - one each for Medical and Non-Medical Research.
You must have a hard copy and read these Guidelines to make sure that these Guidlines are met.
To download a copy of the University Guidlines, follow the below instructions:

1. Go to http://research.drexel.edu
2. Click "Medical IRB" or "Non-Medical IRB" in Quick Links
3. Under "Go to", click "Medical IRB" or "Non-Medical IRB Guidelines"
4. Please keep a copy of the University Guidelines in your office.

(Signed) Schindler, Barbara A.

* "Activated" means that the first new human subject was accrued, or an experimental procedure was performed, or records were reviewed under this protocol on or after the date of last approval: 03/31/2011.
Accordingly, this notice must be sent to the IRB ONLY for the FIRST such accrual since that date.