Attachment A9

IRB Approval
(including all informed consent forms for medical students and residents)

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

April 2011

University of Pennsylvania
Office of Regulatory Affairs
Yvonne Higgins, Executive Director Human Research Protections
Emma Meagher, MD, IRB Executive Chair
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

30-Mar-2011

Paul N Lanken
HUP
3400 Spruce St
Philadelphia, PA 19104-4283
Paul.lanken@uphs.upenn.edu

PRINCIPAL INVESTIGATOR	: Paul N Lanken
TITLE	: The National Institute On Drug Abuse Study of Substance Abuse doc.com Module Project
SPONSORING AGENCY	: No Sponsor Number
PROTOCOL #	: 812983
REVIEW BOARD	: IRB #8

Dear Dr. Paul Lanken:

The above referenced protocol and was reviewed and approved by the Executive Chair (or her authorized designee) using the expedited procedure set forth in 45 CFR 46.110, category 7, on 30-Mar-2011. This study will be due for continuing review on or before 29-Mar-2012.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. Principal investigators are responsible for assuring final approval from other applicable school, department, center or institute review committee(s) or boards has been obtained. This includes, but is not limited to, the University of Pennsylvania Cancer Center Clinical Trials Scientific Review and Monitoring Committee (CTSRMC), Clinical and Translational Research Center (CTRC) review committee, CAMRIS committee, Institutional Bio-safety Committee (IBC), Environmental Health and Radiation Safety Committee (EHRS), and Standing Conflict of Interest (COI) Committee. Principal investigators are also responsible for assuring final approval has been obtained from the FDA as applicable, and a valid contract has been signed between the sponsor and the Trustees of the University of Pennsylvania. If any of these committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study.

If this protocol involves cancer research with human subjects, biospecimens, or data, you may not begin the research until you have obtained approval or proof of exemption from the Cancer Center's Clinical Trials Review and Monitoring Committee.

The following documents were included in this review:

-Email Correspondence dated 01/09/11-03/18/11 re: Evaluation of NIDA Substance Abuse doc.com Module
-IRB Authorization Form signed on 03/07/11
-Letter to NIDA dated 03/25/11 re: Evaluation of NIDA Substance Abuse doc.com Module
-Claim of Exemption Form signed on 12/16/10
-NIDA Study of Substance Abuse doc.com Module Project Full Protocol including A and B Attachments dated 11/19/10
-University of Pennsylvania Informed Consent Form (Draft) Version 1.0 dated 03/28/11
-Drexel University Informed Consent Form (Medical Students)(Draft) received 01/05/11
-Drexel University Informed Consent Form (Resident Physician)(Draft) received 01/05/11
-University of Pennsylvania Informed Consent Form (Medical Residents) Version 1.0 dated 03/28/11

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/regulatoryaffairs.

Thank you for your cooperation.

Sincerely,

Kyle Stephens

Digitally signed by Kyle Stephens
DN: cn=Kyle Stephens, o, ou=IRB, email=kstep@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this document
Date: 2011.03.30 15:28:11 -04'00'

IRB Administrator

OMB No. 0925-XXX
Expiration Date: mm/yyyy

University of Pennsylvania
Informed Consent Form (DRAFT)

Title of the Research Study	**National Institute on Drug Abuse (NIDA) Substance Abuse doc.com Module Evaluation**
Protocol Number	**812983**
Principal Investigator	**Paul N. Lanken, MD** **8 W.Gates bldg, HUP** **3400 Spruce Street** **Philadelphia, PA 19104** **215-614-0913**
Research Project Manager	**Sandra Kaplan, BSN** **215-614-0628**

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether on not to participate. If you decide not to participate, there will be no loss of benefits to which you are otherwise entitled. The research team is going to talk with you about the study and give you this document to read.

Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, a blank copy of this form will be given to you. Keep this form, in it you will find contact information and answers to questions about the study.

What is the purpose of the study?

The Drexel University College of Medicine (DUCOM) and University of Pennsylvania School of Medicine (Penn Med) are collaborating under a contract with JBS International, Inc to conduct a study of the NIDA substance abuse doc.com module. The purpose of the study is to assess the efficacy of this novel educational intervention compared to current standard education in the field of professional education of healthcare providers. Information from your participation will help to understand how this module can affect the training of healthcare providers with regard to their knowledge, attitudes, and communication skills used when they treat patients with substance use disorders.

Why was I asked to participate in the study?

You are being asked to join this study because you are a medical student who is enrolled at the University Of Pennsylvania School Of Medicine undergoing clinical clerkships.

How long will I be in the study? How many other people will be in the study?

The study will take place over a period of 1 year. This means for the next 12 months we will ask you to complete four surveys, spending 10 minutes on each survey; and partake in two education sessions during your Family Medicine rotation that is expected to last 45 minutes each.

There will be up to 708 participants in the study: 400 being medical students, and 308 resident physicians.

Where will the study take place?

All 4 surveys and one of the education sessions will be completed during regularly scheduled class sessions. The other education session will be conducted online – therefore you are able to complete this at any location with a computer and internet connection convenient to you.

What will I be asked to do?

If you agree to participate, the following will occur:

- During your family medicine clerkship rotation, you will complete an educational intervention where you will be assigned to one of two groups; one of which may be the substance abuse doc.com module. We will forward you an email containing the link to the substance abuse doc.com module with a valid username and password. Please refrain from asking other participants about the substance abuse doc.com module or

what those participants learned. Also, please refrain from visiting the NIDA substance abuse doc.com module outside of the study's protocol while the study is ongoing (i.e. during your clinical year).

- Survey completion will take place during regularly scheduled classes and during your ambulatory medicine clerkship:
  1) Prior to beginning clinical year during a regularly scheduled class
  2) On the first day of your family medicine rotation during orientation
  3) On the last day of your family medicine rotation
  4) At the end of your year of clinical rotations during a regularly scheduled class
- The survey instruments you will complete include background information (e.g., your age, gender) and information about your knowledge of, attitude toward, and experience with treating patients with substance abuse issues.
- The total time commitment will be approximately up to 40 minutes for completing 4 surveys. The two education sessions will take 45 minutes each to complete.

How will I benefit from the study?

There may be no benefit to you. However, the information you learn may benefit your medical school education, as well as your knowledge of treating patients with substance abuse issues. Your participation could also help us to make further enhancements to NIDA substance abuse doc.com web-module. In the future, this may help other medical students and physicians.

What other choices do I have? What happens if I do not choose to join the research study?

You are still required to participate in educational activities during your clinical rotation as directed by your clerkship director as part of your overall medical education. The surveys are also a requirement as part of ongoing quality improvement (QI) process for accreditation by LCME (The Liaison Committee for Medical Education). Medical schools are required to asses their overall educational programs and the effects of the "Learning Environment". We also want assess to how and to what degree the learning environment for medical students promotes the development of professional attributes (attitudes, behaviors and identity) in our medical students, specifically in relation to patients with substance use disorders.

You do have the option to refuse to have your results used for research purposes. There will be a box indicating such wishes on the survey. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your clerkship directors and other medical school faculty and staff will not be upset with your decision. There are no negative consequences should you choose not to participate.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all surveys and all the information has been collected. The study may be stopped without your consent for the following reasons:

- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at anytime during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future education or grades. If you no longer wish to be in the research study, please contact the investigator listed at your school; you will be required to notify of your withdrawal in writing.

How will my information be protected?

The research team will make every effort to keep all the information you tell us/provide during the study secure in locked facilities of the Research Project Manager's office.. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. Any documents where you can be identified by name will be kept secure in a locked drawer in the research project manager's office. Individual survey results will not be accessed by other research team members. These documents will be kept confidential. To track you longitudinally, we ask you to fill in the numbers below. No names or identifiers will be used

University of Pennsylvania
Informed Consent Form (DRAFT)

in any study results. Surveys will be de-identified and coded according to school and then participating number – in ascending order. The project manager will have access to identifying information from the study, and will ensure only de-identified data will be analyzed. The Principal Investigator listed at the beginning of this document, or any other faculty affiliated with your medical school will not have access to identified study results. In addition, no identifiable individual data will be available to JBS or NIDA. Only aggregated results will be shared outside of Penn Med and DUCOM. All the documents will be stored in locked facilities for 3 years after the study is completed, and then destroyed. The Privacy Impact Assessment for third party websites will be conducted annually, to ensure that your privacy is protected. You can answer only the questions you choose to answer.

Will I have to pay for anything?

You will not have to pay for anything to participate in this study.

Will I be paid for being in this study?

We can offer you a $5 gift card to Starbucks for timely completion of online web-module and surveys to date.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

Student ID # : _ _ _ _ _ _ _ _ _ **OR** Name: _____

Email: _____

Study ID: _ _ _ _ - _ _

(6 digits – last 4 of your Social Security number and 2 digit month of your birth (e.g., 01 for January)

OMB No. 0925-XXX
Expiration Date: mm/yyyy

Drexel University College of Medicine
Informed Consent Form (Medical Students) (DRAFT)

Title of the Research Study	**National Institute on Drug Abuse (NIDA) Substance Abuse doc.com Module Evaluation**
Protocol Number	**812983**
Principal Investigator	**Barbara A. Schindler, MD** **2900 Queen Lane** **Philadelphia, PA 19129** **215-991-8561**
Co-Investigator	**Dennis H. Novack, MD**
Co-Investigator	**Christof Daetwyler, MD**
Research Project Manager	**Felecia Meyers** **215-629-6916**
Sponsor:	**National Institute on Drug Abuse (NIDA**

You are being asked to take part in a research study of a novel medical education intervention to improve substance abuse education for medical students and resident physicians. Your participation is voluntary. If you decide not to participate, there will be no loss of benefits to which you are otherwise entitled. The research team is going to talk with you about the study and give you this document to read.

Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to print your name and email address and your 6 digit Student Tracking ID at the end of this consent form. We will give you a blank copy of the consent form to keep - in it you will find contact information and answers to questions about the study.

What is the purpose of the study?

Medical educators at the Drexel University College of Medicine (DUCOM) and University of Pennsylvania School of Medicine (Penn Med) are collaborating under a contract with JBS International, Inc to conduct a research study of a novel educational intervention that is based on the NIDA substance abuse doc.com module.

The purpose of the study is to assess the efficacy of this novel educational intervention when added to the standard education on substance abuse compared to standard education alone. This study's results may help to understand how this module can affect the training of healthcare providers with regard to their knowledge, attitudes, and communication skills used when they treat patients with substance use disorders.

Why was I asked to participate in the study?

You are being asked to join this study because you are a medical student who is enrolled at the Drexel University College of Medicine during clinical clerkships.

How long will I be in the study? How many other people will be in the study?

The study will take place over a period of 1 year. Over a period of 12 months you will be asked to complete four surveys, spending 10 minutes on each survey; and partake in two education sessions during your Ambulatory Medicine rotation that are expected to last 45 minutes each.

The study will have up to 708 participants: 400 being medical students, and 308 resident physicians.

Where will the study take place?

Drexel University College of Medicine
Informed Consent Form (Medical Students) (DRAFT)

Two surveys and one of the education sessions will be completed during regularly scheduled class sessions. The two other surveys and the other education session will be conducted online – therefore you are able to complete this at any location with a computer and internet connection convenient to you.

What will I be asked to do?

If you agree to participate, the following will occur:
During your ambulatory medicine clerkship rotation, where you will have been randomly assigned to one of two groups; one of which may be the substance abuse doc.com module. We will forward you an email containing the link to the substance abuse doc.com module with a valid username and password. Please refrain from asking other participants about the substance abuse doc.com module or what those participants learned. Also, please refrain from visiting the NIDA substance abuse doc.com module outside of the study's protocol while the study is ongoing (i.e. during your clinical year).

- Survey completion will take place during regularly scheduled classes and during your ambulatory medicine clerkship:
  1) Prior to beginning clinical year during Intercession II (online)
  2) On the first day of your ambulatory medicine rotation during orientation (paper)
  3) On the last day of your ambulatory medicine rotation (paper)
  4) At or near the end of your year of clinical rotations (online)
- The survey instruments you will complete include background information (e.g., your age, gender) and information about your knowledge of, attitude toward, and experience with treating patients with substance abuse issues.
- The total time commitment will be approximately up to 40 minutes for completing 4 surveys. The two education sessions will take 45 minutes each to complete.

How will I benefit from the study?

There may be no benefit to you. However, the information you learn may benefit your medical school education, as well as your knowledge of treating patients with substance abuse. Your participation may also help us to make further enhancements to NIDA substance abuse doc.com web-module. In the future, this may help other medical students and physicians.

What other choices do I have? What happens if I do not choose to join the research study?

You are still required to participate in educational activities during your clinical rotation as directed by your clerkship director as part of your overall medical education. The surveys are also a requirement as part of ongoing quality improvement (QI) process for accreditation by LCME (The Liaison Committee for Medical Education). Medical schools are required to asses their overall educational programs and the effects of the "Learning Environment". We also want assess to how and to what degree the learning environment for medical students promotes the development of professional attributes (attitudes, behaviors and identity) in our medical students, specifically in relation to patients with substance use disorders.

You do have the option to refuse to have your results used for research purposes. There will be a box indicating such on the survey. Your participation is voluntary. There is no penalty if you choose not to allow your results to be used for the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your clerkship directors and other medical school faculty and staff will not be upset with your decision. There are no negative consequences should you choose not to participate.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all surveys and all their information has been collected. The study may be stopped without your consent for the following reasons:

- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania, or Drexel University Office of Research can stop the study anytime

Drexel University College of Medicine
Informed Consent Form (Medical Students) (DRAFT)

You have the right to drop out of the research study at anytime during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future education or grades. If you no longer wish to be in the research study, please contact the investigator listed at your school; you will be required to notify of your withdrawal in writing.

How will my information be protected?

The research team will make every effort to keep all the information you tell us/provide during the study secure in locked facilities of the Research Project Manager's office. . The Institutional Review Boards (IRBs) of University of Pennsylvania and Drexel University are responsible for protecting the rights and welfare of research volunteers like you. Any documents where you can be identified by name will be kept secure in a locked drawer in the research project manager's office.

To track you longitudinally, we ask you to fill in the numbers below. No names or identifiers will be used in any study results. Surveys will be de-identified and assigned a unique 7 digit study ID for each participant. Only the project manager will have access to identifying information from the study, and will ensure only de-identified data will be analyzed. The Principal Investigator listed at the beginning of this document, or any other faculty affiliated with your medical school will not have access to identified study results. In addition, no identifiable individual data will be available to JBS or NIDA.

Only aggregated results without identifiers will be used in publications or reports outside of Penn Med and DUCOM. All the documents will be stored in locked facilities for 3 years after the study is completed and then destroyed. The Privacy Impact Assessment for third party websites will be conducted annually, to ensure that your privacy is protected.

Will I have to pay for anything?

You will not have to pay for anything to participate in this study.

Will I be paid for being in this study?

We can offer you a $5 gift card to Starbucks for timely completion of online web-module and surveys to date.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs at the University of Pennsylvania by calling (215) 898-2614 or the Office of Regulatory Research Compliance at Drexel University on (215) 255-7857 with any question, concerns or complaints.

Name: _____ _____
(First) (Last)

Email: _____ @ _____

Student Tracking ID: _ _ _ _ - _ _

(6 digits – last 4 of your Social Security number and 2 digit month of your birth (e.g., 01 for January)

OMB No. 0925-XXX
Expiration Date: mm/yyyy

Drexel University College of Medicine
Informed Consent Form
(Resident Physician) DRAFT ONLY

Title of the Research Study	**National Institute on Drug Abuse (NIDA) Substance Abuse doc.com Module Evaluation**
Protocol Number	**812983**
Co-Principal Investigator	**Barbara A. Schindler, MD** **2900 Queen Lane** **Philadelphia, PA 19129** **215-991-8561**
Co-Investigator	**Dennis H. Novack, MD**
Co-Investigator	**Christof Daetwyler, MD**
Research Project Manager	**Felecia Meyers** **215-629-6916**
Sponsor:	**National Institute on Drug Abuse (NIDA)**

You are being asked to take part in a research study of a novel medical education intervention to improve substance abuse education for medical students and resident physicians. Your participation is voluntary. If you decide not to participate there will be no loss of benefits to which you are otherwise entitled. The research team is going to talk with you about the study and give you this consent form to read.

Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to print your name and email address at the end of this consent form. We will give you with a blank copy of the consent form to keep - In it you will find contact information and answers to questions about the study.

What is the purpose of the study?

Medical educators at Drexel University College of Medicine (DUCOM) and the University of Pennsylvania School of Medicine (Penn Med) are collaborating to conduct a study of a novel educational intervention that is based on the NIDA substance abuse doc.com module. While this research study is being conducted under a contract with JBS International, Inc (JBS), the study's sponsor is NIDA. The purpose of the study is to assess the efficacy of this novel educational intervention compared to current standard education in the field of professional education of healthcare providers. This study's results may help to understand how this module can affect the training of healthcare providers with regard to their knowledge, attitudes, and communication skills used when they treat patients with substance use disorders.

Why was I asked to participate in the study?

You are being asked to join this study because you are a resident physician at DUCOM affiliated hospitals.

How long will I be in the study? How many other people will be in the study?

The study will take place over 4 weeks during your outpatient primary care rotation. We will ask you to complete two surveys, spending 10 minutes on each survey; If you are randomized to complete the "NIDA substance abuse doc.com module", you will also complete two education sessions that is expected to last 60 minutes each.

The study will have up to 708 participants; 400 being medical students, and 308 resident physicians.

OMB No. 0925-XXX
Expiration Date: mm/yyyy

Drexel University College of Medicine
Informed Consent Form
Resident Physician DRAFT ONLY

Where will the study take place?

All surveys will be completed online -- therefore you are able to complete this at any location with a computer and internet connection convenient to you. The Research Project Manager (listed on page 1 of this consent form) will email you a unique username and password and the link to access each online survey.

If you are in the intervention group, you will complete the "NIDA substance abuse doc.com module online as for the surveys above but your other education session (debriefing NIDA substance abuse doc.com module) will occur as a regularly scheduled didactic session in your residency program.

What will I be asked to do?

If you agree to participate, the following will occur:

- All of the residents on the same outpatient primary care rotation will have been cluster randomized to either the standard education group or the intervention group (NIDA substance abuse doc.com module + the standard education). If you are in the standard education group, you will be asked to refrain from asking residents in the intervention group about the NIDA substance abuse doc.com module or what those residents learned. In addition, if you are in either group, you will be asked to refrain from visiting the NIDA substance abuse doc.com module outside of the study's protocol while the study is ongoing.
- At or near the start of your outpatient primary care rotation, you will be emailed your unique access information and asked to access the Pre-Survey online and complete it as instructed (~10 minutes).
- If you are in the intervention group *only*:
    - After you complete the Pre-survey, you will be emailed your unique access information and asked to access and complete the NIDA substance abuse doc.com module. We estimate that this will take 60 minutes to complete (three 20 minutes sections).
    - After you complete the NIDA substance abuse doc.ocm module as instructed, you will be asked to participate in a faculty-facilitated debriefing session (~60 minutes) for all the resident physicians who are in the intervention group during the same outpatient rotation.
- On or near the end of your rotation, you will be emailed your unique access information and asked to access the Post-Survey online and complete it as instructed (~10 minutes).

How will I benefit from the study?

There may be no benefit to you. However, the information you learn may benefit your medical education, as well as your knowledge of treating patients with substance abuse issues. Your participation could also help us to make further enhancements to the NIDA substance abuse doc.com web-module. In the future, this may help other medical students and physicians.

What other choices do I have? What happens if I do not choose to join the research study?

Your participation is voluntary. There is no penalty if you choose not to join the research study. You will not lose benefits or advantages that are now, or would come to you in the future. Your residency directors and other medical school faculty and staff will not be upset with your decision. There are no negative consequences should you choose not to participate.

When is the study over? Can I leave the study before it ends?

The study is expected to end after you have completed both surveys (and other study related activities as described above for those in the intervention group) and all of your study related data have been collected. The study may be stopped without your consent for the following reasons:

- You have not followed the study instructions

Drexel University College of Medicine
Informed Consent Form
(Resident Physician) DRAFT ONLY

- The PI, the sponsor or the Office of Regulatory Research Compliance at Drexel University or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at anytime during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future or education. If you no longer wish to be in the research study, please email the Project Manager.

How will confidentiality be maintained and my privacy be protected?

The research team will make every effort to keep all the information you tell us during the study strictly confidential. The Institutional Review Board (IRB) at the University of Pennsylvania is jointly responsible with the IRB at Drexel University for protecting the rights and welfare of research volunteers like you. Any documents where you can be identified by name will be kept secure in a locked drawer in the research project manager's office. No names or other identifiers will be used in any study data or results. Surveys will be de-identified and assigned a unique study id for each participant. Only de-identified data will be analyzed. The Principal Investigator, or any other faculty affiliated with your residency program, will not have access to identified study results. In addition, no identifiable individual data will be available to JBS or NIDA.

Only aggregated results without identifiers will be used in publications or reports outside of Penn Med and DUCOM. All the documents will be destroyed when the study and all of the analyses for this study are completed.

Will I have to pay for anything?

You will not have to pay for anything to participate in this study.

Will I be paid for being in this study?

We can offer you a $15 gift card to Starbucks or Amazon.com for completion of each survey.
In addition, we can offer a total of $75 in Amazon.com gift cards ($25 per 20 minutes completed) to those who complete the study's NIDA doc.com web-module according to the study's protocol.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs at the University of Pennsylvania by calling (215) 898-2614 or the Office of Regulatory Research Compliance at Drexel University on (215) 255-7857 with any question, concerns or complaints.

Name: _____ _____
(First) (Last)

Email: _____ @ _____

University of Pennsylvania
Informed Consent Form – Medical Residents

Title of the Research Study	**National Institute on Drug Abuse (NIDA) Substance Abuse doc.com Module Evaluation**
Protocol Number	**812983**
Principal Investigator	**Paul N. Lanken, MD** **843 Gates, Hospital of University of Pennsylvania (HUP), 3400 Spruce Street, Philadelphia, PA 19104** **215-614-0913** **Paul.lanken@uphs.upenn.edu**
Research Project Manager	**Sandra Kaplan, BSN** **8 Gates, HUP, 3400 Spruce Street, Philadelphia, PA 19104** **215-614-0628** **Sandra.kaplan@uphs.upenn.edu**
Sponsor:	**National Institute on Drug Abuse (NIDA)**

You are being asked to take part in a research study of a novel medical education intervention to improve substance abuse education for medical students and resident physicians. Your participation is voluntary. If you decide not to participate, there will be no loss of benefits to which you are otherwise entitled. The research team is going to talk with you about the study and give you this consent form to read.

Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to print your name and email address at the end of this consent form. We will give you with a blank copy of the consent form to keep - in it you will find contact information and answers to questions about the study.

What is the purpose of the study?

Medical educators at the University of Pennsylvania School of Medicine (Penn Med) and Drexel University College of Medicine (DUCOM) are collaborating under a contract with JBS International, Inc to conduct a study of a novel medical education intervention that is based on the "NIDA substance abuse doc.com module". The purpose of this study is to assess the efficacy of this novel educational intervention *when added* to the standard substance abuse education to improve substance abuse education compared to the standard education *alone*. This study's results may help us to understand how this module can influence the training of medical students and resident physicians with regard to their knowledge, attitudes, and communication skills so that they will be better prepared to provide screening, counseling and referral for their patients with substance abuse.

Why was I asked to participate in the study?

You are being asked to join this study because you are a resident physician at Penn Medicine.

How long will I be in the study? How many other people will be in the study?

You will be in the study for the 4 weeks during your primary care medicine or equivalent outpatient rotation.

There will be a maximum of 708 participants with 400 being medical students and 308 resident physicians.

Where will the study take place?

All surveys will be completed online – therefore you will be able to complete the surveys at any location with a computer and internet connection convenient to you. If you are randomized to complete the "NIDA substance abuse doc.com module", you will also be able to complete this online. The other education

session (debriefing NIDA substance abuse doc.com module) will be during a regularly scheduled didactic session during your outpatient rotation.

What will I be asked to do?

If you agree to participate, the following will occur:

- During your primary care medicine rotation, you will be randomized to either the standard education group or the intervention (NIDA substance abuse doc.com module) group. If you are randomized to the intervention group, we will forward you an email containing the link to the substance abuse doc.com module with a valid username and password. Please refrain from asking other residents about the substance abuse doc.com module or what those participants learned. Also, please refrain from visiting the NIDA substance abuse doc.com module outside of the study's protocol while the study is ongoing (i.e. during this year of residency).
- Survey completion will take place during your primary care medicine rotation for both groups:
  1) On the first day of your rotation during orientation
  2) On the last day of your rotation or within one week of completing the rotation
- The survey instruments you will complete include background information (e.g., your age, gender) and information about your knowledge of, attitude toward, and experience with treating patients with substance abuse issues.
- The time commitment will be approximately up to 20 minutes for completing 2 surveys, and the intervention group education sessions (online module and debriefing) will take 60 minutes each to complete.

How will I benefit from the study?

There may be no benefit to you. However, the information you learn may benefit your medical education, as well as your knowledge of treating patients with substance abuse issues. Your participation could also help us to make further enhancements to the NIDA substance abuse doc.com web-module. In the future, this may help other medical students and physicians.

What other choices do I have? What happens if I do not choose to join the research study?

Your alternative to being in the study is to not be in the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your residency directors and other medical school faculty and staff will not be upset with your decision. There are no negative consequences should you choose not to participate.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all surveys and all the information has been collected. The study may be stopped without your consent for the following reasons:

- You have not followed the study instructions
- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at anytime during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future or education. If you decide to withdraw from the research study, please email the Principal Investigator or Research Project Manager listed at the beginning of this consent form.

How will confidentiality be maintained and my privacy be protected?

The research team will make every effort to keep all the information you tell us during the study strictly confidential. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. Any documents where you can be identified by name will be kept secure in a locked drawer in the Research Project Manager's office.

University of Pennsylvania
Informed Consent Form – Medical Residents

Individual survey results will not be accessed by other research team members. These documents will be kept confidential. To be able to email you your access information and any reminders if needed, we ask you to provide the information below. No names or other personal identifiers will be used in any study results, analyses, datasets or database.

All data in the database will be de-identified of the subject's personal identifying information (PII) and that subject will be assigned a unique 7 digit study ID. Only the project manager will have access to log that links the subject's PII and the subject's 7 digit study ID. The will ensure only de-identified data will be analyzed. The Principal Investigator listed on page one of this consent form or any other faculty affiliated with your medical school or residency program will not have access to an individual subject's study results. Only aggregated results will be used in reports, presentations or publications. All the documents will be destroyed when the study is over. You can answer only the questions you choose to answer.

Will I have to pay for anything?

You will not have to pay for anything to participate in this study.

Will I be paid for being in this study?

We can offer you a $15 gift card to Starbucks or Amazon.com for completion of each survey, and up to $75 in Amazon.com gift cards ($25 per 20 minutes completed) for accessing and completing the NIDA doc.com web-module according the research protocol to compensate you for your time in this study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

Name: _____

Email: _____