UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT INFORMED CONSENT

TITLE OF RESEARCH STUDY:
Testing an Organizational Change Model to Address Smoking in Mental Healthcare

PROTOCOL NUMBER: 823871

PRINCIPAL INVESTIGATOR:
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You are being asked to take part in a research study being conducted by the University of Pennsylvania. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. Whatever you decide, there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with your friends, family or doctor.

If you do not understand what you are reading, do not sign this form. 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 sign this form and a copy will be given to you. Keep this form; in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?
The purpose of the study is to assess whether a smoking cessation training program provided to community behavioral health clinic personnel will encourage clinic employees to address smoking cessation more effectively and improve quit smoking rates and mental health/quality of life functioning among patients.

Why was I asked to participate in the study?
You are being asked to join this study because you provide clinical care or supervise clinical care at a community behavioral health clinic involved with this study.

How long is the study and how long will I be in the study?
The study will take place over a period of 5 years. Your individual participation will take place over a period of 52 weeks and includes 12 sessions during this period. Each session will last from 30 minutes to 2 hours depending on the procedures involved in each session.

How many other clinic personnel will be recruited for this study?
We are recruiting from 14 clinics in the Philadelphia area. We will be recruiting 12-30 clinic personnel at each clinic for a total of approximately 280 clinic personnel participants.

Where will the study take place?
All study sessions will occur at your place of employment. Every attempt will be made to complete assessments in a private space within the clinic. Assessments may also be completed over the telephone if necessary.

What will I be asked to do?
All Personnel:
Over the course of 9 months, you will be asked to participate in 10 training sessions of an intervention called Addressing Tobacco Through Organizational Change (ATTOC). Senior clinic staff has reviewed the study information and has agreed to allow training sessions to occur during normal business hours. These trainings will last from 20 minutes to 3-4 hours. Trainers from the University of California – San Diego will provide in-person ATTOC trainings at Weeks 1 and 12. All other training sessions will be conducted via video or telephone conferencing. At every ATTOC session, your trainers will discuss clinic personnel progress with achieving tobacco treatment related goals by referencing the "Dashboard", a web-based tool used to track and monitor compliance and progress on the 10 ATTOC steps. The dashboard is a visual figure with a numeric indicator using red (no movement), yellow (some progress), and green (completed) colors that enables staff to see progress on key metrics of change. Data are gathered through staff self-report and chart reviews, study measures, and the environmental scan. As a study participant, you will be asked to interact with the Dashboard on a regular basis and update key outcomes such as number of hours devoted to the clinic's cessation goals, CO monitor usage and number of quitline referrals and cessation medication prescriptions dispensed.

At 5 sessions (Baseline and Weeks 12, 24, 36 and 52), we will ask you to complete assessments that measure aspects of your knowledge and attitudes towards nicotine dependence as well as barriers to providing tobacco related treatment to clinic clients. At the baseline visit (which would occur today if you sign this consent document), we will also collect information about your demographics, employment details, smoking behavior and drug and alcohol dependence history. You will be compensated for completing these assessments.

These are voluntary surveys. If you feel uncomfortable with any question you may choose not to answer the question. You may also opt out of the survey at any time. There is no penalty for choosing not to participate. The data collected is stored in a locked file and your questionnaire will be kept confidential.

Study Related Leadership Team and Tobacco Champions:
Each site will choose an individual to serve as a tobacco "champion" and a study related leadership team. Clinic champions and leaders are expected to contribute to the formulation of ATTOC materials such as the Change Plan, Environmental Scan and Communication Plan during training sessions. The tobacco champion will serve as a secretary for the group by recording the frequency of the group's meetings and tracking the status of Change Plan components. The tobacco champions are also asked to review the Dashboard information prior to each training session and summarize the data and progress for the group.

Below is a schedule of study procedures:

Schedule of Study Procedures												
Session	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Study Timepoint	**Baseline**	**Week 1**	**Week 4**	**Week 8**	**Week 12**	**Week 16**	**Week 20**	**Week 24**	**Week 28**	**Week 32**	**Week 36**	**Week 52**
Informed Consent/HIPAA	X											
ATTOC		X	X	X	X	X	X	X	X	X	X	
Dashboard Review		X	X	X	X	X	X	x	X	X	X	
ATTOC Change Plan		X			X						X	X
ATTOC Environmental Scan		X									X	X
ATTOC Communication Plan		X			X						X	X
Personnel Knowledge and Attitudes Assessment and Demographics	X				X			X			X	X

What is ATTOC?

The Addressing Tobacco Through Organizational Change (ATTOC) model is a systems-level intervention to address systemic and cultural barriers that undermine assessment and treatment of tobacco use disorder. ATTOC assumes that effective organizational change requires more than clinic personnel training; it also requires that groups address attitudes and systemic barriers and promote a culture in which tobacco use is not accepted or supported and that tobacco use disorder treatment is integrated into standard practice.

What are the risks?

Training: Some personnel may experience frustration or concern about the need to address their agency's approach to treating nicotine dependence. There may be some discomfort in discussing issues surrounding attempts to improve agency practices and addressing organizational climate and culture which serve as barriers to improvement. The research staff administering the ATTOC training is experienced in helping individuals you should you experience any concerns.

Assessments: Some people can experience anxiety and other types of general distress when they complete questionnaires. These reactions are usually very mild and typically diminish with time. The research staff administering these questionnaires is trained to help you should you experience any concerns.

Threats to Privacy/Confidentiality: Because we want to protect your confidentiality and privacy, we will identify your results with an identification number (not your name). Only authorized study personnel will be able to link your identification number with your name. Although we will try our best to make sure that your information stays private, there is always a risk of a breach of confidentiality. For example, someone who is not part of the research staff or the clinic staff may find out about you participating in this study. There is also a chance that our information security plan may fail and someone outside of the study would get access to your private information. If this happens, we would let you know about the situation as soon as possible and help you find resources to protect your privacy.

Pregnancy: Although there are no known risks related to study procedures for pregnant women or a fetus, there is also no direct benefit from participating in this protocol for pregnant women. Therefore, non-smoking pregnant women will be included in the study. However, we will exclude pregnant women who currently smoke from the study.

How will I benefit from the study?
There is no direct benefit to you for participating in this study. You may gain useful information about how to treat nicotine dependence. Your participation could also help us understand how to better train clinic staff to address smoking cessation, which can benefit you indirectly. In the future, this research may help to set standards for smoking cessation practices in mental health clinics.

What information about me may be collected, used or shared with others?
- Name, address, telephone number
- Email address
- Date of birth
- Social Security Number (W9 forms are needed for compensation)
- Some personal information that may be considered sensitive, such as substance abuse use history, employment information, etc.

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:
- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?
The following individuals and organizations may use or disclose your information for this research program:
- The Principal Investigator (PI) and research staff
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects)
- The University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office that monitors research studies)
- Authorized members of the University of Pennsylvania, the UPHS and School of Medicine workforce that may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.)
- Research collaborators at the University of California – San Diego
- National Institutes of Health
- Philadelphia Department of Public Health Institutional Review Board

The Principal Investigators or research staff will inform you if there are any changes to the list above during your active participation in the trial.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire while the study is active (about 5 years). Paper research records are saved in an archive for 10 more

years and are then destroyed. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- The Philadelphia Department of Public Health Institutional Review Board grants permission
- As permitted by law

How will confidentiality be maintained and my privacy be protected?
Every attempt will be made by the investigators to maintain all information collected in this study strictly confidential. When we travel from the clinic to our center with documents containing your contact information, we will travel with locked cases. We will store your written information in a secure room with limited access. When this information is transferred to a computer, we will control access to the computer files that hold this information, and all computers will be password protected. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law or there may be a breach of confidentiality beyond our control. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Likewise, all demographic data will be reported in aggregate by treatment type, not by clinic, in order to prevent individuals from being identified from this data. If you tell us that you are involved in a situation of child abuse or that you are going to harm yourself, we will have to break confidentiality and report this to local authorities as required by law. Due to the nature of this study, your employer will have knowledge about your decision whether or not to enroll in this program once assessments and trainings are underway.

Will I have to pay for anything?
There will be no charge to you for participating in this research program.

Will I be paid for being in this study?
To reimburse you for the time and effort needed for completing assessments, you may earn up to $100. The payment schedule is as follows:

Clinic Patient Participant Compensation Schedule		
Session	**Time Point**	**Time and Effort Reimbursement**
1	Baseline	$20
2	Week 12	$20
3	Week 24	$20
4	Week 36	$20
5	Week 52	$20
Total		**$100**

Payments will be provided in cash after session assessments are completed. If sessions are completed by telephone, you will receive payment at the next study session or we can schedule a payment pick-up appointment at the clinic. Sessions completed over the telephone will not be eligible for travel reimbursement (payment). Additionally, a check may be sent to you by mail if you are unable to visit the clinic for your payment.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

What other choices do I have?
Your alternative to being in the study is to not be in the study. If you are interested in other research opportunities, we can share research related resources with you. If you are interested in learning about ways to integrate smoking cessation into your practice outside of a research context, we can also share resources with you.

What happens if I do not choose to join the research study?
You may choose to join the study or you may choose not to join 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.

Due to the nature of this study, your employer will have knowledge about your decision whether or not to enroll in this program once assessments and trainings are underway. Your employer has read this consent form and understands the voluntary nature of this study. Your employer has agreed not to consider your study enrollment status decision as a factor that would affect your employability. During the enrollment period at your clinic, we may not be able to voluntarily recruit enough clinic personnel to meet our enrollment quota. If this is the case, your clinic will not be eligible to participate in the study. When clinics are disqualified due to lack of personnel enrollment, we will not disclose the names and enrollment decisions of staff members to clinic leadership. You do not give up your legal rights by signing this form.

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 visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why.
- 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 any time 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 care. If you no longer wish to be in the research study, please contact the study coordinator, Mackenzie Quinn, at 215-898-9941. Any information provided before your withdrawal will remain in the 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, you should speak with the Principal Investigator listed on page one of this form or the study coordinator, Mackenzie Quinn, at 215-898-9941. If you want to talk to someone who is not a part of the research team or if you have any questions about your rights as a research subject, you may contact the Office of Regulatory Affairs with any questions, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614 or the Research Participant Coordinator at the Philadelphia Department of Public Health Institutional Review Board at 215-685-0869.

Financial Disclosure:

Dr. Schnoll, the Principal Investigator at University of Pennsylvania, has served as a consultant to Glaxo Smith Kline and Pfizer. Both are companies that manufacture medications for nicotine dependence, but neither company has any involvement with the present study. If you would like more information, please ask the researchers or the study coordinator.

When you sign this document, you are agreeing to take part in this research study. This means that you have read and understood the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are allowing the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution as was described in this form. You will receive a copy of this consent document.

Signature of Subject: _____

Printed Name of Subject: _____

Date: _____

Signature of Person Obtaining Consent: _____

Printed Name of Person Obtaining Consent: _____

Date: _____

Authorized to Obtain Consent:

- Robert Schnoll, Principal Investigator, 215-746-7143
- Mackenzie Quinn, Study Coordinator, 215-898-9941
- Anna-Marika Bauer, Study Coordinator, 215-746-6827
- Nate Stevens, Research Assistant, 215-746-0120
- Jane Hatzell, Research Assistant, 215-746-3603