UNIVERSITY OF PENNSYLVANIA
RESEARCH STUDY SUMMARY FOR POTENTIAL SUBJECTS

Protocol Title:	**Effects of Metformin on Mood and Cognition during Nicotine Withdrawal (IRB# 824504)**
Principal Investigator:	**Robert Schnoll, Ph.D., Phone: 215-746-7143** **Department of Psychiatry, University of Pennsylvania**
Co-Investigators:	**Rebecca Ashare, Ph.D.** **David Metzger, Ph.D.**
Emergency Contact:	**Frank Leone, M.D., Phone: 267-239-3651** **University of Pennsylvania**

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and the risks of participation. You should ask the study team any questions you have before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The main purpose of this research study is to test the effects of a medication called Metformin (Glucophage) on smoking behavior. You are being asked to take part because you are a cigarette smoker who smokes at least 5 cigarettes per day and are 18-65 years of age.

If you agree to join the study, you will be asked to complete tasks to determine your eligibility, either in-person or remotely by phone/video call. If you are deemed eligible to participate you will also be asked to complete 5 additional sessions, 3 in-person and 2 by phone. The three in-person visits will last between 1.5 to 2 hours and include computer tasks; the two phone sessions will last about 20 minutes.

Your participation in the study will last approximately 1 month. If you are deemed eligible=, you will be given a study schedule that outlines your scheduled sessions.

If enrolled in this study, you may benefit from knowing that you are contributing to the advancement of treatments to help people quit smoking.

The most common risks of study participation are potential side effects from Metformin, the study medication. These side effects tend to be mild, and include diarrhea, nausea, and vomiting. You will be monitored for side effects throughout the study.

The alternative to participation in this program is to decide not to participate. If you do not wish to enroll in this study and wish to be involved in other research, or seek assistance with quitting smoking, we can provide information on other studies at our center or other treatment programs located in the Philadelphia area.

Please note that there are other factors to consider before agreeing to participate in this study, such as additional procedures, use of your personal information, and other possible risks. If you are interested in participating, a member of the study team will review the full study information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA FORM

Protocol Title:	**Effects of Metformin on Mood and Cognition during Nicotine Withdrawal (IRB# 824504)**
Principal Investigator:	**Robert Schnoll, Ph.D., Phone: 215-746-7143** **Department of Psychiatry, University of Pennsylvania**
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WHY AM I BEING ASKED TO VOLUNTEER? You are being asked to participate in this research study because you are a cigarette smoker 18-65 years of age, who smokes at least 5 cigarettes per day. Your participation is voluntary which means you can choose whether or not you want to participate. Before you decide, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do if you decide to participate. The study staff is going to talk to you about these things today. If you have any questions, or find any of the language difficult to understand, please ask the study staff for more information. You may also decide to discuss this decision with your family, friends, or doctor. If you decide to participate, you will be asked to sign this form. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled.

WHAT IS THE PURPOSE OF THIS STUDY? The purpose of this study is to test the effects of a medication called Metformin (Glucophage®) on smoking behavior. This medication is FDA-approved for type-2 diabetes, and its use in this study is investigational.

HOW LONG WILL I BE IN THE STUDY? HOW MANY OTHER PEOPLE WILL BE IN THE STUDY? In total, your participation in this study will last at least 4 weeks; however, your participation may last up to 10 weeks, in the event any scheduling difficulties arise. We ask that you do not participate in any other research studies during this time. In total, 84 smokers will complete this study.

WHAT AM I BEING ASKED TO DO? You will be asked to complete 3 in-person and 2 phone sessions throughout this study, following completion of the Intake tasks. The 3 in-person sessions will last between 1.5 to 2 hours and the 2 phone sessions will last about 20 minutes. Specific information about each visit is provided in the table below and the text that follows.

Study Time Point Table				
Visit	**Day**	**Duration**	**Medication**	**Smoking State**
Intake	Today	3-3.5 hrs.	--	As usual
Baseline	0	1.5-2 hrs.	--	
Remote Check-In #1	7	20 min	Metformin* or Placebo	
Remote Check-In #2	14	20 min	Metformin* or Placebo	
Pre-Quit Testing Day	21	1.5-2 hrs.	Metformin* or Placebo	As usual, until ***24 hrs. before 24-H Testing Day***
24-H Testing Day	23	2 hrs.	Metformin* or Placebo	Abstinent (Mandatory)
* You may be randomized to one of three groups: a low dose of Metformin, a high dose of Metformin, or Placebo				

Intake Session: The purpose of this session is to determine if you are eligible to participate in this study. Tasks listed below that can be completed remotely will be done by phone/video call to reduce the length of in-person tasks. The in-person tasks at our center will last about 1-1.5 hours. You will be asked to:

- Provide a urine sample (at least 30mL [two tablespoons]) for drug and (if applicable) pregnancy tests. If you test positive for any of the following drugs: cocaine, amphetamines, methamphetamines, PCP, barbiturates, tricyclic antidepressants or ecstasy (MDMA), you may not be eligible to participate in this study. Results from this testing are used for research purposes only and will not be shared with you. You will be informed of your eligibility status after testing, but specific results will not be shared.
- **(Females of child-bearing potential only):** Be provided with a urine pregnancy screen and be asked to perform the screening independently. For safety purposes, if you think you are pregnant, we advise that you discontinue study participation. Women (determined to be of childbearing potential) will be instructed to use an approved method of contraception throughout the study. Women who self-report nursing, current pregnancy, or planning a pregnancy will be excluded from the study. There is no penalty for withdrawing from the study at this point and you will still receive travel reimbursement.
- Complete a breath carbon monoxide (CO) assessment.
- Have height, weight and blood pressure measured.
- Provide a list of prescription and/or over the counter (OTC) medications and supplements you are currently taking or recently discontinued.
- Complete a medical history form with a member of the research staff and have a physical examination led by a medical professional.
- Provide an 8.5 mL blood sample (less than 2 teaspoons) that will be used to test your liver and renal (kidney) function. This is <u>required</u> to make sure it is safe for you to take the study medication. When we receive the results of the blood test (within 1-2 days of the Intake visit), a member of staff will contact you for your Final Eligibility Phone Call to let you know if you are eligible for the study.
- Complete a brief mental ability test (Shipley Institute of Living Scale).
- Complete brief psychiatric assessments called the 'MINI' and 'C-SSRS'. During this interview, we will ask you about any current and past depressed mood symptoms as well as other psychiatric symptoms.
- Complete questionnaires about your demographics (e.g., education, income, etc.), smoking history, alcohol use history, and preferred brand of cigarette.
- Schedule your study track.

As you complete the tasks listed above, there is a chance you may not meet of all of the study eligibility criteria (i.e., conditions). If this occurs, you will not be eligible for the study. These criteria are for data quality and/or safety purposes.

During your entire participation in this study, we ask that you:

- Not use any study prohibited drugs (listed above).
- Let us know immediately if you are prescribed a new medication (prior to taking first dose).
- Not be in any other research studies while you are in this study.
- Let us know about any medical concerns and/or symptoms.
- Complete all study sessions as scheduled.
- Follow all study instructions.

<u>Final Eligibility Phone Call</u>: Within one to two weeks of your Intake visit a staff member will call you to inform you of your final eligibility. If you are eligible, you will confirm your study schedule. If you are ineligible, we can refer you to other programs at our center.

<u>Randomization</u>: If eligible, you will be randomized to one of 3 treatment groups. Randomization is like pulling a number out of a hat; you will have the same chance of being given the low dose of Metformin, the high dose of Metformin, or placebo. The placebo pills will look just like the active medication but will contain no active ingredients. Neither you nor the research team will know which group you are in. You will be asked to begin taking

the study medication on Day 1 (the day after your Baseline visit) and continue taking the study medication as directed until you complete the study (Day 23).

Baseline Visit (Day 0): During this 1.5-2 hour visit, you will be asked to report to our center to complete the following tasks:

- Provide a urine sample (at least 30mL [two tablespoons]) for drug and (if applicable) pregnancy tests. If you test positive for any of the following drugs: cocaine, amphetamines, methamphetamines, PCP, barbiturates, tricyclic antidepressants or ecstasy (MDMA), you may not be eligible to participate in this study. Results from this testing are used for research purposes only and will not be shared with you. You will be informed of your eligibility status after testing, but specific results will not be shared.
- Complete a blood pressure assessment.
- Have your blood sugar measured via a handheld glucose monitoring test. For safety reasons, if your blood sugar level is less than 70 mg/dl you may be withdrawn from the study.
- Provide a blood sample (less than 3 tablespoons) to determine biomarkers of inflammation. Because this is experimental and we do not yet understand the role of inflammation in smoking behavior, you will not receive the results or feedback from this analysis. Only some participants will be asked to provide this sample. You will be notified during completion of the Intake tasks if you are part of this group.
- Complete a CO breath test, smoking rate assessment, and medication review.
- Complete questionnaires about side effects/medical concerns, withdrawal symptoms, smoking urges, and mood.
- Complete several computerized tasks measuring mental abilities (such as attention and memory).
- Receive instructions on the study medication. The medication kits for the study may be mailed to you prior to this visit or provided at the visit.

Remote Check-Ins (Day 7 and Day 14): These will be completed remotely by phone or video-call. During these 20-minute sessions, you will be asked to complete the following:

- Complete questionnaires that will ask you about your smoking behavior, medication adherence, mood and side effects.
- Review instructions for the medication.

These sessions should occur on the target date. However, they can be moved by 1 day before or after for scheduling reasons.

Pre-Quit Testing Day (Day 21): During this 1.5-2 hour visit, you will be asked to report to our center to complete the following tasks:

- Provide a urine sample (at least 30mL [two tablespoons]) for drug and (if applicable) pregnancy tests. If you test positive for any of the following drugs: cocaine, amphetamines, methamphetamines, PCP, barbiturates, tricyclic antidepressants or ecstasy (MDMA), you may not be eligible to participate in this study. Results from this testing are used for research purposes only and will not be shared with you. You will be informed of your eligibility status after testing, but specific results will not be shared.
- Complete a blood pressure assessment.
- If you provided a blood sample at the Baseline visit, you will be asked to provide another blood sample (less than 3 tablespoons) to determine biomarkers of inflammation. Because this is experimental and we do not yet understand the role of inflammation in smoking behavior, you will not receive the results or feedback from this analysis.
- Complete a CO breath test, smoking rate assessment, and medication review.

- Have your blood sugar measured via a handheld glucose monitoring test. For safety reasons, if your blood sugar level is less than 70 mg/dl you may be withdrawn from the study.
- Complete questionnaires about side effects, withdrawal symptoms, smoking urges, and mood.
- Complete several computerized tasks measuring mental abilities (such as attention and memory).
- Return empty study medication blister pack(s) and review any additional instructions.

Ideally, this session will be scheduled at the same time of day as your Baseline Session, but it can be scheduled for up to 3 hours earlier or later than the Baseline time. However, it must occur on the target date.

24-H Testing Day (Day 23). The 24-H Testing Day occurs after 24 hours of abstinence from nicotine (not smoking). The Testing Day Visit takes about 2 hours to complete and is split into two parts. Ideally, this session will be scheduled at the same time the Pre-Quit Testing Session was achieved but it can be scheduled for up to 3 hours earlier or later than the Pre-Quit Testing session time. You will complete the following procedures during this visit:

- 24-H Testing Day (Part 1):
    - Provide a urine sample (at least 30mL [two tablespoons]) for drug and (if applicable) pregnancy tests. If you test positive for any of the following drugs: cocaine, amphetamines, methamphetamines, PCP, barbiturates, tricyclic antidepressants or ecstasy (MDMA), you may not be eligible to participate in this study. Results from this testing are used for research purposes only and will not be shared with you. You will be informed of your eligibility status after testing, but specific results will not be shared.
    - Provide a CO sample. Your CO reading must be less than or equal to 8 ppm, or there must be a 50% reduction from the CO collected at the Baseline Visit. If you smoke (even a single puff of a cigarette) or your CO readings do not meet these criteria during the mandatory abstinence period, you may be withdrawn from the study.
    - Complete a blood pressure assessment.
    - Have your blood sugar measured via a handheld glucose monitoring test. For safety reasons, if your blood sugar level is less than 70 mg/dl you may be withdrawn from the study.
    - Complete questionnaires that will ask you about your side effects, withdrawal symptoms, smoking urges, and mood.
    - Complete several computerized tasks measuring mental abilities (such as attention and memory).
    - Return empty study medication blister pack(s).
- 24-H Testing Day (Part 2):
    - Smoke one of your cigarettes in a fully ventilated room in our center.
    - Complete questionnaires about how the cigarette made you feel.

Visit Reminders: For each of your study visits, you will receive reminders via phone call, email or text message (depending on which you prefer). These phone calls will occur 24 – 48 hours prior to your sessions and will include important information for your session, such as location (if in-person), date, and time, or a reminder to stop smoking prior to your visit.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

Study Medication (Metformin). The following are common side effects that have been reported with Metformin extended release (XR), or slow release treatment: diarrhea, nausea, and vomiting. Diarrhea led to discontinuation in 0.6% of patients. Side effects will be monitored at each session.

Other rare side effects of Metformin XR have been reported including abdominal pain, constipation, abdominal distension/swelling, dyspepsia/heartburn, flatulence, dizziness, headache, upper respiratory infection, and taste disturbance (e.g., metallic taste).

Under certain conditions, Metformin may cause lactic acidosis (lactic acid build up in the blood), which is a rare, but serious condition. The symptoms of lactic acidosis are severe and quick to appear. They usually occur when other health problems not related to the medicine are present and very severe, such as a heart attack or kidney failure.

Symptoms include abdominal or stomach discomfort; decreased appetite; diarrhea; fast, shallow breathing; a general feeling of discomfort; muscle pain or cramping; and unusual sleepiness, tiredness, or weakness. Although lactic acidosis is extremely rare, it is fatal in approximately 50% of cases. In more than 20,000 patient-years exposure to Metformin in clinical trials, there were no reports of lactic acidosis.

Strict exclusion criteria are in place to limit the chance of these side effects. Additionally, you will be informed about the possible side effects and asked to watch for any of these symptoms and tell study staff as soon as possible. You will be instructed to take the study medication once daily with your evening meal. You should limit your consumption of alcohol while taking Metformin. Your blood sugar levels, and all side effects, will be closely monitored and the study physician consulted should moderate or severe side effects be reported. If you experience severe side effects, please contact the study physician (Dr. Leone) and study investigator (Dr. Schnoll) right away. The study physician's emergency contact numbers are on the medication blister pack, and the study consent form.

Pregnancy. There are no well-controlled studies in pregnant women with Metformin. Metformin did not cause birth defects in rats and rabbits at doses up to 600 mg/kg/day. This represents an exposure of about two and six times the maximum recommended human daily dose of 2000 mg. Because Metformin can cross the placenta, it should not be used during pregnancy. All female participants of childbearing potential will complete a pregnancy test at the Intake, Baseline, PQ-Testing and 24-H Testing sessions.

Blood Draw. Blood draws may result in bruising and/or slight bleeding at the needle site. This is rare and does not happen often. Occasionally, blood draws may result in a feeling of faintness. This too is rare. A trained professional will draw blood, so the chances of these discomforts are minimal.

Withdrawal. Many people who smoke cigarettes have symptoms of withdrawal when they stop smoking. These symptoms can include sadness and anxiety, irritability, difficulty concentrating, anger, appetite change and weight gain, difficulty sleeping, and decreased heart rate. These symptoms are usually low risk. The study staff know how to identify these symptoms and inform you about them (e.g., how long they last). Although nicotine replacement therapy may help reduce withdrawal symptoms, we ask that you do not use any nicotine-containing products (other than your cigarettes) for the duration of the study.

Psychological Distress: You may experience emotional distress during assessments, from discussing feelings and attitudes about smoking, and/or learning about the risks of smoking. This happens rarely and in almost all cases does not last long and is of low intensity. The research staff can help you if you have any concerns.

Email Communications: Throughout this study you may get appointment reminders via email or choose to ask questions related to the study via email. Email is not a secure method of communication. Email messages travel across the Internet passing through multiple computers before reaching their final destination. It is not possible to know whether an email you send will be viewed along the way. Additionally, if sent messages are not deleted, an email provider may have a folder of everything that is sent. If someone gets access to an email account (for example, a family member), they could see old messages. There are many other ways in which emails are not secure—these are only selected examples. For these reasons we ask that you only use email communication for routine matters and never for personal or confidential messages or questions. If you have questions or concerns that are personal in nature, we suggest you contact the study staff via phone.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE STUDY? During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will let you know as soon as possible if such information becomes available.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY? By participating in this study, you will contribute to research that may help other people quit smoking in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE? The alternative to participation is to decide not to enroll in this study. If you choose not to enroll in this study and would like to quit smoking, you will be given names of smoking cessation programs in the area. If you choose not to participate in the study neither your healthcare nor any benefits due to you will be changed.

WILL I HAVE TO PAY FOR ANYTHING? There will be no charge to you for participating in this research study. You and/or your health insurance may be billed for the costs of medical care during this study if these costs would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

WHAT HAPPENS IF I AM INJURED OR HURT IN THE STUDY? If you have a medical emergency during the study, you should go to the nearest emergency room. You may also contact the Principal Investigator or Study Physician listed on top of page 1 of this form (267-239-3651). You may also contact your own doctor or seek treatment outside the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this form for information about your care.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

WILL I BE PAID IN THIS STUDY? You may receive up to $280 for completing all study requirements, which includes $10 travel reimbursement for each in-person visit. In place of $10/session to cover travel expenses, you may elect to use a round-trip car ride service (i.e., Lyft) which will be arranged and paid for in full by the research study. If you choose to use the ride service, you will not receive $10 for your travel reimbursement and your total visit compensation will be up to $240. Travel will not be paid for a session intended to be in-person if it must be completed by phone.

"Task completion" compensation will depend on you arriving on time for in-person study visits, and following study instructions. If you do not follow instructions, the task completion compensation may be withheld.

You may be eligible for a $50 bonus at the end of the study for successfully completing all sessions. You may also receive a $20 referral incentive for each person successfully referred to the program once your participation has ended, for a maximum of three referrals. The referral bonus will be paid after completion of the last study visit (24-H Testing).

If you are deemed ineligible at any point during the study , we will compensate you $10 to cover your travel costs, unless you have elected to use the ride service for that session or the session was completed by phone.

The Greenphire ClinCard will be the primary form of payment for this study. The ClinCard is a reloadable, pre-paid card for the purposes of compensation. Compensation will be loaded onto the ClinCard within 24 hours of completed visits. Staff may ask you to provide a Social Security Number, or complete a W-9 for this purpose, after determining your eligibility so that a ClinCard can be assigned to you. ClinCards may be mailed to you following your eligibility determination for the study.

The payment schedule is described below:

Day	Study Visit	Visit Compensation	Task Completion	Travel[3]	Bonus	Total
-1	Intake	$20	-	$10		$30
0	Baseline	$30	$10	$10		$50
7	Remote Check-In	$10	$10			$20
14	Remote Check-In	$10	$10			$20
21	Pre-Quit Testing	$30	$10	$10		$50
23	24-H Testing	$40	$10	$10	$50[1]	$110
				Study Total:		**$280**
N/A	Referral Bonus				$60[2]	$60
				Total w/ Referrals:		**$340**

[1]Bonus awarded for completion of ALL study visits
[2]Table shows total compensation for three successful referrals
[3]Only paid if you opt-out of the round-trip car ride service; will not be paid if a visit has to be completed by phone

HOW DOES TRAVELING VIA THE RIDE SERVICE WORK? You may elect to use "Roundtrip", which is a car ride service that collaborates with Lyft to coordinate round-trip rides to study appointments. Study staff will schedule each ride using your first name, last name, and phone number via Roundtrip's HIPAA compliant platform. You will receive a reminder call 24-48 hours prior to your study visit to confirm your visit, interest in using the ride service, and preferred pickup/drop-off locations. You will be asked to provide a location within 15 miles of our center when booking the ride service. If the study staff cannot reach you by 5pm the day prior to your study visit, your ride will be cancelled. You will still be permitted to attend the visit and will receive $10 to cover your travel expenses. If you need to cancel a previously confirmed ride, you must do so by contacting the study staff immediately, preferably by 5pm the day before your appointment. If you fail to notify study staff within this timeframe, you may no longer be permitted to use the ride service at future study visits.

WHEN IS THE STUDY OVER? CAN I LEAVE BEFORE THE STUDY ENDS? This study is expected to end after all participants have completed all visits, and all information has been collected. This study may be stopped at any time if:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study procedures or stop taking study medication (i.e., miss 2 consecutive or 3 or more doses)
- You develop a contraindicated medical condition, or if you are prescribed a contraindicated medication.
- You have a bad reaction to the study medication, or if you become sick while receiving study medication.
- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Should your physician find it necessary, and/or in your best interest, he/she may withdraw you from the study. Withdrawal will not interfere with your future care or participation at our center.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED? We will do our best to ensure your personal information is kept private. However, we cannot guarantee total privacy. All information, results and samples will be identified with an identification number only (not your name). Only authorized personnel will be able to link your identification number to your name. All personal health information and data will be password protected, files will be encrypted, and records will be kept in locked filing cabinets to maintain confidentiality. Results will not be communicated to other personnel or subjects. All analyses will be

conducted on de-identified data. Your personal information may be given out if required by law. However, if information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If asked to provide blood samples at the Baseline and PQ-Testing visits, these samples will be stored in the Penn Mental Health AIDS Research Center (PMHARC) Core Laboratory. You will be asked to complete an additional PMHARC informed consent/HIPAA form to give permission for these samples to be stored and used in future PMHARC research studies. You will still be able to participate in this study even if you do not give this permission.

WHAT INFORMATION ABOUT ME MAY BE COLLECTED, USED OR SHARED WITH OTHERS?

- Name
- Street address, city, county, zip code
- Telephone numbers
- Date of birth
- E-mail address
- Medical and drug use history
- Social Security Number
- Results from all questionnaires, tests, or procedures
- Medical Record Number
- Results from urine for drug screening
- Results from blood for liver and renal function tests and blood sugar monitoring
- Information on smoking, cognition, or HIV-related biomarkers from blood sample

WHY IS MY INFORMATION BEING USED? Your contact information is used by the research team to contact you during the study. Other information and results are used to:

- Conduct the research,
- Oversee the research, and
- To ensure the research was conducted properly.

WHO USES AND/OR SHARES INFORMATION ABOUT ME? The following individuals may have access to your information for this research study:

- The Principal Investigator and research collaborators
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Clinical Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

ELECTRONIC MEDICAL RECORDS AND RESEARCH RESULTS.

What Is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record. If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.). No results from this research study or analyses will be placed in your EMR.

WHO, OUTSIDE OF THE SCHOOL OF MEDICINE, MIGHT RECEIVE MY INFORMATION?

The following University departments are working with the Principal Investigator:

- Center for AIDS Research (CFAR), University of Pennsylvania
- Penn Mental Health AIDS Research Center (PMHARC), University of Pennsylvania

The following are supporting and overseeing the research and the sponsor:

- The Office of Clinical Research, University of Pennsylvania
- The National Institutes of Health (NIH)
- The Abramson Cancer Center, University of Pennsylvania
- The Food and Drug Administration (if necessary)

The following entity is managing participant transportation and has access to first name, last name, and phone number only:

- Roundtrip

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will tell you if there are any additions to the list above while you are in the study. Any additions will be subject to University of Pennsylvania procedures to protect your privacy.

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. 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
- As permitted by law

CAN I CHANGE MY MIND ABOUT GIVING PERMISSION FOR USE OF MY INFORMATION? Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigators for the study. If you withdraw your permission after being enrolled, you will not be able to continue in this study.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION? You will not be able to participate in this research 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 questions, concerns, or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting 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. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the operations of this study. A copy of this form will be given to you.

Name of Research Participant:

PRINT NAME: _____

SIGNATURE: _____ DATE: _____

Name of Person Obtaining Consent:

PRINT NAME: _____

SIGNATURE: _____ DATE: _____