UNIVERSITY OF PENNSYLVANIA
RESEARCH STUDY SUMMARY FOR POTENTIAL SUBJECTS

Protocol Title:	**Targeting the Cholinergic Pathway in HIV-associated Inflammation and Cognitive Dysfunction (IRB# 828125)**
Principal Investigator:	**Rebecca Ashare, Ph.D., Phone: 215-746-5789** **Department of Psychiatry, University of Pennsylvania**
Emergency Contact:	**Ian Frank, M.D., Phone: 215-964-1077** **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 either, the Penn Institutional Review Board (IRB) at (215) 898-2614 for assistance, or the Research Participant Coordinator at the Philadelphia Department of Public Health IRB at (215) 685-0869.

The main purpose of this research study is to examine whether a medication called galantamine hydrobromide (Razadyne) may enhance performance on measures of memory and attention and may affect inflammation in people living with HIV.

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 be asked to complete 8 in-person visits and 6 monitoring phone calls, over the course of two identical 12-week study periods. Four of the in-person visits will include blood draws, cognitive tasks and questionnaires; the remaining in-person visits will only include cognitive tasks and questionnaires. The monitoring phone calls serve to track study medication use, as well as any side effects you may experience. The two study periods will be separated by a 4 week "Washout Period", during which you will not take any study medication or complete study sessions.

Your participation in the study will last approximately 7 months. 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 the knowledge that you are contributing in an important way to increasing scientific knowledge about neurocognitive disease and ways to improve its treatment in people living with HIV.

The most common risks of study participation are potential side effects from the study medication, galantamine hydrobromide. These side effects tend to be mild, and include: nausea, vomiting, diarrhea, dizziness, headache, and decreased appetite. 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, we can provide information on other studies at our center or 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:	**Targeting the Cholinergic Pathway in HIV-associated Inflammation and Cognitive Dysfunction (IRB# 828125)**
Principal Investigator:	**Rebecca Ashare, Ph.D., Phone: 215-746-5789** **Department of Psychiatry, University of Pennsylvania**
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WHY AM I BEING ASKED TO VOLUNTEER? You are being asked to take part in this research program because you have expressed an interest in participating, and meet other program criteria, such as having tested positive for HIV. Your participation is voluntary which means you can choose whether or not to participate. Before you make this decision, you will need to know the purpose of the research program, the possible risks and benefits of being in the research program, and what you will have to do if you decide to participate. The research team is going to talk with you about these things today. Please ask them to explain anything you do not understand, including any language contained in this form.

You do not have to make a decision about participating in this research program today; you can request a copy of this form to review at a later time, or share it with your family, friends, and/or doctor. Whatever you decide, there will be no loss of benefits to which you are otherwise entitled. If you do decide to participate, you will be asked to sign this form and will be given a copy for your records.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY? The main purpose of this research study is to examine whether a medication called galantamine hydrobromide (Razadyne) may enhance performance on measures of memory and attention and may affect inflammation in people living with HIV.

HOW LONG WILL I BE IN THE STUDY? HOW MANY OTHER PEOPLE WILL BE IN THE STUDY? Overall, 120 people will complete this research program over an approximately 5-year period. Your individual participation will last about 7 months.

WHAT AM I BEING ASKED TO DO? The study is divided into two identical 12-week study periods. Within each of these 12-week periods, you will take study medication, complete questionnaires and cognitive tasks and be asked to provide blood and saliva (if applicable) samples for analysis. In one of the study periods, you will take galantamine and in the other, you will take a placebo. Neither you nor the study staff will know which medication you are taking within each study period; however, we can find out this information if necessary for your medical care. Between the 12-week periods, you will not take any study medication for at least 4 weeks or attend any study-related appointments; this is called the "Washout Period." For the duration of the study, you should continue your smoking or non-smoking behavior as usual. Overall, you will complete 8 in-person visits and 6 monitoring phone calls throughout this study. Study visits are described in more detail below.

Intake Session. 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, benzodiazepines, PCP, methadone, barbiturates, ecstasy (MDMA), oxycodone, or opiates, you may not be eligible to participate in this study. Results from this testing are used for research purposes only. They will not be shared with you and will not be placed in your electronic medical record. You will be informed of your eligibility status after testing.

- **(Females of child-bearing potential only):** Be provided with a urine pregnancy screen and will be asked to perform the screening independently. For safety purposes, if you think you are pregnant, we advise that you discontinue study participation. There is no penalty for withdrawing from the study at this point and you will still receive travel reimbursement.
- Provide a breath sample for a carbon monoxide (CO) assessment to confirm your smoking status. Carbon monoxide is a poisonous gas that comprises less than 1% of the air we breathe and is also produced through smoking a cigarette.
- Complete brief psychiatric assessments called the 'MINI' and 'CSSRS' interviews. During these interviews, we will ask you about any current and past depressed mood symptoms as well as other psychiatric symptoms.
- Complete a medical history, where you will be asked about any past medical conditions that you may have been diagnosed with. You will have your blood pressure measured and be asked about any medications that you are currently taking or discontinued taking within the last 2 weeks. You will also complete a brief physical examination, led by a medical professional.
- Complete a brief mental ability test called the 'Shipley Institute of Living Scale'.
- Complete assessments of your demographics, alcohol and smoking history and rate (if applicable), behaviors, and mood.
- Provide an 8.5 mL blood sample (less than 2 teaspoons) that will be used to assess liver and kidney function. This is required to ensure it is safe for you to take the study medication. When the results of the test are received (within 2-7 days of the Intake visit), a member of our staff will contact you to let you know if you are eligible to participate in the study.

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

Final Eligibility Phone Call: A staff member will call you to inform you of your final eligibility. If you are eligible, you will confirm the proposed study schedule discussed at Intake. If you are ineligible, we can refer you to other programs at our center, or in the Philadelphia area.

Laboratory Visits (Weeks 0, 12, 16 and 28): Four times throughout the study (twice during each treatment period), you will attend in-person laboratory visits at our center that will last about 2 hours. During this time, you will:

- 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, benzodiazepines, PCP, methadone, barbiturates, ecstasy (MDMA), oxycodone, or opiates, you may not be eligible to participate in this study. Results from this testing are used for research purposes only. They will not be shared with you and will not be placed in your electronic medical record. You will be informed of your eligibility status after testing, but specific results will not be shared.
- **Smokers only:** Provide a saliva sample to verify smoking status.
- Provide a breath sample for a carbon monoxide (CO) assessment.
- Complete a blood pressure assessment.
- Complete questionnaires that assess smoking behavior (if applicable), mood, and sleep quality.
- Complete computer tasks that test your memory and attention.
- Provide a blood sample (up to 80 mL).
- Receive instructions on how to use your initial supply of medication at the beginning of each treatment period (weeks 0 and 16 only). Medication will be mailed to you prior to the start of treatment or provided at the visit.

Monitoring Phone Calls (Weeks 2, 6, 10, 18, 22 and 26). Six times throughout the study (three times during each treatment period), you will participate in a phone call designed to track your medication use and to monitor any

side-effects you may be experiencing. These phone calls will be scheduled in advance and will last about 15 minutes.

Mid-treatment Visits (Weeks 4, 8, 20 and 24). Four times throughout the study (twice during each treatment period) you will attend in-person mid-treatment visits at our center that will last about 1.5 hours. During this time, you will:

- Complete carbon monoxide (CO), blood pressure, and smoking rate assessments (if applicable).
- Complete questionnaires that assess smoking behavior (if applicable) and mood.
- Complete computer tasks that test your memory and attention.
- Review instructions for your additional supplies of medication, which will be mailed to you or provided at the visit.

Washout Period (Between Weeks 12-16). After your first treatment period, you will not take any study medication for the next 4 weeks. The Washout Period will allow the study medication to be eliminated from your body.

End of Study Phone Call (within a week of last completed visit). Participants will be contacted within a week of their last completed visit for the study. This call will be to discuss any final details of participation and to answer any questions the participant may have.

Sample Analyses.
Some of the blood collected will be used to examine viral load. The remaining blood will be analyzed by testing monocytes and plasma proteins. Monocyte and plasma protein testing will determine if treatment has changed the behavior of monocytes in the blood. The Wistar Institute will conduct additional glycomic analyses on blood samples already collected for the purposes of this study. This additional analysis will not require additional blood samples, and your samples will be completely de-identified before being sent to the Wistar Institute. The results of these analyses are exploratory which means we do not yet understand their role in inflammation or cognitive function, and they will not be shared with you.

Saliva samples will be analyzed for cotinine after collection. Cotinine is a biomarker for exposure to tobacco smoke. The results of these analyses will not be shared with you.

Viral Load and Anti-Retroviral Information. We will ask that you complete a brief questionnaire about your anti-retroviral use at laboratory and mid-treatment visits. For Intake, we will ask you to provide viral load results and may contact your clinic or provider for this purpose. If you are not able to provide these results, we may ask that you review and sign a HIPAA short form for the release of this information for the research study.

HOW WILL I RECEIVE COMMUNICATIONS FROM THE STUDY? As discussed during your initial phone screening, the primary mode of communication throughout the study will be text via the Way 2 Health software platform. You will be contacted up to several times a week with study reminders and 3 times throughout the study for short text-based surveys. You may change your communication preference at any time during the study. If you do not wish to receive text reminders or if you do not have a phone that is compatible with text reminders, you can opt to receive phone call or email reminders.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS? While enrolled in this research program, you will be asked not to use any smoking cessation therapy or other treatments for nicotine dependence, including Chantix®, nicotine gum, nicotine spray, nicotine lozenge, nicotine inhaler and the e-cigarette. The likelihood and severity of the potential risks to you are described below:

Study Medication: The following side effects have been reported by some people who take galantamine (Razadyne). The most common were nausea, vomiting, diarrhea, dizziness, headache, and decreased appetite. All of these side effects have been mild and temporary in nature with the doses of galantamine (8mg, 16mg and 24mg/day) you will receive in the study.

In addition to those listed above, less common (<5% of patients) side effects include depression, stomach discomfort, stomach pain, heartburn, weight loss, extreme tiredness, tremors, slowed heartbeat, and muscle spasms. Rare, but potentially serious side effects occurring in <1% of patients include dysgeusia (change in sense of taste), burning or tingling sensation in hands, arms, legs, or feet, fainting, shortness of breath, difficulty falling asleep or staying asleep, and excessive sweating. To help minimize these side effects galantamine will be prescribed at 8mg per day for the first 4 weeks and then increased to 16mg per day for the following 4 weeks before beginning to take the final dose of 24mg per day for 4 weeks. Because some people may need more time to adjust to the medication, you may be asked to remain on a lower dose of the study medication for a longer amount of time. Remember, neither you nor the study staff will know which treatment period you will be taking galantamine or placebo.

We have compiled stringent exclusion criteria to limit the chance of side effects. You will be assessed for these criteria at the Intake session. We will also monitor all of these side effects regularly using a side effect checklist. If you, as a participant, becomes aware of these symptoms, report them as soon as possible to the research staff so that we can limit any adverse reactions. You should refrain from taking any new prescription or over the counter medications while in the study. Please inform a member of our research staff if you start taking any new medications during your participation.

If you do experience any severe side effects or related medical issues during your participation in the study, please contact the Study Physician (listed on page 1) at the telephone number provided. Dr. Frank's emergency contact information is also on the medication blister pack that you will receive.

Reproductive Risks (**Females only)**: Galantamine (Razadyne) must not be given during pregnancy and/or nursing. Therefore, if you are a woman of child-bearing potential, please notify the study physician if you become or intend to become pregnant during the study period. Any pregnant or nursing women will be excluded from the study. Women of childbearing potential will be provided with a urine pregnancy screen at Intake visit and subsequent laboratory visits and will be instructed to perform the screening independently. For safety purposes, we advise that participants who think they may be pregnant discontinue study participation. There is no penalty for withdrawing from the study at this point and participants will still receive travel reimbursement. By signing this form, if you are of childbearing potential, you agree to use an approved method of contraception (such as condoms and spermicide or birth control pills) or abstain from having sex during your participation in this study.

Blood draw: Blood draws may result in bruising and/or slight bleeding at the needle site or may cause you to feel faint. All of these side effects are rare. Blood will be drawn by a trained professional, reducing the risks of these discomforts.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE PROGRAM? During the course of this program, we may find more information that could be important to you and your health. When feasible, we will notify you as soon as possible if such information becomes available. For example, we would contact you immediately if new information became available about the study medication that might cause you to change your mind about being in the program.

WHAT ARE THE POSSIBLE BENEFITS OF THE PROGRAM? Participants who enroll in this study will benefit from the knowledge that they are contributing in an important way to increasing scientific knowledge about neurocognitive disease and ways to improve its treatment in people living with HIV.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE? The alternative to participation is to decide not to enroll in this program.

WILL I BE PAID IN THIS PROGRAM? To reimburse you for the time and effort needed for completing assessments, you may earn up to $590, which includes $10 for travel-related expenses at each in-person session. 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 may be up to $500. Travel will not be paid for a session intended to be in-person if it has to be completed by phone.

The "task completion" compensation will depend on you arriving on time for scheduled sessions and returning used blister packs by the end of study participation. If you do not follow the study instructions, the task completion compensation may be withheld.

If at any point you are deemed ineligible, you will only be compensated $10 to cover your travel costs, unless you have elected to use the ride service for that session.

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.

You will be eligible for a $40 bonus at the end of each treatment period for successfully completing all visits during that period. You may also receive a $20 bonus for each person successfully referred to the program, for a maximum of three referrals. This will be paid to you after completing the last study visit (Period 2 Lab Visit 2).

The payment schedule is as follows:

Compensation Schedule							
Week	**Period**	**Study Visit**	**Visit Compensation**	**Task Completion**	**Travel[3]**	**Bonus**	**Total**
-2	N/A	Intake	$20		$10		$30
0	1	Lab Visit 1	$35	$15	$10		$60
2	1	Monitoring Call 1	$10		$0		$10
4	1	Mid-Tx Visit 1	$25	$15	$10		$50
6	1	Monitoring Call 2	$10		$0		$10
8	1	Mid-Tx Visit 2	$25	$15	$10		$50
10	1	Monitoring Call 3	$10		$0		$10
12	1	Lab Visit 2	$25	$15	$10	$40[1]	$90
16	2	Lab Visit 1	$35	$15	$10		$60
18	2	Monitoring Call 1	$10		$0		$10
20	2	Mid-Tx Visit 1	$25	$15	$10		$50
22	2	Monitoring Call 2	$10		$0		$10
24	2	Mid-Tx Visit 2	$25	$15	$10		$50
26	2	Monitoring Call 3	$10		$0		$10
28	2	Lab Visit 2	$25	$15	$10	$40[1]	$90
					Study Total:		**$590**
N/A	2	Referral Bonus				$60[2]	$60
					Total w/ Referrals:		**$650**

[1] Bonus awarded to participants that complete every visit in a period, at the end of each period.

[2] Table shows total compensation for three successful referrals

[3] Only paid if you opt out of the round-trip car ride service

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. 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.

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

If you choose to receive text message reminders, you will be responsible for the costs associated with the receipt of these text messages. For example, if you have a monthly text-messaging plan, these messages will count towards your monthly text-messaging total. If you do not have a plan, you will be charged the standard text messaging fees by your wireless provider. You may receive a maximum of 20 text messages from the study each month.

WHAT HAPPENS IF I AM INJURED OR HURT IN THE RESEARCH PROGRAM? In the event that you are hurt or injured as a result of participation in this research program, please contact the investigator listed on page one of this form. We will offer you the care needed to treat injuries directly resulting from participation in this research program. We may bill your insurance company or other third parties, if appropriate, for the costs of the care associated with these injuries; however, you may also be responsible for some of these costs. There are no plans for the University of Pennsylvania to pay you or provide other compensation for the injury. You do not give up your legal rights by signing this form.

WHEN IS THE RESEARCH PROGRAM OVER? CAN I LEAVE BEFORE IT ENDS? This research program is expected to end after all participants have completed all visits and all information has been collected. This program may also be stopped at any time by your physician, the program Sponsor, or the Food and Drug Administration (FDA) without your consent if:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you would be informed if such a decision was made and the reason for this decision.
- You have not followed program instructions.
- The Sponsor or Principal Investigator has decided to stop the program.

If you decide to participate, you are free to leave the research program at any time. Withdrawal will not interfere with your future care or participation at our center.

WHAT HAPPENS TO MY COLLECTED SAMPLES AND INFORMATION? Samples collected as part of this study will be used for multiple analyses, as described above. We would like to store your information (such as demographic information, questionnaire responses etc.) and samples for possible use in future research. This storage may be for an indefinite amount of time. The information and samples you provide may be shared with other research institutions, e.g. The Abramson Cancer Center at Penn, or researchers working with research institutions who want to learn more about neurocognitive disease in people living with HIV. Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code. We will protect your confidentiality by first labeling your information and samples with an identification number only (not your name). We will restrict access to the databases that hold your personal information. Your samples will be stored in a locked, private bank, accessible only by authorized personnel. Permission to store your information and samples for use in future research is optional and you can indicate your choice at the end of this consent form. You may withdraw your permission at any time by contacting study staff and letting us know you no longer want your information and samples to be stored for use in future research. Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Most use of samples or information do not lead to commercial products or to profit for anyone. Additionally, we will not follow up with you about the specific research that will be done, and individual research results obtained as part of future research will not be shared with you.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED? While we cannot guarantee total privacy, we will do our best to make sure that the personal information in your research record is kept private. Your personal information would only be given out if required by law. We will store your information in a secure room with limited access. We will also control access to the computer files that hold this information. We will identify all results from sample collection and analysis with an identification number only (not your name). Only authorized program personnel will be able to link your identification number with your name. Your samples will be stored in our private bank, which can be accessed only by authorized study personnel. Blood samples will be fully de-identified before being sent to the Wistar Institute for additional analyses. If information from this research is published or presented at scientific meetings, your name and other personal information will not be used. 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.

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

- Name, address, telephone number, email address
- Date of birth
- Social Security Number (W-9 form)
- Some personal information that may be considered sensitive, such as medical history, psychological history, alcohol use history, etc.
- Results from physical examinations, tests or procedures, including urine drug screening
- Information on smoking, cognition, or inflammation biomarkers from the blood samples provided at the Intake and Laboratory sessions
- Saliva sample for testing by-products of nicotine (smokers only)
- Medical Record Number

WHY IS MY INFORMATION BEING USED? Your contact information is used by the research team to contact you during the program. Your personal health information and results of procedures are being collected as part of this research program. In some situations, personal health information might be used to help guide your medical treatment.

WHO MAY USE AND SHARE INFORMATION ABOUT ME? The following individuals and organizations may use or disclose your personal health information for this research program:

- The Principal Investigator (PI) and research collaborators
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and the University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office that monitors research studies)
- Way 2 Health team (programming, troubleshooting, monitoring software etc.)
- Authorized members of the University of Pennsylvania and the UPHS, and School of Medicine workforce that may need to access your information in the performance of their duties (e.g., research oversight and monitoring)

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 THE SCHOOL OF MEDICINE, MIGHT RECEIVE MY INFORMATION?
The following are working with the Principal Investigator:

- Center for AIDS Research (CFAR), University of Pennsylvania
- The Wistar Institute

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

- The Office of Clinical Research, University of Pennsylvania
- The Food and Drug Administration
- The National Institutes of Health (NIH)
- The Abramson Cancer Center, University of Pennsylvania
- Philadelphia Department of Public Health Institutional Review Board

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

- Roundtrip

The Principal Investigator or research staff will inform you if there are any changes to the list above during your active participation in the trial. Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. This does not mean that all personal identifying information is being disclosed. Generally, if information has to be released it contains only initials and birth date, or only a unique number, not complete contact information. Any such additions will be subject to Penn UPHS and School of Medicine procedures to protect your privacy.

HOW LONG MAY THE SCHOOL OF MEDICINE USE OR DISCLOSE MY PERSONAL HEALTH INFORMATION (PHI)? Your authorization for use of your personal health information for this specific program does not expire. Your information may be held in a research repository or database. However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this program for a purpose other than this program unless:

- You have given written authorization to do so
- The University of Pennsylvania Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- It is required by law

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

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 program.

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 program 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 who is not directly involved with this program, 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 program. 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 program. 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: _____

Future Use Of Data/Biospecimens:
Please initial and check **YES** if you give permission for us to store your information and some of your blood from this study for use in future research. Please initial and check **NO** if you **do not** give us permission to store your information and some of your blood from this study for use in future research.

☐ YES ☐ NO Participant Initials: _____