Protocol Details

Basic Info

Confirmation Number:	**caijcfed**
Protocol Number:	**824715**
Created By:	**CHAIYACHATI, KRISDA H**
Principal Investigator:	**GRANDE, DAVID T**
Protocol Title:	**The impact of rideshare transportation services on appointment adherence**
Short Title:	**Rideshare services for improved outpatient clinic access**
Protocol Description:	**We propose a randomized control trial (RCT) testing the impact of rideshare service (RSS) on primary care clinic no-show rates among Medicaid adults. Given the novelty, we will deploy the intervention in two phases. Phase 1 will focus on discovering the operational challenges of implementing the intervention using in-depth qualitative interviews and testing operational design strategies for Phase 2. Phase 2 consists of the randomized control trial with questionnaires for the intervention arm.**
Submission Type:	**Social and Biological Sciences**

Resubmission*
Yes

Study Personnel

Principal Investigator

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Training Expiration Date:	
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Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

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HS Training Completed:	
Training Expiration Date:	
Name of course completed :	

Responsible Org (Department/School/Division):

4239 - DM-General Internal Medicine

Key Study Personnel

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Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

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Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Con icts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
In phase 1, all patients sampled will receive the intervention arm (i.e. without a control) will be piloted to understand design challenges for Phase 2, such that we can create modifications to the design for optimal deployment in Phase 2. In order to understand these challenges, we will a) conduct a series of in-depth qualitative interviews of patients, b) conduct field notes by traveling with patients in a ride-share vehicle, and c) monitor uptake of the intervention. To better understand the transportation needs of patients in the West Philadelphia area who attend the Penn Medicine clinic (the same population exclusion and inclusion criteria as Phase 2), we will conduct in-depth qualitative interviews focused on previous transportation experiences and implementation themes related to acceptability and feasibility. For these interviews, patients will be asked after they had completed their clinic appointment and provided with a ride home as compensation for completing the qualitative interview. These qualitative interviews will take place in the return trip home from clinic, including time in the vehicle with the patient. Interviews will be audio-recorded. For the second component of Phase 1, the same researcher conducting the in-depth qualitative interviews will be recording observations with regards to challenges for the patient accessing a rideshare service or challenges on the return trip home. Anticipated challenges may include how patients and drivers manage mobility challenges, coordinating pickups in the absence of utilizing the commonly used rideshare smartphone app, or safety concerns by either the patient or driver. For the third component, we will record the uptake of the intervention (e.g., proportion of patients who are offered a ride who ultimately use it to get to and from clinic) based on variations in the design. For example, changing whether patients call a standard number to request a ride versus we call them, or the timing of the pre-pickup phone call to account for traffic patterns or rideshare care availability in order to standardize the timing of the phone call (e.g. 30 minutes before the pickup time vs. one hour before the pickup time) in order to make sure patients get to their predetermined destination on time (e.g., home or clinic). In phase 2 - the randomized control trial phase, telephone-

based survey data will be collected from patients in the intervention arm where patients will be offered a rideshare service (RSS) transportation option to use on the day of their appointment. When offering the service to the intervention arm, we will consent the patient to participate in a pre-appointment and post-appointment survey at the same time. Patients will be compensated for completing the pre-appointment survey with a free RSS ride to and from their clinic. The pre-appointment survey contains questions regarding previous transportation modes and demographic questionnaire; and the post-appointment survey will assess the patient's experience using RSS. For those who consent over the telephone days prior to their appointment, but do not ultimately use the RSS or do not show-up to their appointment, we will only have results from their pre-appointment survey as that is built into the telephone consent session.

Group Modifications

Describe necessary changes that will or have been made to the study instruments for different groups.

No group modification occurs in Phase 1, the only group modification occurs in phase 2, the randomized control trial phase. Here, both the intervention and control arms will receive a telephone reminder within one week of their appointment (the current standard of care) to control for the effect of a phone call that may remind the patient that they have an upcoming clinic appointment, potentially altering the decision of patients to attend their clinic appointment (our primary outcome of interest). In the control arm where patients do not receive an RSS offer, they will receive a standardized appointment reminder only. In the intervention arm, patients will receive a standardized appointment reminder and offered the RSS transportation option with the pre-appointment survey. Similarly, only the intervention arm will receive the post-appointment survey. When offering the service to the intervention arm, we will also consent the patient for both the pre-appointment and post-appointment survey. Patients will be compensated for completing the pre-appointment survey with a free RSS ride to and from their clinic. The pre-appointment survey contains questions regarding previous transportation modes and demographic questionnaire; and the post-appointment survey will assess the patient's experience using RSS. For those who consent but do not use the RSS or do not show-up to their appointment, we will only administer the pre-appointment survey as that is built into the telephone consent session.

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.

During phase 2, the randomized control trial phase, patients on even number calendar days will be offered RSS while those on odd number days will not be offered. No group assignment will occur in phase 1.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

For phase 1, the pilot phase, in-person qualitative interviews will be audio-recorded after permission is granted from the patient using the informed consent process. This interview will occur over the course of the journey home for the patient. We will purposefully sample patients of varying age categories, genders, and geographic locations over the course of 2-6 week period. Additionally, questions regarding transportation challenges and demographic information will be asked, including age, race, and gender. Patients will be made aware that we are also making notes regarding challenges observed while traveling with the patient. For phase 2, when offering the service to the intervention arm, we will consent the patient to participate in a pre-appointment (approximately 15 minutes including consent) and post-appointment survey (less than five minutes). Patients will be compensated for completing the pre-appointment survey with a free RSS ride to their clinic. The pre-appointment survey contains

questions regarding previous transportation modes and demographic questionnaire; and the post-appointment survey will assess the patient's experience using RSS. For those who consent pre-appointment but ultimately do not use the RSS or do not show-up to their appointment, we will only administer the pre-appointment survey because that occurs during the telephone consent.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

Once qualitative interviews or surveys have been completed, each study participant will be assigned a unique identification number that will be linked to their name and survey data. These identification numbers will be added to each study participants's audiotapes (phase 1), field observation notes (phase 1), and electronically recorded survey data (phase 2) to allow for tracking of responses. Transcripts created from audiotapes in the phase 1 development phase will be stripped of any identifying information by transcribers educated in qualitative data preparation techniques and the importance of confidentiality. Transcripts will be stored in password protected sections of the computer. Phone surveys (phase 2) results will be entered into REDCap, a secure-web-based application that provides data management assistance for surveyed information. REDCap provides automated export procedures for seamless data downloads to excel and common statistical packages. Any paper study materials (including notes or data summaries) will be kept in locked cabinets. This information will be accessible only to study personnel who need the information for data collection. The PI(s) will be responsible for creating and maintaining the database. Following the completion of data collection and assessment of potential response bias, the file linking subject numbers and personal identifiers will be erased. This system will consist of two separate but related systems: a management information system (MIS) and primary data management system (PDMS). The MIS will track all subjects who were approached and will include their participation status, name, age, and zip code. Periodic reports will be generated to assess whether recruitment is proceeding on schedule and identify any recruitment problems. The PDMS will include all subject survey data. Relational database software, such as Microsoft Access, will be used to maximize management information tool flexibility and to prepare data files for statistical analysis. Any identifiable information will be destroyed no later than July 1, 2017 and most likely earlier than that date. Furthermore, the data will only be reported in an aggregated format, without individual identifiers. This includes avoiding the reporting of any identifiable information used in the analysis of these data.

Radiation Exposure*

Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?

No

Human Source Material*

Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?

No

CACTIS and CT Studies*

Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?

No

CAMRIS and MRI Studies*

Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?

No

Cancer Related research not being conducted by an NCI cooperative group*

Does this protocol involve cancer-related studies in any of the following categories?

No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

CTRC Resources*
Does the research involve CTRC resources?
No

If the answer is YES, indicate which items is is provided with this submission:

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Survey research (the main focus of the research is administration of a survey to research subjects)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

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Department budget code

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

Funding Sponsors

Name:	**UNIVERSITY OF PENNSYLVANIA**
Type:	**UPENN Internal**

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.
Not applicable

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND Sponsor

none

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Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Pending

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

Grant Application (ldi2015pilotgrant_krisdachaiyachati.pdf)

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research
Not applicable

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract
We propose a randomized control trial (RCT) testing the impact of rideshare services (RSS) on reducing primary care clinic no-show rates for Medicaid patients, the main outcome of the study. We will assess the patient experience after each ride using a telephone-based survey. Secondary aims focus on characterizing transportation efficiencies (such as time between pickup and drop-off locations), measures of uptake, the timing of clinic attendance, and operational costs. The study has two phases. Phase 1 will focus on discovering the challenges of implementing the intervention through in-depth qualitative interviews, field observations occurring simultaneously as the interviews, and pilot testing different ways patients can access the RSS. For phase 2, the full pilot involving randomization for the intervention. All adults with established primary care at the Penn Medicine Clinics, who have Medicaid, do not require wheelchair accessible rides, and body mass index (BMI) less than 40 will be eligible.

Objectives

Overall objectives
We propose a randomized control trial (RCT) testing the impact of rideshare services (RSS) on outpatient no-show rates. In the intervention arm, we will administer pre-appointment and post-appointment surveys to assess current transportation modes and the acceptability of using RSS. Secondary aims focus on describing the efficiency of the RSS transportation (e.g., travel distance and travel time), misuse of the service, clinic check-in times, and costs. Given the novelty, we will test the intervention in two phases. Phase 1 will focus on discovering the challenges of implementing the intervention through structured qualitative methods and field testing to inform the final operating procedures for phase 2, the randomized control trial.

Primary outcome variable(s)
Our primary outcome is for Phase 2 - the frequency of missed appointments in the intervention arm and the control arm.

Secondary outcome variable(s)
For the intervention arm only - patient perceptions of reliability, timeliness, and safety with regards to the RSS intervention. For both arms - clinic check in times.

Background
Reliable transportation for primary care appointments is a significant burden for low-income patients in urban areas, limiting their accessibility to outpatient, primary care and ultimately shifts their care utilization patterns towards more costly, acute care settings either because of preference or medical need. Surveys of low-income patients indicate that between 24-51% of patients reported having ever missed or rescheduled a clinic appointment because of unreliable transportation. Without reliable and accessible transportation, patients shift their preference away from primary care clinics towards the overuse of acute care settings for ambulatory care sensitive conditions - a key target of the U.S. Agency for Healthcare Research in Quality for reducing low-value, high cost care in our health system. A variety of transportation options exist for patients. However, traditional transportation modes are inconvenient, unreliable, or costly for low-income patients. Medicaid finances NEMT with door-to-door van services by outsourcing to private companies or will provide public transportation passes. The eligibility to access these services is broad for the Medicaid population in Pennsylvania, including individuals with supplemental security income benefits and pregnant women below the federal poverty level. However, NEMT services are seen as inconvenient, require advanced scheduling of 3-5 days, and are relatively inflexible to changes to the location or timing of pickups and drop-offs. Taxis are an alternative door-to-door service, but are costly. When personal vehicles are accessible, parking can be a significant time and financial burden. Finally, for low-income patients, the accessibility of friends and family are limited because they too have significant health care needs or require their personal vehicles for work. An RSS-based intervention that provides a cheap, reliable alternative transportation for low-income patients to outpatient appointments may ultimately improve patient access to primary care services, potentially improving patient health and reduce costs in our healthcare system. In the long run, RSS could have a positive return on investment for a health system in a more capitated payment system or represent an alternative transportation strategy for state Medicaid programs.

Study Design

Phase*
Not applicable

Design
We propose a mixed-methods study incorporating surveys into an RCT designed to improve patient transportation accessibility for Medicaid patients with primary care appointments at the internal medicine practices at Penn Medicine. Our primary outcome is to determine the frequency of missed appointments in the intervention and control arm. This data will be complemented by pre- and post-appointment surveys. The study population includes adult Medicaid patients with primary care appointments at Penn Medicine. The RSS in this study will be provided for free to patients, matching the current non-emergency medical benefit provided by the state Medicaid program and voucher based transportation. The study will be completed in two phases. Phase 1 will focus on discovering the challenges of implementing the intervention through field testing and qualitative interviews. In phase 1, all patients sampled will receive the intervention arm (i.e. without a control) will be piloted to understand design challenges for Phase 2, such that we can create modifications to the design for optimal deployment in Phase 2. In order to understand these challenges in Phase 1, we will a) conduct a series of in-depth qualitative interviews of patients, b) conduct field notes by traveling with patients in a ride-share vehicle, and c) monitor uptake of the intervention. Overall we will test the RSS design with approximately 75 patients until design challenges have been solved. Of the 75 patients we will randomly sample approximately 20 of them to complete in-depth interviews. The in-depth qualitative interviews will help us better understand the transportation needs of patients in the West Philadelphia area who attend the Penn Medicine clinic (the same population exclusion and inclusion criteria as Phase 2), allowing us to make any necessary adjustments to the design to match the transportation needs for low income patients. During the in-depth qualitative interviews, we will focus on previous transportation experiences and implementation themes related to acceptability and feasibility. For these interviews, patients will be asked after they had completed their clinic appointment and provided with a ride home as compensation for completing the qualitative interview. These qualitative interviews will take place in the return trip home from clinic, including time in the vehicle with the patient. Interviews will be audio-recorded. For the second component of Phase 1, the same researcher conducting the in-depth qualitative interviews will be recording observations with regards to challenges for the patient accessing a rideshare service or challenges on the return trip home. Anticipated challenges may include how patients and drivers manage mobility challenges, coordinating pickups in the absence of utilizing the commonly used rideshare smartphone app, or safety concerns by either the patient or driver. For the third component, we will record the uptake of the intervention (e.g., proportion of patients who are offered a ride who ultimately use it to get to and from clinic) based on variations in the design. For the initial design, the patient will receive a phone call with one week which will serve as an appointment reminder, an offer to be a participant in this study, and instructions on how to access the RSS on the day of the appointment. Then on the morning of the appointment, the patient will receive a text reminder with instructions on how to access RSS. The patient calls a hotline to request the ride and a research team member coordinates the ride using a dispatch tool developed by Lyft. To test different designs, we may, for example, change whether patients call a standard number to request a ride versus we call them, or alter the timing of the pre-pickup phone call to account for traffic patterns or rideshare care availability in order to standardize the timing of the phone call (e.g. 30 minutes before the pickup time vs. one hour before the pickup time) in order to make sure patients get to their predetermined destination on time (e.g., home or clinic). This process will inform the final operating procedures for phase 2, the full trial of the intervention where we test the primary aim of missed appointments. Additional covariates will be collected from the electronic medical record, including Charleson comorbidity index, BMI, provider, missed appointment history, continuity, and basic demographic data. For both phases of the study, If patients have an address in W. Philadelphia but need a ride from a different location, they can still access RSS. They can only request a ride, though, that is no more than the cost of the ride from their home to the clinic (estimate $10). This is similar for the return ride home the cost of the ride cannot exceed the ride from the clinic to home. Therefore, patients will have the flexibility to take a ride from or to anywhere in the city within those cost limits. UPHS is currently a party to a non-disclosure agreement with Lyft. UPHS is also negotiating a services agreement for the purposes of the study and will consider future agreements with Lyft to provide transportation.

Study duration
Approximately 6-8 months. One to three months will be devoted towards the phase 1 field testing of the

intervention. Phase 2 will be the RCT where we estimate it will take approximately three to five months to reach our target numbers in both arms.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
We have successfully completed numerous mixed-methods and RCT studies testing the implementation of novel methods for improved health care delivery and create innovative strategies in a variety of settings, including Penn Medicine. The team includes investigators experienced in primary care delivery, social determinants of health, survey methods, qualitative interview techniques, and rapid cycle innovation. The experience acquired and infrastructure developed from these studies will ensure successful completion of the proposed work and we have established infrastructure (physical and electronic) to ensure human subjects research protection. Moreover, we have teamed up with Lyft, who will be providing the technical support and web-based platform to access their drivers for this intervention. Lyft® is a nationwide, RSS company that utilizes a smartphone app and web-based interfaces for ride requests and financial transactions. We will hire a research assistant who will assist with contacting patients in both arms (per the protocol), coordinating the rides for patients, and collecting clinic level data. This research assistant will have have HIPAA certification and CITI training completed. UPHS is currently a party to a non-disclosure agreement with Lyft. UPHS is also negotiating a services agreement for the purposes of the study and will consider future agreements with Lyft to provide transportation.

Characteristics of the Study Population

Target population
Adult (older than 18 years old), Medicaid patients with primary care appointments at the internal medicine practices at Penn Medicine. Patients included in the study will have established primary care at the Penn Medicine clinics and have addresses in the electronic medical record designating a West Philadelphia zip code. Patients with BMI greater than 40 or who require wheelchair accessible transportation will be excluded because of the limited availability of accommodating vehicles. These individuals will be screened through the electronic medical record for BMI before being called for consent and via the pre-appointment survey for patients requiring wheelchair accessible transportation. Over the phone, the latter group will be offered the ability to connect with Logisticare, the current company providing Medicaid sponsored wheelchair accessible rides to clinic. For phase 1, we will enroll up to 75 patients, of which 20 or so patients will receive in-depth qualitative interviews. For phase 2, we will enroll 572 patients in the intervention arm and compare them to 572 individuals in the control arm.

Subjects enrolled by Penn Researchers
667

Subjects enrolled by Collaborating Researchers
0

Accrual
A weekly list of eligible patients and patient phone number(s) will be generated by the Penn Medicine clinic staff or by our research team based on a our pre-specified inclusion criteria. From this list we will be able to collect eligible patients for phase 1 and for phase 2 when we will require contact information for both the control and intervention arms. Any staff contacting patients will be HIPAA certified.

Key inclusion criteria
Adult (18 years old), Medicaid patients with primary care appointments at the internal medicine practices at Penn Medicine. Patients included in the study will have established primary care at the Penn Medicine clinics. Additionally, patients will have addresses in the West Philadelphia zip codes.

Key exclusion criteria
Patients with BMI greater than 40 or who require wheelchair accessible transportation will be excluded because of inability to guarantee vehicles that will be able to accommodate patients' physical needs.

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
None

Subject recruitment
Using the EPIC electronic medical record database, our research team will collaborate with the clinic staff to identify and call eligible patients within a week of their scheduled appointment to offer the RSS and obtain consent for the qualitative portions.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

Subject recruitment (phase2_telephonereminderconsent.docx)

Subject recruitment (v2_phase1and2_telephonereminderconsent_wtrackchanges.docx)

Subject recruitment (v2_phase1and2_telephonereminderconsent_cleaned.docx)

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

In phase 1 and phase 2, patients will receive a free RSS transportation for completing the qualitative interviews and questionnaires. Estimated $5-10 USD. The cost of the rides will not exceed the market rate of traveling from the western most part of West Philadelphia to the Penn Medicine Clinics.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Not applicable

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
Yes

A. Deception/incomplete disclosure is typically only acceptable in studies with no more than minimal risk. Please detail why this study is minimal risk.

This study provides no more than minimal risk because patients all require some form of transportation to clinic, either walking or motor vehicle. For those not walking to clinic, we are simply providing a transportation alternative for the intervention arm. Currently, Medicaid patients are eligible to receive transportation services through Medicaid's Non-Emergency Medical Transport Program. For the control arm, their mode of transportation will be the typical mode they use to get to clinic.

B. The deception/incomplete disclosure should have no adverse effects on welfare. Please outline how all adverse effects are minimized.

Patients in the control arm will not be offered the rideshare service. They will not know they did not receive the intervention. Because our primary aim is missed appointment rates, we do not want to alter their motivation or mode they choose to use when attending their clinic by knowing they were not offered a ride or "lost" the opportunity to receive a free ride. This poses no more than minimal harm to the patients because they will not lose out on the opportunity to use the service and they travel to clinic as they normally would.

C. The IRB must determine that the value of the study is sufficient to warrant waiving some aspects of the requirement for full disclosure in the informed consent process. Please outline the scientific validity for using deception in this instance.

The deception is requested so as to not influence the behavior of patients in how they typically travel to clinic. Should patients know that this service is being tested and realize they are not receiving the intervention, they may engage differently with a future appointment, thereby altering our main outcome - missed appointments.

D. There is no alternative to address the scientific question in a valid manner but to use deception/ incomplete disclosure. Other effective, non-deceptive approaches are not feasible. Please detail why alternatives are not feasible.

By informing them of the rideshare program and that they are not offered the intervention may impact their impressions with the clinic (changing their behavior about whether they might attend the clinic) and therefore choose not to go to their clinic appointment. Alternatively, they might consider utilizing a rideshare service themselves. These choices and behavior changes would differentially impact our scientific question and make our results biased.

E. Debriefing is done, when appropriate, and the deception/incomplete disclosure is explained to the participant before the end of participation in the research. Please detail if you are debriefing participants, and if not, why not.

No. For the control arm, their interaction with the clinic is going to be how they typically engage and

travel to their clinic. This study is not removing something from them nor is it interacting with them in any harmful way to impact their clinical care. The observation arm is simply receiving a clinical reminder. The only risk for the observers is that we are collecting data from their electronic medical record. We have protections in place for their privacy.

F. When appropriate, subjects could be informed prospectively of the use of deception/incomplete disclosure and consent to its use: see the suggested consent language: ***"In some research studies, the investigators cannot tell you exactly what the study is about before you participate in the study. We will describe the tasks in the study in a general way, but we can't explain the real purpose of the study until after you complete these tasks. When you are done, we will explain why we are doing this study, what we are looking at, and any other information you should know about this study. You will also be able to ask any questions you might have about the study's purpose and the tasks you did. Though we may not be able to explain the real purpose of the study until after you complete the tasks, there are no additional risks to those that have been described in this consent form."***

Not applicable.

Analysis Plan
The most recent Stata version will be used for statistical analyses with all hypothesis testing conducted at a two-sided, type I error rate of 0.05. The primary analysis will consist of an unadjusted intent-to-treat hypothesis testing using a logistic regression model to assess the binary of attending their clinic appointment versus not. We will estimate regression models adjusting for covariates of interests, including Charleson comorbidity index, BMI, provider, missed appointment history, continuity, and basic demographic data. Descriptive statistics will be used to analyze the survey results and secondary aims.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

  Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- x **Wherever feasible, identifiers will be removed from study-related information.**

  A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
- x **A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)**

  Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.
- x **Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.**

Subject Confidentiality
Protection against risk precautions are taken to ensure that strict confidentiality is maintained. All research materials will be inaccessible to anyone other than the investigators. Each subject will be assigned a unique identification number that will be linked to sensitive information, including the

subject's name, mailing address, and phone number in a password protected data file stored on a secure server. These identification numbers will be added to each survey for tracking purposes. A separate file will be created, linking the patient and their identification numbers. Following the completion of our data analysis, the file linking patient numbers and personal identifiers will be erased. Any audio recordings used to create transcriptions will be eliminated and destroyed after analyzing the transcript. No identifiable information will be transcribed. All survey data will use the study ID code and will not include any personally identifiable information. No results will be reported in a personally identifiable manner. Previous research we have conducted that has employed precautions has demonstrated that these techniques are very successful in assuring the protection of subjects. Personal identifiers (names, address, and telephone numbers) will be removed from the data set once calculations have been made. This pertains particularly to distance calculations between the home address or pickup/drop-off location and the clinic. These personal identifiers are used solely for the purposes of contacting the patients for the qualitative portions and to coordinate the transportation service.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
The privacy of our subjects is a critical priority for our research team. Our main interaction with patients will occur in the initial pilot phase where we will observe and conduct interviews with patients en route to their clinic. For the main intervention, patients will receive a phone call. We will utilize their names and telephone numbers as a primary means of contacting them. For the intervention arm, interviews will occur over the telephone. Patients will always retain the option to not have their information or interviews used for the purposes of the qualitative portion of the study. Questionnaire data and observation notes will be deidentified and aggregated to protect the privacy of patients.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
No. Only aggregate, de-identified data and analysis will be reported to non study personnel.

Data Protection*

x	**Name**
x	**Street address, city, county, precinct, zip code, and equivalent geocodes**
x	**All elements of dates (except year) for dates directly related to an individual and all ages over 89**
x	**Telephone and fax number**
	Electronic mail addresses
	Social security numbers
x	**Medical record numbers**
	Health plan ID numbers
	Account numbers
	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers/serial numbers
	Web addresses (URLs)
	Internet IP addresses
	Biometric identifiers, incl. finger and voice prints
	Full face photographic images and any comparable images
	Any other unique identifying number, characteristic, or code
	None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision

of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable.

Consent

1. Consent Process

Overview
For Phase 1's in-depth qualitative interview consents will occur in person or over the phone. Study participants will receive a copy of a written consent form with a description of the study purpose and procedures, the risks and benefits of participation, the procedures for maintaining confidentiality, how to contact the study investigator with questions or to decline to participate, and that the decision about participation will have no effect on their medical care. Audio-recording of any interviews in phase 1 will only occur after consent has been completed. For those who are in Phase 1 but do not receive the in-depth qualitative interviews we will pilot the pre- and post-surveys that we are going to administer in Phase 2. This data will not be used in the final analysis as we may make modifications to the intervention or the questions in the surveys that will alter the response of participants. For Phase 2, patients will be asked to verbally consent to the study prior to administering the telephone-based pre-appointment and post-appointment surveys over the phone. They will retain the option to not complete the survey during the pre- and post-appointment phone call. We will be requesting approval from the IRB for consent without written documentation for the RCT portion of the study.

Children and Adolescents
Not applicalbe

Adult Subjects Not Competent to Give Consent
Competency, in-person or over the phone, will be assessed by one of the research coordinators or research assistants. The assessment will be informal. No legally authorized representative will be used to provide consent.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
Yes

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

Written Statement of Research (phase2_telephonereminderconsent.docx)

Written Statement of Research (v2_phase1and2_telephonereminderconsent_cleaned.docx)

Written Statement of Research (v2_phase1and2_telephonereminderconsent_wtrackchanges.docx)

Risk / Benefit

Potential Study Risks
This study involves no more than minimal risks to subjects. Demographic data will be acquired from both the electronic medical record and surveys. Other covariates listed elsewhere will be extracted from the electronic medical record. A patient's choice to enter into a vehicle offered through a rideshare service will incur no greater risk, to our knowledge, then entering into the vehicle of a taxi or personal vehicle driven by the patient or acquaintance. These forms of transportation are already in use by patients. The additional domains of possible risk involves subject privacy and confidentiality. For the survey components of the study, the risk to privacy and confidentiality will be minimized because any identifying information (e.g., participant name, home address, and phone number) will be destroyed as soon as it is no longer necessary for the study. The study materials will be kept on a secure computer in the locked office of the PIs for the duration of the study. The data obtained by this study will only be reported in an aggregate format, never identifying any individual respondents and posing no risk of damage or liability to participants of the study.

Potential Study Benefits
The benefits of the study involve increased understanding of the impact of rideshare services on a patients ability to access their outpatient clinic appointment. Based on the outcomes of our study, we hope to inform medical centers about the impacts of addressing transportation barriers on the ability of patients to access medical appointments.

Alternatives to Participation (optional)
They can travel to clinic how they normally would.

Data and Safety Monitoring
The principle investigator and research personnel will meet every two weeks to discuss the study's progress, any breaches of privacy, data integrity concerns or safety concerns. An interim analysis will be conducted once we reach 100 and 300 patients in the intervention arm.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
The minimal risks to subject confidentiality and privacy will be greatly outweighed by the significant future benefits to improving the transportation access to outpatient clinics in order to understand the impact of improved transportation access on missed appointment rates for Medicaid patients.

General Attachments

The following documents are currently attached to this item:

Informed consent form (phase2_telephonereminderconsent.docx)

Questionnaires (phase1questionnaire.docx)

Questionnaires (phase2questionnairepost-appointment.docx)

Questionnaires (phase2questionnairepre-appointment.docx)

Informed consent form (phase1_consentform_rideshare_2016.docx)

Cover Letter (rideshare_coverletter_initialsubmission.docx)

Additional forms (phase2_telephonereminderwithoutconsent.docx)

Informed consent form (v2_phase1_consentform_rideshare_wtrackchanges.docx)

Questionnaires (v2_phase1questionnaire_cleaned.docx)

Cover Letter (v2_rideshare_coverletter_initialsubmission_revised.docx)

Informed consent form (v2_phase1_consentform_rideshare_cleaned.docx)

Questionnaires (v2_phase1questionnaire_wtrackchanges.docx)

Questionnaires (v2_questionnairepost-appointment_cleaned.docx)

Questionnaires (v2_questionnairepost-appointment_wtrackchanges.docx)

Questionnaires (v2_questionnairepre-appointment_cleaned.docx)

Questionnaires (v2_questionnairepre-appointment_wtrackchanges.docx)

Additional forms (v2_phase2_telephonereminderwithoutconsent_cleaned.docx)

Additional forms (v2_phase2_telephonereminderwithoutconsent_wtrackchanges.docx)

Modification

Basic Info

Confirmation Number:	**ccidahbh**
Protocol Number:	**824715**
Created By:	**CHAIYACHATI, KRISDA H**
Principal Investigator:	**GRANDE, DAVID T**
Protocol Title:	**The impact of rideshare transportation services on appointment adherence**
Short Title:	**Rideshare services for improved outpatient clinic access**
Protocol Description:	**We propose a study testing the impact of rideshare service (RSS) on primary care clinic no-show rates among Medicaid adults. Given the novelty, we will deploy the intervention in two phases. Phase 1 (the "PIlot") will focus on discovering the operational challenges of implementing the intervention, conducting questionnaires, and testing operational design strategies for Phase 2 (the "Trial"), the randomized control trial with pre- and post-appointment questionnaires.**
Submission Type:	**Social and Biological Sciences**

PennERA Protocol Status

Approved

Resubmission*
No

Are you submitting a Modification to this protocol?*

Yes

Current Status of Study

Study Status

Currently in Progress

If study is currently in progress, please enter the following

Number of subjects enrolled at Penn since the study was initiated

271

Actual enrollment at participating centers

0

If study is closed to further enrollment, please enter the following

Number of subjects in therapy or intervention

0

Number of subjects in long-term follow-up only

0

IRB Determination
If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. For a modification to be considered more than minimal risk, the proposed change would increase the risk of discomfort or decrease benefit. The IRB must review and approve the proposed change at a convened meeting before the change can be implemented unless the change is necessary to eliminate an immediate hazard to the research participants. In the case of a change implemented to eliminate an immediate hazard to participants, the IRB will review the change to determine that it is consistent with ensuring the participant′s continued welfare. Examples: Convened Board Increase in target enrollment for investigator initiated research or potential Phase I research Expanding inclusion or removing exclusion criteria where the new population may be at increased risk Revised risk information with active participants Minor risk revisions that may affect a subject′s willingness to continue to participate Expedited Review Increase in target enrollment at Penn where overall enrollment target is not exceeded or potentially sponsored research Expanding inclusion or removing exclusion where the new population has the same expected risk as the previous, based on similarities of condition Revised risk information with subjects in long-term follow-up Minor risk revisions with no subjects enrolled to date
Expedited Review

Modification Summary
Please describe any required modification to the protocol. If you are using this form to submit an exception or report a deviation, enter 'N/A' in the box below.
Adding research assistant

Risk / Benefit
Does this amendment alter the Risk/Benefit profile of the study?
No

Change in Consent
Has there been a change in the consent documents?
No

If YES, please choose from the options below regarding re-consenting

Deviations

Are you reporting a deviation to this protocol?*

No

Exceptions

Are you reporting an exception to this protocol?*

No

Protocol Details

Resubmission*
Yes

Study Personnel

Principal Investigator

Name:	**GRANDE, DAVID T**
Dept / School / Div:	[redacted]
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	
HS Training Completed:	
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

Name:	**CHAIYACHATI, KRISDA H**
Dept / School / Div:	[redacted]
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	
HS Training Completed:	
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**GARFIELD, CHERYL**
Dept / School / Div:	[redacted]
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	
HS Training Completed:	
Training Expiration Date:	
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Other Investigator

Name:	**ROSIN, ROY**
Dept / School / Div:	[redacted]
Campus Address Mail Code	
Address:	
City State Zip:	
Phone:	
Fax:	
Pager:	
Email:	
HS Training Completed:	
Training Expiration Date:	
Name of course completed :	

Responsible Org (Department/School/Division):

4239 - DM-General Internal Medicine

Key Study Personnel

Name:	**YEAGER, ALYSSA**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**ASCH, ELIZABETH L**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SHEA, JUDY A**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**CARTER, TAMALA**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**LOPEZ HAYNA, STEPHANIE**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	

Name:	**MUGO, BRIAN**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	

Name:	**HUBBARD, REBECCA A**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SHI, CATHERINE Y**
Department/School/Division:	[redacted]
HS Training Completed:	
Training Expiration Date:	
Name of course completed:	

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Con icts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Social and Biological Sciences

Study Instruments
Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. Provide validation documentation and or procedures to be used to validate instruments. For well know and generally accepted test instruments the detail here can be brief. More detail may be required for a novel or new instrument. For ethnographic studies identify any study instruments to be used (i.e. for deception studies) and describe in detail where, when and how the study will be conducted and who or what are the subjects of study. Note: For more information on how to conduct ethical and valid ethnographic research, follow the link For oral histories or interviews provide the general framework for questioning and means of data collection. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Include a copy of any novel or new test instruments with the IRB submission.
In phase 1 (the "Pilot"), all patients sampled will receive the intervention (i.e. without a control) to understand design challenges for Phase 2 (the "Trial"), such that we can create modifications to the design for optimal deployment in Phase 2. There is no difference in the study instruments used in Phase 1 or Phase 2. The only additional component for Phase 1 (the Pilot) will be monitoring the uptake of the intervention. Moreover, in Phase 1, there is no control arm, so all individuals called will be offered the service because we are testing variations in the design of administering the service. Regarding the study instruments, a telephone-based survey will be completed for those who are offered the rideshare service (RSS) transportation option to use on the day of their appointment (the pre-appointment survey) and within 24 hours of their appointment (the post-appointment survey). When offering the service to the intervention arm, we will consent the patient to participate in the pre-appointment and post-appointment survey at the same time. Patients will be compensated for completing the pre-appointment survey with a free RSS ride to and from their clinic. The pre-appointment survey contains questions regarding previous transportation modes and demographic questions; and the post-appointment survey will assess the patient's experience using RSS. In addition, an in-depth interview will be audio-recorded directly after the post-appointment survey. These are meant to get open-ended feedback about the service and future modifications. We are audio-recording the in-depth questions only for accuracy. To monitor uptake in Phase 1, we will record the uptake of the intervention (e.g., proportion of patients who are offered a ride who ultimately use it to get to and from clinic) based on variations in the design. For example, changing whether patients call a standard number to request a ride versus we call them, or the timing of the pre-pickup phone call to account for traffic patterns or rideshare care availability in order to standardize the timing of the phone call (e.g. 30 minutes before the pickup time vs. one hour before the pickup time) in order to make sure patients get to their predetermined destination on time (e.g., home or clinic). For those who consent over the telephone days prior to their appointment, but do not ultimately use the RSS or do not show-up to their appointment, we will only have results from their pre-appointment survey as that is built into the telephone consent session.

Group Modifications
Describe necessary changes that will or have been made to the study instruments for different groups.
No group modification occurs in Phase 1, the only group modification occurs in phase 2, the randomized control trial phase. Here, both the intervention and control arms will receive a telephone reminder within one week of their appointment (the current standard of care) to control for the effect of a phone call that may remind the patient that they have an upcoming clinic appointment, potentially altering the decision of patients to attend their clinic appointment (our primary outcome of interest). In the control arm where patients do not receive an RSS offer, they will receive a standardized appointment reminder only. In the intervention arm, patients will receive a standardized appointment reminder and offered the RSS transportation option with the pre-appointment survey. Similarly, only the intervention arm will receive the post-appointment survey. When offering the service to the

intervention arm, we will also consent the patient for both the pre-appointment and post-appointment survey. Patients will be compensated for completing the pre-appointment survey with a free RSS ride to and from their clinic. The pre-appointment survey contains questions regarding previous transportation modes and demographic questionnaire; and the post-appointment survey will assess the patient's experience using RSS. For those who consent but do not use the RSS or do not show-up to their appointment, we will only administer the pre-appointment survey as that is built into the telephone consent session.

Method for Assigning Subjects to Groups

Describe how subjects will be randomized to groups.

During phase 2, the randomized control trial phase, patients on even number calendar days will be offered RSS while those on odd number days will not be offered. No group assignment will occur in phase 1.

Administration of Surveys and/or Process

Describe the approximate time and frequency for administering surveys and/or evaluations. For surveys, questionnaires and evaluations presented to groups and in settings such as high schools, focus group sessions or community treatment centers explain how the process will be administered and who will oversee the process. For instance, discuss the potential issues of having teachers and other school personnel administer instruments to minors who are students especially if the content is sensitive in nature. Describe the procedure for audio and videotaping individual interviews and/or focus groups and the storage of the tapes. For instance, if audio tape recording is to be used in a classroom setting, describe how this will be managed if individuals in the class are not participating in the study. Explain if the research involves the review of records (including public databases or registries) with identifiable private information. If so, describe the type of information gathered from the records and if identifiers will be collected and retained with the data after it is retrieved. Describe the kinds of identifiers to be obtained, (i.e. names, social security numbers) and how long the identifiers will be retained and justification for use.

There is no difference in the study instruments used in Phase 1 or Phase 2 or how they are administered. Regarding the study instruments, a telephone-based survey will be completed for those who are offered the rideshare service (RSS) transportation option to use on the day of their appointment (the pre-appointment survey) and within 24 hours of their appointment (the post-appointment survey). When offering the service to the intervention arm, we will consent the patient to participate in the pre-appointment and post-appointment survey at the same time. Patients will be compensated for completing the pre-appointment survey with a free RSS ride to and from their clinic. The pre-appointment survey contains questions regarding previous transportation modes and demographic questions; and the post-appointment survey will assess the patient's experience using RSS. In addition, an in-depth interview will be audio-recorded directly after the post-appointment survey. These are meant to get open-ended feedback about the service and future modifications. We are audio-recording the in-depth questions only for accuracy.

Data Management

Describe how and who manages confidential data, including how and where it will be stored and analyzed. For instance, describe if paper or electronic report forms will be used, how corrections to the report form will be made, how data will be entered into any database, and the person(s) responsible for creating and maintaining the research database. Describe the use of pseudonyms, code numbers and how listing of such identifiers will be kept separate from the research data.

Once qualitative interviews or surveys have been completed, each study participant will be assigned a unique identification number that will be linked to their name and survey data. These identification numbers will be added to each study participants's audio recording and electronically recorded survey data for tracking of responses. Transcripts created from audiotapes of the in-depth interviews will be stripped of any identifying information by transcribers educated in qualitative data preparation techniques and the importance of confidentiality. Transcripts will be stored in password protected sections of the computer. Survey responses will be entered into a database behind the Penn Medicine Academic Computing Services Firewall. Any paper study materials (including notes or data summaries) will be kept in locked cabinets. This information will be accessible only to study personnel who need the information for data collection. The PI(s) will be responsible for creating and maintaining the database. Following the completion of data collection and assessment of potential response bias, the file linking subject numbers and personal identifiers will be erased. This system will consist of two separate but related systems: a management information system (MIS) and primary data management

system (PDMS). The MIS will track all subjects who were approached and will include their participation status, name, age, and zip code. Periodic reports will be generated to assess whether recruitment is proceeding on schedule and identify any recruitment problems. The PDMS will include all subject survey data. Relational database software, such as Microsoft Access, will be used to maximize management information tool flexibility and to prepare data files for statistical analysis. Any identifiable information will be destroyed no later than July 1, 2017 and most likely earlier than that date. Furthermore, the data will only be reported in an aggregated format, without individual identifiers. This includes avoiding the reporting of any identifiable information used in the analysis of these data.

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
No

CTRC Resources*
Does the research involve CTRC resources?
No

If the answer is YES, indicate which items is is provided with this submission:

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Survey research (the main focus of the research is administration of a survey to research subjects)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
	Diagnostic test/procedure (research-related diagnostic test or procedure)
	Obtaining human tissue for basic research or biospecimen bank
x	**Survey instrument**
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Sponsors

Business Administrator

Name:	**NICHOLSON, MELISSA A**
Dept / School / Div:	[redacted]
Phone:	
Fax:	
Pager:	
Email:	

Department budget code

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

Funding Sponsors

Name:	**UNIVERSITY OF PENNSYLVANIA**
Type:	**UPENN Internal**

Funding sponsors billing address
If you have selected a commercial or industry sponsor, please provide the appropriate address and contact information for the Sponsor for the purposes of billing for IRB review fees (initial review, continuing review and convened modification fees apply here). If the Sponsor is not industry/ commercial, this information is not necessary to provide with your application.
Not applicable

Funding sponsors gift
Is this research being funded by a philanthropic gift?
No

Regulatory Sponsor

IND Sponsor

none

000 - 000 - 0 - 000000 - 0000 - 0000 - 0000

Industry Sponsor

None

Project Funding*
Is this project funded by or associated with a grant or contract?
Pending

Sponsor Funding
Is this study funded by an industry sponsor?
No

Status of contract

The following documents are currently attached to this item:

Grant Application (ldi2015pilotgrant_krisdachaiyachati.pdf)

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research
Not applicable

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract
We propose a randomized control trial (RCT) testing the impact of rideshare services (RSS) on reducing primary care clinic no-show rates for Medicaid patients, the main outcome of the study. We will assess the patient experience after each ride using a telephone-based survey. Secondary aims focus on characterizing transportation efficiencies (such as time between pickup and drop-off locations), measures of uptake, the timing of clinic attendance, and operational costs. The study has two phases. Phase 1 (the "Pilot") will focus on discovering the challenges of implementing the intervention by pilot testing different ways patients can access the RSS. For phase 2 (the "Trial"), the study will involve randomization of patients for the intervention. All adults with established primary care at the Penn Medicine Clinics, who have Medicaid, and do not require wheelchair accessible rides will be eligible.

Objectives

Overall objectives
We propose a randomized control trial (RCT) testing the impact of rideshare services (RSS) on outpatient no-show rates. In the intervention arm, we will administer pre-appointment and post-appointment surveys to assess current transportation modes and the acceptability of using RSS. Secondary aims focus on describing the efficiency of the RSS transportation (e.g., travel distance and travel time), misuse of the service, clinic check-in times, and costs. Given the novelty, we will test the intervention in two phases. Phase 1 will focus on discovering the challenges of implementing the intervention to inform the final operating procedures for phase 2, the randomized control trial.

Primary outcome variable(s)
Our primary outcome is for Phase 2 - the frequency of missed appointments in the intervention arm and the control arm.

Secondary outcome variable(s)
For the intervention arm only - patient perceptions of reliability, timeliness, and safety with regards to the RSS intervention. For both arms - clinic check in times.

Background
Reliable transportation for primary care appointments is a significant burden for low-income patients in urban areas, limiting their accessibility to outpatient, primary care and ultimately shifts their care utilization patterns towards more costly, acute care settings either because of preference or medical need. Surveys of low-income patients indicate that between 24-51% of patients reported having ever missed or rescheduled a clinic appointment because of unreliable transportation. Without reliable and accessible transportation, patients shift their preference away from primary care clinics towards the overuse of acute care settings for ambulatory care sensitive conditions - a key target of the U.S. Agency for Healthcare Research in Quality for reducing low-value, high cost care in our health system. A variety of transportation options exist for patients. However, traditional transportation modes are inconvenient, unreliable, or costly for low-income patients. Medicaid finances NEMT with door-to-door van services by outsourcing to private companies or will provide public transportation passes. The eligibility to access these services is broad for the Medicaid population in Pennsylvania, including individuals with supplemental security income benefits and pregnant women below the federal poverty level. However, NEMT services are seen as inconvenient, require advanced scheduling of 3-5 days, and are relatively inflexible to changes to the location or timing of pickups and drop-offs. Taxis are an alternative door-to-door service, but are costly. When personal vehicles are accessible, parking can be a significant time and financial burden. Finally, for low-income patients, the accessibility of friends and family are limited because they too have significant health care needs or require their personal vehicles for work. An RSS-based intervention that provides a cheap, reliable alternative transportation for low-income patients to outpatient appointments may ultimately improve patient access to primary care services, potentially improving patient health and reduce costs in our healthcare system. In the long run, RSS could have a positive return on investment for a health system in a more capitated payment system or represent an alternative transportation strategy for state Medicaid programs.

Study Design

Phase*
Not applicable

Design
We propose a mixed-methods study incorporating surveys into an RCT designed to improve patient transportation accessibility for Medicaid patients with primary care appointments at the internal medicine practices at Penn Medicine. Our primary outcome is to determine the frequency of missed appointments in the intervention and control arm. This data will be complemented by pre- and post-appointment surveys. The study population includes adult Medicaid patients with primary care appointments at Penn Medicine. The RSS in this study will be provided for free to patients, matching the current non-emergency medical benefit provided by the state Medicaid program and voucher based transportation. The study will be completed in two phases. Phase 1 (the "Pilot") will focus on discovering the challenges of implementing the intervention through field testing. In phase 1, all patients sampled will receive the intervention (i.e. without a control) will be piloted to understand design challenges for Phase 2, such that we can create modifications to the design for optimal deployment in Phase 2. In order to understand these challenges in Phase 1, we will a) conduct survey and in-depth interviews over the telephone and b) monitor uptake of the intervention. Overall we will test the RSS design with approximately 75 patients until design challenges have been solved. Of the 75 patients we will randomly sample approximately 20 of them to complete in-depth interviews. The in-depth qualitative interviews will help us better understand the transportation needs of patients in the West Philadelphia area who attend the Penn Medicine clinic (the same population exclusion and inclusion criteria as Phase 2), allowing us to make any necessary adjustments to the design to match the transportation needs for low income patients. During the in-depth qualitative interviews, we will focus on previous transportation experiences and implementation themes related to acceptability and feasibility. For these interviews, patients will be asked after they had completed their clinic appointment

and provided with a ride home as compensation for completing the qualitative interview. These qualitative interviews will take place over the phone. Interviews will be audio-recorded. For the third component, we will record the uptake of the intervention (e.g., proportion of patients who are offered a ride who ultimately use it to get to and from clinic) based on variations in the design. For the initial design, the patient will receive a phone call with one week which will serve as an appointment reminder, an offer to be a participant in this study, and instructions on how to access the RSS on the day of the appointment. Then on the morning of the appointment, the patient will receive a text reminder with instructions about the driver and time of pickup. The patient can also call a hotline to request the ride and a research team member coordinates the ride using a dispatch tool developed by Lyft. To test different designs, we may, for example, change whether patients call a standard number to request a ride versus we call them, or alter the timing of the pre-pickup phone call to account for traffic patterns or rideshare care availability in order to standardize the timing of the phone call (e.g. 30 minutes before the pickup time vs. one hour before the pickup time) in order to make sure patients get to their predetermined destination on time (e.g., home or clinic). This process will inform the final operating procedures for phase 2, the full trial of the intervention where we test the primary aim of missed appointments. Additional covariates will be collected from the electronic medical record, including Charleson comorbidity index, provider, missed appointment history, continuity, and basic demographic data. For both phases of the study, If patients have an address in W. Philadelphia but need a ride from a different location, they can still access RSS. They can only request a ride, though, that is no more than the cost of the ride from their home to the clinic (estimate $10). This is similar for the return ride home the cost of the ride cannot exceed the ride from the clinic to home. Therefore, patients will have the flexibility to take a ride from or to anywhere in the city within those cost limits. UPHS has completed a non-disclosure agreement, Business Associate, and Service Agreement with Lyft.

Study duration
Approximately 6-8 months. One to three months will be devoted towards the phase 1 field testing of the intervention. Phase 2 will be the RCT where we estimate it will take approximately three to five months to reach our target numbers in both arms.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
We have successfully completed numerous mixed-methods and RCT studies testing the implementation of novel methods for improved health care delivery and create innovative strategies in a variety of settings, including Penn Medicine. The team includes investigators experienced in primary care delivery, social determinants of health, survey methods, qualitative interview techniques, and rapid cycle innovation. The experience acquired and infrastructure developed from these studies will ensure successful completion of the proposed work and we have established infrastructure (physical and electronic) to ensure human subjects research protection. Moreover, we have teamed up with Lyft, who will be providing the technical support and web-based platform to access their drivers for this intervention. Lyft® is a nationwide, RSS company that utilizes a smartphone app and web-based interfaces for ride requests and financial transactions. We will hire a research assistant who will assist with contacting patients in both arms (per the protocol), coordinating the rides for patients, and collecting clinic level data. This research assistant will have have HIPAA certification and CITI training completed. UPHS has completed a non-disclosure agreement, Business Associate, and Service Agreement with Lyft.

Characteristics of the Study Population

Target population
Adult (older than 18 years old), Medicaid patients with primary care appointments at the internal medicine practices at Penn Medicine. Patients included in the study will have established primary care at the Penn Medicine clinics and have addresses in the electronic medical record designating a West Philadelphia zip code. Patients who require wheelchair accessible transportation will be excluded

because of the limited availability of accommodating vehicles. These individuals will be screened through the electronic medical record for BMI before being called for consent and via the pre-appointment survey for patients requiring wheelchair accessible transportation. Over the phone, the latter group will be offered the ability to connect with Logisticare, the current company providing Medicaid sponsored wheelchair accessible rides to clinic. For phase 1, we will enroll up to 75 patients, of which 20 or so patients will receive in-depth qualitative interviews. For phase 2, we will enroll 572 patients in the intervention arm and compare them to 572 individuals in the control arm.

Subjects enrolled by Penn Researchers
667

Subjects enrolled by Collaborating Researchers
0

Accrual
A weekly list of eligible patients and patient phone number(s) will be generated by the Penn Medicine clinic staff or by our research team based on a our pre-specified inclusion criteria. From this list we will be able to collect eligible patients for phase 1 and for phase 2 when we will require contact information for both the control and intervention arms. Any staff contacting patients will be HIPAA certified.

Key inclusion criteria
Adult (18 years old), Medicaid patients with primary care appointments at the internal medicine practices at Penn Medicine. Patients included in the study will have established primary care at the Penn Medicine clinics. Additionally, patients will have addresses in the West Philadelphia zip codes.

Key exclusion criteria
Patients who require wheelchair accessible transportation will be excluded because of inability to guarantee vehicles that will be able to accommodate patients' physical needs.

Vulnerable Populations

	Children Form
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
x	**None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
None

Subject recruitment
Using the EPIC electronic medical record database, our research team will collaborate with the clinic staff to identify and call eligible patients within a week of their scheduled appointment to offer the RSS and obtain consent for the qualitative portions.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

Subject recruitment (v2_phase1and2_telephonereminderconsent_wtrackchanges.docx)

Subject recruitment (v2_phase1and2_telephonereminderconsent_cleaned.docx)

Subject recruitment (phase2_telephonereminderconsent.docx)

Subject recruitment (v4_telephonereminderconsent_trkchg.docx)

Subject recruitment (v4_telephonereminderconsent_clean.docx)

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

In phase 1 and phase 2, patients will receive a free RSS transportation for completing the qualitative interviews and questionnaires. Estimated $5-10 USD. The cost of the rides will not exceed the market rate of traveling from the western most part of West Philadelphia to the Penn Medicine Clinics.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Not applicable

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
Yes

A. Deception/incomplete disclosure is typically only acceptable in studies with no more than minimal risk. Please detail why this study is minimal risk.

This study provides no more than minimal risk because patients all require some form of transportation to clinic, either walking or motor vehicle. For those not walking to clinic, we are simply providing a transportation alternative for the intervention arm. Currently, Medicaid patients are eligible to receive transportation services through Medicaid's Non-Emergency Medical Transport Program. For the control arm, their mode of transportation will be the typical mode they use to get to clinic.

B. The deception/incomplete disclosure should have no adverse effects on welfare. Please outline how all adverse effects are minimized.

Patients in the control arm will not be offered the rideshare service. They will not know they did not receive the intervention. Because our primary aim is missed appointment rates, we do not want to alter their motivation or mode they choose to use when attending their clinic by knowing they were not offered a ride or "lost" the opportunity to receive a free ride. This poses no more than minimal harm to the patients because they will not lose out on the opportunity to use the service and they travel to clinic as they normally would.

C. The IRB must determine that the value of the study is sufficient to warrant waiving some aspects of the requirement for full disclosure in the informed consent process. Please outline the scientific validity for using deception in this instance.

The deception is requested so as to not influence the behavior of patients in how they typically travel to clinic. Should patients know that this service is being tested and realize they are not receiving the intervention, they may engage differently with a future appointment, thereby altering our main outcome - missed appointments.

D. There is no alternative to address the scientific question in a valid manner but to use deception/ incomplete disclosure. Other effective, non-deceptive approaches are not feasible. Please detail why alternatives are not feasible.

By informing them of the rideshare program and that they are not offered the intervention may impact their impressions with the clinic (changing their behavior about whether they might attend the clinic) and therefore choose not to go to their clinic appointment. Alternatively, they might consider utilizing a rideshare service themselves. These choices and behavior changes would differentially impact our scientific question and make our results biased.

E. Debriefing is done, when appropriate, and the deception/incomplete disclosure is explained to the participant before the end of participation in the research. Please detail if you are debriefing participants, and if not, why not.

No. For the control arm, their interaction with the clinic is going to be how they typically engage and travel to their clinic. This study is not removing something from them nor is it interacting with them in any harmful way to impact their clinical care. The observation arm is simply receiving a clinical reminder. The only risk for the observers is that we are collecting data from their electronic medical record. We have protections in place for their privacy.

F. When appropriate, subjects could be informed prospectively of the use of deception/incomplete disclosure and consent to its use: see the suggested consent language: ***"In some research studies, the investigators cannot tell you exactly what the study is about before you participate in the study. We will describe the tasks in the study in a general way, but we can't explain the real purpose of the study until after you complete these tasks. When you are done, we will explain why we are doing this study, what we are looking at, and any other information you should know about this study. You will also be able to ask any questions you might have about the study's purpose and the tasks you did. Though we may not be able to explain the real purpose of the study until after you complete the tasks, there are no additional risks to those that have been described in this consent form."***

Not applicable

Analysis Plan
The most recent Stata version will be used for statistical analyses with all hypothesis testing conducted at a two-sided, type I error rate of 0.05. The primary analysis will consist of an unadjusted intent-to-treat hypothesis testing using a logistic regression model to assess the binary of attending their clinic appointment versus not. We will estimate regression models adjusting for covariates of interests, including Charleson comorbidity index, provider, missed appointment history, continuity, and basic demographic data. Descriptive statistics will be used to analyze the survey results and secondary aims.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Data confidentiality

- x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**
- x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

  Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
- x **Wherever feasible, identifiers will be removed from study-related information.**

  A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.
- x **A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)**

  Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.
- x **Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.**

Subject Confidentiality

Protection against risk precautions are taken to ensure that strict confidentiality is maintained. All research materials will be inaccessible to anyone other than the investigators. Each subject will be assigned a unique identification number that will be linked to sensitive information, including the subject's name, mailing address, and phone number in a password protected data file stored on a secure server. These identification numbers will be added to each survey for tracking purposes. A separate file will be created, linking the patient and their identification numbers. Phone surveys results will be entered into REDCap, a secure-web-based application that provides data management assistance for surveyed information. REDCap provides automated export procedures for seamless data downloads to excel and common statistical packages. Following the completion of our data analysis, the file linking patient numbers and personal identifiers will be erased. Any audio recordings used to create transcriptions will be eliminated and destroyed after analyzing the transcript. No identifiable information will be transcribed. All survey data will use the study ID code and will not include any personally identifiable information. No results will be reported in a personally identifiable manner. Previous research we have conducted that has employed precautions has demonstrated that these techniques are very successful in assuring the protection of subjects. Personal identifiers (names, address, and telephone numbers) will be removed from the data set once calculations have been made. This pertains particularly to distance calculations between the home address or pickup/drop-off location and the clinic. These personal identifiers are used solely for the purposes of contacting the patients for the qualitative portions and to coordinate the transportation service.

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy

Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
The privacy of our subjects is a critical priority for our research team. Our main interaction with patients will occur in the initial pilot phase where we will observe and conduct interviews with patients en route to their clinic. For the main intervention, patients will receive a phone call. We will utilize their

names and telephone numbers as a primary means of contacting them. For the intervention arm, interviews will occur over the telephone. Patients will always retain the option to not have their information or interviews used for the purposes of the qualitative portion of the study. Questionnaire data and observation notes will be deidentified and aggregated to protect the privacy of patients.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
No. Only aggregate, de-identified data and analysis will be reported to non study personnel.

*Data Protection**

- x **Name**
- x **Street address, city, county, precinct, zip code, and equivalent geocodes**
- x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- x **Telephone and fax number**
- **Electronic mail addresses**
- **Social security numbers**
- x **Medical record numbers**
- **Health plan ID numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers/serial numbers**
- **Web addresses (URLs)**
- **Internet IP addresses**
- **Biometric identifiers, incl. finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**
- **None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable.

Consent

1. Consent Process

Overview
The consent procedures will be the same for Phase 1 and 2. For both phases, consent will occur over the phone and will be a consent for the pre- and post-appointment survey and post-appointment in-depth interview. Audio-recording of the in-depth questions will only occur after consent has been completed. Patients retain the option to not complete the survey during the pre- and post-appointment phone call. Responses for Phase 1 will be analyzed separately from the data from Phase 2, as we may make modifications to the intervention or the questions in the surveys that will alter the response of participants. We will be requesting approval from the IRB for consent without written documentation for the RCT portion of the study.

Children and Adolescents
Not applicable.

Adult Subjects Not Competent to Give Consent
Competency, in-person or over the phone, will be assessed by one of the research coordinators or research assistants. The assessment will be informal. No legally authorized representative will be used to provide consent.

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
Yes

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

Written Statement of Research (v2_phase1and2_telephonereminderconsent_cleaned.docx)

Written Statement of Research (v2_phase1and2_telephonereminderconsent_wtrackchanges.docx)

Written Statement of Research (v4_telephonereminderconsent_trkchg.docx)

Written Statement of Research (v4_telephonereminderconsent_clean.docx)

Written Statement of Research (phase2_telephonereminderconsent.docx)

Risk / Benefit

Potential Study Risks
This study involves no more than minimal risks to subjects. Demographic data will be acquired from both the electronic medical record and surveys. Other covariates listed elsewhere will be extracted from the electronic medical record. A patient's choice to enter into a vehicle offered through a rideshare service will incur no greater risk, to our knowledge, then entering into the vehicle of a taxi or personal vehicle driven by the patient or acquaintance. These forms of transportation are already in use by patients. The additional domains of possible risk involves subject privacy and confidentiality. For the survey components of the study, the risk to privacy and confidentiality will be minimized because any identifying information (e.g., participant name, home address, and phone number) will be destroyed as soon as it is no longer necessary for the study. The study materials will be kept on a secure computer in the locked office of the PIs for the duration of the study. The data obtained by this study will only be reported in an aggregate format, never identifying any individual respondents and posing no risk of damage or liability to participants of the study.

Potential Study Benefits
The benefits of the study involve increased understanding of the impact of rideshare services on a patients ability to access their outpatient clinic appointment. Based on the outcomes of our study, we hope to inform medical centers about the impacts of addressing transportation barriers on the ability of patients to access medical appointments.

Alternatives to Participation (optional)
They can travel to clinic how they normally would.

Data and Safety Monitoring
The principal investigator and research personnel will meet every two weeks to discuss the study's progress, any breaches of privacy, data integrity concerns or safety concerns. An interim analysis will be conducted once we reach 100 and 300 patients in the intervention arm.

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
The minimal risks to subject confidentiality and privacy will be greatly outweighed by the significant future benefits to improving the transportation access to outpatient clinics in order to understand the impact of improved transportation access on missed appointment rates for Medicaid patients.

General Attachments

The following documents are currently attached to this item:

Cover Letter (rideshare_coverletter_initialsubmission.docx)

Additional forms (citi-sl-socialandbehavioralresearchcourse.pdf)

Additional forms (phase2_telephonereminderwithoutconsent.docx)

Informed consent form (v2_phase1_consentform_rideshare_wtrackchanges.docx)

Questionnaires (v2_phase1questionnaire_cleaned.docx)

Cover Letter (v2_rideshare_coverletter_initialsubmission_revised.docx)

Questionnaires (v2_questionnairepost-appointment_cleaned.docx)

Informed consent form (v2_phase1_consentform_rideshare_cleaned.docx)

Questionnaires (v2_phase1questionnaire_wtrackchanges.docx)

Questionnaires (v2_questionnairepost-appointment_wtrackchanges.docx)

Questionnaires (v2_questionnairepre-appointment_cleaned.docx)

Questionnaires (v2_questionnairepre-appointment_wtrackchanges.docx)

Additional forms (v2_phase2_telephonereminderwithoutconsent_cleaned.docx)

Additional forms (v2_phase2_telephonereminderwithoutconsent_wtrackchanges.docx)

Cover Letter (lyft_coverletter_initialsubmission_2016_0916.docx)

Additional forms (subscriptionagreement-lyftuphslyft09-14-16.docx)

Additional forms (signed_lyftagreement_09162016rrosin.pdf)

Additional forms (cititraining1_sr.pdf)

Additional forms (cititraining_brianmugo.pdf)

Additional forms (cititraining1_sr.pdf)

Informed consent form (v4_telephonereminderconsent_clean.docx)

Informed consent form (v4_telephonereminderconsent_trkchg.docx)

Questionnaires (v4_post-apptsurveyquestions_trkchg.docx)

Questionnaires (v4_post-apptsurveyquestions_clean.docx)

Additional forms (hipaa_stephanie.pdf)

Questionnaires (phase2questionnairepost-appointment.docx)

Informed consent form (phase2_telephonereminderconsent.docx)

Questionnaires (phase1questionnaire.docx)

Questionnaires (phase2questionnairepre-appointment.docx)

Informed consent form (phase1_consentform_rideshare_2016.docx)

Cover Letter (lyft_coverletter_revision_2016_oct10.docx)

Questionnaires (v4_pre-apptsurvey_clean.docx)

Questionnaires (v4_pre-apptsurvey_trkchg.docx)

Additional forms (v4_telephoneremindernoconsent_clean.docx)

Additional forms (v4_telephoneremindernoconsent_trkchg.docx)