

## 1) Protocol Title

Tailored Approaches to Improve Medication Adherence

## 2) Objectives

**Primary Objective:** To culturally tailor a technology-based individualized adherence intervention for Black and Latino patients with uncontrolled HTN or T2DM, who are non-adherent to their medications, and determine its acceptability.

**Secondary Objective:** To assess the feasibility of the methods and procedures to implement the individualized adherence intervention within a primary care practice in New York City.

**Tertiary Objectives:** To compare the efficacy of a tailored adherence intervention to a single patient education (PE) session on:

- a. Change in medication adherence at 3 months.
- b. Blood pressure (BP) reduction at 3 months.
- c. HbA1c reduction at 3 months.

**Hypotheses:** Among 40 Latino and Black patients with uncontrolled hypertension (HTN) or type 2 diabetes those randomized to the intervention, compared to those randomized to PE, will:

- a. Exhibit higher rate of adherence to their antihypertensive or anti-diabetic medications at 3 months.
- b. Exhibit a greater reduction in systolic and diastolic BP at 3 months.
- c. Exhibit a greater reduction in HbA1c at 3 months.

## 3) Background

Despite advances in treatments for cardiovascular-related diseases (CVD; e.g., hypertension [HTN], type II diabetes mellitus [T2DM]) over the past three decades, CVD remains the leading cause of death in adults. T2DM affects 29.1 million people in the U.S., and the incidence is growing rapidly. (Center for Disease Control and Prevention, 2014) CVD incidence is nearly three-fold higher in patients with T2DM. (Fox et al., 2015) Blacks have the greatest burden of T2DM in the U.S., with nearly 5 million Black adults having diabetes. (Blackwell DL, 2014) As compared to Whites, Blacks and Latinos are 80% more likely to be diagnosed with diabetes and more than three times as likely to experience complications such as end stage renal disease, blindness, and lower extremity amputations. (Blackwell DL, 2014) Uncontrolled HTN, a leading risk factor for CVD, is the single most important predictor of subsequent cardiovascular morbidity and mortality among patients with T2DM. HTN occurs in more than 50% of patients with T2DM, and T2DM patients have a 1.5 to 3-fold risk for HTN. Latinos are the fastest growing ethnic group in the US with a growth rate of 43% compared to 23% among whites over the past decade. (Ennis SR, Ríos-Vargas M, & Albert NG, 2011) This increase is four times the nation's 9.7% growth rate, and accounts for more than half of the total U.S. population increase of 27.3 million during this period. (Ennis SR et al., 2011) This growth is

accompanied by a significant increase in cardiovascular disease (CVD)-related morbidity and mortality.(Davidson et al., 2007) Despite increasing trends in the awareness and treatment of hypertension (HTN) among all groups, Latinos have the lowest blood pressure (BP) and blood glucose control rates in the US.(Yoon, Ostchega, & Louis) While barriers to optimal HTN control, such as poor access and low awareness, explain some of the disparities in disease control between Latinos and whites, BP control rates still remain lower among Latinos who receive treatment compared to whites.(Liu, Liu, Tsilimingras, & Schiffrin). Blacks in particular, have the highest prevalence of HTN in the US with approximately 42% affected, an estimate that is nearly 50% higher than the prevalence rates in Whites. These differences become even more striking after considering the significantly earlier onset of HTN and higher rates of cardiovascular disease, diabetes, stroke, and end stage renal disease in Blacks compared to Whites. Poorer medication adherence among Blacks and Latinos may explain the disproportionately lower rates of BP control in these patient populations when compared to Whites. Nearly 60% of Blacks with T2DM have poor glucose control and poor blood pressure (BP) control.(McWilliams, Meara, Zaslavsky, & Ayanian, 2009) Poor medication adherence is a major contributor to inadequate BP control, and is associated with 125,000 deaths annually.(Morris & Schulz, 1992) Despite over 30 years of research dedicated to understanding adherence behaviors in hypertensive patients, data in minority patients is scant. More importantly, translation of adherence interventions to community-based primary care practices where majority of minority patients receive care is non-existent. Thus, the development of tailored interventions targeted at improving medication adherence in this high-risk population is needed to address the racial/ethnic disparities in BP and glucose control. To address this gap, this proof of concept study will assess the feasibility and compare the efficacy of a tailored technology-based adherence intervention (TAI) vs. a single patient education session (PE) on medication adherence among 40 Latino and Black patients with uncontrolled HTN or type 2 diabetes. Findings from this pilot study will lay the foundation for developing a larger, multi-site randomized controlled trial to improve medication adherence and blood pressure control among Latinos and Blacks.

#### **4) Inclusion and Exclusion Criteria**

##### **Screening Procedures:**

Potentially eligible patients will be identified using two methods:

1. An RA will work with clinic physicians at the ambulatory care center to identify potentially eligible patients. The RA will screen the EHRs of patients with upcoming clinic appointments to determine initial eligibility (i.e., high blood pressure/type 2 diabetes diagnosis and date, race/ethnicity) and will review the list of potentially eligible patients with clinic physicians.
2. By asking primary care providers (PCP) to refer patients who meet the eligibility criteria to a research assistant (RA) who will then conduct an onsite screening and consent visit. Once a patient is identified who fulfills the inclusion criteria, a letter, signed

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by the referring provider, will be sent to the patient, explaining the study and providing a telephone number, for him/her to call if s/he is interested in participating. If the patient gets in contact with study staff, the study staff will provide more information about the study (via telephone or in a dedicated space in the clinic).

### **Eligibility Criteria:**

Potentially eligible patients must (a) have uncontrolled HTN defined as BP $\geq$ 140/90 mmHg on at least two consecutive visits in the past year (or BP $\geq$ 130/80 for patients with diabetes and/or kidney disease) or uncontrolled T2DM defined as A1c $>$ 7%(Fox et al., 2015) on at least two consecutive visits in the past year; (b) have been prescribed at least one antihypertensive or oral anti-diabetic medication; and (c) self-identify as Latino or African American/Black and be  $\geq$  18 years of age.

Patients will be excluded if they (a) refuse or are unable to provide informed consent; (b) currently participate in another HTN or type 2 diabetes study; (c) have significant psychiatric comorbidity (determined by EMR and confirmed by the patient's PCP); or (d) plan to discontinue care at the clinic within the next 3 months.

Vulnerable populations including adults unable to provide informed consent, pregnant women, and prisoners will be excluded from this study.

### **5) Number of Subjects**

A total of 40 subjects will be recruited for this study.

### **6) Recruitment Methods**

Potentially eligible subjects will be recruited in four ways:

1. First, after identifying potentially eligible patients via the EHR review, the physician will briefly introduce the study to any patient they deem suitable. Those patients who are interested and give either verbal consent to the physician will speak to the RA, who will provide additional information and a study brochure. Patients who remain interested may complete informed consent and the first screening visit at that time, or may be scheduled for a screening visit at a later date.

The information obtained from the EHR for pre-screening will be: race/ethnicity, high blood pressure and/or type 2 diabetes diagnosis and date, and MRN. Patients found to be initially eligible based on this information will be presented to Bellevue physicians to determine suitability for the study. If the potential participant is not deemed suitable for the study by the physician, does not keep their screening appointment, or does not agree to participate once approached, all PHI collected from these subjects will be discarded and not retained for study purposes.

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2. Second, healthcare providers will continue to refer patients during the trial. Healthcare providers as well as nurses, and patient care assistants (PCAs) will be given a card which gives the inclusion criteria; the provider/nurse/PCA will explain to potential participants that there is a study in which s/he might be interested in participating. If the patient expresses interest, the healthcare providers, nurse or PCA will give the patient a card with the study staffs' telephone number. The same follow-up procedures will be used as noted in method 1.
  
3. Third, to maximize our reach, a random sample of patients who participated in Dr. Schoenthaler's IRB approved project #11-0053 and indicated on the main project consent form that they are willing to be re-contacted in the future will be contacted by Dr. Schoenthaler. In order to contact these patients, the following information will be obtained from Dr. Schoenthaler's trial: Name, mailing address, and phone number. This information will be used to contact the patients via a postal letter and then by a phone call. The letter will include a brief description of the project and the reason why they are being contacted to participate. It will also provide information about how to get in touch with Dr. Schoenthaler to schedule an in person visit and it will inform participants that Dr. Schoenthaler will be contacting them soon via a phone call. During the call the Dr. Schoenthaler will explain that the purpose of the project and the patient's responsibilities. If the patient expresses interest in completing the survey and agrees to participate at this point, s/he will be scheduled for the consent visit.

In order to randomly select patients to receive an interest letter, each and patient that completed project #11-0053 will be assigned a number. Using a random number table, three patients will be chosen to receive a letter. We will then use the following procedures for each patient: If the first patient chosen refuses to participate when called, research personnel will approach the second person chosen, and so on until a participant agrees to the project or the list is exhausted. This process will continue until all potential patients are contacted and invited to participate in the study.

4. Fourth, flyers will be hung in the clinic waiting rooms. The flyer will include a brief description of the project and information about how to get in touch with Dr. Schoenthaler to schedule an in person visit, if the patient is interested in obtaining more information or being screened for the study.

## **7) Study Timelines**

The duration of participation for each study subject is three months. Based on our previous studies with this patient population, we estimate that we will recruit 6 patients per month to participate in the study. Thus, it is anticipated that 3.5

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months will be needed to recruit all study subjects. The estimated date of study completion is 24 months.

### **8) Study Endpoints**

The primary objective will be accomplished through 10 individual key informant interviews with Black patients with uncontrolled HTN or type 2 diabetes. The interviews will elicit ideas to improve medication adherence, examine Black and Latino patients' use of technology, attitudes toward mHealth interventions, and elicit their feedback of intervention prototype designs including the cultural relevance of the program content, acceptability of the format and mode of delivery.

The secondary objective, which will evaluate feasibility of the intervention will be assessed through an ongoing formative evaluation to identify barriers and facilitators to implementation in a primary care setting, which will be used to inform necessary protocol modifications and continuously refine the methods.

The tertiary objective of medication adherence to prescribed antihypertensive or anti-diabetic medications at 3 months will be assessed with the well-validated 8-item self-report Morisky Medication Adherence Scale (described in Section 9).

The tertiary outcome of reduction in blood pressure (BP) from baseline to 3 months. BP will be assessed with a validated automated BP monitor (WatchBP) based on American Heart Association guidelines.

The tertiary outcomes of reduction in HbA1c from baseline to 3 months with an automated validated point-of-care device based on American Diabetes Association guidelines.

### **9) Procedures Involved**

#### **Consent/Screening/Baseline/Randomization Visit**

Consent procedures: All potentially eligible patients will meet with the study research assistant (RA) who will explain the study in clear, easy-to-understand language. The required information for informed consent will be summarized orally to the patient by the bilingual RA during the initial in-person contact and will be presented again in a comprehensive written consent/authorization form. The consent process will be conducted in a dedicated space at the primary care clinic. The study staff will adhere to the SOP: Informed Consent Process for Research (HRP-090). Specifically, during the consent meeting, the RA will explain the following study procedures: that patients will have a 50-50 chance of being in the tailored adherence intervention (TAI) or patient education (PE) session; that they will be asked to give permission for their charts to be reviewed; that participation is completely voluntary, and that not every patient is accepted into the study (this will be decided during the screening).

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To ensure comprehension, subjects will be asked to repeat back to the RA the salient points of the consent form to make sure that they understand the study they are agreeing to participate in. If a participant asks for help while reading the consent, or evidences a problem in reading the consent, the RA will read and explain the consent him/her.

If the participants speak Spanish they will receive a Spanish Consent form. The Spanish consent form will be explained by the bilingual RA. A Spanish version of the consent form will be provided to the IRB once the English version is approved.

Blood Pressure Measurements: Following the consent procedures, the RA will take 3 BP measurements at 1 minute intervals using a validated automated device (WatchBp), with the patient seated comfortably for 5 minutes prior to the measurements, following AHA guidelines. The average of these 3 readings will be used as the BP measure for the baseline visit.

HbAc Measurements: Following BP measurements, a blood specimen will be collected via fingerstick by a clinic nurse and analyzed using a validated point-of-care device (Afinion AS100 Analyzer), which provides A1C results from a finger stick in 3 minutes. To participate further, participants must have SBP $\geq$ 140 or DBP $\geq$ 90 mmHg (the mean of the 3 BP measurements) and A1c $>$ 7%

Medication Adherence Assessment: Following physiological measurements, patients will complete the well-validated 8-item Morisky Medication Adherence Scale (MMAS) to determine eligibility. Patients with a total MMAS score  $<$ 6 will be considered ineligible for the trial. Patients who are considered non-adherent by MMAS will be randomized to either the TAI or PE condition..

Self-Report Measures: After determining eligibility, patients will complete self-report study measures (see table of measures below and attached), with the assistance of the RA in a private room in the clinic. In addition, to ensure patient privacy, all data collected will be stored in a safe and secure place that only study personnel will be able to access.

<b>Measures</b>	<b>First visit</b>	<b>3 Month visit</b>
Blood pressure measurements	X	X
HbA1c measurements	X	X
Questions about yourself	X	
Questions about your memory	X	
Questions about your doctor	X	
Questions about your access to medical care	X	
Questions about your ability to pay for things you need	X	
Questions about feeling depressed or sad	X	X
Questions about your daily stress	X	
Your quality of life	X	X

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Health Literacy	X	X
Medical Conditions you have	X	X
Readiness to take your medications	X	X
Confidence to take your medication	X	X
Motivation to take your medication	X	X
Your ability to get your medications	X	X
Beliefs about your high blood pressure	X	X
Support to take your medications	X	X
Your medication-taking behaviors	X	X
Chart Review	X	X

**Patient Education (PE) group:** Following the completion of study measures, patients randomized to the PE group will complete patient education session on topics unrelated to type 2 diabetes, HTN and medication management using the same technology platform as the intervention group, with the assistance of a trained RA, if needed. After completing the module, the patients will be thanked, given reimbursement to defray transportation costs (\$20), and scheduled for the 3 month visit.

**Tailored Adherence Intervention (TAI) group:** Following the completion of the study measures, patients randomized to the TAI group will complete the technology-delivered tailoring survey and engage with intervention strategies that are matched to individualized adherence profile identified in the survey. After completing the program, the patients will be thanked, given reimbursement to defray transportation costs (\$20), and scheduled for the 3 month study visit.

**Three-Month (post randomization) Study Visit will be the same for both groups:** Patients will have 3 BP measurements taken using the automated BP device, have their HbA1c measured with the point-of-care device, and complete the self-report measures with the assistance of the RA in a private room in the clinic. . In order to facilitate completion of the 3-month follow-up visit, patients will receive a reminder post card containing the study contact information.

**Exit Interviews:** To evaluate the effectiveness and relevance of the intervention to the patients, we will conduct individual exit interviews with 10 randomly selected intervention participants. The interview questions will ask participants' opinion on the intervention approach. The interviews will help us determine which intervention components are most effective in assisting participants in taking their medication as prescribed, and which components of the intervention can be improved to make it more relevant to the target population. Patients will receive \$10 for completing the interviews.

## 10) Data Management

**Sample size calculation:** For the primary aim, we will recruit 10 patients of the target patient population to culturally tailor the technology-based adherence intervention to ensure saturation of themes will be reached. For the secondary and tertiary aims, we will enroll 20 patients per group (40 total); allowing for a 15% rate of attrition that will yield a final sample of approximately 15 patients per group who complete the study. Given the paucity of studies on medication adherence among Latinos and Blacks with hypertension, there is not sufficient data for power estimation. However, this pilot study will give us the opportunity to calculate the power needed to carry out a larger trial.

**Randomization and blinding:** To ensure a roughly equal assignment of patients to the two groups, we will use a block size of 4 with a permutation of 2 patients randomly assigned to each group, with the investigators blind to the permutation. Following CONSORT guidelines, (Bellg et al., 2004; Resnick et al., 2005) the randomization sequence will be generated by the statistician and kept in sealed opaque envelopes in a locked cabinet away from the study site. Once the RA has identified a patient that has met eligibility criteria and provided consent, the research assistant (RA) will call the study statistician for the patient's group assignment. All randomized subjects will be included in the analyses using intent-to-treat strategies. As is true for most behavioral interventions, the patient cannot be blinded to the group assignment. (Bellg et al., 2004) However, the RA conducting the data collection will be blinded to the patients' group assignments and a separate RA will be used for data collection

### Data Analysis

**Creation of Individualized Adherence Profiles:** To create individualized adherence profiles, we will first use standard linear regression, modeling scheduling adherence metric values (transformed, if needed) for patients in terms of their scores on each available barrier variable from the tailoring survey. Barrier variables significantly related to patient adherence will be used to create individualized profiles through cluster analysis. We will use adaptive clustering methods to determine an appropriate choice for the clustering method and the number of clusters. For cluster analyses, all barrier variables will be transformed to have values between 0-1 so they are comparable; they will also be ordered so that larger scores indicate worse levels for the associated barrier. Clusters will then consist of disjoint subgroups of patients with similar scores on the transformed significant barrier variables and will correspond to distinct adherence profiles. The most salient barriers for an adherence profile will be those with relatively higher scores compared to other barriers. Different tailored intervention strategies will be developed for the adherence profiles, addressing the most salient barriers for those profiles. Each patient of the proposed study will be assigned to the individualized adherence profile whose centroid (i.e., the vector of averages of barrier scores for the profile) is closest to the vector of barrier scores for that patient.

### Analyses for the Primary Aim:

**Analysis for the Secondary Aim:** Feasibility of the intervention will be assessed through an ongoing formative evaluation to identify barriers and facilitators to implementation in

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a primary care setting, which will be used to inform necessary protocol modifications and continuously refine the methods. This will be achieved through informal interviews with clinic staff and an observational report created by Dr. Schoenthaler that will inquire about space requirements to implement the study, any changes in workflow that can be attributed to the implementation of the study (e.g., increase in patient-provider communication about adherence, increase in BP/glucose monitoring of high risk patients), and modifications that were made to the initial study design that are needed to support and maintain it after the proposed study has ended. We will also assess reach of the intervention, which will be assessed as the proportion of the target population who volunteer to participate in the study. For this study, baseline rates will be calculated to determine the ratio of eligible participants invited to participate vs. those that enroll in the study. Data collected on participant's sociodemographic characteristics (e.g., age, gender, educational attainment, income), health literacy, and comorbid conditions will be used to determine if there are any differences between eligible participants that do not enroll vs. enrollees. Independent t-tests and the chi-square statistic will be used to determine if there are any significant differences between the groups. Reasons for not enrolling in the program will also be documented. In addition to these outcomes, exit interviews will be used to assess participants' acceptability and satisfaction with the program and to acquire feedback with respect to barriers and facilitators of participation in the program.

### **Analysis for the Tertiary Aims:**

**The effect of treatment on adherence status at 3-months.** Adherence will be measured as a continuous variable. A linear regression will be performed using the final assessment of adherence as a response and randomization group as a predictor. Other variables that may potentially have an effect on adherence such as age, gender, level of education and comorbidity will also be included if these variables are not balanced between groups by the randomization or if they are determined by univariate analysis to be significantly predictive of adherence.

**The effect of treatment on BP reduction at 3-months.** BP will be treated as continuous systolic BP (SBP) and diastolic BP (DBP) variables measured at baseline and 3-months. The effect of treatment on these variables over time will be assessed using differences in differences estimation whereby pre-intervention SBP and DBP values are subtracted from post-intervention values, and change amounts by study group are compared using t tests. The significance level will be set at  $\alpha=.05$ . Analysis of covariance will be used in place of a t test, if covariates are needed.

**The effect of treatment on HbA1c reduction at 3-months.** HbA1c will be treated as a continuous variable at baseline and 3 months. The effect of treatment on HbA1c over time will be assessed using differences in differences estimation whereby pre-intervention HbA1c values are subtracted from post-intervention values, and change amounts by study group are compared using t tests. The significance level will be set at  $\alpha=.05$ . Analysis of covariance will be used in place of a t test, if covariates are needed.

**Data Management:** Dr. Schoenthaler will oversee the data management for this study. All data will be double entered by RAs and compared using automated comparison programs. Inconsistent data entry will be resolved against the raw data, and comparisons will continue until all inconsistency is removed. Periodically, Dr. Schoenthaler will review all data for duplicate records, illogical collection dates and contingencies, and outlier values using program syntax created for each file. Reasons for dropout and loss to follow-up will be tabulated by condition. The results of analyses using imputed values will be compared with the results obtained with only complete cases. If the results indicate that attrition is significantly related to one or more baseline variable, predicted values from a logit model will be used as a covariate in all subsequent analyses, thereby correcting for differential attrition. All randomized participants will be included using intent-to-treat analytic strategies. While randomization is expected to produce well-balanced groups, analyses will determine baseline differences between the groups on demographic or prognostic variables. If significant differences are found, these variables will be included in a logit model to predict group assignment, and predicted values from the final logit model will be used as a covariate in all subsequent analyses.

**Data Storage and Confidentiality:** PHI obtained during pre-screening (with a waiver of authorization) will not be retained unless the subject provides informed consent. Any PHI collected after informed consent will be entered as part of the data set. To ensure confidentiality, baseline and 3 month data will be associated with an individual participant only by an assigned identification number, the code for which will be kept in a password protected file accessible only by the study team. Procedures have been centrally developed to ensure the confidentiality of information, such as encrypting all data, storing all hard copies of study related data in locked cabinets, password protecting all electronic files, ensuring that participant information is not identified with participant names, and that analyses are conducted and reported by group rather than by individual participants. All data will be maintained on a secure, physical and password-protected central computer server. Prior to inclusion in any data set (internal and external), data will be stripped of all identifying information. Access to the HIPAA-compliant database will be controlled by passwords, which are encrypted and required to meet standard security requirements.

**Procedures for audiotapes:** In this study, audio recordings of the semi-structured interviews will be completed to identify themes related to barriers and facilitators of medication adherence. These data will be used to tailor the adherence intervention program. All recordings will be conducted in a private dedicated room at the primary care clinic. Permission and signed informed consent will be sought from participants to complete the audiotape interviews. All participants will be informed that audiotaping is optional and refusal to sign the informed consent will not limit their participation in the study. In addition, participants have the right to review the tapes and can request for withdraw of the tapes at any time after giving consent without penalty. In the event that a participant requests withdrawing tapes, the tapes will be erased and destroyed. Withdrawing tapes from the study will not impact the care that patient receives or provider delivers at the Ambulatory Care Practice. To ensure confidentiality, all tapes will be assigned a unique study identifier and will be stored in locked file cabinets in a

safe and secure dedicated room that only study personnel will be able to access. No names will be transcribed from the tapes to ensure that there is no identifiable information during the coding process and included in the report.

### **11) Provisions to Monitor the Data to Ensure the Safety of Subjects**

This study does not include more than a minimal level of risk.

### **12) Withdrawal of Subjects**

Patients can be removed from the study without his or her approval if they fail to adhere to the study protocol (i.e., keep scheduled appointments or follow directions) and/or exhibit critical blood pressure readings at study visits (i.e.,  $\geq 180/110$  mmHg) that require close monitoring from his or her primary care doctor.

Patients may withdraw from participation at any time without penalty. Withdrawing from the study will not impact the care that patients receive at the Ambulatory Care Practice. Patients may also withdraw authorization for use or disclose his/her protected health information for the study.

If patients do decide to withdraw consent, they will be asked to contact the principal investigator, Dr. Schoenthaler to let her know. Dr. Schoenthaler or another member of the study team will discuss with patients any considerations involved in discontinuing participation in the study. Patients will be informed that already collected data may not be removed from the study database. However, they will be asked whether they intend to withdraw from the entire study (all data collection) or would only like to stop participating in the patient education/counseling calls with the Research Assistant. If the patient agrees to continue with data collection, they will be contacted for the final three month visit to collect the remaining study data. We will also seek permission to collect data from the patient's medical chart. If they agree, this data will be handled the same as research data.

### **13) Risks to Subjects**

This study does not include more than a minimal level of risk. Though we expect the level of risk due to this study to be small, there are some potential risks we would like to make patients aware of:

Elevated blood pressure or blood glucose: One of the reasons patients are eligible for this study is because they have high blood pressure or type 2 diabetes. Although patients are receiving regular care from their primary care doctor while participating in this study, it is possible that their blood pressure or blood glucose might become higher and will require close attention. If this happens, we will refer patients back to their doctor for treatment.

Inconvenience or Discomfort: Patients may feel the study visits are inconvenient. They may also feel uncomfortable answering some of the study questions. Patients can refuse to answer any questions they wish. There is also a minimal risk that being audiotaped may make patients uncomfortable. However, the research team is taking many steps to

ensure that patients do not feel uncomfortable during the audiotaped interview with the Research Assistant. In addition, patients' name will not be transcribed from the audiotapes to ensure that there is no identifiable information included in the report. All audiotapes will be stored in a safe and secure place that only study personnel will be able to access.

Violation of patient's privacy: Because patients' blood pressure and HbA1c recordings, survey responses, and the patient education/tailored adherence sessions will be used as a source of data for this study, there is a potential risk of a violation of privacy. However, the research team is taking many steps to ensure that patients' private information is kept safe. All study visits will be conducted in a dedicated room at the primary care clinic. Additionally, all data will be stored in a safe and secure place that only study personnel will be able to access.

#### **14) Potential Benefits to Subjects**

We cannot promise any immediate benefits to patients from taking part in this research. However, possible benefits include the following: Patients may be more likely to take his or her high blood pressure or anti-diabetic medications as a result of the information they receive during the course of the study. They may also lower their blood pressure and improve their quality of life.

#### **15) Vulnerable Populations**

N/A

#### **16) Sharing of Results with Subjects**

All participating patients can choose to receive their individual adherence profiles and adherence summary reports at the end of the 3-month study.

#### **17) Setting**

All potential subjects will be identified and recruited at the Bellevue Ambulatory Care Practice located on the second floor of Bellevue Hospital Center. All data collection will also be conducted in a dedicated space at the Ambulatory Care Practice. Semi-structured interviews will be conducted in a dedicated private office located on the sixth floor of Bellevue Hospital Center.

#### **18) Resources Available**

This team is well-qualified to carry out the proposed study. This is a multidisciplinary team that comprises a clinical hypertension specialist (Dr. Ogedegbe) and a behavioral scientist (Dr. Schoenthaler). Drs. Ogedegbe and Schoenthaler have worked together for the past ten years on at least four R01 grants targeting blood pressure control in primary care based practices; thus, this is a well-established collaboration. Ms. De La Calle and Mr. Barrios have been working with Drs. Schoenthaler and Ogedegbe for the past 5

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years. They extensive experience delivering community and practice-based interventions for Latino and Black patients.

**Feasibility of recruitment plan:**

Antoinette Schoenthaler is an Assistant Professor of Medicine at NYU School of Medicine. She has extensive experience working on community- and practice-based trials and training clinic staff in the delivery of patient-centered counseling techniques. She is currently the PI of a NIH/NHLBI-sponsored K23 trial in community-based primary care practices. Dr. Ogedgebe is a Professor of Medicine at Bellevue/NYU School of Medicine. He is a board-certified internist, hypertension specialist, and an Attending Physician at the Bellevue Hospital Ambulatory Care practice. He also has extensive experience implementing practice-based trials and is the PI of a NIH/NHLBI-sponsored R01 in Bellevue Ambulatory Care clinic. Based on their current work in primary care practices, Drs. Schoenthaler and Ogedgebe will coordinate involvement of the Medical Director and clinic staff in identification and recruitment of eligible patients as well as coordinate with the study staff to address any logistic issues that may arise in the process of patient screening and enrollment.

Because of our prior record of successful patient recruitment in the Bellevue Ambulatory Care Practice, and the large number of hypertensive patients seen at these practices, we should be able to recruit the 6 patients/month that the study timeline requires. Dr. Schoenthaler will devote 10% of her time to conducting and completing the research. Dr. Ogedgebe will devote approximately 2.5% of his time to the project. The research staff (Ms. De La Calle and Mr. Barrios) will each dedicate 50% of their time to conducting the research.

**Facilities:** This study will take place at the Bellevue Ambulatory Care Practice located within Bellevue Hospital Center. Bellevue employs 25 primary care providers, including internists, family practitioners, nurse practitioners, physician assistants, and bilingual support and administrative staff. Dr. Schoenthaler currently has an ongoing study at the Ambulatory Care Practice with dedicated space to conduct her research.

**Adherence to the protocol:** To ensure adherence to the study protocol, Drs. Schoenthaler and Ogedgebe will meet with primary care providers and clinic staff at the study site prior to participant enrollment. The study rationale, its significance and procedures will be explained. Physicians will be given laminated pocket cards that list eligibility criteria, contact and other relevant information for the research staff.

Ms. De La Calle will conduct the screening, consent, enrollment procedures and all study assessments. She will be trained on the proper conduct of each piece and will be required to practice explaining the consent and administering the study assessments with the co-investigators several times before going into the field. Dr. Ogedgebe will be responsible for training Ms. De La Calle in proper blood pressure measurement techniques. Mr. Barrios, a bilingual RA will obtain consent. He has previous experience working on

practice-based intervention trials and as part of this work has obtained informed consent from demographically diverse participants.

## **19) Prior Approvals**

N/A

## **20) Recruitment Methods**

Potentially eligible subjects will be recruited in three ways:

1. Providers at the participating site will be asked to identify hypertensive patients in their practices through the use of ICD-9 billing codes. Once a patient is identified who fulfills the inclusion criteria, a letter, signed by the referring provider, will be sent to the patient, explaining the study and providing a telephone number, for him/her to call if s/he is interested in participating. If the patient gets in contact with study staff, the study staff will provide more information about the study (via telephone or in a dedicated space in the clinic). If the patient is interested in participating the study staff will make an appointment with the patient to seek informed consent.
2. Healthcare providers will continue to refer patients during the trial. Healthcare providers as well as nurses, and patient care assistants (PCAs) will be given a card which gives the inclusion criteria; the provider/nurse/PCA will explain to potential participants that there is a study in which s/he might be interested in participating. If the patient expresses interest, the healthcare providers, nurse or PCA will give the patient a card with the study staffs' telephone number. The same follow-up procedures will be used as noted in method 1.
3. Third, to maximize our reach, a random sample of patients who participated in Dr. Schoenthaler's IRB approved project #11-0053 and indicated on the main project consent form that they are willing to be re-contacted in the future will be contacted by Dr. Schoenthaler. In order to contact these patients, the following information will be obtained from Dr. Schoenthaler's trial: Name, mailing address, and phone number. This information will be used to contact the patients via a postal letter and then by a phone call. The letter will include a brief description of the project and the reason why they are being contacted to participate. It will also provide information about how to get in touch with Dr. Schoenthaler to schedule an in person visit and it will inform participants that Dr. Schoenthaler will be contacting them soon via a phone call. During the call the Dr. Schoenthaler will explain that the purpose of the project and the patient's responsibilities. If the patient expresses interest in completing the survey and agrees to participate at this point, s/he will be scheduled for the consent visit.

In order to randomly select patients to receive an interest letter, each and patient that completed project #11-0053 will be assigned a number. Using a random number table, three patients will be chosen to receive a letter. We will then use the following procedures for each patient: If the first patient chosen

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refuses to participate when called, research personnel will approach the second person chosen, and so on until a participant agrees to the project or the list is exhausted. This process will continue until all potential patients are contacted and invited to participate in the study.

### **21) Local Number of Subjects**

Characteristics of the study population:

Forty patients with hypertension will be recruited to participate in this study. Patients will be ages 18 and over and include both males and females. Patients must self-identify as English or Spanish-speaking Latino(a)s or African/American Black (see inclusion criteria in section 4).

### **22) Confidentiality**

To ensure confidentiality, data will be associated with an individual patient only by an assigned identification number, the code for which will be kept in a locked drawer accessible only by the study team. Prior to inclusion in any data set (internal and external), data will be stripped of all identifying information.

### **23) Provisions to Protect the Privacy Interests of Subjects**

During the recruitment, the RA will meet with the potential participants, individually in a private space to give a fuller description of the study in clear, easy to-understand language, including the following: patients will provide informed consent to be enrolled in the study; they have a 50-50 chance of being in either study group; they will be asked permission to have their charts reviewed; and not every patient is accepted into the study (this will be decided during the screening). Permission will also be asked to audiotape the patient education or counseling sessions. Patients giving permission to have the interviews audiotaped will be provided with a separate consent form that will be explained in easy to- understand language and follow the procedures outlined above. Refusal to participate in an audiotaped interview will not limit patients' ability to participate in the study. The protocol and consent form will be approved by the Institutional Review Boards at New York University School of Medicine. During the consent procedures the RA will provide a copy of the consent form for him/her to read; if the participant asks for help, or evidences a problem in reading the consent, the RA will read and explain the consent him/her. If the participant desires to participate, s/he will sign, and the RA will co-sign. If the patient desires to participate in the study at this point, they will be asked to provide written consent. During the consent procedures, the RA will use the following general principles to ensure patient privacy is maintained:

- Use non-medical terminology and simple explanations whenever possible
- Identify the patients' role in the study for which they are being recruited
- Make certain that patients understand that the information they give on a questionnaire or in an interview is confidential.
  - Explain that the patients name will not be on any of the study materials, but rather, a study number and initials identify patients. The patient's

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- name will not be attached to the information in any way, even if information is written up about the study later.
- Explain who has access to the information. The patient must be told that others will see the information, but they will be people connected with the study.
- Assure patients that they will not experience any pain or discomfort participating in the interview. Many patients are concerned about additional pain or discomfort; assure the patient that this interview is “talking only”.
- Talk honestly about the role the patient plays in research studies. Explain that although the patient may gain nothing from participation, information learned from his/her participation and that of the other patients may lead to improvements in the treatment of hypertensive patients in the future.
- Assure patients that they have the right to withdraw from the study at any time and that the choice to withdraw will not affect the services that they receive from the clinic in any way.

### **24) Payment of Participation**

Patients will \$20 for participating in the main study and an additional \$10 if they agree to complete an exit interview.

### **25) Cost to Subjects**

There will be no cost to the patient for participating in this study.

### **26) Consent Process**

The required information for informed consent will be summarized orally to the patient by the bilingual RA during the initial in-person contact and will be presented again in a comprehensive written consent/authorization form. The consent process will be conducted in a dedicated space at the primary care clinic. The study staff will adhere to the SOP: Informed Consent Process for Research (HRP-090). Specifically, during the consent meeting, the RA will explain the following study procedures: that patients will have a 50-50 chance of being in the tailored adherence intervention (TAI) or single patient education (PE) session; that they will be asked to give permission for their charts to be reviewed; that participation is completely voluntary, and that not every patient is accepted into the study (this will be decided during the screening).

To ensure comprehension, subjects will be asked to repeat back to the RA the salient points of the consent form to make sure that they understand the study they are agreeing to participate in. If a participant asks for help while reading the consent, or evidences a problem in reading the consent, the RA will read and explain the consent him/her.

If the participants speak Spanish they will receive a Spanish Consent form. The Spanish consent form will be explained by the bilingual RA. A Spanish version of the consent form will be provided to the IRB once the English version is approved.

## 27) Process to Document Consent in Writing

The study staff will adhere to the SOP: Informed Consent Process for Research (HRP-090). If the patient is interested in participating, the RA will provide a copy of the consent form for him/her to read; if the patient asks for help, or evidences a problem in reading the consent, the RA will read and explain the consent him/her. If the patient desires to participate, s/he will sign, and the RA will co-sign.

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