ATTACHMENT 3A

HELP PARTICIPANT SCREENING QUESTIONNAIRE AND HELP EVALUATION CONSENT FORM

Form Approved
OMB No. 0990-
Exp. Date XX/XX/20XX

HEALTH EMPOWERMENT LIFESTYLE PROGRAM
Participant Screening Questionnaire

Name of Participant: _____ Date: _____/ _____/_____

Interviewer: _____

"Good morning/afternoon, my name is ____, I am a nurse/community health worker/health educator at the Lawndale Christian Health Center. In partnership with the University of Illinois-Chicago's Midwest Latino Health Research, Training & Policy Center, we are participating in a research study that consists of implementing and evaluating an educational program entitled: *Health Empowerment Lifestyle Program* (HELP). The purpose of this program is to increase knowledge and skills in the management and control of type 2 diabetes, hypertension and in the reduction of overweight/obesity.

If you are eligible and decide to participate you will increase your knowledge and self-care skills about how to manage the chronic conditions addressed in this study. You also will be involved in a supportive group environment during the health education classes with other participants that may have similar experiences as yours in managing their weight and controlling their type 2 diabetes and hypertension. Also, if you are eligible, during the first group meeting you will have your weight and hypertension assessed, and a finger prick to draw a drop of blood to determine your blood glucose level (what is known as HbA1C), if you have not received one in the past 4 weeks. Your participation in this study involves minimum risk to you and if you decide not to participate at this time, it will not affect the services that you are receiving at the Lawndale Christian Health Center (LCHC).

Therefore, we are (calling/talking to you) to find out if you are eligible to participate in this study, and if you are, then to find out if you are interested and available to participate. To achieve that, we would appreciate it if you will answer some questions that are necessary for us to determine if you qualify for this program."

The following questions will help us ensure you are eligible to take part in this class. If anything I ask you makes you feel uncomfortable, please let me know and we can skip to the following question.

1. How old are you?

|___|___|

☐ **ELIGIBLE -** person is older than 18 and younger than 66 years
☐ **INELIGIBLE -** person is younger than 18 or 66 and older

2. Are you Hispanic/Latino?:

☐ Yes
☐ No

What is your racial group? Mark all that apply.

☐ American Indian or Alaska Native
☐ Asian
☐ Black/African American
☐ Native Hawaiian or Other Pacific Islander
☐ White

☐ **ELIGIBLE -** person is Hispanic/Latino or African American
☐ **INELIGIBLE -** person is not Hispanic/Latino or African American

3. If the interviewee is a **woman:**
Are you currently pregnant, or do you plan to get pregnant in the next 3 months?

☐ Yes
☐ No

☐ **ELIGIBLE -** person is NOT pregnant and does NOT plan a pregnancy in the next 3 months

4. Have you been diagnosed with any one of the following conditions by a medical care provider?

☐ Type 2 diabetes

☐ High blood pressure

☐ **ELIGIBLE -** person has been diagnosed with diabetes or high blood pressure
☐ **INELIGIBLE -** person has NOT been diagnosed with diabetes or high blood pressure

5. Have you been told by a health care provider that you need to lose weight?

☐ Yes
☐ No

☐ **ELIGIBLE -** person is overweight
☐ **INELIGIBLE -** person is not overweight

6. During the next 3 months, will you be traveling out of town?

☐ Yes
☐ No

☐ **ELIGIBLE -** person will NOT be traveling
☐ **INELIGIBLE -** person will be traveling

Instructions to interviewer:

Is the person eligible?

☐ Yes If the person **IS** eligible ask if they would be willing to participate in the class and come to the first class to learn more about the project.

☐ Yes
☐ No

If the answer is yes:

☐ Ask them to provide the best day/time for participation in the health .....education class
☐ Obtain participant's contact information:
Phone # 1, land line: _____
Phone # 2, cell: _____
E-mail address: _____

Day of the Week available for class	11 am – 1 pm	5:30 – 7:30 pm
Monday		
Tuesday		

Wednesday		
Thursday		
Friday		

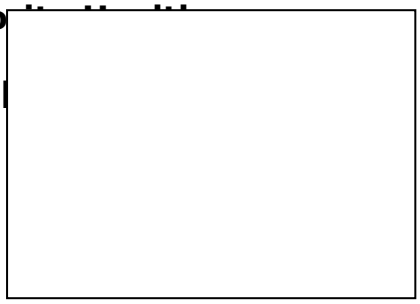
☐ No **If you mark INELIGIBLE at ANY question, the person is NOT eligible.** Let the participant know that he/she cannot be part of the class, and explain why (tell them which question made them ineligible).

Thank the participant for their time.

University of Illinois at Chicago
Research Information and Consent for Participation in Social Behavioral Research

Patient Centered Care Collaboration to Improve Mino

Health Empowerment Lifestyle Program (HEL
Evaluation Consent



University of Illinois at Chicago

Midwest Latino Health Research Training and Policy Center

Aida Giachello, PhD – Principal Investigator (a-giachello@northwestern.edu, 312-1104);
Rosemary George, Center Director (rjgeorge@uic.edu, 312-413-4083)

Sponsor: Department of Health and Human Services, Office of Minority Health, Westat

What is the purpose of this research?

The Health Empowerment Lifestyle Program (HELP) is a research study supported by funds obtained from the US Centers for Disease Control and Prevention (CDC) to reduce diabetes and its complications among Hispanics/Latinos and African-Americans in the US. Additional sponsors include the Patient Centered Care Collaboration to Improve Minority Health Initiative ~~are~~ of the US Department of Health and Human Services (USDHHS)- Office of Minority Health (OMH) and Westat Research Inc. In partnership with the University of Illinois-Chicago (UIC)'s Midwest Latino Health Research, Training & Policy Center and the Lawndale Christian Health Center, we are implementing and evaluating, as part of the research project, an educational program titled: *Health Empowerment Lifestyle Program* (HELP). The purpose of this program is to increase knowledge and skills in the management and control of type 2 diabetes, hypertension and in the reduction of overweight/obesity.

The research project consists of identifying people with type 2 diabetes, hypertension who are overweight or obese and to engage them in a 10 week course *Health Empowerment Lifestyle Program* (HELP) on the management and control of these conditions. In the first meeting of the program (session one) and as part of the research study, we collect information from people like you who are our study participants, in order to find out if the educational program is helpful–in increasing participants knowledge and self-care skills. Community Health Workers (CHWs)/educators at the Lawndale Christian Health Center, as

paid staff at the clinic, will be conducting the educational classes, collecting and tracking all the necessary information needed in this study.

Why am I being asked?

We have asked Lawndale Christian Health Center to identify active clinic patients who have been told/or diagnosed by their medical provider/physician that they have diabetes, hypertension and/or are overweight or obese. Your name was selected from a computer generated list as someone who has these conditions and who meets the other study eligibility criteria. We want you today to know all the facts related to this study and after you understand them, to decide whether or not to commit to participate. The goal of this study is to develop culturally, linguistic and health literacy appropriate educational programs for the management and control of chronic diseases. The health conditions in question are hypertension, type2 diabetes and overweight and obesity.

Your participation in this research study is voluntary. You can decide not to participate in the different tests (e.g., AIC, blood pressure) or not to answer the questions of the questionnaires or skip some particular question that you may feel uncomfortable with. You can also withdraw from the classes at any time without affecting your relationship with the staff or the services that you receive from Lawndale Christian Health Center.

What procedures are involved?

- You are being asked to attend 12 group sessions, including the 10 week HELP educational classes that will take place at the Lawndale Christian Health Center. These classes are part of the research study.

- You will be asked to answer some questions at the beginning (group session one) and the end of the program (group session 12): 1) About yourself (e.g., age, sex), 2) Your knowledge of diabetes, obesity, and hypertension, 3) How you are taking care of yourself 4) Your experience with health care providers, and 5) How you feel. The form to be given to you in the first group meeting is 5-pages long and we estimate that it may take you up to 30 minutes to complete. A similar questionnaire will be given to you at the end of the program (group session 12) will take you a little longer (35 minutes) as it has 6 pages. Filling out these questionnaires is a part of the research study. The results will be shared with the team of investigators at the University of Illinois-Chicago's Midwest Latino Health Research, Training & Policy Center. The information will be given to UIC in a de-identified form, and identifiable private health information about yourself (PHI) will not be shared with UIC as part of the research.

- You will be asked to allow the clinic staff/health educators to weigh you, take your blood pressure; take a drop of blood to test your sugar level. This test is called the hemoglobin AIC and its value will tell us your average blood sugar level in the past 3 months. These same tests will be repeated in group session 12 at the end of the program. These tests are also part of the research study. Again, the results of these tests will be given to UIC in a de-identified form, that means that private health information about yourself (PHI) will not be shared with UIC as part of the research. Clinic staff will see your personal information as they will be collecting it. Information on your blood test, the HbA1C, will also be recorded in your patient record as part of standard clinic policy.

What are the potential risks and discomforts?

There is minimal risk associated with the activities of this project. The risk associated may be primarily emotional or psychological in nature. You may be bothered by some of the questions in the questionnaires or dealing with the stress associated with a particular finding of one of the tests (e.g., high blood pressure, high HbA1C) that you will receive in sessions 1 and 12 of the study. If you experience some emotional or psychological discomfort from answering the knowledge questionnaires or dealing with the stress associated with an unfavorable clinical finding, you have the right to refuse to answer any question. At any time that you feel bothered by any activity involved in the study, the clinic staff are trained to provide you with the names of individuals within the health facility or outside organizations to call to help you with your worries, if necessary. You will also be encouraged to contact your medical provider/physician if necessary.

There is a possibility that you may be concerned about confidentiality of information. We will comply with the Privacy Act and take necessary steps to keep patient information private and secure. Lawndale Christian Health Center and UIC will take the following steps to minimize risk associated with breaching confidentiality in this project. Those steps include: 1) using a unique project identification number for each patient, 2) storing data securely at each site and providing access only to trained staff on an as required basis, and 3) not giving access to the data other than to those on the project.

However, there is the possible risk of a breach of privacy as others in the educational classes may find out identifiable information about you and may share these information in and outside the group, over which we have little control. Although other participants will be asked to respect each other's privacy, privacy and confidentiality cannot be 100% guaranteed.
Again, we are minimizing risks of data breaches in the way in which we are engaging in collecting data/information in this study (explained above) and by explaining to you all the facts and procedures involved in this research through

this Participant Consent Form before you sign it. Only clinic staff directly involved with the study will have access to data identifying you. Clinic staff will keep records and forms in a locked file when not in use. Information shared with the Midwest Latino Health Research, Training, and Policy Center at the University of Illinois at Chicago, will be destroyed after one year following the completion of this project and any research reports or articles.

By explaining the purpose of the study, we hope that you have enough information to make a decision about your participation. If you decide not to answer any of the questions, you will not suffer any negative consequences. For example, you will continue receiving services from the Lawndale Christian Health Center if you decide not to participate in this study.

Are there benefits to taking part in the classes or in the research?

The goal of this study is to increase the management and control of chronic diseases in the areas of hypertension, type2 diabetes and weight management through the implementation of a culturally- and health literacy-appropriate educational program and curriculum. You will directly benefit from this study by increasing your health knowledge and self-care skills about management and control of these conditions. You may also receive social support from other study participants in the group that may help you understand the challenges and learn about strategies to overcome the diverse health problems. Participants, like you, will benefit by increasing your knowledge and self-care skills of these chronic conditions. There are also other benefits such as:

- It has the potential to help us understand how to reduce health disparities, delay medical complications and reduce premature deaths related diabetes and cardiovascular conditions among racial and ethnic minority groups.
- It may allow the Lawndale Christian Health Center to integrate this program as part of their regular health education activities, depending on the study results.
- The team of investigators of the study may share the lessons learned in this study so other groups can benefit from them.
- It has the potential to improve the health and quality of life of current and future participants in the educational classes and to delay medical complications.

The benefits far outweigh any possible risk involved in the study. In addition, your participation in taking the clinical tests and providing answers to the questions on the evaluation forms will provide the researchers with information that they can use to improve future educational classes.

What other options are there?

Yes. You have the option to not participate in this study. If you decide not to participate, or if you have additional questions, feel free to contact the community health workers/educators conducting the educational classes at the Lawndale Christian Health Center or the research project staff at the University of Illinois-Chicago (see information below) for any questions regarding the nature of this study, how you were selected or any other concerns that you may have about the procedures, data collection and/or about how we are protecting your confidentiality or privacy.

What about your privacy?

The information obtained from your clinical tests, and the information that you will provide on the questionnaires will not have your name on them. We do ask for a code so we can match the same person's answers before and at the end of the program. However, your answers to the questions are not traceable to you. They also are not reported to your doctor or anyone connected with your health care. Nothing that you write on the forms can influence your health care or your ability to participate in this educational program or any other program. The hemoglobin AIC, will be recorded in your medical record as part of Lawndale Christian Health Center's normal process of recording labs.

Also, the research results may be provided to the funding agency in a progress report, or published or discussed during presentations in conferences. Information will be reported in a summary fashion and no information that would reveal your identity will be provided. Any research discussions will not include your name. No information that is obtained in connection with this study will be identified with you outside of the clinic.

Finally, the UIC Institutional Review Board (IRB) for the protection of human subjects in research and the State of Illinois auditors may review information to ensure that the research is being conducted properly.

What are the costs for participating in this research? You will incur no costs for participating.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

We don't expect you to have any expenses associated with this study. If you need a bus pass for transportation, arrangements will be made to provide one. If you have other expenses, you will not be reimbursed. But keep in mind that your involvement can potentially help benefit your community.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time, at your own convenience.

Who should I contact if I have questions?

You may ask us any questions you have now. If you have questions later, you may contact the researchers at:

UIC Midwest Latino Health Research Center (Main phone number: 312-413-1104). They are:

Aida Giachello, PhD – Principal Investigator, a-giachello@northwestern.edu, 312-413-1104; or

Shaffdeen Amuwo, PhD –Co-Principal Investigator, UIC School of Public Health, Amuwo@uic.edu, 312 996-5955.

Rosemary George, Center Director (rjgeorge@uic.edu, 312-413-4083).

What are my rights as a research subject?

If you have any questions about your rights as a research subject, you may call the UIC Office for Protection of Research Subjects at 312-996-1711 (local) or 1-866-789-6215 (toll-free) or e-mail OPRS at <mailto:uicirb@uic.edu>uicirb@uic.edu.

Remember: Your participation in this research is voluntary. By participating in this research, you will be a research subject. Your decision whether or not to participate will not affect your current or future relations with the Lawndale Christian Health Center or with the University of Illinois at Chicago, or any other participating or partnered organization. If you decide to participate, you are free to withdraw at any time without affecting these relationships. You will be given a copy of this form for your information and to keep for your records.

By participating in these tests and answering the questions you are helping us to know the impact or effect of these classes on people like yourself, and how we can make the program more effective in the future. It also helps us to obtain the necessary evidence to inform other organizations who want to know if this program works.

We ask that you read this form and ask any questions you may have before agreeing to participate in ~~be in~~ the research.

Signature of Subject or Legally Authorized Representative

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I have been given a copy of this form.

Signature	Printed Name	Date

Signature of Researcher (the Researcher's signature must be inscribed on the same date as the subject's)

Signature	Date