

University of Illinois at Chicago

Diabetes Empowerment Educational Program Consent

"Chicago Southeast Diabetes Community Action Coalition"



Why am I being asked?

You are being asked to be a subject in a research study about diabetes conducted by Aida Giachello, PhD, Director of the *Midwest Latino Health Research, Training, and Policy Center* at the *University of Illinois at Chicago and Margaret Davis, R.N., M.S. of Healthcare Consortium of Illinois*, and by _____ (*name of organization collecting data*)_____.

You have been asked to participate in the research because you have expressed an interest in diabetes education. We ask that you read this form and ask any questions you may have before agreeing to be in the research.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University, Health Care Consortium of Illinois or _____ (name of organization collecting data) _____. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Why is this research being done?

This research is being conducted to will be focused on evaluating the effectiveness of the coalition in reducing the prevalence and severity of diabetes through providing non-medical services, increasing access to services including diabetes education, and improving the quality and cultural appropriateness of diabetes education through collaboration and education of providers. In order to develop improved diabetes education, we need information from you regarding your knowledge and behaviors. This program is being done for research purposes.

What is the purpose of this research?

The purpose of this study is to develop and expand services and educational methods for improving the control of diabetes, and to evaluate how they can be implemented in different communities and health care settings.

What procedures are involved?

If you agree to be in this research, we would ask you to do the following things: Overview: Diabetes classes will meet for two hours, one time per week for 12 weeks. You are expected to attend all sessions. If you miss a session, an alternate class site will be made available when possible. If you miss 3 or more sessions, you may be withdrawn from this study.

During the diabetes educational classes, you will be expected to:

- sign an attendance contract
- bring a relative or household member to as many sessions as possible
- learn to measure your blood glucose
- perform physical activity appropriate to my medical status.
- select one relative or household member to complete a brief questionnaire
- weigh in – at each class
- have your blood pressure taken – at each class
- have your blood glucose checked using the finger stick test – at each class

Further, you agree to notify the Diabetes team if you change doctors, clinics, address or telephone number.

As a research participant, you agree to be interviewed by a member of the Diabetes Team at the beginning of the study, at 3, 6 and 12 months. At the follow-up interviews at 3, 6 and 12 months after the classes have

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finished, a questionnaire will be administered similar, to the one given on the first day of class to assess the knowledge gained and changes in behavior. You will be given a choice of locations for the interview, including your home. The initial interview may take up to 30 minutes. Each additional interview may take up to 20 minutes. You may also have the option to a phone interview for the follow up interviews at 3, 6 and 12 months. You **can refuse to answer** any question. This is one part of our research. If you express interest in providing feedback about how to improve these classes, you may be invited to participate in another part of our research which includes focus groups. Approximately 400 subjects may be involved in this research at the University of Illinois at Chicago.

What are the potential risks and discomforts?

You may experience a small amount of discomfort associated with physical activity performed and/or the finger stick blood test. You may refuse to participate in the physical activity. You will be told the results of the tests and measurements at each class. If any results are abnormal, you will be referred to your usual source of medical care, and a Diabetes Research Team member will check to see if you have been able to see a health care professional. There are no risks involved in answering questions. You have the right to refuse to answer any question.

Are there benefits to taking part in the research?

The primary benefits to participate include early identification of undiscovered diabetes or potential risk for diabetes. You may benefit from these classes by gaining more information about diabetes, its complications and its control; by improving your ability to measure your blood glucose; by learning new ways to control your weight, how to select food, cook, and exercise; and learning ways to communicate with your family and providers about your health concerns/problems.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

What about privacy and confidentiality?

The only people who will know that you are a research subject are members of the research team. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Institutional Review Board monitors the research or consent process); or
- if required by law.

This research may also be provided to the funding agency in a progress report. Information will be reported in a summary fashion but no information that would reveal your identity would be provided.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

All research records maintained during this evaluation research project will be kept in confidential and secure files. All research personnel accessing data files will sign confidentiality forms agreeing not to discuss any information being collected except with the data team and investigators. These surveys will be maintained for the life of the project and destroyed 5 years after the project has ended per Illinois law.

What are the costs for participating in this research? None.

Will I be reimbursed for any of my expenses or paid for my participation in this research? No.

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Can I withdraw or be removed from the study?

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so, including but not limited to :

- Missing 3 or more educational sessions and not making up these missed sessions
- Refusal to participate in alternate sessions if a session is missed.

Who should I contact if I have questions?

The researchers conducting this study are Aida Giachello, PhD and Margaret Davis, R.N., M.S. You may ask any questions you have now. If you have questions later, you may contact the researchers at:

UIC Midwest Latino Health Research Center 312-413-1952

Aida Giachello, PhD – Principal Investigator or Lee Losey, M.P.H. - Project Evaluator

Healthcare Consortium of Illinois 708-841-9515

Margaret Davis, R.N., M.S. – Co-Principal Investigator

What are my rights as a research subject?

If you have any questions about your rights as a research subject, you may call the Office for Protection of Research Subjects at 312-996-1711.

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 University, Health Care Consortium of Illinois or ____ (name of agency collecting data) _____. If you decide to participate, you are free to withdraw at any time without affecting that relationship. You will be given a copy of this form for your information and to keep for your records.

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

Date

Printed Name

Signature of Researcher

Date (must be same as subject's)