Title of Research:

Investigator(s):

IRB Approval #:    OSP #:

Sponsor:

You and your child (Name) are being asked to be in a research study.

The name of this study is “In-home Diabetes Education for Rural Black Families.”

This study is being done by Susan Black, PhD, RN and Barbara White, PhD, RN. They are professors of nursing at the University Of Alabama Capstone College Of Nursing.

Who is paying for this study?
This study is supported by a small grant from the NIH National Center of Minority Health and Health Disparities Project to the University of Alabama. The grant pays the expenses of the study like supplies and mileage. The investigators are not receiving extra money for doing this study.

What is the purpose of this study—what is it trying to learn?

This study is trying out a new approach to diabetes education for African American families. We want to learn whether giving diabetes education to an adult with type 2 diabetes, an adult support person without diabetes and a child aged 10-18 will lead to better diabetes control for the adult with diabetes, better family support for the adult with diabetes, and healthier living for the support person and the child. Also, we want to learn whether African American families like the program and how it can be improved.
Why is this study important—What good will the results do?
The results may show doctors and nurses a better way to help Black people with diabetes take care of themselves. They may also lead to a diabetes teaching program that can be run by Black people in their own communities.

Why have I been asked be in this study?
You have been asked to be in this study because you are a Black (African American) adult who has had type 2 diabetes for at least 3 months and you told your physician or diabetes educator that you would be interested in learning more about this study. You also said that you have another adult who would be willing to be a support person for you and attend the study meetings and that a child aged 10-18 lives in your household. Your child is being asked to be in the study because children whose parent(s) have diabetes need to know about diabetes too. Many of them help adults with their diabetes care, and they have a high chance of becoming diabetic themselves someday. They need to learn more preventing diabetes.

How many other people will be in this study?
This is a small study. Only 5 Black families—a total of 15 people—will be in it. If the families like the program, we will do a bigger study with more families.

What will we be asked to do in this study?
If you and your child (and the adult support person) agree to be in this study, you will take part in 7 home visits, counting this one. This visit will become an assessment visit, which will probably take about 2 hours more. All three of you will be interviewed about your experiences with diabetes and diabetes education, how family members do or do not help with your diabetes care, where you get information about diabetes, and what you would like to know about diabetes. All of you will be asked to complete some questionnaires (surveys) about what you know about diabetes, your general health, how active you are, and what you eat. Your height, weight, and blood pressure will be checked. These measurements are confidential—the nurses will not share them with other family members. You will be given some "homework". You will be taught how to fill out a three-day food record and how to use a pedometer. A pedometer is a little plastic box that clips to your clothing and counts how many steps you walk in a day. The homework must be done within the next week and mailed to the study office. You will be given stamped envelopes for doing this. The nurses will use all this information to plan diabetes education that meets your needs and fits your family. Last, you, your child, and the adult support person will be asked to set a time for the next visit.

The next four visits will be the teaching visits. They will be scheduled about every month for 4 months. They will last about 2 to 2 1/2 hours each. There will be four main topics for these visits:
Healthy eating for you and the family, making healthy choices about food in the home and when eating out, and reading food labels. You will receive a cookbook with healthy recipes and a food pack of healthy foods for the family to try.

How and when to test your sugar, what your diabetes medicines are doing for you, and the signs of high and low blood sugar. The family will review or learn how to test sugar, what to do about high and low sugar, and what symptoms require a visit to the doctor. You will be given 50 test strips to test your sugar during the study.

The importance of activity for you and for the other family members. This will include choosing good shoes, teaching family members how to check your feet, and thinking of ways to increase activity that fit into your life.

Ways the family can help you care for your diabetes and work together on health for the whole family.

At each visit:

- Your blood pressure and weight will be checked and you will have a finger-stick sugar test.
- You, your adult support person, and the child will be asked to set a goal related to the teaching and make a plan for how you will reach that goal before the next visit. For example, you might plan to check your blood sugar twice each day for one month or try two new recipes from the cookbook before the next visit. Your child might plan to eat grilled chicken rather than cheeseburgers in restaurants.

Between visits you will need to keep some records about how you are coming in meeting the goal. You will be given calendars to help you do this. The nurses will talk with you about your progress in meeting the goal at the next visit. Also, at each visit the family will have time to ask questions about new problems or things said at the last visit.

The last two visits are follow-up visits. These will occur about one month and three months after the teaching visits are over. At these visits there will be no new teaching. You and your child will be asked many of the same questions you were asked at the assessment visit and about changes in yourself or the family since the program. Your A1C will be measured again, either by your doctor if you are having a clinic visit anyway or by us. Your knowledge of diabetes will be tested again, and you and the child will complete another three-day food record. At the last visit you will be asked to complete some short questionnaires about the program and to talk with us about how you think the program should be changed or improved. These visits will last about 2-2 1/2 hours each.

Prospect Initials____________
There is nothing experimental about the education you will receive. The new thing about this study is the plan to conduct it in the home and to involve an adult support person and a child.

Your child will receive a free movie ticket after the first visit (today) and after the fifth visit. Each of you will receive a $30 gift certificate to Wal-Mart in appreciation of your time and effort when you finish the whole study.

How much time will I spend being in this study?
You will spend about 35 hours being in this study over the next 10 months. This includes 14-16 hours in home visits, and 15-20 hours working on your goals and keeping up your goal calendar. Your child will spend about 20 hours being in the study.

Will being in this study cost us anything?
The main cost to you and your child is the time you will spend in the home visits and working on your goals between visits. If the needed A1C tests are available from your physician at the right times (you were making a routine visit to them), we will use those results and the test will be covered by your insurance. If we draw the blood for the A1C, the study will pay for it.

What are the benefits of being in this study?
Although we cannot promise good results, it is possible that you and your family will learn more about living with diabetes and protecting good health. You and your child may feel good about learning more about diabetes care and staying healthy.

What are the risks (dangers or harms) to me if I am in this study?
The main risk seen for you from being in this study is from having blood drawn for the A1C tests. The needle stick may hurt briefly, you may have a small bruise where the needle went in, or you may feel faint for a moment. Very rarely an infection or clotting of the blood in the vein may occur. The amount of blood drawn is about 2 teaspoons. Losing this small amount of blood is not harmful. Also, you, your child, your adult support person, or we will also prick your finger to check your blood sugar when we visit. This is a little uncomfortable but the discomfort does not last long and only a drop of blood is needed. If your adult support person or your child does it, we will teach them how to do it and will help them to do it correctly. If you don’t want them to do it at all, we will do it.

Your child may get bored or sleepy during the home visits or may worry about getting their homework done. We will try to avoid this by trying to make the teaching interesting for children. We will also complete children's activities first so
they do not miss out on sleep or homework. Depending on their age and interest, children will not spend as much time in the visits as you and the adult support person.

**Will I be paid for any necessary medical treatment during the study?**

We do not anticipate any medical harm to you from this study. If a medical event does occur, we will arrange for appropriate care such as CPR or transportation to a hospital but the cost of this transportation and any needed care will be at your expense.

**How will my privacy be protected?**

We will not tell anyone you are in this study. Doing the study in your own home protects your privacy. You do not have to answer any questions or give us any information that you do not want to. We must tell you that as nurses we are legally required to report any signs of spouse, child, or elder abuse that we see or suspect.

**How will my confidentiality be protected?**

We will protect your information by giving your family and each person in this study an identification number. Your names will not appear on any study document besides this consent form. There is no way to link consent forms and names with data. The data from the study will be kept in locked file drawers in locked offices. No one will have access to it except the investigators. We will publish scientific articles on this study but no families, towns, or Alabama counties will be identified. No one will be able to tell who you are.

**Do we have to be in this study?**

No. If you decide to be in this study it should be because you really want to volunteer. You can refuse to be in the study at all. You can also start the study and decide to stop at any time. If you refuse or if you start the study and then stop it, you will not lose any benefits or rights you would normally have.

If you start and then stop, you and your child may keep any items you have been given (the healthy food pack, the cook book, test strips, movie tickets) up to that point in the study. You would not receive the gift certificate.

**If we don’t want to be in the study, are there other choices?**

If you do not want to be in this study, the other choice is to refuse. We will thank you for your time and leave.
What if new information is learned during the study that might affect my well-being or decision to continue in the study?

If new information about diabetes treatment becomes available that affects diabetes education, we will tell you about it or we will add it to our education program. You can tell us at any time whether you want to continue in the study or not.

What if we have questions, suggestions, concerns, or complaints?

If you have questions about the study now, please ask them. If you have questions or concerns later, you can reach Dr. Black at 205-348-xxxx or Dr. White at 205-348-yyyy. If you have questions about your rights as a person taking part in a research study, call Ms. Tanta Myles, The Research Compliance Officer of the University of Alabama at 205-348-8461 or toll-free at 1-877-820-3066.

What else do we need to know?

You do not give up any of your legal rights by signing this consent form.

You will be given a copy of this consent form to keep. Save it in case you want to review it later or you decide to contact the investigator or the university about the study.

The University of Alabama Institutional Review Board (IRB) is the committee that protects the rights of people in research studies. The IRB may review study records from time to time to be sure that people in research studies are being treated fairly and the study is being carried out as planned.

Also, the IRB conducts a survey of research participants about their experiences in a UA study. To complete it, ask the investigator for a copy or call IRB at (877)-820-3066. This is a free call. The survey can also be found on the IRB Outreach website at http://osp.ua.edu/site/PRCO_Welcome.html. The only identification requested is whether you are connected with UA or are from the outside community. Your response helps us improve our research protection program.

You may also ask questions, make suggestions, or file complaints and concerns at this website.

I have read this consent form. I and my child have had a chance to ask questions. Our questions have been answered. I freely agree that I and my child will take part in it.
NOTES:
This study addresses common concerns of African Americans about being “experimented on” and about investigators profiting from research grants. Separate consent form used for Adult Support Person. Separate assent to be obtained from Child. Reading level 7.6.