

The following information is provided as a sample informed consent form. Researchers also need to review the information related to the Institutional Review Board for Human Subjects on the Samford University Website.

Informed Consent

Title of Research: Measurement of Blood Sugar Levels with Two Different Machines
Investigator: Jane Doe, Pharm D. Candidate

Before agreeing to participate in this research study, it is important that you read the following explanation of this study. This statement describes the purpose, procedures, benefits, risks, discomforts, and precautions of the program. Also described are the alternative procedures available to you, as well as your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

Explanation of Procedures

This is a research study that compares the accuracy of two different blood sugar level measuring machines. People choosing to participate in this study will have their blood sugar levels taken by two methods: (1) the BloodGlucose[®] machine and (2) the DiabetesSugar[®] machine. The two devices used to measure blood sugar levels will be shown to all participants before agreeing to participate in the study. This study is being conducted as a senior research project by a pharmacy student for graduation from the pharmacy school at Samford University. The length of participation should be less than 15 minutes (time to measure blood sugar levels by the two machines and complete required paperwork).

The blood will NOT be used to determine if a person has AIDS (Acquired Immune Deficiency Syndrome) or is HIV positive. Also, the blood will NOT be used to determine if a person is using illegal drugs and/or substances. The blood will be used ONLY to measure blood sugar levels.

Blood will be obtained by sticking the finger with a fine-point needle. A few drops of blood will be placed on two special pieces of paper. The paper will then be inserted in the machines to measure blood sugar levels. A band-aid will be placed on the finger afterwards. If blood can not be obtained after the third finger stick, the study will not continue unless the volunteer wishes to continue.

Risks and Discomforts

In a willing and cooperative participant, there should not be any risks or discomfort from having the blood sugar level measured. A small amount of pain may occur upon sticking the finger with the fine-point needle. Although remote, possible risks include injury to the finger if the participant moves suddenly while sticking the finger with the fine-point needle. Therefore, all participants will need to remain still and cooperative during the two blood sugar level measurement periods.

Benefits

There are no immediate benefits to participating in this study unless an elevated blood sugar level is identified. However, the results of the study may influence how persons or patients have their blood sugar levels measured in the future.

Alternative Procedures

If a person chooses not to participate, an alternative procedure is not necessary, unless the person believes that they have a high blood sugar level. Other methods to obtain blood sugar levels include taking blood from a vein using a needle and syringe or using other types of machines that use blood obtained by sticking the finger with a fine-point needle.

Participant's initials: _____

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Withdrawal Without Prejudice

Participation in this study is voluntary; refusal to participate will involve no penalty. Each participant is free to withdraw consent and discontinue participation in this project at any time without prejudice from this institution.

Confidentiality

All information gathered from the study will remain confidential. The results of the blood sugar measurements may be published for scientific purposes, and the participants' identity will not be revealed. Only the researcher and Samford University IRB will have access to the study data and information. All study results and information will be kept in a locked draw and then destroyed after the project is completed.

Costs and/or Payments to Subject for Participation in Research

There will be no costs for participating in the research. Also, participants will not be paid to participate in this research project.

Payment for Research Related Injuries

Samford University has made no provision for monetary compensation in the event of injury resulting from the research. In the event of such injury, Samford will provide assistance in locating and accessing appropriate health care services. The cost of health care services is the responsibility of the participant.

Questions

Any questions concerning the research project and/or in the case of injury due to the project, participants can call Dr. Bob Que (faculty advisor for this project) at 205-726-XXXX. Questions regarding rights as a person in this research project should be directed to name (please place name of current IRB chairman here), Samford University Institutional Review Board Chairman, at 205-726-XXXX.

Agreement

This agreement states that you have received a copy of this informed consent. Your signature below indicates that you agree to participate in this study.

Signature of Subject

Date

Subject name (printed)

Signature of Researcher

Date

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