

INFORMED CONSENT FORM FOR PARTICIPATION IN S.T.E.P. Program

Purpose of the program:

1. You are invited to participate in a 12-week Program which will look at how increasing your exercise may help you to better control your blood sugar, weight and cholesterol levels.

2. **Procedures to be followed:**

You will be asked to visit the clinic at two (2) scheduled times: once in the beginning and then again after about 12 weeks. During each visit, you will be asked questions about your health, the medications you are taking, and your diet. Your weight and height will be measured. Blood samples will be collected using a fingerstick to measure your blood sugar (glycosylated hemoglobin) and cholesterol levels. The questionnaire, measurements, and blood tests will take about 20 minutes, and will be conducted by the clinic staff

At the first visit, you will be given a pedometer and shown how to use it.. You should wear it immediately and over the next 2 days to get your base number of steps you take on a normal day of activities.

3. **Discomforts and risks:**

You may experience some possible hypoglycemia when you increase your exercise routine, so discuss with your educator how to avoid hypoglycemia.

4. **Benefits:**

Participation in this program may help you better control your blood sugar and/or blood cholesterol levels.. At the end of the program, you will be given your laboratory results, and advised on their implications for your future care.

5. **Alternative procedures that could be utilized:**

You can choose not to participate in this Program and continue to follow your current regimen for controlling your blood sugar levels.

6. **Confidentiality:**

Records containing your name and test results will be kept confidential at the clinical center and the test laboratory. Information and any results collected during this program will be coded and used to evaluate the benefits of the program. The information collected will not be sold, shared or licensed to others. No individual identities will be used in any reports or publications resulting from this program.

7. **Medical Care and Program Questions:**

Standard medical care is available during your participation in this program.. By participating in this program you are not waiving any rights against the health center for injury resulting from negligence. If you have any questions about this program, your medical care, or if you feel you have any side effects, you can call your program supervisor at the following phone number:

Name of Healthcare Professional: _____

Phone Number to Call for Questions: _____

8. **Participation and termination:**

Participation in this test is entirely voluntary. You are completely free to withdraw from participating in this program at any time without penalty or loss of benefits to which you are otherwise entitled. You will be informed of any new information that may affect your willingness to participate. You may be asked to leave the Program at any time if you do not follow the program procedures or at the discretion of your healthcare provider.

9. **Consent to Participate**

I hereby consent to voluntarily participate in this program. I agree to release the results of the blood glucose and cholesterol tests to my physician and my program supervisor. I also understand the results of the blood glucose and cholesterol tests will not be released to any other individuals, outside of those involved with this program, without my express consent in writing.

I hereby release any and all claims I, or anyone claiming by or through me, now have or may hereafter acquire against the program staff, and any other person or organization connected in any way with the blood glucose and cholesterol tests for any and all damages or injuries resulting from or arising out of my participation in the blood glucose and cholesterol tests or any services provided in connection with this screening.

All components of this program may not be resold to any third person, and no claim may be submitted to any third party insurance program, whether public or private.

I have read and understand the consent form and have had an opportunity to discuss this Program with a member of the clinic staff. All my questions regarding my rights as a research participant concerning this Program have been answered to my satisfaction and I hereby willingly consent to participate in this Program. A copy of this consent form has been given to me.

Signature of Participant	Date	Signature of Healthcare Prof	Date
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Participants Address	Healthcare Professional Name and Title
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Participants City	State	Zip	Healthcare Professional Affiliation/City/St/Zip
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Participant's Date of Birth	Healthcare Professional Phone Number
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