OMB Clearance Number: 2528-0337 Expires: XX/XX/XXXX

# Attachment P: The Obesity & Type II Diabetes Risk Assessment Blood Spot Samples

If you require information to be presented in an accessible format or reasonable accommodations to participate in this study, please contact us with any specific requests by calling XXX-XXX-XXXX or emailing XXXX@XXXX.XXX. If you require language assistance to participate in this study, please contact us with any specific language assistance requests or needs.

#### **Paperwork Reduction Act Burden Statement**

This collection of information is voluntary and will be used to evaluate the US Department of Housing and Urban Development's Community Choice Demonstration. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, gathering, and maintaining the data needed, and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB number for this collection is OMB 2528-0337 which expires on XX/XX/XXXX. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to NAME at XXXX@XXXXXXXXX or call XXX-XXXX-XXXX.

# **Privacy Act Statement**

**Authority:** Section 502 of the Housing and Urban Development Act of 1970 (Public Law 91-609) (12 U.S.C. §§ 1701z-1; 1701z-2(d) and (g)).

**Purpose:** Evaluation of the Community Choice Demonstration (CCD).

**Routine Use:** The information will be used for the purpose set forth above and may be provided to Congress or other Federal, state, and local agencies, when determined necessary.

**Disclosure:** Records will be used for research and statistical analysis and will not be used to make

decisions that affect the rights, benefits, or privileges of specific individuals.

**SORN ID:** Community Choice Demonstration Evaluation Data Files, HUD/PDR-09

Note: Some study activities are being funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

### [To be given to participants at study visits]

# What to expect from your results report

- Which specific results will be available?
  - O Your blood spot sample will be mailed to a laboratory where they will test it to determine your blood glucose (sugar) levels (Hemoglobin A1c). The sample will be linked to you through your participant code, not your name. Once results are available, the study team will send you your HbA1c test result, what the result means, and resources should you need to follow-up with your medical provider.
- When results will be returned to me?
  - O The test results will be sent to you in about a month.
- How results will be shared with me?
  - O Your report and results will be mailed to you through certified mail.
- Who will share the results with me?
  - The study coordinator will access your results through a secure, online portal. The coordinator will then create your individual results report and mail it to the home address you provided at the time of the blood spot test.
  - O You can also follow up with the study Principal Investigator, who is a primary care physician, if you have questions about your results.
  - O We will also provide you with contact information for local health clinics should you need to follow-up with a physician to discuss your results and next steps.
- Who will have access to my results?
  - O The results will be used as part of the study. We will not share the results with your medical team.

[to be mailed to participants with their Hemoglobin A1c results]

#### **Results Report**

STUDY LOGO

Dear XXX,

Thank you for participating in the MOVED Study! As part of the study, we checked the sugar level in your blood. In this letter, we tell you about your results.

## Understanding the test

Measurement of Hemoglobin A1c is used for diabetes risk assessment in individuals with no diabetes. It is also used to measure how well their blood sugar is controlled in patients diagnosed with diabetes.

Your Results (Example)

Hemoglobin A1c: 6.2% H, Range: 4.0%-6.0%

Estimated Average Glucose (Calculated): 131 mg/dL, Range: 68-126 mg/dL

# **Understanding your results**

When it comes to the numbers, there's no one-size-fits-all target. A1C target levels can vary by each person's age. It can also change if a person is already on medicine for diabetes. Your target may be different from someone else's target.

A1C test results are reported as a percentage. The higher the percentage, the higher your blood sugar levels over the past two to three months.

**For people not on medicines to lower their blood sugar**, the A1C test can be used to diagnose diabetes:



- If your A1c level is lower than 5.7%, your levels are normal.
- If your A1C level is between 5.7 and less than 6.5%, your levels are in the prediabetes range.
- If you have an A1C level of 6.5% or higher, your levels are in the diabetes range.

**For people with diabetes**, the A1C test is used to measure how well your blood sugar is controlled. It can help you and your health care provider figure out if you are eating the right foods and on the right medicine.

**Your HbA1c level** was **high,** and we recommend you follow-up with your health care provider. These test results do NOT make or confirm a diagnosis which can only be determined by a qualified health professional.

**Your HbA1c level** was **normal**. That is good news. Please remember, a medical diagnosis can only be determined by a qualified health professional.

# What is pre-diabetes?

Prediabetes is a condition where blood sugar levels are higher than normal but not high enough to be called type II diabetes. Prediabetes increases your risk of developing type II diabetes, heart attack, stroke and other medical problems.

## What is diabetes?

Diabetes mellitus, commonly referred to as diabetes, is **a condition in which the body's blood glucose**, **or blood sugar**, **is too high.** Glucose comes from the food we eat and is the body's main source of energy. It is helped to reach the cells of the body by insulin, a hormone produced in the pancreas. Diabetes occurs when the body produces no or insufficient quantities of insulin to do this, and so glucose builds up in the blood.

**Persistently high blood glucose levels can, over time, cause health problems such as heart disease, stroke, kidney failure and vision loss.** With proper treatment, however, diabetes can generally be managed effectively, and complications minimized. Treatment will usually be required throughout a person's life.

<u>Local health clinics and provider contact information</u>
For people who do not have a regular health care provider, we have included this list.

[UPDATE LIST DEPENDING ON LOCATIONS]

Principal Investigator contact information: Craig Pollack, MD, MHS; <a href="mailto:cpollac2@jhmi.edu">cpollac2@jhmi.edu</a>, 410-955-4201