MOVING TO OPPORTUNITY FINAL EVALUATION

INTERVIEWER INSTRUCTIONS FOR DRIED BLOOD SPOT COLLECTION

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As part of the Moving to Opportunity (MTO) final, or long-term, evaluation survey, interviewers collected dried blood spots from adult survey respondents. The information below is an excerpt from the interviewer training manual used by the Institute for Social Research (ISR), which administered the MTO final surveys. The MTO measurement protocols were based on another ISR-administered survey, the Health and Retirement Survey.

Protocol for Collecting Dried Blood Spots

The initial consent form that the respondent signed included consent for the interview, the physical measurements, and the dried blood spot samples.

Important Note!

If the Respondent said that s/he is taking blood thinner or anticoagulants (Section HPH, question 6e) or has hemophilia, the blood spots will be skipped by the Blaise interview program. This is for safety reasons. You will not see any questions about blood spot consent.

Do not collect blood spots unless you are instructed to do so by the Blaise instrument!

There is a specific question earlier in the Blaise questionnaire that is used to determine if it is safe for the Respondent to complete the test. If the Respondent indicates that he or she is a hemophiliac or on blood thinners, the Blaise program will automatically skip over the blood spot collection. Some respondents misunderstand the question and report that they are taking aspirin or a heart medication like Plavix. These are not true blood thinners, and if this is what they are taking, the question should be answered "no." Below is the question in Blaise and the associated QxQ that determines whether or not it is safe to collect the blood spots.

HPH6e:
Do you have hemophilia, or are you taking any anticoagulant medicines, or blood thinners such as Heparin or Coumadin?

1 Yes
5 No

QxQ: "Probe for name of drug if R just says she takes a blood thinner. If R says she takes Plavix (clipidogrel), aspirin, or Ticlid (ticlopidine), this question should be answered "no," as these are <u>antiplatelet</u> medications, not <u>anticoagulants</u>. The anticoagulants or blood thinners we refer to in this question (the most common of which are Coumadin, heparin, or warfarin) are much more powerful than Plavix, and require regular blood tests (usually weekly) to determine the level of medication in the patient's system."

If you do not feel it is safe for the Respondent to perform the test, skip it. If for any reason you feel it is not safe for you to complete the blood collection, please skip it.

After determining if it is safe to take the blood sample (question HPH6e), we ask the Respondent again for verbal consent before collecting the sample. The questions are shown below. Be ready to answer Respondents' questions about safety, confidentiality, and the purpose for and importance of the blood sample component of our research.

HDB1
Next, I would like to collect a small sample of your blood. To do this, I will clean your finger with an alcohol wipe, then using a small instrument I will prick your finger and collect enough blood to fill six small circles on a collection card.

Do you agree to go ahead with the blood sampling?

1	**Yes**	
5	**No**	**Go to HDB10**
8	**DON'T KNOW**	**Go to HDB10**
9	**REFUSED**	**Go to HDB10**

HDB2
Your blood spots may be helpful to this study in the future. We may one day have ways to test blood that are not known today. For example, future tests of blood spots may look for markers of infection or disease. Any of your blood that we do not use will be stored for future study, with your permission. We will never do genetic testing on your blood.

Will you allow us to store your blood spots for future use?

1 Yes
5 No

HDB3
Interviewer: **Collect blood spots according to instructions on instruction sheet**

ENTER [1] to continue

Remember, you won't see this sequence of questions if the Respondent said s/he is taking blood thinners or anticoagulant medication or has hemophilia. Collect blood spots only if you see this instruction!

After you collect the blood spots, as with the earlier measures, the Blaise program will ask you specific questions about how the blood spots were collected. Specifically, you will be asked who pricked the Respondent's finger, how many circles were filled on each card, and how many times the Respondent's finger was pricked. You will also be asked to enter the bar code number from the Lab Authorization Form on the blood spot cards.

HDB12 will come up in Blaise if the Respondent is eligible for blood spot collection and you do not collect the blood sample, asking you to record the reason(s) the test was not completed.

HDB12_
Why didn't R complete the blood sample?

ENTER all that apply
For multiple response, use [Space] or [-] to separate responses

1 R felt it would not be safe
2 Iwer felt it would not be safe
3 R refused or was not willing to complete the measurement
4 R tried but was unable to complete the measurement
5 R did not understand instructions
6 Equipment malfunction, supplies not available
7 Other – specify

Even if the Respondent signed the consent form for the interview, he/she may refuse the blood spot collection. If the Respondent does not agree to provide a blood sample, he/she will not receive the additional $25 incentive at the end of the interview.

It is important to encourage respondents to complete all parts of the interview wherever possible. Be prepared to answer any question the Respondent asks. You can use the Physical Measure FAQs, the Physical Measures Information Form, and information found in this study guide to do so.

Blood spots will be collected on two cards: a card with a shiny coating for hemoglobin (HbA1c) and cholesterol (Total Cholesterol and High Density Lipoprotein) analysis, and a card without the shiny coating for C-Reactive Protein (CRP) and for storage for later analysis of Epstein-Barr Virus antibodies and cortisol.

DBS Card

The Physical Measures Information Form tells the respondent what each test is for. HemoglobinA1c, also known as A1c, is typically used by physicians to measure an individual's blood sugar levels over the course of the last three months when screening for diabetes. HDL cholesterol, also known as high density lipoproteins, is typically measured to determine an individual's "good cholesterol" in the blood. Total cholesterol measures the level of total cholesterol. The storage (non-shiny) card will be used for the analysis of C-Reactive Protein, a marker of inflammation. These tests will all be performed by an a certified and accredited laboratory.

In addition to the four tests that will be reported back to the respondent, the rest of the blood samples will be stored and later analyzed for Epstein-Barr Virus antibodies and cortisol, both of which are markers for stress. These results will not be reported back to the respondent because they will be conducted by a research laboratory rather than a laboratory that is certified to provide test results to patients.

All samples will be kept secure and will be identified by a number only—the labs will not know the Respondent's name. **For that reason, it is important that the respondent keep the Physical Measures Report form and that you put on that form the bar code label containing the Respondent's ID number.** That is the number by which results will be stored and reported.

Inform the Respondent that you are going to need to prick one of his/her middle fingers. The finger prick can be done on either hand, whichever the Respondent prefers. In order to prepare

for the test, ask the Respondent to either massage his/her fingers or "shake" his/her hand in a downward motion for approximately 10 seconds. (There is no need to time this.)

To begin the collection, remove the lab authorization form, the blue pad, the wound kit and the foil packet labeled "Storage: Retain for CRP" (this packet contains the card that will be used for storage and analyzed for CRP) from the Blood Spot zipper bag. Remove one of the numeric ID labels from the lab authorization form and place it on the Physical Measures Report Form. Next, lay the blue pad, blue side down, on the table. Open the wound kit over the blue pad, remove the blood spot collection card with the shiny coating (this card will be used for HbA1c, TC and HDL analysis) and place one of the ID labels from the authorization form on the front of the card. *Be careful not to touch the collection portion of the cards.* Open the additional foil packet and remove the second (storage) blood spot card. Remove this card and place one of the ID stickers from the lab authorization form on the front of this blood spot collection card, again being careful not to touch the collection portion of the cards. Do <u>not</u> write in the patient's name on the cards; they will be identified only by the ID number on the label. You will also be asked to enter the ID number from the label into the Blaise application after you have completed the sample collection.

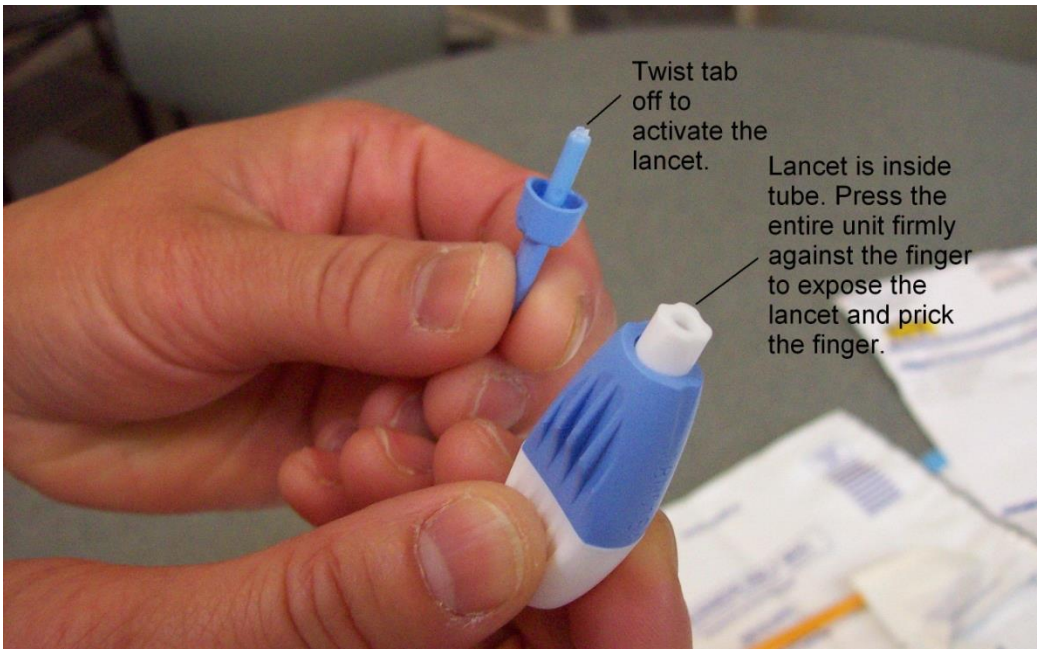
Tip: Do not mix the collection cards and foil bags. Place each card on top of the appropriate foil storage bag.

Remove the remainder of the contents of the wound kit from the plastic bag and place on the blue pad. Open the wound kit and remove its contents (two lancets, a gauze pad, a bandage, and an alcohol wipe), laying them out on the blue pad. Before proceeding further, remove the exam gloves from your bag and put them on. Some interviewers find it help to open the gauze pad package and the bandage at this time—laying them out on top of their wrappers. Remove the alcohol swab from its package.

Layout of DBS supplies

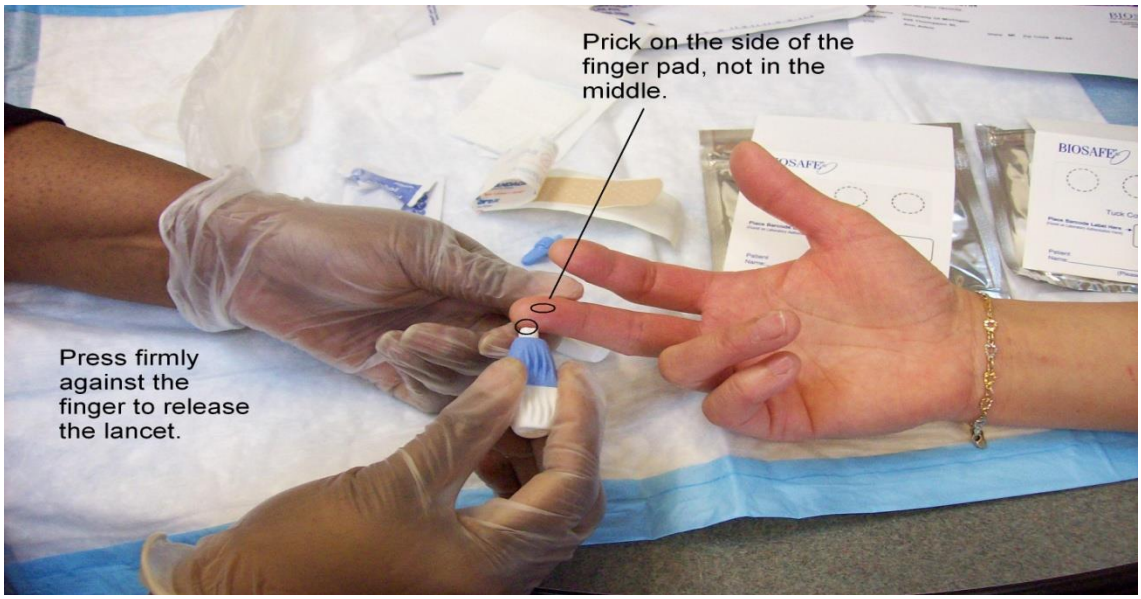
Tip: To save time, lay out the materials on the blue pad while the Respondent is completing the ACASI portion of the interview. Roll the blue pad up and set it aside until it is time to take the samples.

Next, ask for the Respondent's finger to prick. Choose one of the two middle fingers on the Respondent's hand. Let the Respondent choose which finger to be pricked. Clean the Respondent's finger with the alcohol wipe. Wait a minute for the alcohol to evaporate.



Lancet

Take the lancet provided and twist the tab off the lancet to break the seal. You will see a small round tube at the end of the lancet. This is where the needle comes out. Press that small round tube firmly against the finger, holding the lancet between your fingers. You want to prick the cleaned finger, just to the side and top of the finger pad where the finger is very fleshy, but not in the middle of the finger pad. While holding the Respondent's hand firmly, press down **firmly** against the finger, so that the small tube retracts into the lancet case. Do not remove the device until an audible click is heard.



Position lancet

TIP: Don't be timid! Press very firmly against the finger so the lancet penetrates deep enough to get good blood flow. If the Respondent's hand is heavily callused, you will need to press hard against the finger to penetrate the callus and get a good blood drop.

A drop of blood should begin to pool at the top of the Respondent's finger. You may need to ask the Respondent to gently squeeze the finger from the base toward the finger tip if the blood is releasing slowly. Using the gauze pad provided, wipe the first drop of blood off the Respondent's finger.

Begin with the treated card (with the shiny coating). Once a large drop of blood has formed on the finger, take the Respondent's finger and allow the blood to drop in the left-most circle on the blood collection card. The blood drop should be large enough that it will drop onto the collection card. You should not dab or wipe the spot onto the card, but let it drop onto the card. If that drop of blood does not fill the circle completely, take the next drop of pooled blood on the Respondent's finger and place it <u>next</u> to the previous drop of blood in the same circle.

Try not to overlap the blood drops, as the sample may not be analyzable. If the drop of blood appears to pool on the card rather than spreading out to fill the circle, gently tap the side of the card to release the surface tension and spread the blood. Continue the process of forming drops of blood and dropping them on the card until the entire circle is completely filled. Once the circle is completely filled with blood, repeat this process until the second spot on the analysis card is filled. Next, fill the first two spots of the storage card. If the Respondent's finger is still bleeding sufficiently fill the third circle on the analysis card and then the storage card, in that order, until all three circles are filled on both blood collection cards. Give the Respondent the bandage to put over the finger prick.

Place the gauze pad, alcohol wipe, wrappers, used lancet and blue pad in the plastic bag and throw all of the materials away in the trash. The lancet is auto-retractable, which limits the risk of exposure and eliminates the need for a Sharps container. Remove your gloves, peeling from the inside out, and place them in the trash bag.

Leave the blood collection cards out to air dry for 10 to 15 minutes while you complete the questions in Blaise, finish the rest of the interview, pay the respondent, update the Respondent's address and collect contact person information.

Once the blood collection cards have dried, <u>put on another pair of gloves</u> to close the analysis cards and seal them in the appropriate foil bag. The storage card should be placed in the foil packet marked Storage: Retain for CRP. Leave the desiccant packages in the foil bags. Record the date and time on the upper portion of the lab authorization form. Place both the foil bags (containing the blood collection cards) and the top (large) portion of the lab authorization form in the mailing envelope that is provided. Place your used gloves in the zipper bag for disposal.

Take the mailing envelope back home with you—do not drop it in the mail. You will ship this and others blood spot bags to the Ann Arbor office on a weekly basis in a UPS envelope. While at your home, the blood spot envelopes should be stored in a cool, dry, place. They should not be kept in your car trunk.

Mailing the Samples

The blood sample bags should be mailed weekly to the Ann Arbor office. You will be given blood spot transmittal forms (NCR forms) to fill out. Place all of the blood spot samples collected during the week in a separate UPS envelope with blood spot transmittal forms. Do not put the blood spot bags in a UPS bag with other study materials.

Safety Precautions

It is important to review all of the materials that you have been provided with during training before you begin conducting interviews. Being knowledgeable about each of the measures, understanding the correct way to conduct each of the measures as well as the possible problems that may occur with each, will allow you to be better prepared to both prevent accidents as well as to respond correctly if one does occur.

We need to make sure that we protect the safety of both the Respondent and the Interviewer at all times when conducting the measures. The number one thing that you can do to protect your safety is to conduct the measures as they are described in the materials. These procedures have been carefully designed and reviewed by health care researchers and experts, and have been used successfully in thousands of in-home interviews.

A copy of the Universal Precautions for the Prevention of Transmission of Blood-borne Infections is included in the Appendix and will be reviewed at training. These precautions are guidelines set forth by the Centers for Disease Control to prevent the transmission of infections via blood.

Obtaining blood with an auto retractable lancet used for a finger prick poses minimal risk for transmission of a blood-borne pathogen. If used appropriately, the lancet is never exposed except when actually pricking the finger, at which point it will prick the skin and retract. The measures conducted are minimally invasive and are measures that many individuals commonly conduct in their homes – for example, diabetics prick their finger daily to check their blood sugar level. Obtaining a dried blood spot sample is a procedure that is safe for both you and the Respondent when completed correctly.

Some main points to keep in mind include:
You must wear gloves at all times when you are conducting the blood spot collection.
You must wear gloves when handling the samples and when cleaning any spills or other bodily fluids such as blood.
When removing your gloves, do so by peeling them from the inside out so that any bodily fluids on the gloves will not come in contact with anything.

Always carry extra gloves in case one breaks, or there is an interruption that requires you to take off the gloves. Do not re-use gloves; always use a fresh pair.

Two additional safety handouts are included in the Appendix: First Aid Tips and Hand Hygiene. The first aid guide provides instructions for handling situations where a Respondent continues to bleed from the finger prick or bleeds excessively. On the other side are tips for handling Respondents who are feeling faint. The Hand Hygiene worksheet is from the Centers for Disease Control (CDC) and offers information regarding the importance of ensuring hand hygiene to reduce the risk of infection. We will provide interviewers with hand sanitizer. Please be sure to use this before and after completing the measures.

It is important to think of the Respondent's safety and comfort level with even the non-invasive measures. For example, some individuals are very uncomfortable with having their blood pressure taken. The feeling of the cuff inflating may provoke a sense of anxiety or fear that the cuff will not stop inflating. The Respondent should be assured that the reading will only take a short time to complete and the cuff will deflate automatically. If possible, continue with the measure unless the Respondent is very uncomfortable or irritated by the blood pressure measurement.

The best way to calm a Respondent's fears or address their concerns is to be knowledgeable and well prepared, have your materials organized so you can complete the measure easily, and to explain what will happen. Carefully explain each measure to the Respondent, then ask any questions that may appear in the Blaise survey. Confirm the Respondent's understanding of the measurement.

Hygiene is also a major concern: you will be provided with alcohol wipes that can be used on all of the equipment. If at any time the Respondent is concerned about the instruments, offer to clean it with an alcohol wipe, or have the Respondent wipe it off. The wipes can be used on the scale and the rafter's square (plastic triangle).

Treat the request to conduct each measure in a professional manner. If you relay the message that these measurements are important for our research and that the requests are not extraordinary, the Respondent will be more likely to agree to participate.
Finally, record the measurements accurately in the Blaise instrument and on the Physical Measures Report Form. All of these tips will help to ensure both your safety and that of your Respondents.

The measures conducted as part of MTO pose minimal risk to Respondents. *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The protocols and procedures you will use to conduct these measures have been reviewed and approved by the Institutional Review Board, sometimes referred to as the IRB, and determined to pose minimal risk to Respondents. Regardless, as we've reviewed, it is important to keep in mind the procedures we've presented in this session and in your materials in order to further minimize any risks.

Adverse events associated with the interview or with the physical measures or biomarkers must be reported to the IRB. An adverse event is defined as "Any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research." However, it is important to remember that there is a thin line here because of the fact that these measures should pose minimal risk. If a Respondent falls or is seriously injured while conducting one of the physical measures, we must report such an event to the IRB. You would contact your Team Leader and have an incident report filed. However, if, for example, you are at the Respondent's door and the Respondent trips while answering the door, this would not be considered an adverse event caused by the research. It is always best to check with your Team Leader if an incident occurs while you are interviewing a Respondent and you are unsure whether it should be reported or considered an adverse event. Remember, it is best to err on the side of caution!

HbA1c Assays

Interviewers shipped the dried blood spot cards to the Survey Research Center (SRC) at the University of Michigan. The Survey Research Center then shipped the cards to Flexsite Diagnostics of Palm City, FL to be assayed for HbA1c. Flexsite (which was recently acquired by Geonostics, Inc.) is certified under the Clinical Laboratory Improvement Amendments (CLIA). The laboratory stored the samples in the original foil at -70 C and, during processing, for less than a day at room temperature. The laboratory eluted the blood spots and assayed them using Roche's Tina-Quant HbA1c method on a Cobas Integra Analyzer. This method is an immunochemical assay certified by the National Glycohemoglobin Standardization Program (NGSP).

Moving to Opportunity Adult Health Assessment

As part of the Moving to Opportunity final evaluation, your interviewer has been trained and certified to do in-home physical health measurements. You will be asked to stand to have your height, weight and waist measured. Your interviewer will also ask to measure your blood pressure and collect a few drops of blood to measure cholesterol and a few other health indicators. This page tells you a little more about the measures.

Preparing for the measures:
Your interviewer will ask you to take off any outer clothing such as your shoes or big jackets that might get in the way of taking your measurements.

The Measures

Height, weight and waist size
When height is put together with other measurements such as weight or waist size, estimates of being either overweight or underweight can be created.

Blood Pressure
Blood pressure is an important indicator of heart health. While low blood pressure can be a problem for some adults, high blood pressure happens more often. A healthy diet and exercise can help keep your blood pressure at a good level. We will be measuring your blood pressure two times using an automated blood pressure cuff that fits over your upper arm. The American Heart Association suggests keeping your blood pressure at 120 / 80 or lower.

Blood Analysis
We would like to take a small amount of blood by finger prick. Your interviewer will first clean your finger with alcohol and then will prick your finger. The blood that forms will be dropped onto a small card and mailed to a laboratory. The blood spots will be analyzed for total cholesterol, HDL-cholesterol, and Hemoglobin A1c (a measure related to blood sugar), and C-reactive protein (a measure of inflammation related to heart disease). The following levels are recommended by the American Heart Association:

- Total cholesterol < 240 ml
- HDL cholesterol > 40 ml
- HgA1c <7 mg/dl
- CRP < 3mg/L

Your results
Your interviewer will give you the results of your measurements if you would like them. We will make your blood test results available to you at a later date.

More information
You can get more information on diabetes or heart disease from the American Diabetes Association (1-800-342-2383, http://www.diabetes.org) or the American Heart Association (1-800-242-8721, http://www.americanheart.org).

Moving to Opportunity Adult Physical Measures Report Form

Below are the results of your physical measurements, taken by the University of Michigan interviewer for the Moving to Opportunity project. We encourage you to keep these for your records and share them with your doctor on your next visit.

Date of measurement: _____, Time: _____ am / pm

Height: _____ feet, _____ inches **Weight:** _____ pounds **Waist:** _____ inches

Blood pressure measurements

Measurement	1st Measurement	2nd Measurement
Systolic Reading	mmHg	mmHg
Diastolic Reading	mmHg	mmHg
Pulse	P	P
Irregular Heartbeat Indicator*	☐ Yes* ☐ No	☐ Yes* ☐ No

*If the Irregular heart beat indicator is marked "yes", it means the blood pressure machine indicates some irregularity in your heartbeat. Although this can be normal, if you have not already talked about this with your doctor, we suggest that you do so.

If you gave a blood sample, your results will be ready in about four weeks. To get your results, call the number below and ask to speak with Customer Service. When you give them your ID number, the operator will tell you your blood test results and the normal range for each test.

Your blood sample ID number is: _____

Results for blood tests will be made available to you when the lab work has been completed.

When you receive your results, write your results in the spaces below. We encourage you to share the information with your doctor on your next visit.

Total cholesterol: _____ ml HgA1c: _____ mg/dl

HDL cholesterol: _____ ml C-Reactive Protein: _____ mg/L

Thank you for your participation in the Moving to Opportunity project!
University of Michigan toll free lines: 1-877-647-2122 (English) 1-800-643-7605 (Spanish)