Attachment G: The Child Assessment and The Obesity & Type II Diabetes Risk Assessment: Consent

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 40 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@XXXXX.XXX or call XXX-XXX-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.

You are being asked to continue your participation in an important research study called Mobility Opportunity Vouchers to Eliminate Diabetes and Obesity (MOVED). MOVED will help researchers better understand the effects of neighborhood conditions on the health and well-being of adults and children. This is one of the potential follow-up studies that was noted when you enrolled in the Community Choice Demonstration.

There are two parts of the MOVED study. One part looks at how housing and neighborhood environments impact your family's health, including conditions like obesity and type II diabetes. This part of the study is being paid for by the National Institutes of Health (NIH) and led by researchers at Johns Hopkins University. The U.S. Department of Housing and Urban Development (HUD) is funding a second part of the study. This part looks at how neighborhoods affect children's well-being and is being led by researchers at Abt Global.

Researchers from Johns Hopkins University and Abt Global are working closely together on the MOVED study. You might remember someone from Abt who completed the baseline data collection with you, about 2 years ago. Johns Hopkins University will be conducting the remainder of the data collection for both parts of the study at the same time to make it easier for families to be involved.

Your continued participation in the MOVED study is completely voluntary. When we say "you" in this form, we mean yourself. We are also asking for your permission to allow the same child who we collected data on last time to take part in the study. When we say "your child" we refer to the child that we are asking you to allow to participate in MOVED. If your child is 10 or older, we will also ask them if they want to take part.

Study Summary

This section provides a shortened description of the study. More information about the study is provided below in the section titled Study Details. You can ask questions about the study now and at any time in the future.

What activities does the study involve?

- The study includes a survey and several measurements.
- We will measure height and weight, and waist circumference for you and your child, as well as blood pressure for you. We will provide you with your blood pressure measurements.
- We will observe the area where you live to look for different conditions that may affect health.
- The researchers will also ask the adults taking part in the study for a small blood sample collected by finger prick to test for diabetes. You will be provided with the results of this test.
- If you have a child aged 2-15, we will ask you some questions about your child. If your child is 8 or older, we will ask them some questions directly.
- For some people, we will measure how much activity you do during the day by asking you and your child to wear an accelerometer.
- Some people will be asked to take part in a longer interview as well.
- Interviewers will come to your home to conduct the survey and take these measurements at two points – we already collected data once about two years ago, and we are asking to continue to collect data now.

Is the study voluntary?

- Yes, continuing to participate in this study is completely voluntary. Your choice to take part in or not take part in this study will also not affect your enrollment in the Community Choice Demonstration.

How will the study team protect and use your data?

- The study team will keep your data confidential to the extent allowed by law. But if someone is at risk of harm, we may need to notify the authorities.
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- We also want to inform you that our research team is required by law to report to authorities certain serious situations if we see them in the home or if they are shared with us during an interview or visit. These situations include: suspected child abuse or neglect; suspected elder abuse or neglect; and threats of immediate harm to yourself or to someone else.

- There is a risk that your data may be disclosed accidentally but we will take a number of steps to prevent this from happening.

What happens to the data you provide?

- If you do choose to take part, we will link data collected by researchers from Abt Global for the Community Choice Demonstration with data our team at Johns Hopkins collects in this study, MOVED.

Will I receive an incentive?

- After you complete the study activities during each visit to your home, you will receive an electronic gift card by email to thank you for your time. We will show you a chart later on in this document so that you can see information on the amount you may get.

Study Details

This section of the form provides more details on MOVED.

1. **Why is this research being done?**

- There are two main purposes of this research. First, millions of Americans have obesity and type II diabetes. The home and neighborhoods where people live can impact the risk of becoming overweight and developing type II diabetes along with other medical conditions. The data being collected from you will help researchers learn if helping families move to different neighborhoods affects their risk of obesity and type II diabetes.

- Second, the research seeks to better understand how housing and neighborhood environments affect children's well-being. This study will help researchers learn if helping families move to different neighborhoods affects child health and development.

2. **Who can join this study?**

- Families who are enrolled in the Community Choice Demonstration at one of the following housing agencies and are in either the standard services group or the comprehensive mobility-related services group:
    - Cuyahoga Metropolitan Housing Authority (CMHA; Cuyahoga County, Ohio)
    - Allegheny County Housing Authority (ACHA; Allegheny County, Pennsylvania)
    - Housing Authority of the City of Pittsburgh (HACP; Pittsburgh, Pennsylvania)
    - Metropolitan Development and Housing Agency (MDHA; Nashville, Tennessee)
    - Metropolitan Council Housing and Redevelopment Authority (Metro HRA; Minneapolis, MN)

3. What will happen if you join this study?

If you agree to be in this study, an interviewer will visit your home two times. You might remember that we visited your home about two years ago.. We are asking to visit your home a second time now. The home visit will take about two and half to three hours. We will invite one adult and one child from each household to take part in the study. This is the same child who we previously collected data on. The child will be 2 to 15 years old at the initial visit, and was selected at random to take part in the study. During the home visits, both the adult and the child will be asked to take part in some or all of the following activities:

Interviewer-led questionnaire

- Trained interviewers will ask survey questions to you. They will also ask survey questions to any child taking part who is 8 years old or older.
    - The adult survey will include questions around diet and exercise, how you view your home and neighborhood, your mood and feelings, and the housing environment. The survey will also include questions on your child's education, social interactions, physical health, mood, feelings, and behaviors, as well as your caregiving practices using survey questions that have been tested and used in other studies. If your child is between the ages of 2-9, we will also ask about your child's diet and physical activity. The adult survey should take about 70 minutes, and the survey about your child should take about 30 minutes.
    - All participating children 2 years of age or older will be asked to complete a brief activity on a tablet that measures their ability to plan, focus attention, remember, and juggle multiple tasks.
        - Children aged 8 years and older will also answer questions about their school and neighborhood experiences and feelings.
        - Children aged 10 years or older will answer those questions and some additional questions about their diet and physical activity, school environment, screentime, and their mood and feelings.
        - Children aged 12 years and older will also be asked additional questions about health behaviors and how they see their identity, including their sex and sexual orientation.
        - The child survey assessment can take up to about 30 minutes but will probably take less than 15 minutes *[depends on age of child]*.
    - Both you and your child can skip any questions you don't want to answer.

Height, weight, and waist circumference

- Interviewers will measure the height, weight, and waist circumference of you and your child again, just like we did at the start of the study, so we can follow any changes over time.

Accelerometer

- Interviewers will offer some adults and children the chance to wear an accelerometer again. An accelerometer measures how much physical activity you are doing. Selected people will wear the accelerometer on their wrist, like a wristwatch, for 7 days in a row. If you wore this last time, interviewers will offer you an opportunity to wear the device again.

Blood spot sample

- At the home visit, the interviewer will collect a small blood sample from the adult, just like last time. Most blood samples from finger pricks have DNA in them, which is the genetic code for each person. The blood will be used for HbA1c, which is a measure of your blood sugar and can be used to measure risk of diabetes. The blood sample you give for this research study will be tested for diabetes risk and then immediately thrown away. Your samples will be used as part of this research study only and will not be used or distributed for future research.
- Your blood spot sample will be mailed to a laboratory. The laboratory will test it to determine your blood glucose (sugar) levels (Hemoglobin A1c). The sample will be linked to you through your code, not your name.

Blood pressure assessment

- At the home visit, the interviewer will also measure the adult's blood pressure, just like last time. A blood pressure test measures the pressure in the arteries as the heart pumps. Research staff will wrap an inflatable cuff around your arm and then inflate the cuff, gently tightening it on your arm. This will allow the research staff member to measure your blood pressure and assess your risk for hypertension, or high blood pressure. Your blood pressure will be taken 3 times and then averaged.

Interviewer home and neighborhood observation

- At the home visit, the interviewer will record observed conditions in your home and neighborhood surroundings that may impact health, just like they did last time. This would include things like broken windows, peeling paint, pets with fur, whether the neighborhood was mostly residential or businesses, whether most buildings were occupied, and presence of trees, parks.

Will research test results be shared with you?

- This study involves research tests that may produce data that could be useful for your medical care. HbA1c (blood sugar) results will be mailed to you in about a month along with a fact sheet explaining what your test result means.
- You will also be provided with your blood pressure results in writing along with a fact sheet that explains what your results mean.
- You will be provided with details about local health care clinics. You may contact a study team member who is a clinician to discuss your results.
- You will not be provided with information about your child's survey or assessment results.

How long will you be in the study?

- Data will be collected from you and your family over the course of about 2 years. You signed a consent form similar to this about 2 years ago. You are now being asked to

continue your participation in the study.

4. What happens to data that are collected in the study?

- If you agree to participate in MOVED, your data will be used to answer the research questions and inform the development of several reports. The results of the NIH-funded data collection will be published in articles prepared by Johns Hopkins University. The results of the HUD-funded data collection will be published by HUD based on a report prepared by Abt Global.

- Researchers will use your data only for research purposes. HUD will not use your data to determine your eligibility for any current or future housing assistance or receipt of other benefits.

- Data from the study will be shared with HUD and linked with data from the Community Choice Demonstration. Your data will be kept in a secure place and may be used as part of future research studies for up to 30 years.

- You will not be identified individually in any published research reports. Those reports will summarize findings for large groups of individuals and will not report results for any one individual.

- Johns Hopkins University will collect and store your and your child's survey answers on a secure server maintained by third-party vendor Qualtrics. When the period of data collection is finished, all of your details will be removed from the secure server.

- Johns Hopkins University will collect and store your child's responses to the brief activity on the tablet on a secure server maintained by third-party vendor Reflection Sciences. When the period of data collection is finished, all of your details will be removed from the secure server.

- The research team will keep private the details you give us from the start of the study, including your personal details. Data will be stored by Johns Hopkins University and Abt Global in compliance with Johns Hopkins University and NIH's data retention policies and data use agreements with HUD, before being returned to HUD for long-term storage. Your data and personal details will be kept private by Johns Hopkins University, Abt Global, and HUD and its project partners to the full extent given by law.
- To encourage children to be open in sharing information with the interviewers, we have promised that we will keep their information private. We will therefore not be sharing the information that children provide with you. When children are asked questions, you will be out earshot of them but still able to see them.

5. Will my information be used in the future? Can it be used for additional studies?

- To fully understand how the program helped you and the other members of your household long-term, HUD may wish to continue learning from data collected in this study for up to 30 years. We understand that sounds like a very long time, but research from an earlier HUD study has shown the benefits of moving to a different neighborhood for families and especially their children as they grow into adults. HUD and the research team want to be able to continue that research with this new study.

- The information you will provide for this study is important for research on how to help families with housing. HUD and its project partners will make two versions of the data available. Neither version of the data will include any identifying information about you. Only HUD-approved researchers will be able to use the first version of the data. HUD will require anyone who they provide access to these data to commit to protecting the data, and to presenting results in summary form only. The other version of the data will be available to the public. There will be no restrictions on who can use the public version of the data. Because there are no limits on who could use the public data, HUD will take additional steps to make sure your identity is protected. They will do this by including more summarized information. For example, rather than showing that a study participant is 30 years old it would show that the study participant is between 25 and 35 years old.

6. What are the risks or discomforts of the study?

Answering survey questions

- The survey presents minimal risk to you. You may feel uncomfortable when answering some questions. You can skip any question you do not feel comfortable answering. You may stop the survey at any time.

Measuring height and weight

- Providing the research team with height and weight, and waist measurement involves minimal risk to you. Height and weight will be collected like it is done at a doctor's office.

Wearing an activity monitor

- There are no known risks to wearing a physical activity monitor called an "accelerometer" However, in studies done in the past, some people said that the accelerometer is "annoying" to wear or caused irritation to the skin. Therefore, if you prefer not to wear the activity monitor, you may refuse. If you do choose to wear the activity monitor and have any negative side effects, you should take the device off right away and give it back to us following the directions that we will give you.

Getting a blood spot sample

- The blood spot presents some risk to people. Because the blood spot requires 1 prick on your finger that gets a small amount of blood, it may cause some discomfort. Occasionally a bruise develops at the fingerstick site. Rarely, a person faints during a fingerstick.

Taking blood pressure

- You may feel a little uncomfortable when getting your blood pressure taken because the inflatable cuff tightens on your arm. You will only feel the tightness on your arm for a moment. You can always ask the research staff to stop taking your blood pressure at any time. We will do our best to take each measurement as quickly as possible to avoid discomfort.

Interviewer visits to the home and neighborhood

- There are no known risks associated with this portion of the study. The interviewers are trained and follow strict study procedures.

About your private details

- There is a risk that details about you may become known to people outside this study. Responses and measurements will be kept unidentified and labeled with a unique code to protect your privacy. Because we will share the data collected in this research study with

HUD and Abt, there is a risk that your personal details and enrollment in this research study will be known by others. HUD, Abt and Johns Hopkins University will do their best to keep your data safe.

7. Are there benefits to being in the study?

- If you take part in this study, you may help researchers, doctors, future housing assistance programs, and policymakers understand how neighborhood environment impacts health outcomes, like type II diabetes and obesity, and other life experiences of adults and children.

8. What are your options if you do not want to be in the study?

- You do not have to participate in MOVED. You will still be a part of the Community Choice Demonstration if you decide not to take part in MOVED. Your housing voucher and services will not be affected if you choose not to take part in this study.

9. Will it cost you anything to be in this study?

- There is no financial cost to participate in the study. There is, however, a time commitment. Study participants are asked to participate in two study visits that each take about 2 ½ to 3 hours.

10. Will you be paid if you join this study?

- There are several things we will ask you and your child to do as part of this study. We appreciate your willingness to help us with this important research. To thank you, the interviewer will send you an electronic gift card by email. The total amount of the gift card will depend on what activities you complete. The chart below shows how the amount on your electronic gift card will change with each activity you take part in for the study.

Activity for Adult	Amount at second visit
MOVED Survey	$70
Height/Weight/Waist Circumference	$20
Additional Measurements	
• Blood Pressure	$15
• Blood spot	$25
TOTAL AMOUNT	**$130**

- Some families will be selected for an in-depth follow-up interview for which they will receive a gift card in this amount:

In-depth interviews for some Adults	$100

We will give selected families more information about this in the future. If you are selected for those interviews, you can then decide whether or not to participate.

- This study also asks questions of you about the child that you are the parent or guardian of. There are some activities for the child to complete as well. You as the parent/guardian will also get an electronic gift card via email for each of the activities below that are completed. The chart below shows how the amount on your electronic gift card will change with each of these child-focused

activities completed:

Activity for Adult and/or Child	Amount at second visit
Survey of the parent/guardian about the child.	$20
Children 8 or older will also be asked to complete a short survey and complete an activity on a tablet.	$15
Additional Measurements	
• Height, weight, and waist measurement	$20
TOTAL AMOUNT	**$55**

- *[Insert this sentence and table only for people asked to wear accelerometer.]* The electronic gift card value will also be increased for those who are asked to and agree to wear an accelerometer that measures motion.

Activity for Adult and/or Child	Amount at second visit
Adult wearing an activity monitor (gift card will be distributed upon return of device)	$35
Children wearing an activity monitor (gift card will be distributed upon return of device)	$35
TOTAL AMOUNT	**$70**

11. Can you leave the study?

- You can agree to be in MOVED now and change your mind later.
- If you wish to leave the study, please tell us right away. You can do so by calling us at XXX-XXX-XXXX or emailing us at XXXX@XXXX.XXX.
- Leaving the study will not stop you from being able to take part in the Community Choice Demonstration.
- It also will not affect your Housing Choice Voucher or any services you get through the Community Choice Demonstration.

If you leave the study, Abt Global, Johns Hopkins University, and HUD may use data about you and your child that they have already collected but we will not collect any additional details from you.

12. Why might we take you out of the study early?

You may be taken out of the study if:
- Staying in the study would be harmful.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study, Abt Global, Johns Hopkins University, and HUD may use or share your data that they have already collected if the data is needed for this study or any follow-up activities.

13. What treatment costs will be paid if you are injured in this study?

- Although we do not anticipate that participants will experience injury as a result of this study, in the event that you are injured, Johns Hopkins University, Abt Global, HUD, and NIH do not have programs to pay you if you are hurt or have other bad results from being in the study.

- The costs for any treatment or hospital care you get as the result of a study-related injury that are not covered by a health insurer will be billed to you.

- By signing this form, you will not give up any rights you have to seek compensation for injury.

14. What is the Institutional Review Board (IRB) and how does it protect you?

- This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a person who takes part in a research study. You can contact the IRB if you have other questions, concerns, or complaints about this research study. You may contact the IRB at XXX-XXX-XXXX or XXXX@XXXX.XXX.

If you have any questions about this study, you may contact the research team:

- The Johns Hopkins University Principal Investigator, at XXX-XXX-XXXX, or by email at NAME@jhmi.edu
- The Johns Hopkins University Project Coordinator, by email at XXX@jhu.edu
- If you cannot reach the Principal Investigator or wish to talk to someone else, call the IRB office at XXX-XXX-XXXX or email at XXXX@XXXX.XXX.

15. What does your signature on this consent form mean?

- Your signature on this form means that you have reviewed the details in this form, you have had a chance to ask questions, and you agree to join the MOVED study that includes data collection funded by both NIH and HUD. You will not give up any legal rights by signing this consent form.
- Federal law protects individuals with disabilities which may include individuals with diabetes. Nothing in this study will prevent you from exercising your rights under such laws. For more information, please visit https://www.hud.gov/fairhousing.

Printed Name

Signature of Participant consenting to their own enrollment Date

16. Parent/Guardian Permission Statement

Please click the appropriate box next to the name of the child in the household to indicate if you give or do not give your permission for that child to take part in the study. Please note that if you click yes, the research study will be explained to the child if they are 10 and older in language they can understand. The child will be encouraged to ask questions about the study now and at any time in the future. Even if you give your permission, the child can choose not to participate.

- ***YES** means:*
  Yes, I agree to have my child take part in the MOVED study that includes data collection funded by both NIH and HUD and to the matching of my child's information to the other data noted above until they turn 18.

- ***NO** means:*
  No, I do not agree to have my child take part in the MOVED study.

_____ □ ***YES*** □ ***NO***
Child Name Child Age

_____
Printed Name of Participant consenting to enrollment of their child

_____
Signature of Participant consenting to enrollment of their child Date

_____
Printed Name of Person Obtaining Consent

_____
Signature of Person Obtaining Consent Date

17. Optional Health Care Records Activity

- As a part of this study, the researchers may ask to see your health care records from your health care providers and health insurance companies. We want to make sure that you know that all your responses and personal details will be kept private as much as possible. We will keep all survey responses, health measures, and contact information secure on a password protected server. Only the research team can access your health care records.

<u>Opt-in for allowing access to health care records</u>

- We may seek to review your health care records from your health care provider and insurer as a way to understand your use of healthcare services. The doctor's office, hospital, or insurance company will not have access to any of the study's information.

- Do you agree to allow us to access your health care records so we can find out about your health care?

YES _____ _____
Signature of Participant Date
(or Parent/Legally Authorized Representative Signature, if applicable)

NO _____ _____
Signature of Participant Date

(or Parent/Legally Authorized Representative Signature, if applicable)

- Do you agree to allow us to access your child's health care records so we can find out about your child's health care?

YES _____ _____
Signature of Participant Date
(or Parent/Legally Authorized Representative Signature, if applicable)

NO _____ _____
Signature of Participant Date
(or Parent/Legally Authorized Representative Signature, if applicable)

18. Future Contact for additional studies

- To fully understand how the Community Choice Demonstration affected you and the other members of your household long-term, researchers may wish to continue learning from this study. We would like your permission for our research team to contact you about other related studies that you or your child may be eligible for in the future.

Please sign and date your choice below:

YES _____ _____
Signature of Participant Date
(or Parent/Legally Authorized Representative Signature, if applicable)

NO _____ _____ABT:
Signature of Participant Date
(or Parent/Legally Authorized Representative Signature, if applicable)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT.