Form Approved
OMB No. 0920-1100
Expiration Date: XX/XX/XXXX

Identification of behavioral and clinical predictors of early HIV infection

(Project DETECT)

Attachment 11a

Phase 2 Consent Form (English)

Form Approved
OMB No. 0920-1100
Expiration Date: XX/XX/XXXX

UNIVERSITY OF WASHINGTON
CONSENT FORM

Phase 2 Participants

Evaluation of New HIV Testing Technologies in Clinical Settings with High HIV Incidence: Group 4

David Katz, PhD MPH	Acting Assistant Professor, Global Health	206/744-5877
Joanne Stekler, MD MPH	Associate Professor, Medicine	206/744-8312
Andy Cornelius	Research Study Assistant	206/616-5578
Emergency 24-hour number	**Dr. Joanne Stekler**	**206/744-3000**

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

You are being asked to volunteer for this research study because you participated in Part 2 of this study and some of your HIV tests were positive while some were negative. The purpose of this research is to understand when rapid HIV tests can detect HIV in the earliest stage of infection, when people are only beginning to develop anti-HIV antibodies. In this part of the study we are trying to figure out when different rapid HIV tests can detect HIV. Approximately 100 other people in the Seattle area will also be participating in this study. This study is being conducted by the University of Washington and the Centers for Disease Control and Prevention (CDC).
The information below is to help you decide whether to take part in the study.

STUDY PROCEDURES

This study will include between one (1) and nine (9) visits over the next 70 days. The complete follow-up schedule will involve return visits at 3, 7, 10, 14, 21, 28, 42, 56, and 70 days after your initial visit. We will ask you to come back until either all of your HIV tests agree or until 70 days have passed, whichever happens sooner. If you agree to participate, we will schedule all nine (9) of your visits today.

If your test results are not all positive at visit 9, we may ask you to continue returning for follow- up study visits once a month for up to one year or when all your test results are positive, whichever happens sooner.

We will ask you for detailed contact information, and will call or text you the day before each appointment to remind you to come. Because it is very important that you come to the
appointments as scheduled, if you need to miss an appointment for any reason, please call one of the study staff as soon as possible to reschedule.

At each study visit:
We will swab your mouth up to four times to collect oral fluid samples for rapid tests – and storage. We will also draw about 4 mL of your blood (less than 1 teaspoon) to use for up to five rapid HIV tests and one HIV/syphilis combo rapid test. A 10 mL tube of blood will also be drawn at this time for follow-up laboratory tests. In addition, we will draw about 20 mL of your blood (about 4 teaspoons) for storage for future testing. During each visit small sample of this amount of blood will be used to perform an HIV RNA test which tests your blood for the HIV virus (viral load). We will draw these tubes of blood at one time with one needle stick.
Altogether, we will draw about 2 tablespoons of blood. If the full blood draw is not completed at your study visit you may be invited to return to finish the full volume of the draw at a later date.

The research assistant will also complete a set of up to five rapid HIV tests for you using finger stick samples. You will have your finger pricked with a small needle called a lancet for each test (up to five times). The small drop of blood from each finger will be tested immediately on each rapid test.

If you are also enrolled in another research study (e.g. ACTG 5354 or GAIN), we may use your plasma (a component of your blood) that came from blood drawn by that study for the specimen testing or storage that we describe in this consent form. We may also obtain the laboratory HIV test results completed as part of the other study. We would still draw 4mL of blood for the rapid HIV tests for Project DETECT and collect oral fluid specimens for testing. We would do this to reduce the total amount of blood you have drawn for research.

You will also be asked to complete interviews using a computer. One interview will ask you questions about your background, sexual practices and drug use. For example, the interview may ask you about the last time you had sex or if you have ever had an STD in the past. We will also ask you whether you have been to a doctor for HIV, and if you are taking medicines for HIV, called anti-retrovirals. You will also be asked to complete a more detailed interview on the computer during your last visit.

The answers that you give in the interviews will not be connected to your name. Only researchers will see the answers you give. This data will be stored along with your blood samples to potentially be used for future research. Your answers will never be seen by the police, your employer, your health insurance or any health departments. You may refuse to answer any question or item in the interview that you do not wish to answer.

We may also ask you to complete a Release of Information form with us to request records of your recent HIV test results from your provider.

These study procedures should take about 1 hour to complete at each study visit. The first and last study visits may take longer (as long as 1.5 hours) as a result of extra interviews at those visits.

RISKS, STRESS, OR DISCOMFORT

The oral swab, finger sticks or blood draw could cause a small amount of discomfort, bleeding, or bruising. You may experience increased stress or anxiety while having discussions about HIV infection. We will take steps to minimize any stress or anxiety by providing you with factual information about HIV and risks for getting HIV in language that you can understand. We will answer any questions that you may have.

The questions we will ask you about your sexual behavior and drug use may make

you feel uncomfortable. However, you do not have to answer any questions that you do not want to answer and you can stop answering the questions at any time. The data you provide will be deidentified and only used for research purposes, and study staff will not see your name connected to your answers.

As mentioned above, some of the data you provide may be used for future research, and some your blood and oral fluid samples will be frozen and stored for future testing. No personal information about you (such as your name or birthdate) will be included. These samples will be processed and stored with a study ID instead of your name. UW, the CDC and other researchers may use these data and samples for research in the future. Nothing that could be linked to you will be kept. We are not sure what studies might be done in the future. They might include standard tests as done at hospitals, tests for HIV or other viruses or on your immune system (ability to fight infection). We will not test for genetic problems or use the blood for cloning or commercial purposes. Because nothing that identifies you will be stored with your samples, we will not be able to provide you with results of testing that we may do in the future. The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.

You may feel that participating in a research study is a breach of your privacy since we are collecting information about you related to your HIV status and may have access to your clinic records. We will take steps to minimize this by talking with you about the research, the purpose of the research, and who may have access to your clinic records as part of this research. We will discuss all of this information with you in a private room.

ALTERNATIVES TO TAKING PART IN THIS STUDY

Your alternative to participating in this study would be to not participate. You will not lose any other benefits in the clinic just because you do not want to be in the study.

BENEFITS OF THE STUDY

If you have recently become HIV infected you may benefit from the additional HIV testing performed as part of this study and from the opportunity to discuss local resources for HIV care and services in the area with study staff. Sometimes tests give a false positive result. This means that the test result was positive for HIV when the person being tested does not actually have HIV. If your test results from the Part 2 study were believed to be false positive, then participating in the Part 3 study may help you learn more about these results.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the Centers for Disease Control and Prevention (CDC) to conduct this study.

PROTECTION OF RESEARCH INFORMATION

All of the information you provide will be kept private. However, if we learn that you intend to harm yourself or others or that you or someone you know is being abused, we must report that to the authorities.

We will record your name and other personal identifying information while you are in this study in order to contact you for follow-up visits. The data we collect for the study will be coded with a unique study ID, but some members of the UW study team will have access to the link between your personal identity and your study ID to contact you or connect your test results from your clinic record to your study record. The study sponsor, CDC, will not have access to any of your personal identifying information. The link for this data will be destroyed after the records retention period required by state and/or federal law.

All of the data we collect will be kept in a locked cabinet or password-protected computer files. Results that are published from this study will not include any personal information about you.

If any of your rapid HIV tests show different results, we will help you interpret your results. We will give you the results of all of the rapid tests while you are in the clinic, and you will get HIV RNA results (test that shows HIV in your blood) by phone or at a follow-up visit.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

All answers that you give will be kept private. This is so because this study has been given a Certificate of Confidentiality. This means anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report to the proper authorities suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

There are few other limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without any penalty or loss of benefits to which you are otherwise entitled.

There is no cost to you for the study. You will receive $40 for each visit for participating in this study. You may receive up to $360 for participating in this part of the study if you need to complete all nine (9) study visits, which may be considered taxable income. The study staff may collect your name, address and social security number for tax purposes.

If after completing the first nine visits you are asked to return for monthly follow-up study visits you will receive $40 each for these visits and could receive up to an additional $400 for this extended participation. However, few people will need to be followed for a full year.

RESEARCH-RELATED INJURY

If you think you have a medical problem or illness related to this research, contact Joanne Stekler by paging her (206-744-3000) right away. She will treat you or refer you for treatment.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about

my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject

Signature of subject
Date

Copies to: Researcher
Subject

Johns Hopkins University
Phase 2 Consent Form

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Ending the HIV Epidemic Through Point-of-Care Technologies (EHPOC): Performance Evaluation of Novel POC HIV Tests in Baltimore

Application No.: IRB00274090

Sponsor/Supporter/Funded By: Centers for Disease Control and Prevention (CDC)

Principal Investigator: Matthew Hamill, MBChB, MPH, PhD

Address: Johns Hopkins University
School of Medicine
MFL Center Tower Suite 381
5200 Eastern Avenue
Baltimore, MD 21224

Email: mhamill6@jhu.edu
Phone: 410-550-9080

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. In this study all of the study procedures and information collected at any site will be the same.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this research is to evaluate how well the different types of rapid HIV diagnostic tests work. We are hoping that this study will be valuable in updating and developing guidelines for HIV testing. The research will also let us understand if testing for HIV RNA, or the actual virus in the blood, using rapid tests can detect infection earlier. Studying the use of rapid HIV tests is important so we can improve linkage to HIV treatment and prevention services.

If you agree to participate in this research, you will visit a clinic 3 times during a 12-week period. You will be placed at random in one of two groups using computer software. This is like "flipping a coin". Your activities include the following:

- Provide blood and oral fluid samples – it can cause discomfort
- Answer questions related to your health and behaviors – you may get bored or uncomfortable
- Agree for us to send confidential samples to the CDC who are sponsoring the study
- Allow us to access your medical records to record the results of any medications, examination findings or laboratory results

Participating in this research will not cost anything to you. All research related costs are covered by the study. If you participate, you may benefit from early detection of HIV and/or syphilis and learning more about your sexual health. Your participation can also help others in the future.

2. Why is this research being done?

This research is being done for three reasons: 1) to compare different tests used to diagnose HIV infection, 2) to evaluate how rapid HIV viral load tests help to link people to appropriate medical care. HIV viral load test works by detecting actual HIV virus in the blood. 3). To compare different tests for diagnosing syphilis.

This study will help us understand what type of test is most effective in early detection of HIV. Early detection of HIV is important so treatment and prevention can start in a timely manner.

Syphilis can cause poor long-term health effects. We want to know if a rapid test for syphilis improves the treatment for syphilis.

Who can join this study?

You may join this study if you meet the following criteria:

- Aged 18 or older
- Living with or at high risk for HIV
- Those living with HIV who do not have a documented undetectable HIV viral load during the last 6 months or who do not take HIV medications every day
- Willing to provide blood and oral fluid samples
- Willing to answer questions regarding your sexual health and behaviors
- Willing to have your laboratory results shared with your clinician
- Willing to attend follow-up visits

- Willing for samples to be sent to the CDC for analysis and storage.
- Willing to be take part in the study procedures

3. What will happen if you join this study?

If you agree to be in this study, you will be placed in one of two groups by a computer software. This is like *"flipping a coin"* and called 'randomization'). You will perform the same study activates regardless of the group you are in. We will ask you to do the following things:

- Attend a study visit 3 times during a 12-week period.
- During the first visit, provide up to 24ml of blood, which is about 5 teaspoons.
- During the last visit, provide up to 10ml of blood, which is about 2 teaspoons.
- During the first and last visit, provide up to 5mls of oral fluid, which is about 1 teaspoon.
- During each visit, answer questions about yourself, your sexual health, and your behavior.

On the rare occasions that participants have discrepant HIV test results (where one or more test if negative and one or more test is positive), we will arrange more intensive follow up. This will allow us to inform you if your HIV test is in fact negative or positive. For these individuals we will offer follow up on the following days, after the baseline visit:

- Day 3 (window minus 1 day to plus 2 days)
- Day 7 (window minus 1 day to plus 2 days)
- Day 10 (window minus 1 day to plus 2 days)
- Day 14 (window minus 1 day to plus 3 days)
- Day 21 (window minus 3 day to plus 3 days)
- Day 28 (window minus 3 day to plus 7 days)
- Day 42 (window minus 7 day to plus 7 days)
- Day 56 (window minus 7 day to plus 7 days)
- Day 70 (window minus 7 day to plus 14 days)

At each of these visits we will collect up to 10 ml (about 2 teaspoons) of blood and up to 5 ml (about 1 teaspoon) of oral fluid. A questionnaire on HIV symptom and care at every visit; and a behavioral survey on day 28 and final visit only

Communicable diseases:

The law requires us to report positive tests to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by Maryland law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

Will research test results be shared with you?

This study involves research tests that may produce information that could be useful for your clinical care. We will share this information with you.

- Your HIV and syphilis test results will be shared with you.

How long will you be in the study?
You will be in this study for 12 weeks.

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

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.
Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way. One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify, you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required. Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens is required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

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

Blood Draw
Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Interviews or questionnaires
You may get tired, embarrassed, or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Test Results
We anticipate the following risks associated with HIV and syphilis testing in this study:

- Increased stress due to having discussions about HIV and/or syphilis infection and results.
- Discomfort due to discussions about past medical and sexual history.
- Discomfort due to having medical records accessible to study staff, monitors, and Johns Hopkins regulatory and oversight staff

Identifiable private information
There is the risk that information about you may become known to people outside this study.

6. Are there risks related to pregnancy?
There are no foreseen risks to those who are pregnant or who may become pregnant while taking part in this study

7. Are there benefits to being in the study?
You may or may not benefit from the following by being in this study:

- Rapid HIV and syphilis test results.
- Earlier HIV care or prevention services.
- Earlier syphilis care and treatment.
- Preventing onward spread of HIV and syphilis to others.
- Learning more about your sexual health

If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?
You do not have to join this study. Other options include routine sexual heath and HIV clinical care that you should discuss in detail with your doctor or other health care professionals. If you do not join, your care at Johns Hopkins or Baltimore City Health Department will not be affected.

9. Will it cost you anything to be in this study?
You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

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

If you join this study, you will be given $40 as token of appreciation for any in person visit. The $40 will be given as an Amazon, Walmart, or other type of gift card. You will not receive the token of appreciation if you withdraw or are removed from the study.

You may be required to provide your social security number to be given the token of appreciation for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

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.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- 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 early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine, Baltimore City Health Department and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
- We will take the utmost care to ensure your information is always protected and secure.
- All conversations about your sexual and other behaviors will take place in a private area. This includes conversations about your medical history and laboratory results.
- We will provide you with a Certificate of Confidentiality that prohibits us from giving your information to anyone not connected to the research.
- Only the study team will have access to your study records.
- All of your study data will be stored on a secure, password protected Johns Hopkins Cloud-based platform where all data protection safeguards are in place.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

15. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

16. What does a conflict of interest mean to you as a participant in this study?

There are no financial or other conflicts of interest associated with this study. You may also call the Office of Policy Coordination 410-361-8667 for more information. The Office of Policy Coordination reviews financial interests of researchers and/or Johns Hopkins.

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

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive 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.

18. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor or research team member for the ClinicalTrials.gov study registration number.

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 research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator, Dr. Matthew Hamill at 410-550-9080 ext. 2001. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Dr. Matthew Hamill at 410-550-9080 ext. 2001 during regular office hours and at 646-645-0590 after hours and on weekends.

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

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

_____

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

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. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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