Informed Consent for Participation in a Research Study

Title of Research Study: ***Clinical Evaluation of the FilmArray® Global Fever (GF) Panel***
Investigator(s): Aileen Chang, M.D., Department of Medicine

Key Information:

You are being asked to take part in a research study to determine if a new diagnostic test called the FilmArray Global Fever (GF) Panel can detect and identify certain germs in blood that cause illness and short-term fevers. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?
We are conducting a study to determine if a new diagnostic test called the FilmArray Global Fever (GF) Panel can detect and identify certain germs in blood that cause illness and short-term fevers. You are being asked to participate because you have a fever or have reported having a fever in the past two days and we would like to collect a blood specimen from you in order to do this test. By doing this study, we hope to learn the utility of this new diagnostic test. Your participation in this research will last about 30 minutes.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
There are no direct benefits for taking part in this study. However, we hope the information we gain from this study may someday make it easier and faster for doctors to diagnose individuals potentially infected with germs that cause illness and short-term fever. This study will benefit George Washington University's understanding of the frequency of the fever germs detected by the Global Fever Panel in your area. For a complete Description of benefits please refer to the Detailed Consent.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?
There is minimal risk associated with the collection of a blood specimen. You may experience some mild pain, discomfort, or bruising at the site of skin puncture. These risks are no greater for this study than for standard of care testing from blood samples. In addition to the risks listed above, you may experience a previously unknown risk to participating in this study. For a complete Description of risks please refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THIS STUDY?
You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled. As a student/employee, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s) or employment status.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?
The person in charge of this study is Drs. Gary Simon and Aileen Chang. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is (202) 741-2222.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

You may be eligible to participate in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.
Please take the time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. If you decide to take part in the study, you will be asked to sign this form, and you will be given a signed copy of this form to keep. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Why is this study being done?
We are conducting a study to determine if a new diagnostic test called the FilmArray Global Fever (GF) Panel can detect and identify certain germs in blood that cause illness and short-term fevers. This study is being conducted in at least three different locations across the world and a total of at least 1,500 people will be enrolled. This study is jointly funded by the U.S. Army Medical Materiel Development Activity (USAMMDA) and the U.S. National Institute of Allergy and Infectious Diseases (NIAID) through contracts with BioFire Defense, LLC, and by BioFire Defense. Results of this study will be submitted to regulatory agencies for review. This test may be able to help in the identification of organisms that cause fever.
You are being asked to participate because you have a fever or have reported having a fever in the past two days and we would like to collect a blood specimen from you in order to do this test.

What am I being asked to do?
This study involves the collection of a 6ml or approximately 1 teaspoon blood specimen once. If you choose to participate, we will collect a specimen from you and record your temperature, age, sex, date the specimen was collected, what symptoms you have in addition to fever, if you are currently taking any medications, if you received a vaccination in the past month, and we may request from your health care provider the results from lab tests run for your illness.

Your blood specimen will be labeled with a study number. It will not be labeled with your name or any other information that would allow it to be identified as yours. This is done so that the people who perform the testing on the specimen will not know your identity.

Use of the FilmArray Global Fever Panel is considered experimental, so the results of the test will not be provided to you or your doctor and will not affect treatment decisions. A portion of the specimen will be shipped to BioFire Defense for additional pathogen testing and storage for future evaluations of the FilmArray. Any remaining specimen will be stored by the clinical laboratory for future studies.

How long will I be in the study?
You will be in the study for less than one day (participation will take about 30 minutes). Records must be kept for two years after study completion. Your blood specimen may be stored indefinitely to allow future testing with the FilmArray system should changes be made to improve the system.

How many other participants will be in the study?
This study is taking place in at least three locations across the world. About 1500 participants will be involved in the study worldwide with about 200 at George Washington University.

What are the risks?
There is minimal risk associated with the collection of a blood specimen. You may experience some mild pain, discomfort, or bruising at the site of skin puncture. These risks are no greater for this study than for standard of care testing from blood samples. There is a possible risk of loss of confidentiality.
In addition to the risks listed above, you may experience a previously unknown risk to participating in this study.

What are the benefits to participating in the study?
There are no direct benefits for taking part in this study. However, we hope the information we gain from this study may someday make it easier and faster for doctors to diagnose individuals potentially infected with germs that cause illness and short-term fever. This study will benefit George Washington University's understanding of the frequency of the fever germs detected by the Global Fever Panel in your area.

VOLUNTARY PARTICIPATION
Research studies include only people who choose to take part. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. There will be no penalty or loss of benefits to which you are otherwise entitled. We will still give you medical care and answer any questions you have. Your decision will not affect your relationship with your doctor or the study team in any way.
Whom do I call if I have questions or problems?
If you experience a side effect or injury which may be related to the study, please contact a study investigator during the workday: **Aileen Chang, MD, at (202) 741-2200**. If you have questions about the procedures of this research study, please contact a research coordinator during normal working hours at (202) 741-2230.
For questions regarding your rights as a participant in human research, call the GWU Office of Human Research at (202) 994-2715.

RESEARCH-RELATED INJURY
If you are injured from being in this study, medical care is available to you at George Washington University, as it is to all sick or injured people. The George Washington University has not set aside any money to pay the costs for such care. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. If you are injured from being in this study, medical care related to the study related injury as determined by a physician, will be paid for by BioFire Defense, LLC. You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

RIGHT OF INVESTIGATOR TO WITHDRAW
The Principal Investigator (PI) may withdraw you from the study without your consent if considered appropriate. This may occur if you were entered into the study but did not correctly meet the study criteria, or if it is in the best interest of your health to be withdrawn from the

study. The sponsor may also terminate the study. The PI will share any new information that could change how you feel about continuing in the study.

COSTS AND COMPENSATION TO PARTICIPANTS

You will not be charged, nor will your insurance company be charged for any test or procedure that is completed solely for the purpose of this study. The parts of your care that would normally be done as standard treatment will be billed to you or your insurance company. If you complete all required study procedures, you will receive a $15 gift card for your time.

By signing this consent form, you acknowledge and agree that, in the event that this research project results in the development of any marketable product, you will have no ownership interest in the product and no right to share in any profits from its sale or commercialization.

GENETIC TESTING

No human genetic testing/manipulation will be performed by BioFire Defense or as part of this research study. Genetic testing/manipulation will be performed on the virus, bacteria or parasite nucleic acids (Ribonucleic Acid (RNA) / Deoxyribonucleic Acid (DNA)) isolated from your blood sample.

Future genetic testing or research on your samples will only be done with your permission. A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally offers the following protections:

• Health insurance companies and employer-based group health plans may not request your genetic information that we get from this research.

• Health insurance companies and employer-based group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

• All health insurance companies and group health plans must follow this law. All employers with 15 or more employees must follow this law as of November 21, 2009. The protections offered by GINA apply regardless of when the research that obtained the genetic information was conducted, even if prior to the effective date.

Be aware that this law does not protect you against discrimination on the basis of your genetic information by companies that sell life insurance, disability insurance, or long-term care insurance. If you agree to allow genetic testing, we ask that you indicate it at the end of this consent form. You will not be provided the results to any of the testing that is done as part of this research study or future studies.

Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment.

These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease

AUTHORIZATION FOR USE OF YOUR HEALTH INFORMATION

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. Signing this document means you allow us, the researchers in this study, and others working with us to use some information about you for this research study.

Federal law requires that hospitals, researchers, and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. This kind of information is known as "protected health information" or "PHI." This section tells you your rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information if you participate in the study. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study. If you sign this document, you give permission to all health care providers at The GW Medical Faculty Associates (GW MFA) [and George Washington University Hospital (GWUH)] to use or disclose (release) your health information that identifies you for the research study described in this consent form.

We may go into your medical records to obtain personal health information. PHI will be used during the study and to confirm accuracy of the information as needed after the study enrollment. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. The information we will use and keep in our research records includes basic demographic information such as your age and sex as well as your temperature, what symptoms you have in addition to fever, current medications, recent vaccination(s), the results of any malaria parasite counts (if they are performed as part of your routine clinical testing), and potentially the results of any other tests performed as part of the routine clinical testing for your fever illness.

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner. We may also need to disclose information if required by law.

A description of this clinical trial will be 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. The study is: NCT02968355.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team

    - The Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
    - Human Research Protection Organization (DoD/US Army)
    - BioFire Defense, LLC
    - The Department of Defense
    - The Food and Drug Administration and Centers for Disease Control and Prevention.
- If we share study information with groups outside of George Washington University we will not share your name or identifying information. Your study information will only be labeled with the assigned study number, so they will not know your identity.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

- You do not have to sign this Authorization, but if you do not, you may not participate in the research study. The GW MFA and GWUH may not withhold or refuse to treat you based on whether you sign this Authorization.
- You may change your mind and revoke (take back) this Authorization at any time, except to the extent that The GW MFA and/or GWUH has already acted based on this Authorization. If you revoke this Authorization, you will no longer be allowed to participate in the research described in this Authorization. To revoke this Authorization, you must write to:*Aileen Chang at 2150 Pennsylvania Ave 5-416, Washington, DC 20037*
- Even if you revoke this Authorization, The GW MFA and/or GWUH may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research.
- This Authorization does not have an expiration date.
- Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

Your signature below certifies the following:

- You have read the information provided above (or it was communicated to you).
- You have received answers to all of your questions and have been told whom to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

SIGNATURES FOR ADULT PARTICIPANTS (18 years of age and older)

Research Participant (Subject):
I have read this consent form and have been given the chance to ask questions. I agree to participate in this research described above, titled "Clinical Evaluation of the FilmArray® Global Fever (GF) Panel."

Participant's Name (printed)	Participant's Signature	Date

Research Participant (Subject):
With regard to use of my samples for genetic testing related to future research:

_____ NO: I do not authorize the use of my provided samples for genetic testing related to future research. This choice does not affect my eligibility to participate in the Global Fever Panel study.

_____ YES: I authorize the use of my provided samples for genetic testing related to future research. This choice does not affect my eligibility to participate in the Global Fever Panel study.

Participant's Name (printed)	Participant's Signature	Date

Legally Authorized Representative (if applicable):
I am authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the research described above, titled "Clinical Evaluation of the FilmArray® Global Fever (GF) Panel."

Legally Authorized Representative's Name (printed)	Legally Authorized Representative's Signature	Date

Check Relationship to Participant:
☐Parent Spouse Child Sibling Legal Guardian Other: _____

Research Personnel Obtaining Consent:
I have given this research participant (or his/her legally authorized representative, if applicable) information about this study that I believe is accurate and complete. The participant has indicated that he or she understands the nature of the study and the risks and benefits of participating.

Name of person obtaining consent (printed)	Signature of person obtaining consent	Date