THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Informed Consent for Participation in a Research Study

Title of Research Study: ***A Randomized Controlled Trial of Biofire Film Array Gastrointestinal (GI) Panel Compared to Usual Care for Evaluation of Acute Infectious Diarrhea in the ED***

Investigator: ***Dr. Andrew Meltzer, Department of Emergency Medicine***

Investigator Contact Information: ***202-741-2952***

Study Coordinator: ***Nataly Montano***

Study Coordinator Contact Information**:** ***202-741-2917***

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have come into the emergency department complaining of symptoms that may be related to infectious diarrhea.

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GW. If you decide not to take part, you can still receive medical care from GW.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator at ***202-445-7044***

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.

Why is this research being done?

This research study will test a laboratory test called Film-Array Gastrointestinal (GI) Panel. This lab test can identify the bacteria or virus that may be causing your symptoms. This test will enable the ED doctor to better understand the cause of your diarrhea to try to determine the best treatment. The primary goal of this study is to determine if testing ED patients who complain of infectious diarrhea will lead to more optimal use of antibiotics. Optimal use of antibiotics is defined as the antibiotic (if any) is most appropriate to treat a specific pathogen.

How long will I be in the study?

We expect that you will be in this research study for 30 days. This includes 3 follow up phone calls.

How many people will take part in this research study?

We expect about 180 people will take part in the entire study.

What happens if I agree to be in this research?

Once you have agreed to participate in this research study you will be asked to provide a stool sample to the study team. After you provide a stool sample, you will be randomized to one of two groups. This means that the group you are in will be determined by chance, kind of like flipping a coin.

Group One receives usual care per treating ED clinician. In addition, Stool sample collected in triage (or as soon as possible.) The collected sample will be frozen at -80◦C and tested with the Film Array GI Panel at the conclusion of the study.

Group Two will have a stool sample collected in triage (or as soon as possible.) Film Array GI Panel test will be performed as soon as possible and the results will be communicated to treating ED clinician. In addition, this group will still receive usual care per treating ED clinician.

Usual care may include 1) Stool Culture and/or 2) Clostridium Difficile Testing and/or 3) Ova & Parasites stool test and/or 4) No stool testing and/or 5) Film Array GI Panel. Since the Film Array GI Panel (test that is being used in this study) is already offered at GWU, the test may also be ordered as usual care. The course of usual care will be ordered separately and at physician's discretion.

The research team will gather the following information from you or from your health care record:

- Chief complaint
- History of Present Illness
- Past Medical History
- Vital Signs

- Travel History
- Medications
- Contact Information

Once you are discharged from the hospital, the research coordinator will contact you for a follow up call on Day 2, Day 7 and Day 30 from your hospital discharge. These calls will consist of a short questionnaire relating to course of symptoms, additional medical care you received and other relevant medical information. In case the research coordinator is unable to reach you, research coordinator will call the emergency contact listed on your patient information form to inquire about follow-up and/or your new contact information.

You will be asked to sign a release/obtain of information to keep on file, in the event that you are seen in another hospital facility. This will allow us to easily obtain your records for review.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to provide a stool sample and complete the three follow up calls on Day 2, 7, and 30 following your discharge from the hospital.

What other choices do I have besides taking part in the research?

You do not have to agree to be in this study to be treated for presumed infectious diarrhea. Your alternative is to not be in this study.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled. This will not have no effect on your healthcare treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However if you do not give permission to use your Protected Health Information (PHI), you may not take part in this study because your PHI is needed in order to conduct the study.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have collected about you. However, no new PHI will be collected from you after you cancel your permission.

This authorization does not expire unless you cancel it.

To cancel your permission, you will need to send a letter to Dr. Andrew Meltzer stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

Andrew Meltzer, MD

Department of Emergency Medicine

2120 L Street NW, Suite 450

Washington, DC 20037

Is there any way being in this study could be bad for me?

The risks and discomforts associated with participation in this study are not greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

There are limited physical risks associated with participation in this study. This laboratory test, Film Array GI Panel, is a test that is already available for ED clinicians to order in for patients in the Emergency Room.

There is a low risk that information that we collect about you in this study may be seen by people who are not on the study team. To prevent loss of confidentiality, all data will be encrypted and no identifiable information about you will be stored with data. All study documents both electronic and hard copy will be either locked in file drawers in the study coordinator's office or on password-protected computers.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

You will not receive any financial payments from Biofire Diagnostics LLC, 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.

Will being in this study help me in any way?

You will not receive any direct benefits from participating in this research. The information form this research study may lead to a better standard of care in the future for people with infectious diarrhea.

Can I be removed from the research without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include

1. The study doctor thinks it is necessary for your health or safety
2. You do not follow study protocol.

3. Administrative reasons require your withdrawal.
4. Bio Fire Diagnostics LLC has stopped payments to support the study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens to my information collected for the research?

If you are in this study, your medical records may become part of this research. They may be seen by a number of other people or groups associated with the study. We will be collecting information about medical procedures performed and discharge information.

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel.

Except as required by law, name, social security number, address, telephone number, or any other direct personal identifier will not identify you. The results of this research study may be presented at a scientific or medical meeting or published in scientific journals. However, your identity will not be disclosed.

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of your health information. This section tells you about your rights regarding your health information. You are free to not allow these uses. If you do that though, you cannot participate in the study.

Protected Health Information (PHI) that may be used and released (disclosed) in this study includes information such as:

- This consent form
- Demographic information (age, sex)
- Information about your medical history from your medical records (medications, past medical history, social history, vital signs)
- Results of physical examination
- Admission and discharge information
- Health care expenses (the cost of standard work-up)
- Questionnaires that you complete
- Laboratory Results (results of Film Array GI Panel and other tests ordered)

By signing this form, you allow the use, sharing, copying and release of your PHI to carry out the study by your healthcare providers and by the study doctor and his research team.

You also allow the study doctor and the research team to release your health information to:

- GWU Institutional Review Board (the “IRB”) to ensure protection of the rights of research subjects

- Office of Human Research at GWU to ensure safety in research
- Accrediting agencies and GWU legal counsel
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care.
- Bio Fire Diagnostics LLC. Any data that is released to Bio Fire will be de-identified, i.e. name and contact info will be removed.

You may request to review or have a copy of your PHI collected during this study. This right to review and copy your PHI only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

Your PHI will be treated confidentially to the extent permitted by applicable laws and regulations. Once your health information from this study is used or released as explained in this section, it is no longer protected by the Privacy Rule.

By signing this form you authorize the Study Doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of the study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

Stool Sampling and Future Research

Research using human stool is an important way to try to understand human disease. You have been given this information because the investigators want to include your stool in a research project. There are several things you should know before allowing your tissues to be studied.

If you are randomized into the control group, your stool sample will be stored in a freezer at -70◦C for testing at the conclusion of the study. If you are randomized into the experimental group, your stool sample will be tested immediately (i.e. same day as ED visit).The sample will be linked to your study ID number, which will be related to your identifiable information in a password-protected excel document. You have the right to refuse to allow your samples to be studied, but if you do, we will not be able to include you in the study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research without your consent.

In addition to the study described above, do you consent to allowing your samples to undergo further testing in future yet-to-be-described research provided future research meets the following three criteria: (1) personal information is handled safely; (2) you retain the right to withdraw consent; and (3) any new research studies must be approved by an ethics-review board.

_____ (initial here) I consent to allowing my samples to be used for future research provided it meets criteria described above.

_____ (initial here) I do not want my samples used for any future research not described in this consent.

How will my privacy and health information be protected?

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. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form

The use and release of protected health information is for the purpose of collecting data for this study.

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Hospitals, clinics, health care providers, and health plans that provide health care to you during the study

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- A safety monitoring board {include only if applicable};
- Institutional officials who are responsible for compliance;

Some of the tests in this study may have been done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results will be recorded in your medical record. These study results will be included in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care will also be included in your medical record.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

Are there any costs for participating in this research?

There are no charges for your participation. Neither you nor your insurance will be billed. Standard of Care procedures will be billed in the usual manner.

Will I be paid for my participation in this research?

If you agree to take part in this research study, we will pay you $100 for your time and effort.

What else do I need to know?

This research is being funded by Biofire Diagnostics LLC.

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Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____

Signature of person obtaining consent Date