
MEDICAL FACULTY ASSOCIATES

THE GEORGE WASHINGTON UNIVERSITY Research Consent Form

Evaluation of Therapeutic Antimicrobial levels for Central Nervous System - Related Infections

Principal Investigator or Study Doctor: Dr. Michael Seneff (202) 715-4591

GWU IRB Reference number: **IRB#100828**

1) INTRODUCTION

You are invited to participate in a research study of Evaluating Antibiotic Levels in the Cerebrospinal Fluid (CSF) and the Central Nervous System (CNS). You are being asked to take part in this research study because you have a pre-existing CSF drainage device and are concurrently on treatment with an Antibiotic of interest to the study. Your participation is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. You do not have to take part in this study to receive care at George Washington University Hospital (GWUH) or the GWU Medical Faculty Associates (MFA). You may not receive any benefit from taking part in this study, however, the research may give us knowledge that may help people in the future. This study is being conducted by the investigators listed above from the Division of Critical Care Medicine.

Before you decide to participate, please take as much time as you need to ask any questions and discuss this study with anyone at GWUH, with family and friends, your personal physician or other health professional.

2) WHY IS THIS STUDY BEING DONE?

There are currently very few studies evaluating the penetration of various antibiotics into the CSF and the central nervous system (Brain) for the treatment of various infections (such as meningitis). With the growing number of newer generation of antibiotics, it is essential that we investigate their utility for treatment of these infections. Because your current condition has necessitated the placement of a CSF drainage device (EVD or lumbar drain) and you happen to be on an antibiotic of interest, you are an ideal candidate for this study.

The research will be conducted at the George Washington University Hospital only.

3) HOW MANY PEOPLE WILL TAKE PART IN THE STUDY

About **100** participants will be asked to take part in this study. Initially, we will be conducting a pilot study including only 10 patients.

4) WHAT IS INVOLVED IN THIS STUDY?

If you choose to take part in this study, the following activities/procedures will take place because of the research:

- A member of the research team will draw a small amount of CSF from your pre-existing CSF drainage device on 4 consecutive days. At the same time, about a table-spoon of blood will be collected from you to compare CSF and blood antibiotic levels.

5) HOW LONG WILL I BE IN THIS STUDY?

CSF and blood drawing will be for four consecutive days.

You can choose to stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

6) WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?

Since you already have a CSF drainage device (one has been placed by your surgeon), you will not be required to have any invasive interventions for the purposes of this study. Only small amounts of CSF and blood will be drawn on the indicated days which are associated with very minimal risk. All attempts will be made to draw blood from a pre-existing IV access (thus no need for extra needle-sticks). On rare occasions, we may have to obtain blood directly from a vein. All CSF/Blood draws will be performed by trained healthcare professionals and physician members of the study team. As with any investigational study, there may be risks that are unknown to us at this time. You will be informed if we learn of any new findings that might affect your willingness to be in the study.

7) ARE THERE POTENTIAL BENEFITS TO TAKING PART IN THIS STUDY?

If you agree to take part in this study, we cannot and do not guarantee or promise that you will receive any direct benefits from this study.

8) WHAT ARE MY OPTIONS?

You do not have to take part in this study if you do not want to participate. Should you decide to take part and later change your mind, you can do so at anytime. Your study doctor can explain these options in detail or refer you to the appropriate doctor for more information.

9) WILL I RECEIVE PAYMENT FOR BEING IN THIS STUDY?

You will not be paid for taking part in this study.

10) WHAT WILL IT COST ME IF I DECIDE TO PARTICIPATE IN THIS STUDY?

There will be no cost to you for participating in this study.

11) ARE THE RESEARCHERS BEING PAID FOR THE STUDY?

No. The researchers do not receive payment for their participation in this study.

12) WHO PAYS FOR MY MEDICAL CARE IF I BECOME ILL OR INJURED BECAUSE OF THE 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. 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 also should promptly notify the study doctor in the event of any illness or injury.

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.

13) WHAT ABOUT CONFIDENTIALITY?

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

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

14) HOW WILL MY PRIVACY BE PROTECTED?

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. You are free to not allow these uses and releases by not signing this form.

Protected health information that may be used and released (disclosed) in this study includes information such as

- This consent form;
- Your age and gender;
- Laboratory results of your blood and CSF including white blood cell, creatinine and antibiotic levels.

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

- the Study Doctor and his research team;
- other healthcare providers such as labs which are part of the study;
- GWU Institutional Review Board (“IRB”) or its authorized representatives, accrediting agencies, as well as representatives of the Office of Human Research

- Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- GWU, GWU Hospital or GWU MFA workforce who are involved with your care and the research.

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

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time except where a healthcare provider has already used or released your health information, or relied on your permission to do so. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI or new biological specimens will be collected from you after you revoke your authorization.

Your protected health information 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 protected health information for the purpose of this 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.

15) CAN I WITHDRAW FROM THE STUDY LATER?

You may withdraw from the Study at any time. Leaving the Study will not affect your current or future medical care at GWUH or the GWU MFA. If you choose to no longer be in the study, you should call or write to the Study Doctor right away.

16) CAN I BE TAKEN OFF THE STUDY?

The study Doctor or sponsor can decide to stop your participation in this study at any time. You could be taken off the study for reasons related solely to you (for example, not following study-related directions from the study Doctor, circumstances that may develop and offer alternatives, or a serious reaction) or because the entire study is stopped.

17) WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research subject. Research related injury should be reported to Dr. Seneff. His telephone number is **(202) 715-4591**.

18) **CONSENT DOCUMENT**

If you agree to participate in this study, please sign below:

After you sign this Consent Form, the research team will provide you with a copy. Please keep a copy of this document in case you want to read it again.

DOCUMENTATION OF CONSENT

Subject's Name (printed) and Signature

Date

Name (printed) and Signature of Person Obtaining Consent

Date

Principal Investigator's Signature

Date

DO NOT SIGN AFTER THE EXPIRATION DATE OF: 12 / 18 / 2010

