

Title of Study: Blastocystis Infection in Gulf War Illness

Principal Investigator: Ken Boorum

BACKGROUND: You are being asked to take part in a research study. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study. The purpose of this study is to determine if symptoms seen in Gulf War Veterans may be due to Blastocystis infection. This study is being conducted by Kenneth Boorum of the Blastocystis Research Foundation. You will be asked to provide answers to questions about your experience in the Persian Gulf War, and to provide a stool sample that we will test.

ABOUT BLASTOCYSTIS: Blastocystis is a protozoan (germ) that infects humans who consume contaminated water or food. Common symptoms are abdominal pain, constipation, and diarrhea. But patients also report fatigue, skin rashes, and joint pain. Not everyone who has the infection has symptoms. Some of the symptoms are not typical of what doctors would expect to see in a gastrointestinal infection. So this infection may have been overlooked in veterans. In the last several years, a number of research groups have made advances in our understanding of the disease. New tools for diagnosing Blastocystis infection are available. Some researchers believe that Blastocystis can produce different symptoms in different people, and that the age and genetic background of the host may influence those symptoms or even whether someone has symptoms at all. In this study, we will ask you to provide a stool (fecal) sample. We will use that sample with diagnostic tests which have been found to be more reliable at identifying Blastocystis infection.

HOW THIS MAY HELP VETERANS: Researchers have found that although Gulf War veterans have certain symptoms at a higher rate, those symptoms are also found in civilians. The identification of an infection would help explain why these symptoms are found in both civilians and veterans. Researchers are currently working on diagnostics and treatments for Blastocystis infection in many European, Asian, and Middle Eastern countries. Identifying Blastocystis in Gulf War Veterans would allow the research being done in the civilian disease to be applied to veterans.

RISKS: We do not believe this study will present any unusual risks for you.

BENEFITS: We can not promise any benefits to you from your being in this study.

CONFIDENTIALITY: Results of this study may be published, but your identity will not appear in any such publication. We will keep all research records that identify you private to the extent allowed by law. When you provide your samples, they will be coded with the ID number on your questionnaire, and that is the only information that will be provided to the clinical researchers. The records that have your name and addresses will be kept in a secure area at BRF's office in Corvallis, Oregon.

PERSON TO CONTACT: If you have any questions, please contact Kenneth Boorum at 815-572-9701 or by e-mail at kboorum@bhomcenter.org.

INSTITUTIONAL REVIEW BOARD: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. You can contact Dr. Dan Sheehan from BRF's IRB board at irb@bhomcenter.org

VOLUNTARY PARTICIPATION: It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason.

RIGHT OF INVESTIGATOR TO WITHDRAW: We plan on testing all samples that we receive. However,

Title of Study: Blastocystis Infection in Gulf War Illness

Principal Investigator: Ken Boorum

unforeseen circumstances may arise which prevent us from testing samples, such as loss of samples in shipping, or a condition which renders the samples unusable.

COSTS TO PARTICIPANTS AND COMPENSATION: You will not be paid to participate in this study. We will not charge you to participate in this study.

NUMBER OF PARTICIPANTS: We expect to enroll 20 participants.

SAMPLE RETENTION: Researchers often wish to retain stool samples so they can run additional tests to check for other organisms, or help verify new tests they have developed. Samples are identified only by a code number. Your name does not appear on the sample. Some people may not want their stool samples to be retained, so you can indicate here whether we can retain your sample after the end of this project.

- YES, my sample(s) may be saved for future gastrointestinal research**
 NO, my sample(s) must be destroyed at the end of this research project

RIGHT TO WITHDRAW: You have the right to withdraw your consent in the future by notifying the researcher.

RESEARCH PARTICIPANTS' RIGHTS: I have read or have had read to me all of the preceding information. This paper has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

If I have any questions about this study or if any problems arise during the study, I can call:

Kenneth Boorum at 815-572-9701 or kboorum@bhomcenter.org

If I have concerns or questions about this research study that the investigator has not answered, I can contact Dr. Dan Sheehan from BRF's IRB board at irb@bhomcenter.org

I am aware of my rights as a participant, and I voluntarily consent to participate in this study. I confirm that I have read this consent and authorization document which explains what this study is about and how and why it is being done. I will receive a signed consent form or a photocopy of it.

I agree to participate in this research study as described in this document.

Participant's Name

Participant's Signature

Date

Signature of Investigator

ID NUMBER: _____

Dear Veteran,

Thank you for your help in this study. We are working to determine if the symptoms veterans are experiencing may be due to Blastocystis infection, a disease which has a high prevalence in the Middle East, and more recently, some areas of the United States. This would allow information that scientists are publishing about *Blastocystis* infection to be applied to Gulf War Veterans.

If you would like to participate in the study, please complete this survey, and return it with the informed consent forms in the pre-addressed stamped envelope. When we receive the survey, we will send you materials and information on submitting a sample to complete the second part of the project.

Thanks again for your help.

Sincerely,

Ken Boorom
Blastocystis Research Foundation
815-572-9701
director@bhomcenter.org

RETURN TO THIS ADDRESS:

**BRF
5060 SW Philomath Blvd, #202
Corvallis, OR 97333**

(1) NAME: _____

(2) ADDRESS:

(3) PHONE NUMBER: _____

(4) E-MAIL ADDRESS: _____

THIS PAGE CONTAINS CONFIDENTIAL PATIENT INFORMATION. This form is intended only for the use of the named addressee and may contain information that is confidential or privileged. If you are not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this facsimile is strictly prohibited. If you have received this facsimile in error, please notify the sender immediately.

ID NUMBER: _____

(1) CURRENT AGE: _____

(2) SEX (M/F): _____

(3) WHAT WERE THE DATES OF YOUR DEPLOYMENT?: _____

(4) WHAT WAS YOUR TITLE? _____

(5) HOW OLD WERE YOU WHEN YOU WERE DEPLOYED? _____

(6) WHAT BRANCH OF THE MILITARY WERE YOU ASSOCIATED WITH (i.e. Army, National Guard)?

(7) WHAT DESCRIBES YOUR WORK WHILE YOU WERE DEPLOYED?

I was in a support position

I served on the battle field

(8) WHAT TYPE OF WORK DID YOU DO?

(9) HOW LONG WERE YOU DEPLOYED IN THE MIDDLE EAST? _____ months

(10) DID YOU SPEND ANY TIME IN SAUDI ARABIA?

NO

YES

(11) IF YES:

WHAT WAS THE NAME OF THE BASE? _____

HOW MANY MONTHS DID YOU SPEND AT THAT BASE? _____

(12) DID YOU EAT ANY LETTUCE OR UNCOOKED VEGETABLES (CABBAGE, SNOW PEAS, BLUEBERRIES, ETC.) WHILE YOU WERE **IN SAUDI ARABIA**?

NO

YES

Not sure

(12A) DID YOU EAT ANY LETTUCE OR UNCOOKED VEGETABLES WHILE YOU WERE **IN OTHER PERSIAN GULF COUNTRIES**?

NO

YES

Not sure

ID NUMBER: _____

(12B) WHERE DID YOU GET YOUR DRINKING WATER? **CHECK ALL THAT APPLY.**

- Bottled water
 Tap water from military-supplied drinking water sources in Saudi Arabia
 Tap water from military-supplied drinking water sources in Iraq
 Water from other sources (Please describe: _____

(13) ARE YOU ON PARTIAL OR FULL DISABILITY?

- NO
 YES – WHAT PERCENTAGE? _____

(14) WHAT WAS THE FIRST SYMPTOM YOU NOTICED (PICK ONE)

- Dermatological (skin rash)
 Neurological (fatigue, headaches, muscle twitching, widespread pain)
 Gastrointestinal (change in stool color, ribbon stools, abdominal pain, loose stools)
 Joint pain

(15) WHEN DID YOU NOTICE THIS SYMPTOM?

- While I was deployed
 After deployment (how long: _____)

(16) HAS ANYONE BIOLOGICALLY RELATED TO YOU (i.e. A CHILD, BROTHER, SISTER, PARENT) DEVELOPED SYMPTOMS SIMILAR TO YOURS? YES NO(17) DO EITHER OF YOUR BIOLOGICAL PARENTS HAVE CHRONIC GASTROINTESTINAL ILLNESS OR RECURRING DIARRHEA? YES NO(18) WHAT THINGS HAVE YOU FOUND THAT MAKE YOU FEEL BETTER (WHAT REDUCES THE LEVEL OF SYMPTOMS)

WHICH SYMPTOMS DO YOU HAVE?:

(19) Gastrointestinal

- Food allergies. What foods? _____
 Abdominal pain
 Diarrhea
 Constipation
 Nausea
 Vomiting
 Reflux
 Other gastrointestinal: _____

ID NUMBER: _____

(20) Neurological

- Fatigue
- Headaches
- Burning feeling on skin
- Muscle twitching
- Numbness in hands
- Other neurological: _____

(21) Inflammatory

- Joint pain
- Pain/irritation in eyes
- Skin rashes
- Difficulty breathing / chronic cough
- Other inflammatory _____

(22) WHAT DIAGNOSIS HAVE DOCTORS GIVEN FOR YOUR ILLNESS?

- Irritable bowel syndrome
- Chronic fatigue syndrome
- Fibromyalgia
- Post-Traumatic Stress Syndrome
- Psychosomatic illness
- Other: _____

(23) HAVE DOCTORS PRESCRIBED ANY TREATMENTS? IF SO, PLEASE INDICATE BELOW:

(24) DO THE TREATMENTS REDUCE THE SYMPTOMS?

- NO, NOT AT ALL
- YES, SOME REDUCTION
- YES, A GREAT DEAL OF REDUCTION
- ALMOST ALL SYMPTOMS GONE