Investigator: Garth Swanson, M.D.

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Title of Study: Circadian Misalignment as a disease risk factor in Inflammatory Bowel Disease

Sponsor: Rush Gastroenterology – Division of Digestive Diseases

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you have Ulcerative Colitis (UC) or Crohn's disease (CD) which are types of Inflammatory Bowel Disease (IBD).

What is the purpose of this study?

The purpose of this study is to explore the role your sleep/wake cycle (circadian rhythm) has on your disease.

How many study subjects are expected to take part in the study?

We expect to enroll 68 subjects with IBD; 34 subjects with Crohn's disease and 34 subjects with Ulcerative Colitis.

What will you be asked to do?

You will be asked to attend two clinic visits 14 days apart. You will be asked to complete a packet of questionnaires that inquire about your health and sleep habits. This will take about 45 minutes. You also have a physical examination at your first visit. You will be asked to wear a wrist actigraphy device (Actiwatch) that will measure your sleep-wake activity during this 14 day period along with a sleep diary which you will be asked to complete. At the end of the 14 days, we will draw about 3 tablespoons of blood and you will be asked to submit a stool and urine sample. Also, at the end of 14 days sigmoid tissue samples will be collected during an optional unprepped limited flexible sigmoidoscopy procedure. If you choose to not participate in

the procedure you can still participate in the rest of the study. The sigmoid portion of the colon is the final segment of the colon. Feces are stored in the sigmoid colon until they are ready to be eliminated from the body through the anal canal and rectum. Per standard of care, a pregnancy test will be given prior to the limited flexible sigmoidoscopy if you are a female of childbearing potential.

How long will you be in the study?

Your participation in this study will take 14 days from the time of your initial visit.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you or the study is canceled.

What are the possible risks of the study?

This research study is of relatively low risk. However, some potential risks may arise.

Specifically:

1) You may feel uncomfortable by the amount of time involved with the study including completing the questionnaires, completing the sleep diary and attending two office visits.
2) You may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection during your blood draw.
3) You will be asked to collect a stool and urine sample. Collecting a stool and urine sample involves placing a "hat" that will be provided by our staff on your commode (toilet) before you are seated. This hat will collect the stool and urine. You may experience emotional stress related to handling with your own stool and/or urine. Mishandling stool and urine can lead to infections, however, a safe hand washing technique will be taught and reduce this risk.
4) The optional unprepped limited flexible sigmoidoscopy procedure involves the doctor looking at part of your colon in order to obtain tissue from the colon. It will involve only the area that is closest to your anus. This type of procedure is not associated with much discomfort. Most patients either experience no discomfort or minimal bloating. With any procedure such as this, there is a risk of bleeding when tissue samples are taken. This risk is estimated to be less than 1 in 1000 per biopsy taken. If bleeding occurs, it will usually stop by itself and does not usually require hospitalization, blood transfusion or other procedures. There is also a risk of a tiny tear or perforation (causing a hole) in your colon. This is extremely rare but a possible complication. In a routine colonoscopy, which inspects two feet of the colon, the risk for perforation is 1 out of every 30-50,000. The limited sigmoidoscopy procedure involves only the area that is closest to your anus and there is an even smaller risk for perforation. If a tiny tear or perforation in the intestine occurs, you may experience pain and fever. If you experience a tiny tear or perforation and have symptoms concerning for this complication, you should contact the Principal Investigator of the study, Garth Swanson, M.D., immediately, by calling 312-942-5861. You may need to be hospitalized and undergo surgery, to repair the tear or perforation.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** If you take part in this study, you may help others in the future.

What other options are there?

You do not have to join this study. If you do not join, your care will not be affected. The only alternative to participating in this study is not to participate.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law.

Unique assigned identification numbers will be used along with your initials for identifying your written information. Any records identifying you will also be kept confidential to the extent permitted by applicable laws and/or regulations. If the results of this study are published, your identity will remain confidential as well. Once the study is complete, all unique identifiers will be removed. Until that time, the information will be stored and password protected on a secure server.

People outside of Rush may need to see or receive your information for this study. Examples include government agencies such as the Food and Drug Administration (FDA) and National Institutes of Health (NIH) safety monitors.

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study staff may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

In order to conduct the study, the study doctor, Dr. Garth Swanson, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

There is no cost to participate in this study.

What financial disclosure(s) apply to this study?

Rush University Medical Center is being paid by departmental funding to conduct this research. A portion of this money may go to the study doctor to compensate for other institutional research related costs.

Will you be compensated or paid?

Upon completion of the two visits (whether you complete the flexible sigmoidoscopy or not), you will receive $200 in total.

Your participation in this research study may contribute to the development of commercial products from which others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Dr. Garth Swanson at 312-942-5861. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

_____	_____	_____
Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

_____ _____
Signature of Individual Obtaining Consent Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR:
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

_____ _____
Signature of Witness/Translator Date of Signature
Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____ _____
Signature of the Principal Investigator Date of Signature
Check here if Principal Investigator obtained consent and a separate signature is not required.