PARTICIPANT INFORMATION AND CONSENT FORM

Gut dysbiosis as a mechanism driving increased cancer risks among night shift workers

Principal Investigator (PI): Parveen Bhatti, PhD
Cancer Control Research, BC Cancer
Telephone number: 604-675-8055

Co-Investigator(s): Rachel Murphy, PhD
School of Population and Public Health, University of British Columbia
Telephone number: 604–822–1397

Amee Manges, MPH, PhD
BC Centre for Disease Control
Telephone number: 604-707-2743

Project Manager: Agnes Lai, MSc.
Cancer Control Research, BC Cancer
Telephone number: 604-675-8056
Email: nightshift-gut@bccrc.ca

Sponsors: Canadian Cancer Society, Canadian Institutes of Health Research

Your participation is voluntary

You are being invited to take part in this study because you responded to a posting. Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving. If you decide that you want to terminate your participation in this study, you should notify the study staff.

This consent form describes the procedures that are being carried out for research purposes. Please review the document carefully when deciding whether or not you wish to be part of the research study and discuss it with others if you wish. Please ask the study staff to explain any information that you do not understand. If you wish to participate in this study, you will be asked to sign this form.

Approximately 300 participants will take part in this study, all from British Columbia. 200 night shift workers, and 100 day shift workers will take part.

Who is conducting this study?

Dr. Parveen Bhatti, the principal investigator has received financial compensation from the Canadian Cancer Society and the Canadian Institutes of Health Research for the work required in conducting this study. This means that BC Cancer has received funding to do this study. However, none of the study researchers will receive any personal payments.

Background

Many British Columbians are employed in jobs that involve night shift work. Night shift work has been linked to increased risks of certain types of cancer. To protect the health of night shift workers we need to understand the biological mechanisms by which night shift work causes cancer. One possible mechanism involves disruption of the microbes that live in our gut, whose normal functioning is critical to maintaining good health.

What is the purpose of the study?

The purpose of this study is to identify differences in the makeup and function of gut microbes between night shift workers and day shift workers that may contribute to increased risks of cancer. We will also determine how differences in demographics, lifestyle factors, and job-related factors between night shift and day shift workers contribute to differences in the makeup and function of gut microbes.

Who can participate in this study?

You may be able to participate in this study if you*:*

- Are 18 to 65 years of age
- Are a night shift or day shift worker
  - Night shift workers primarily work night shifts (at least 3 days per week of 7 or more hours ending no earlier than 6am) for the past 6 months or more
  - Day shift workers work only day shifts (at least 3 days per week of 7 or more hours ending no later than 6pm) and does not work from home for the past 6 months or more
- Have a regular bowel movement

Who should not participate in this study?

You will not be eligible to participate in this study if you:

- Have a personal history of cancer or have been diagnosed with a sleep disorder (e.g., sleep apnea, narcolepsy)
- Have travelled across time zones in the past 3 months
- Are currently using melatonin supplements
- Had a prescription for antibiotics in the past 6 months
- Are currently pregnant

These are the main reasons why you may not be able to participate. The study staff will discuss the eligibility criteria with you in more detail.

What are my responsibilities?

If you decide to participate in this study, you will be asked to read and sign this consent form. In total, your participation will take approximately **one hour and ten minutes**. Your responsibilities will include:

1. Complete an on-line questionnaire which collects demographic (e.g., gender identity), health (e.g., bowl movements), lifestyle (e.g., sleep habits), employment (e.g., job satisfaction), and living environment (e.g., quality of neighbourhood) data (30 minutes). You will not have to answer any question that makes you feel uncomfortable.

2. Collect a stool sample, using a kit that will be mailed to you, from your first bowel movement after waking up from sleep during the work week (10 minutes).
   a. For night shift workers, this will be after waking from day sleep.
   b. For day shift workers, this will be after waking from night sleep.

3. After collecting the stool sample, complete an online 24-hour dietary recall which collects information on food and drinks consumed over the past day (30 minutes).

   You will be required to log into the ASA24 Dietary Assessment website to provide detailed information about all foods, beverages and supplements you consumed over the past 24 hours, including breakfast, lunch, supper, and snacks, before the collection of a stool sample. No personally identifiable data will be collected (https://epi.grants.cancer.gov/asa24/respondent/features.html).

   The ASA24 platform is hosted by Information Management Services (IMS) and managed by the National Cancer Institute (NIH) in the United States. Neither NCI nor the ASA24 system will receive your name nor any identifying information. They will only have access to a unique login code that we will provide to you. After data collection is complete, the study team will export the food and nutrient analysis output files and save them to the BC Cancer servers. BC Cancer is not managing the data shared with this service and that BC Cancer is not endorsing this service. Your response data will be used exclusively for this study.

What are the possible harms and discomforts?

Given that collection of stool samples may be embarrassing to some individuals, the protocol does pose some risk, beyond ordinary daily activity.

What are the potential benefits of participating?

There will be no direct benefits of this research to you as a participant or any immediate benefits to others. You should not expect to get direct health benefits from taking part in this study. What is learned from this study may help patients in the future.

What if new information becomes available that may affect my decision to participate?

You will be advised of any new information that becomes available that may affect your willingness to remain in this study.

What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw later, you have the right to request the withdrawal of your information [and/or samples] collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data [and/or samples] will not be able to be withdrawn for example where the data [and/or sample] is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data [and/or samples], please let the study staff know.

Can I be asked to leave the study?
In case of any change in your health status or changes in your eligibility (criteria listed in the sections: Who can participate in this study and who should not participate in this study), the study staff may withdraw you from the study.

How long will study-related data and samples be kept?
Your study records including confidential information about you collected during the study will be kept at a secure location for at least five years after study completion. Biological specimens will be completely used up as part of the stud and will not be retained after study completion.

How will my taking part in this study be kept confidential?
Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk that someone could get access to the information we have stored about you, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and samples are sent to places outside of Canada, you may not be afforded the same rights. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us, and we will make every effort to protect these as described below.

Study-related data and coding:

- All information gathered for use in the study is referred to as the 'study-related data'. This data may include your medical records, biological materials, genetic information, completed questionnaires and/or diaries, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you, and will be used on all study-related data that leave BC Cancer unless otherwise specified in this form (this is referred to as 'coded data').
- Coded data (including genetic information) from this study may be pooled and shared with researchers from around the world for future studies that are unknown at this time. It may also be added to public databases, published, or presented at scientific meetings. The aim of these future studies is to benefit people by improving our understanding of health conditions like cancer.

Who will have access to my study-related data?

Your study-related data will be reviewed by the sponsor of this study, or their representatives at BC Cancer. The BC Cancer Research Ethics Board or regulatory authorities and auditors may also look at your study-related data for the purpose of overseeing the conduct of the study. By signing this form you are authorizing such access.

Email Communication

We would like to use your email address to communicate with you about this research study and so you can return your completed consent form to us. Please note that some webmail services (e.g. Gmail, etc.) may store email contents outside of Canada where privacy and data security standards may be different. Under the Freedom of Information and Protection of Privacy Act (British Columbia), we require your consent to send your personal information (such as your name and health information) outside of Canada. If you ever want to stop communicating by email or have any questions about this topic, please contact the study nurse or study doctor in charge of the study at your centre.

What happens if something goes wrong?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. In case of research injury or side effects, medical care will be provided or you will be referred for appropriate medical care at no cost to you.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

What will the study cost me?

There will be no costs for participating, nor will you benefit from participating. Your participation may increase the knowledge of factors associated with reducing cancer risk among night shift workers. The research using your biological materials and data may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

Remuneration

You will receive $100 (cheque or e-gift card) after completing the study to compensate you for your time and effort.

Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the study staff.

Who do I contact if I have any questions or concerns about my rights or privacy as a participant?

You can contact BC Cancer Research Ethics at reb@bccancer.bc.ca, or 604.877.6284. Please reference the study number H24-01713 when contacting Research Ethics so staff can better assist you.

By signing this form, you do not give up any of your legal rights and you do not release the sponsor, Principal Investigator, researchers, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you.

You will be given a copy of this signed and dated consent form prior to participating in this study.

When and where can you learn about the study findings?

Results of this project will be published in scientific journals and presented at meetings; never disclosing individual results; and always acknowledging the generous contribution of study information by participants. We expect study results to be available starting in 2027.

Night Shift Work and Gut Microbiome

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.

I will receive a signed copy of this consent form for my own records.

It may be possible to use the information and sample that you provided for this study for other studies at BC Cancer. Please check the desired boxes below:

- ❑ I allow my information and sample to be used for other studies at BC Cancer
- ❑ I am willing to be contacted for possible participation in other studies at BC Cancer

I consent to participate in this study

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____
Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date

Participant Assistance

Complete the following declaration only if the participant is unable to read:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and,
- Informed consent was freely given by the participant.

_____	_____	_____
Signature of Impartial Witness	Printed Name	Date

Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:

- The informed consent discussion was interpreted by an interpreter, and,
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter declaration and signature:

By signing the consent form I attest that I provided a faithful interpretation for the discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

_____	_____	_____
Signature of Interpreter	Printed Name	Date