The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A Pilot Study of the Effect of the Microbiome on Immune Checkpoint Inhibitor Response in Melanoma**
Principal Investigator:	**Daniel Spakowicz**
Sponsor:	**Pelotonia**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

The purpose of this research:

To test if the bacteria in your gut affect whether you will respond to your cancer treatment or experience any side effects from the treatment

Why am I being asked to participate in the study?

You will soon undergo treatment with a drug called an “immune checkpoint inhibitor”, which interacts with the immune system and may be affected by the bacteria in your gut.

The study duration:
16 weeks total after starting your course of immunotherapy treatment.

The research procedures to be followed:
Upon consenting, you'll be asked about your medical history including medications and asked to complete a Food Frequency Questionnaire (FFQ). You will be asked to provide a stool sample at 2 clinic visits, and up to two additional samples if you have an immune-related adverse event (irAE), such as a rash or diarrhea, or as a control for not developing an irAE during the 16-week study period.

The most important risks or discomforts:
The risks associated with this protocol are expected to be minimal. There is potential for psychological and social discomfort associated with stool collection and health questionnaires, but both can be completed in the privacy of your home.

The reasonably expected benefits:
Improved understanding of the role of gut bacteria is response to cancer treatments will be of great benefit to the scientific community. Additionally, participants may have feelings of self-empowerment and pride in contributing to scientific knowledge.

1. Why is this study being done?

New evidence suggests that the bacteria in your gut strongly affect your immune system, and possibly whether individuals will respond to some cancer treatments. This study will test if gut bacteria can predict response to treatment or side effects that involve the immune system.

2. How many people will take part in this study?

89 Participants will be recruited from the OSUCCC Cutaneous Oncology Clinic, which operates a site at the Martha Morehouse Medical Plaza

3. What will happen if I take part in this study?

At the melanoma screening visit, study staff will explain the study and will inform you if you qualify for this study. If you decide to participate in this study, the researcher will explain all details of the study and answer any questions you might have. Once you have signed consent, you will proceed with standard treatment. For the study, we will collect your medical history with review of current medications and past steroid and antibiotic use, and have you complete a Food Frequency Questionnaire (FFQ). At this time, you will be mailed four stool collection kits. Upon the start of immunotherapy, you will be asked to mail in a stool sample.. During the 12 weeks of treatment and the additional 4 weeks of follow time, you will be asked to provide a stool sample if you experience an immune related adverse event (irAE) or as a control for not developing an irAE. You will also be asked to bring in a stool sample to your 12-week appointment.

A detailed breakdown of study activities for each study visit can be found below:

Screening and Consent, Week -4-0 (x minutes)

- Sign informed consent
- Complete questionnaires
- Receive stool sampling kits
- Weight, height, blood pressure, heart rate, temperature, and respiratory rate will be recorded from the nursing notes when available or the electronic medical record.

Start of Trial; Baseline, Week 0 (x minutes)

- Submit stool collection
- Weight, height, blood pressure, heart rate, temperature, and respiratory rate will be recorded from the nursing notes when available or the electronic medical record.

Follow for irAE event during treatment/post treatment, Week 0-16 (x minutes):

- If participants experience >= grade 2 toxicity (CTCAE v5), participants will be asked to collect their next bowel movement and submit the sample via mail.
- Weight, height, blood pressure, heart rate, temperature, and respiratory rate will be recorded from the nursing notes when available or the electronic medical record.

End of Treatment

- Submit stool sample
- Weight, height, blood pressure, heart rate, temperature, and respiratory rate will be recorded from the nursing notes when available or the electronic medical record.

4. How long will I be in the study?

The study duration is 16 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Stool collection is the only procedure that will be completed for this study that is not standard of care for this participant population. The risks associated with this protocol are expected to be minimal.There is also a small potential for psychological and social discomfort with a stool collection. Finally, our questionnaires may also pose a psychological risk, as some people do not wish to record personal information about their food intake habits.

7. What benefits can I expect from being in the study?

The benefits to you are minimal, as well. Further understanding of the microbiome is an important benefit to the scientific community. Additionally, it is our experience that research study participants derive significant emotional and psychological benefits from

participation in cancer prevention clinical trials. These involve feelings of self-empowerment and pride in contributing to scientific knowledge.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

All study-related procedures and tests will be performed at no cost to you.

10. Will I be paid for taking part in this study?

No.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, de-identified data will be made publicly available upon publication to support the reproducibility of the published analyses. Biospecimens will not be shared.

14. Will my study-related information be kept confidential?

Yes, efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Furthermore, we will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Data gathered as part of your participation in the Total Cancer Care Protocol (if applicable) including genomic data;
- Information gathered for this research about:
  - HIV / AIDS
  - Hepatitis infection
  - Sexually transmitted diseases

Other reportable infectious diseases
Physical exams
Laboratory, x-ray, and other test results
Diaries and questionnaires
The diagnosis and treatment of a mental health condition

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Daniel Spakowicz at (614) 293-1797.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **Frank White at (614) 685-1734 Frank.white@osumc.edu**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact **the Office of Responsible Research Practices at 1-800-678-6251**.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Kari Kendra at 614-293-4320.**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time