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

Study Title: **Total Transplant Care Protocol (TTCP)-Surgical**

Principal Investigator: **Ken Washburn, MD**

Sponsor: None

- **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.

1. Why is this study being done?

The purpose of this study is to develop an archive or biorepository where we can store biological samples and a registry of medical data from patients. This biorepository will be managed by the Comprehensive Transplant Center. This biorepository will connect data to samples that researchers can study now and in the future in order better understand disease and how to better treat these diseases.

We invite you to participate in this research study because you are under the care of a Comprehensive Transplant Center-affiliated physician and will soon have a surgical procedure. We think there is a lot of information stored in your medical histories and biological samples that can be studied to change the way we prevent, diagnose and treat disease in the future.

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

We anticipate thousands of patients will take part in this study.

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

When you take part in this study, you will let us:

- **Review your medical records:** This includes your health information as well as answers to any questionnaires you complete as part of your medical care visit. This will help researchers study what you and other patients have in common.

- **Store tissue:** If you have a biopsy or surgery to remove tissue or an organ, there is usually leftover tissue or samples. We may study this leftover tissue that the lab usually throws away. Your surgery will not be different if you agree to take part in this study. In addition, if you elect to have an autopsy and sign the autopsy consent form, extra tissue may be collected for research.

- **Take samples of blood:** As part of your standard treatment, your doctor will collect blood from your vein for clinical tests, and during this time, we may collect some additional blood for research (~3 tablespoons).

- **Collect tissue samples from previous procedures:** If you have undergone a biopsy or surgical procedure in the past at OSU or another facility and tissue was collected, you give permission for us to access that tissue and you donate it for use in this study. Your donated tissue may be used immediately for research or may be stored indefinitely for future research purposes. This signed consent form will serve as a release form for your samples.

- **Permission to re-contact you in the future**: Your voluntary gift of data and samples will be used to increase knowledge of disease processes and associated outcomes. By participating in this study, you are giving us and others working with us, such as your doctor, permission to re-contact you in the future to discuss other matters associated with this study. One future use of your data and samples is to help match patients to future research studies that might be of benefit. When new studies are developed, we may contact you to see if you are interested.

4. How will my data and samples be stored and used for future research?

Storage and Coding of Your Data and Samples: Your samples will be securely housed in locked freezers, refrigerators, or cabinets, as appropriate, within The Ohio State University Wexner Medical Center (OSUWMC) Comprehensive Transplant Center Human Tissue Biorepository on OSU property. When your samples leave the operating room or clinic and are received by the Biorepository, they will be given a unique identification number that cannot be directly connected to your personal health information.

Only select staff members, as a part of their assigned duties, would be able to connect the unique identification number to you as a patient through a master list that is kept behind the secured firewall of OSUWMC. The number of personnel allowed to access links and re-identify information is kept at a minimum, and any access is appropriately monitored to ensure compliance. Select clinical data would be labeled with the same

unique identification number and would be securely stored in password protected databases within the OSU firewall.

Usage: All research data and samples may be used immediately for research or will be stored indefinitely at OSU for future research purposes. This future research can include diseases related to your surgery or secondary research regarding other diseases and purposes. Other researchers may request to use your samples or data. When the research staff at the Biorepository receives a request for use of your donated data or samples for a research project, an in-house scientific review committee will review the request. The researcher requesting the data and samples must have their research plans reviewed by the OSU Institutional Review Board (IRB), a committee that ensures the rights and welfare of human research subjects. If the request has been approved or exempted by the IRB, has scientific merit, and is deemed appropriate, the scientific review committee will approve samples and clinically relevant data to be released to the researcher in non-identifiable manner, i.e., the data and samples cannot be directly traced back to you. Because the data and samples will be de-identified or coded prior to these research activities, you will not be notified at the time that additional research is conducted and no additional informed consent will be obtained from you.

Incidental Findings: All future studies with your samples and data will be for research purposes only and are not intended for clinical diagnoses or therapeutic purposes. Studies may have an extremely rare possibility of uncovering incidental findings especially with data from your DNA (genetic material in your cells). If the biorepository is notified of these findings, and, if you would like, we will give a best faith effort to link the finding with you as a patient and inform a Comprehensive Transplant Center physician. The physician will determine if the findings warrant further testing and if they are medically actionable. Please initial below regarding whether we should approach your physician in the very rare likelihood an incidental finding might occur.

☐ **Yes,** I want my physician to be contacted for suspected incidental findings that might be medically actionable.

☐ **No,** I do not want my physician to be contacted for suspected incidental findings that might be medically actionable.

Options for Consent: By signing this form, you give OSU permission to use your clinical data, biological samples and any genetic materials obtained from your specimens for use in research to learn about, prevent, or treat diseases and other health problems that might affect patients.

If you donate samples to the biorepository, participation in the registry, where we store your medical information, is mandatory. However, if you DO NOT want to donate biological samples, but would like to allow researchers access to your health data you can agree to participation in the registry alone. Donating your samples to the biorepository without associated data is not an option. Please initial in the below box if you DO NOT want to donate tissue, but would like to donate data from your medical records.

☐ I **DO NOT** want to donate tissue, but I would like researchers to have access to my medical records for research purposes.

5. How long will I be in the study?

The actual time required to enroll in the study will be about 20 minutes when the study is explained and you provide informed consent. All of the data and samples will be collected as part of your routine medical care when you are already having samples collected so this will not require extra visits. If extra research blood or biopsies are taken while clinic blood or biopsies are being taken as a part of your standard care, this could extend your procedures by seconds to a few minutes. For future studies that may benefit you and for which you are found to be eligible, we cannot predict how many times, if any, you might be contacted.

6. 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 to leave the study will not affect your future relationship with The Ohio State University, your doctors, or your transplantation status.

If you decide to withdraw, written notice will need to be provided, and, by default, no future additional samples or information will be collected for use in this study. For your samples that are already stored in the biorepository, the written request for the destruction of stored samples will need to be explicitly stated in the written notice. However, samples and data that have already been distributed to researchers and are being used for research prior to the date of the request will continue to be used for that current study.

We will keep the results of any research that has been performed prior to withdrawal of your consent. If you decide to withdraw from the study, we will contact you discuss the options stated above, answer questions, and to confirm your decision.

To notify the study team that you no longer want to participate, please write or email to

The OSUWMC Comprehensive Transplant Center,
Attention: Total Transplant Care Protocol,
395 W. 12th Ave, 1st Floor, Columbus, OH 43210
Ken.Washburn@osumc.edu

7. What risks, side effects or discomforts can I expect from being in the study?
You may experience one or more of the risks below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate associated with being in this study. We will answer any questions you have about these risks.

- **Risk of studying tissue samples:** Because these tissue specimens are studied after your doctor has already removed them as part of your regular biopsy or surgery, there are no additional risks associated with this part of the study. The doctor will not

change the standard biopsy or surgery in any way if you decide to take part in the study.

- **Risk of taking additional blood samples:** There are no additional risks to you of taking extra blood during a regularly scheduled blood draw.

- **Risk of obtaining tissue from a previous procedure:** Because these tissue samples were collected from a previous procedure, there are no additional risks to you for this part of the study.

- **Risks associated with loss of privacy:** Your personal health information will be used and disclosed as provided in this form. The risks associated with this part of the study are low. There is a risk that your personal information could be given to someone who is not permitted to see it, but many steps are taken to prevent this. The electronic medical record system and tissue tracking database is password protected and can only be accessed by authorized people to perform their job duties.

- **Risks associated with genetic research:** It is possible future research on your donated samples might involve genetic testing, but you would not be at any risk from this testing unless there is a breach of confidentiality. If there were a breach of confidentiality, you are still protected by a federal law, called the Genetic Information Nondiscrimination Act (GINA). GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
  - Health insurance companies and group health plans may not request your genetic information from this research.
  - Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility or premiums.
  - Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this federal law. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under Ohio law, health insurance companies cannot ask about the results of a genetic test or use any information obtained from genetic testing to make decisions about providing coverage or benefits for health care services.

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

There may be no direct benefit to you if you take part in this study. We hope the information learned from this study will benefit other patients in the future. By studying clinical data and samples from thousands of patients, we hope that we might improve the treatment of diseases. We also hope to find out if new drugs will help future patients. There is a chance that future medical or scientific products may come from research that used your tissue and/or data. If this happens, you will not receive financial compensation.

9. 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.

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

There is no cost to you for taking part in this study.

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

There will be no payment to you for taking part in this study. Your de-identified samples and data may be used to make new products or technologies. You will not be paid even if these new products or technologies are sold or make money. You cannot choose how your samples and personal information will be used. If you do not want to let others decide how your samples and information will be used, then you should not donate your samples.

If you agree to participate, your samples will be considered a gift to The Ohio State University. The university may sell or share your samples and personal information with others, such as private companies, government agencies, or other universities. The university will be paid if your samples and personal information are sold.

The Biorepository that will process and store your samples is a cost neutral facility (non-profit), and any fees paid to the facility for samples or data are for cost recovery purposes and not for financial gain. These fees will offset the costs of the biorepository and allow us to procure and process more samples for OSU researchers so more studies can be performed. We hope this study will help doctors find new ways to take better care of patients.

12. 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.

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

This is not a treatment study. The medical treatment you are currently receiving will not be affected if you take part in this study. Being in a research study does not take the place of routine physical exams or visits to your own doctor and should not be relied on to diagnose or treat medical problems. You and your doctor will always decide on the best treatment for you. 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 participants in research.

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

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing this form, you are permitting researchers at OSU to use personal health information for research purposes. You are also allowing OSU to disclose your personal health information to any organization participating in a research-related data or information exchange in connection with this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

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. 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).

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 records. 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.

The Biorepository will keep your information in password protected databases and locked research files in a secure environment and will protect it to the full extent of the law. Your samples will be kept in freezers in locked laboratories in a secure environment and will only be labeled with a code number and not any of your personally identifiable information.

Some of your specimens and genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A

researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

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;
- Survey
- 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;
- 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
- Records about any study drug you received;
- Records about the study device; and

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

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- 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 <u>may</u> 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. 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 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 Sandra Meadows in the Office of Responsible Research Practices at 800-678-6251.

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 Brenda Reader, PhD, Brenda.Reader@osumc.edu.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact, HIPAA Privacy Officer, Suite E2140, 600 Ackerman Road, Columbus, OH 43201 (614) 293-4477.

If you are injured as a result of participating in this study or for questions about a study-related injury, please contact, Brenda Reader, PhD, at Brenda.Reader@osumc.edu.

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.

Permission to re-contact you in the future: By participating in this study, you are giving us and others working with us, such as your doctor, permission to re-contact you in the future to discuss other matters associated with this study. One future use of your data and samples is to help match patients to future research studies that might be of benefit. When new studies are developed, we may contact you to see if you are interested.

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 subject	**Signature of subject**
	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