BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
BSWH Clinics that service Central and North Texas

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: **The Texas Immuno-Oncology Biorepository:** Collection of patients' biospecimens for analysis of immunological and molecular biomarkers that predict benefit/resistance to cancer immunotherapies (TIOB)

National Clinical Trial # NCT05371756

PRINCIPAL INVESTIGATOR ("PI"): Ronan Kelly, MD

TELEPHONE NUMBER: 214-818-8472

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering taking part in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future. Taking part in this study is voluntary.

Key Information –

1. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?

You are being asked to take part in this research study because you were identified as having a high risk for or diagnosed cancer by a physician.

2. WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to collect and store tissue and bodily fluids from cancer participants who are receiving either standard of care checkpoint inhibitors (a form of cancer immunotherapy that helps to stop the immune system from attacking cancer cells), immunotherapy drugs, surgery, or other treatments recommended by a physician. Samples from participants with pre-cancerous, malignant, and normal tissues may also be collected.

The primary focus is to understand the immunological and molecular changes that are occurring in participants that are receiving surgery or US Food and Drug Administration (FDA) approved and novel (new or original) immuno-oncology drugs. We plan to do this by sharing your samples and data that have been prepared to protect your privacy. This may include removing information that can directly identify you, like your name, date of birth, or medical reference number. In some cases, we may share limited data that includes certain details, such as the dates when samples were collected, but not your name or other direct identifiers. These samples and data may be shared with researchers within and outside Baylor Scott & White Health (BSWH) to study and analyze them, following the Health Insurance Portability and Accountability Act of 1996 (HIPAA) guidelines for privacy and security.

We think that you will be in the study for about 5 years, unless you screen fail, withdraw consent, are administratively withdrawn, or become too frail to take part in the study.

3. WHAT WILL I BE ASKED TO DO IN THIS STUDY?

If you decide to take part in this study, you will be asked to sign this consent form and privacy authorization before any study related activity can be completed. Participation will include specimen collection (about every three to six months) such as blood (about 5-6 tablespoons), urine, saliva and stool, completing a questionnaire and allowing researchers to review and collect information from your medical record for research purposes. You will also be asked to allow the researchers to use the tissue that was left over after any cancer-related surgery or biopsy (procedure that involves removing a small sample of tissue) to evaluate for research purposes.

The samples and data collected from you may be shared with researchers both within and outside BSWH for several research projects. In these cases, we will not release any identifying information, such as your name, date of birth, or medical record number, and the information will be prepared to protect your privacy.

4. WHY MIGHT I WANT TO TAKE PART IN THIS STUDY?

If you agree to take part in this study, there will not be direct medical benefit to you. We hope that the information learned from this study will benefit other participants with this disease in the future.

5. WHY MIGHT I NOT WANT TO TAKE PART IN THIS STUDY?

It may hurt when you are having your blood drawn. There is also a chance that you will have a bruise at the place where the needle is stuck in your arm. There is also a slight chance that the place where the needle is stuck will become infected.

For a complete description of known risks, refer to the" what are the risks of the study" section of this consent form and privacy authorization.

6. WHAT OTHER OPTIONS ARE THERE?

Your other option is not to participate in this study. Being in this study is completely voluntary and you do not have to take part.

7. HOW WILL TAKING PART IN THE STUDY AFFECT ME FINANCIALLY?

There is no additional cost to you if you take part in this study. You will not be paid for being in this study.

remainder of page intentionally left blank

Detailed Information Section

How Many People Will Take Part in This Study?
About 10,000 people will take part in this study at multiple BSWH sites across north and central Texas.

What Will I Be Asked to Do?
For all participants, you will be asked to allow the researcher to review your medical records and copy the information from these records into their research charts for this project. This information will be reviewed by the researcher and their staff to answer the specific question as outlined above.

You will be asked to complete a questionnaire at every visit which will ask you questions about your health, medical, lifestyle, diet and so on. The questionnaire should take 30 minutes or less to finish. Once you have completed the questionnaire you will give it to the researcher or their staff so that they can review them for their research report.

You will be asked to allow the researchers to use the tissue that was left over after any cancer-related surgery or biopsy to evaluate for their research project. Your collected samples and data that have been prepared to protect your privacy may be shared with researchers both within and outside BSWH for research purposes.

If you are receiving surgery to treat your cancer as part of your care, you will join the "Surgical Arm" of the study (Table 1). If you are receiving an FDA approved or novel immuno-oncology drug to treat your cancer as part of your care, you will join the "Immunotherapy (IO) Arm" of the study (Table 2). For all participants, on Year 3 or Month 36 you will transition from active participation to follow-up, where the researcher will review your medical records and copy the information from these records into their research charts, until Year 5 or Month 60.

remainder of page intentionally left blank

Table 1. Schedule of Assessments for the Surgical Arm

Surgical Arm								
Study Visit	Pre-Op	Surgery	Year 1[d]			Years 2-3[d]	Years 4-5[d]	End of Study[f]
Study Month	-	0[b]	1	6	12	18, 24, 30, 36	42, 48, 54	60
Visit Window[a]	-	-	-21d/+60d	± 90d	± 90d	± 90d	± 90d	± 90d
Study Procedures								
Obtain Consent form and privacy authorization	X							
Clinical Data	X		X	X	X	X	X	X
Tissue	X[e]							
Blood	X		X	X	X	X		
Stool	X[c]		X[c]	X[c]	X[c]	X[c]		
Urine	X[c]		X[c]	X[c]	X[c]	X[c]		
Saliva	X[c]		X[c]	X[c]	X[c]	X[c]		
Baseline Questionnaire	X							
Follow Up Questionnaire			X	X	X	X		
Research Tissue Biopsy	X[e]							
End of Study form								X

[a] "d" is days
[b] The Study Month number begins from the date of Surgery
[c] Optional but encouraged
[d] After Month 6, visits will occur every 6 months
[e] Collected only if determined to be in excess by a qualified pathologist (a physician who diagnose diseases and conditions based on laboratory tests) or provider
[f] "EOS" is End of Study and this visit can occur earlier than Month 60 for reasons listed in the *How Long Will I Be in The Study?* Section
± visits can be completed plus (additional) or minus (less than) the planned schedule visit (Study Day)

remainder of page intentionally left blank

Table 2. Schedule of Assessments for the Immunotherapy (IO) Arm

Immunotherapy Arm					
Study Visit	Pre-IO	IO Start	Years 1-3	Years 4-5	End of Study[e]
Study Month	-	0[b]	3, 6, 9, 12, 15, 18, 21, 24, 27, 30, 33, 36	39, 42, 45, 48, 51, 54, 57	60
Visit Window[a]	-	-	± 45d	± 45d	± 45d
Study Procedures					
Obtain Consent form and privacy authorization	X				
Clinical Data	X		X	X	X
Tissue	X[d]				
Blood	X		X		
Stool	X[c]		X[c]		
Urine	X[c]		X[c]		
Saliva	X[c]		X[c]		
Baseline Questionnaire	X				
Follow Up Questionnaire			X		
Research Tissue Biopsy	X[d]				
End of Study form					X

[a] "d" is days
[b] The Study Month number begins from the date of IO Start
[c] Optional but encouraged
[d] Collected only if determined to be in excess by a qualified pathologist or provider
[e] "EOS" is End of Study and this visit can occur earlier than Month 60 for reasons listed in the *How Long Will I Be in The Study?* Section
± visits can be completed plus (additional) or minus (less than) the planned schedule visit (Study Day)

Leftover/Discarded tissue: If you are having a surgery related to your cancer as part of your care, we are asking you to let us collect some of the discarded tissue (not required for clinical diagnosis). The tissue will be saved and transferred to the research laboratory for tissue processing and analysis. All tissue samples removed will be examined and approved by a staff pathologist before any samples will be used for research purposes and stored in the research laboratory.

Extra biopsy for research: If you are having a needle biopsy to take a sample of a mass that might be cancer, we are asking that you let us collect about 4 to 8 extra tissue samples for research.

Blood samples: You will be asked to allow the researcher to collect blood samples from you. You will be asked to donate up to 80 mL per collection, about 5-6 tablespoons, (not to go above 250 mL per month including this protocol as well as other coexisting research protocols in which the participant is participating). Blood collection will occur at regular intervals (pretreatment or baseline and about every three to six months) to coincide, if possible, with routine follow up visits of your cancer therapy (such as restaging [imaging procedure used to assess the amount or spread of cancer in the body after treatment] computed tomography scans [CT, imaging technique that uses X-rays to create detailed images of the body]) or regular clinical visits.

Stool samples: You will be asked to allow the researcher to collect stool samples from you. You will be asked for your collection of stool specimen (which can be done either at home or at the clinic) within 72 hours of treatment initiation and thereafter about every three to six months for the duration of your cancer diagnosis. You will be provided with collection materials in a kit by the key study personnel, or the kit will be sent to you by mail. You can bring your samples to the designated location, or alternatively, you can mail your sample to the study investigators using a prepaid mailer.

Urine samples: You will be asked to allow the researcher to collect urine samples at regular intervals (pretreatment or baseline and about every three to six months) to coincide, if possible, with routine follow up visits of your cancer therapy (such as restaging CT scans) or regular clinical visits.

Saliva samples: You will be asked to allow the researcher to collect saliva samples at regular intervals (pretreatment or baseline and about every three to six months) to coincide, if possible, with routine follow up visits of your cancer therapy (such as restaging CT scans) or regular clinical visits.

Leftover Biological fluids. Just as there is left-over tissue that is not required for patient care or diagnosis and would normally be discarded, there are left-over biological fluids in the Pathology Department Clinical Laboratory that would normally be discarded that could be collected for research. We are asking you to let us collect some of the discarded biological fluids (not required for clinical diagnosis) for research purposes.

If it is determined you do not have cancer, you will be removed from the study and no other follow-up collections will take place. The collected specimens may remain in the Texas Immuno Oncology Biorepository (TIOB) inventory and serve as controls for future research unless you request your specimens to be withdrawn and/or destroyed.

Tissue, bodily fluids, or blood samples taken from you in this study may be used to establish a cell line that could be patented and licensed. There are no plans to pay you for this, or other products should this occur.

How Long Will I Be in The Study?

You will be in this study for no more than 5 years, unless you screen fail, withdraw consent, or become too frail to take part in the study.

The researcher may decide to take you off this study if they feel that it is in your best interest, if you are not able to follow the rules of this study, if this study is stopped before it is finished or if new information becomes available that indicates it would be best for you to stop being in this study.

You can stop taking part in this study at any time. If you decide to stop taking part in this study, you should let the researcher or their staff know so.

What Are the Risks of The Study?
It may hurt when you are having your blood drawn. There is also a chance that you will have a bruise at the place where the needle is stuck into your arm. There is also a slight chance that the place where the needle is stuck will become infected.

If you are already undergoing a biopsy of your cancer, collecting 4-8 additional biospecimens may cause a small chance of bleeding or infection.

The risks of undergoing a biopsy of your cancer either as part of standard of care or for research purposes include:

- Tenderness
- Bleeding
- Bruising
- Infection
- Delayed Healing
- Scarring
- Hypopigmentation or loss of skin color

Local anesthesia (drugs will be used to prevent pain and discomfort during procedures) will be given prior to the biopsy and therefore discomfort will be minimized.

The most likely risk of letting us store your samples and your information is accidental release of your information. To limit the risk of any accidental release or misuse of your information we have about you will be kept confidential and protected to prevent unauthorized access.

Risks of genetic testing: The level of genetic analysis that is planned may involve every gene in an individual. Genetic testing involves a pre-symptomatic laboratory test of an individual's genes, gene products, or chromosomes to produce genetic information, which may or may not be associated with an ongoing disease, disorder, or syndrome affecting the individual. Accordingly, it is expected that some mutations will be identified that may have clinical significance outside of the research setting. Genetic research often raises the issue of privacy and confidentiality; safeguards are in place to protect genetic information and personal health information (PHI).

This study involves genetic testing, and emotional risk is considered if genetic information is disclosed, identifying genetic markers, and indicating specific diseases that you may develop or be pre-disposed. Genomic studies that generate information about your personal health and medical condition can provoke anxiety and confusion. With any genetic or molecular analysis comes a risk of loss of confidentiality. We will try to protect your confidentiality as much as possible, but there may be a risk of loss of confidentiality

The researchers may decide to share data gathered from your samples to help further research into different diseases including cancer. We do this by putting information into scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about diseases.

If you agree to take part in the study, some of your genetic and health information might be placed into one or more scientific databases. There are many kinds of scientific databases; some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “database of Genotypes and Phenotypes (dbGaP)". A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with approval may be able to see and use your information that has been prepared to protect your privacy, along with information from many other people.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future.

If you have additional questions about these risks, ask the researcher.

Your doctor may be an investigator in this research study. If so, they are interested both in your medical care and in the conduct of this research. Before you sign up for this study or at any time during the research, you may discuss your care with another doctor who is not associated with this study. You are not under any obligation to take part in any research study offered by your doctor.

What If I am Injured While Taking Part in This Study?
The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, you should tell the researcher or their staff and they will help you to get necessary medical care. You or your insurance company may need to pay for the medical care. Baylor Scott and White Health, Baylor Scott and White Research Institute and BSWH Cancer Center – College Station, BSWH Cancer Center – Killeen, BSWH Specialty Clinic – Marble Falls, BSWH Cancer Center – Round Rock, BSWH Vasicek Cancer Center – Temple, BSWH McClinton Cancer Center - Waco, BSWH Charles A. Sammons Cancer Center-Waxahachie, BSWH Charles A. Sammons Cancer Center – Dallas, BSWH All Saints Medical Center – Ft. Worth, Texas, BSWH Charles A. Sammons Cancer Center – Duncanville, Texas, have not set funds aside to pay you money if you are hurt. You have not given up any of your legal rights by signing this consent form and privacy authorization.

What About Confidentiality?
You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute (“BSWRI”) and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Scott & White Medical Center – Temple and other health care providers depending on where you have received care (collectively,

"Your Health Care Providers") get your permission before giving any of your health information to other people. There are study monitors and auditors who need to review your information to make sure this study is done correctly. These people may look at or make notes about your information while they are doing this review. When you sign this form, you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Boards), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections, and the Association for the Accreditation of Human Research Protection Programs. This also includes the following groups of people who are working with the sponsor of this study: BSWH Cancer Center – College Station, BSWH Cancer Center – Killeen, BSWH Specialty Clinic – Marble Falls, BSWH Cancer Center – Round Rock, BSWH Vasicek Cancer Center – Temple, BSWH McClinton Cancer Center - Waco, BSWH Charles A. Sammons Cancer Center- Waxahachie, BSWH Charles A. Sammons Cancer Center – Dallas, Translational Genomics Research Institute (TGEN), Johns Hopkins University, BSWH All Saints Medical Center – Ft. Worth, Texas, BSWH Charles A. Sammons Cancer Center – Duncanville, Texas. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

- This could also be information about alcohol abuse.

You do not have to give this permission and it is your right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 3434 Live Oak St, Dallas, TX 75204. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your

Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

We are not sure of all the research questions that we may identify in the future, however all questions and testing will be related to the care you receive for your cancer. We may collect additional blood, urine, saliva, stool, and tissue.

Additional Financial Information
There are no costs to you for being in this study and you will not be paid for being in this study.

What are My Rights as a Participant?
Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason.

Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call If I have Questions or Problems?
If you have concerns, complaints or questions about this study or have a research-related injury, contact the Principal Investigator, Dr. Ronan Kelly at 214-818-8472.

For concerns, complaints, or questions about your rights as a research participant or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 254-215-9697.

remainder of page intentionally left blank

Statement of Person Obtaining Consent:

I have explained to _____(printed name of participant) the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the participant.

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Confirmation of Consent by Research Participant:

You are making a decision about being in this study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all pages in this form. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a participant in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

_____ _____ _____
Signature of Participant Date Time