**Do not alter any of the following text, except as indicated\*\*\***

## **Authorization to Use Your Health Information for Research Purposes**

We are committed to respecting your privacy and to keeping health information that identifies you safe. In addition, the Health Insurance Portability and Accountability Act (HIPAA), a federal law, provides additional protections of your medical records and related health information. In order for the study doctor and study staff to use and share ***(if you will not be sharing information with external study partners and/or organizations you may delete “and share”)*** health information that identifies you for this study, your written approval, called your “authorization”, is needed. If you agree to take part in this study and sign this form, you are giving the study doctor and study staff permission to use and share your health information.

If you have questions, concerns, or complaints about the use or sharing of your health information or would like a copy of the Banner Notice of Privacy Practices, you may contact the Banner Research HIPAA Liaison at 602-839-4583 or BHResearchCompliance@bannerhealth.com.

***Do I have to give permission to use my health information?***

You do not have to give your permission. However, if you decide you do not want your health information used you will not be able to take part in this study. ***If applicable add a comma after the word study as well as the following phrase: including receiving any study-related intervention.*** If you do not give your permission to use your health information, it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or eligibility for benefits.

***What health information will be*** ***used OR used and shared for this study?***

The health information you are allowing the study doctor and study staff to use and share for study purposes includes:

***Modify (add or delete) information in the list below to reflect all health information that may be used or disclosed for research purposes******. NOTE: If health information to be used/shared is identified in the ICF, the information below should match the ICF’s language/list.***

* All information in a past, present, or future hospital or doctor’s medical records
* Demographic information (such as age, gender, or race)
* Personal identifiers (such as your name, address, phone number, or social security number)
* Medical history
* Results of physical examinations
* Lab tests, imaging results, or both
* Diaries and questionnaires
* Records about prescribed medication or study agent(s)
* Records about medical devices or study device
* Health plan or health insurance records
* Billing Information
* Sexually transmitted disease (STD) testing results
* Acquired immunodeficiency syndrome (AIDS) testing results
* Human immunodeficiency virus (HIV) testing results
* Other communicable disease testing results
* Substance abuse information: Specify what information
* Mental health information: Specify what information ***NOTE: There are special considerations with regard to psychotherapy notes, including extra privacy protections. If your study will include these notes, contact the Banner Health Privacy Office to discuss the extra protection requirements (which includes a separate HIPAA authorization prior to use or disclosure).***
* Genetic health information: Specify what information

***If your study involves a review of a participant’s medical record AND will not be collecting information on STDs, AIDS, HIV, other communicable disease, substance abuse, and/or mental health information AND you have deleted these items from the bulleted list above, you MUST add the following statement (delete conditions as applicable – i.e., condition remains in bulleted list above):***

The study staff and sponsor’s monitor may see information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (for example, genetic testing), alcohol abuse, and/or drug abuse while reviewing your health records for this study. They WILL NOT collect or share this type of information for the purposes of this study.

***If your study is collecting information on STDs, AIDS, HIV, other communicable disease, substance abuse and/or mental health information add the following statement. Revise list of conditions as appropriate. Otherwise delete.***

The study staff will collect and use; collect, use and share information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (for example, genetic testing), alcohol abuse, and/or drug abuse results, but only for this study.

***Who will my health information be shared with? Why?***

Once we have the information listed above, we may share some of it internally with:

* The University of Arizona (UA) and the UA Institutional Review Board, who may need to see the information to make sure the study is done safely and properly
* Authorized members of the Banner University Medical Group, Banner Health, and the University of Arizona, such as administrative staff members from the Banner Research and University of Arizona compliance departments, who may need to see the information to make sure the study is done safely and properly

***Delete the following bullet if participants will not be paid or receive reimbursement in your study. Revise the bullet as appropriate (i.e., remove***

* If you receive compensation or reimbursement for taking part in this study, information identifying you may be used or shared as necessary to provide that compensation.

If you agree to take part in this study a copy of this signed authorization, signed study consent and some of your research records will be saved into your electronic medical record (EMR) at Banner Health. As a result, healthcare providers and staff who are not working on this study, but who may provide you medical treatment in the future, will know that you are taking part or took part in this study. In addition, your health plan may see this form during a medical record review.

***If absolutely no study information will be shared with external entities use the following statement. Otherwise delete.***

We will not share any of your information with anyone outside of Banner Health and the University of Arizona.

***Delete bullets that are not applicable to your study. You may add other individuals or organizations as applicable to your study. NOTE: If individuals or organizations are described in the ICF, the information below should match the ICF.***

We may share some of this information with individuals or organizations outside of Banner Health and the University of Arizona. The following entities may receive your health information:

* Insert name of the external IRB of record (i.e., Pediatric/Adult Central Institutional Review Board (CIRB) of the National Cancer Institute, who may need to see the information to make sure the study is done safely and properly
* Insert sponsor name (External party only; if none - delete this bullet), who is sponsoring the study, or their agents
* Laboratories and other individuals and organizations that may need to see your health information in connection with this study
* Study monitors and auditors who make sure that the study is being done properly
* Government agencies and public health authorities, such as the U.S. Department of Health and Human Services (HHS); HHS Office for Human Research Protections (OHRP); HHS Office of Research Integrity (ORI); and the U.S. Food and Drug Administration (FDA), or other regulatory agency as required
* Your primary care physician or a specialist taking care of your health

The individuals or organizations who get your health information may not be required by the HIPAA privacy law to protect it. Some of those people may be able to share your information with others without your separate permission.

***When will my permission to use my health information expire?***

Your permission to use and share your information does not expire. Therefore, unless you cancel your permission (as instructed below) the study doctor and study staff will be allowed to use and share your information for this study ***Delete the following if your study does not include any future research*** and any future research described later in this form.

***What do I need to know if I decide to cancel my permission?***

After signing this form, you may decide to cancel your permission to use your health information. If you cancel your permission, you will not be able to stay in this study. Please note that any health information collected before you canceled your permission may still be used as described in this form. The study staff is required by law to report any bad side effect you have even if you have canceled your permission.

***How do you cancel your permission?***

In order to cancel your permission, you must notify the study doctor or study staff in writing at:

Study Doctor/Study Staff Name or Site Name

Mailing Address

Email Address, if applicable; otherwise remove

***Will I be able to look at or get a copy of my study records during the study?***

***Revise as applicable to your study.***

You will not be able to look at or get a copy of your information that was created for this study until it is completed.

## **Add the following sections (tables) as appropriate for the study**:

|  |
| --- |
| **Optional Research Activity - Permission to Use and Share Health Information**Optional research activity is part of this study. If you choose to take part in this optional activity your health information will be used and sharedfor the activity.You can still be in the main part of the study even if you do not give permission to the use *and sharing* of your PHI for the optional activity. However, if you agreed to take part in the optional research activity you must also give your permission to the use and/or sharing of your information below.***If multiple activities, insert an initial statement and line for each. Number each option (i.e., Optional Study #1; Optional Study #2, etc).***In the study consent, you agreed to Add brief description of the optional activity or activities. Example: ... have the optional procedure to remove a sample of your cancer before you start the study drug. By initialing the line below, you agree to allow your health information to be used and shared for the optional study activity described above.\_\_\_\_\_ Initials |

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| **Optional Future Research Activity - Permission to Use and Share Health Information NOTE: From a HIPAA perspective, future research is unrelated to the current study. For instance, data or specimens will be shared with researchers not involved in this study. Or the researchers will use the data or specimens for research on other diseases.** The study you are agreeing to take part in involves future research. Below is a description of the optional future research purposes (for example, future studies). Your health information may be used and shared for such purposes. You can still be in the main part of the study even if you do not give permission to the use and sharing of your information for the future research. However, if you agreed to take part in the optional future research you must also give your permission to the use and sharing of your information below.***If multiple future research options, insert an initial statement and line for each. Number each option (i.e., Optional Research #1; Optional Research #2, etc).***In the study consent, you agreed to Add brief description of the optional future research. Example: ... allow the sponsor to use any leftover blood or tumor samples collected for this study for future research to learn more about cancer and other diseases. By initialing the line below, you agree to allow your health information to be used and shared for the optional future research described above.\_\_\_\_\_ Initials |

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| ***Delete the following, if your study does not include mandatory future research (see note above regarding “definition” of future research).*** **Future Use of Health Information**If you choose to sign this form you are giving permission for the use and sharing of your health information for future research purposes (for example, future studies). Below is a description of the type of future research that may be done.Add brief description of the future research. |

**TO BE FILLED OUT BY STUDY PARTICIPANT ONLY**

Please **print** your name, **sign**, and **date** below if you agree to allow the use and sharing of your health information as described in this form.

**You will be given a copy of this form after it has been signed.**

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Printed Name of Participant |  | Signature of Participant (18 or older and able to consent) |  | Date |
| ***Remove this section if you did not request IRB approval to obtain study consent from a LAR*** |  |  |  |  |
| Printed Name of Legally Authorized Representative (LAR) |  | Signature of Legally Authorized Representative |  | Date |
| LAR’s Relationship to Participant: |  |