## Instructions

*This consent form is for medical research, including collection of biospecimens or research that will access HIPAA protected information. Delete the RED text prior to submitting this form to the IRB. Required language* *is in* *regular text. Additional language, as appropriate, is in comments.* ***Grey language is required by Banner if conducting research at B-UMC.***

**Consent and/or Parental Permission (if applicable) to Participate in Research**

## Study Title:

**Principal Investigator:**

**Consent Version: MM/DD/YYYY**

**Sponsor and/or Funder:** (delete if not sponsored)

**Conflict of Interest Statement:** (If applicable per COI management plan, delete if no COI management plan exists for researchers on this protocol)

**Summary of the research**

**This is a consent form for participation in a research study.** Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether to participate.

If your consent is more than 4 pages, provide a brief explanation of the project in non-technical language that is concise and focused and that will most likely assist a prospective subject to understand the research and choose to participate. This presentation of information is to be short and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. This summary may be a page or more, depending on the study. This summary should include:

* The purpose and expected duration
* Major requirements of the study
* The most important risks and/or benefits
* Other alternatives to participating, if appropriate
* Time commitment

## [If applicable]: The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study doctor.

**Why is this study being done?**

Explain the purpose of the study and a statement that the study involves research.

**What will happen if I take part in this study?**

Explain the procedures to be done. Specifically identify any procedures that are for research only. Include:

* The probability for random assignment to each treatment
* The subject’s responsibilities

**How long will I be in this study?**

Explain the expected duration of the subject's participation.

**How many people will take part in this study?**

Identify the approximate number of subjects you plan to enroll in the study, both total (study-wide) and local (if different).

**What benefits can I expect from being in this study?**

Explain any reasonably expected benefits to subjects or others.

* When there is no intended clinical benefit to the subject, a statement to this effect
* Do not include statements of unproven claims of effectiveness or certainty of benefit, either implicit or explicit

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

Explain any reasonably foreseeable risks or discomforts to the subjects because of participation or procedures from the research. Explain, if applicable, that a particular treatment or procedure may involve risks that are currently unknown or foreseeable.

Explain that if there are significant new findings that may impact a subject’s participation they will be informed.

**What other choices do I have if I do not take part in this study?**

Explain that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Describe any appropriate alternative procedures or courses of treatment. For some studies, the only alternative would be to not participate.

**When may participation in the study be stopped?**

Under what circumstances the subject's participation may be stopped by the investigator, the consequences of a subject's decision to withdraw from the research, and the procedures for orderly withdrawal of participation by the subject.

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

Please note, while you *may* submit to the IRB after feasibility approval and/or when an IP number is provided, it is advised that you wait to submit the project until the consent form has been reviewed by UAHS for financial edits. When submitting to IRB, UAHS feedback should be incorporated into the consent version submitted to IRB. Once IRB approved, the final consent must be emailed to crc@email.arizona.edu to ensure the correct financial information has been incorporated.

For research involving more than minimal risk, include the following elements as applicable, otherwise delete the below language:

*Option 1, if injury coverage* ***is*** *offered by Sponsor*:

If you experience illnesses or injuries related to your participation in the study, medical treatment will be provided to you. The medical costs of diagnosis and treatment may be covered by the Sponsor as long as the (insert investigational drug/ device /material name) was given correctly and according to the Sponsor’s instructions, and the injury was not due to the natural progression of a pre-existing condition. Please speak with the study team if you have questions about coverage of costs for injury. The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

*Option 2, if injury coverage* ***is******not*** *offered by Sponsor or the study is NOT funded:*

If you experience illnesses or injuries related to your participation in the study, medical treatment will be provided to you. Any costs of such care will be billed to you or your insurance provider. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries. Please speak with the study team if you have questions about coverage of costs for injury.

Required language for all research involving more than minimal risk: The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

**What are the costs of taking part in this study?**

*Explain who will pay for the study procedures and/or medications required for participation*. *If third party payers are expected to pay for standard care treatment, identify what the subject will be responsible for.*

*Interventional studies:*

The (insert investigational items supplied) and services performed for research only will be provided at no charge to you or your insurance company. Routine medical care performed while participating in the study will be billed to you and/or your insurance company. This will include (but is not limited to) (insert general care references such as physical exam and lab work if applicable), administration of medications, and the treatment of side effects.

Not all insurance companies are willing to pay for services performed in a clinical trial. You will be responsible for any charges that your insurance does not cover including regular co-payments and deductibles. Please speak with your insurance company to find out what you may be financially liable for.

*Non-Interventional:*

There are no anticipated additional costs for you to be in this study, except for your time.

Regular medical care performed while participating in study will be billed to you and/or your insurance company as usual. Not all insurance companies are willing to pay for services performed in a clinical trial. Please speak with your insurance company to find out what you may be financially liable for.

**Will I be paid for taking part in this study?**

Discuss the amount and timing, including a description of any proration, of any compensation (monetary and/or non-monetary).

[If subjects will receive compensation, include the following text]:

Any payment for participation in a research study is considered taxable income for you. If your payment for this research study or a combination of research studies is $600 or more for all or any dollar amount for undocumented noncitizens in a calendar year (January to December), you will receive the appropriate IRS Form for tax reporting purposes from the university. Please note, if you are an employee of UArizona, any compensation from a research study is considered taxable income.

[If subjects will receive compensation and/or reimbursement, include the following text]:

For any compensation or reimbursement, you receive, we are required to obtain identifiable information such as your name, address, and [for amounts >$50] Social Security number for financial compliance purposes.

**Will my data or specimens be stored for future research?**

The consent must include either:

* A statement that identifiers will or will not **[choose one]** be removed from the private information or biospecimens, and that after such removal, the information or biospecimens may be used for future research studies without additional informed consent [Include a description of what information/specimens will be stored and whom they will be shared with (both internal and outside the institution). Explain what research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc.]; or
* A statement that the identifiable information or biospecimen, even if identifiers are removed, will not be used, or distributed for future research.

If your study is funded by the NIH or another agency that requires a Data Management Plan, relevant information from your Data Management Plan will need to be included in this section.

**Will my specimens be sold for commercial profits?**

Describe whether subjects will or will not share in any commercial profit from the use of their biospecimens, even if identifiers are removed.

**Will I hear back on any results that directly impact me?**

Describe whether any clinically relevant results will be disclosed to subjects, and if so, under what conditions.

**Will Whole Genome Sequencing be done with my specimen?**

Describe, if known, whether whole genome sequencing will be done.

# Will my study-related information be shared, disclosed, and kept confidential?

# Specify the extent, if any, to which confidentiality of identifiable records will be maintained. Specify the entity(ies) which would potentially share or have access to research files and remove those that are not applicable.

It is anticipated there will be circumstances where your study related information and Protected Health Information (PHI) will be released to persons and organizations described in this form. If you sign this form, you are giving permission to the research team to use and/or disclose your PHI for this study. Your information may be shared or disclosed with others to conduct the study, to comply with regulations, and to help ensure that the study has been done correctly. These other groups may include:

# (leave applicable entities) Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies

# Banner University Medical Group and Banner Health

# The University of Arizona (UA) and the UA Institutional Review Board

# (if applicable) The sponsor and/or funder supporting the study, their agents or study monitors

* Your primary care physician or a specialist taking care of your health.

If you agree to take part in this study a copy of this signed informed consent form 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.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

**What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?**

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

* Specify what PHI, including specific data elements that will be used.

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number. **[If applicable]** If you receive compensation for participating in this research study, information identifying you may be used or disclosed as necessary to provide that compensation.

Your existing health records may include 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 (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and **[If applicable]** study sponsor’s monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

**When will my authorization expire?**

There is no expiration date for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be in effect.

**Do I have to sign this authorization form?**

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; but it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

 ***Use this language when future research is NOT optional***

Also, by signing this form you are authorizing and permitting uses and/or disclosures of your PHI for future research purposes (e.g., future studies) as described in this document.

***Use this language when there is additional optional research***

## Optional Research Activity

## Optional research activity is part of this project. If you choose to participate in this optional activity your PHI shall be included for this optional activity.

By initialing the line below, you agree to allow your PHI to be used and/or disclosed for the optional research activity referenced above.

\_\_\_\_\_ Initials

***Use this language when future research is optional***

**Future Use of PHI**

## Future research activity is part of this project. If you choose to participate in the future research activity your PHI will be included in this future research activity.

By initialing the line below, you agree to allow your information to be used and/or disclosed for the optional future research referenced above.

\_\_\_\_\_\_\_ Initials

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

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under “Who can answer my questions about the study” at the end of this document.

**Will access be limited to my research study record during this study?**

You may or may not have access to the research information developed as part of this study until it is completed [Describe].

# Who can answer my questions about this 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 the Human Subjects Protection Program Director at 520-626-8630 or online at https://research.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, general questions, concerns, or complaints about the study you may contact **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (insert PIs name here)**

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 BannerResearchCompliance@bannerhealth.com.

To cancel your authorization for access to PHI you must notify the *Principal Investigator* and/or *Research Team* in writing at the following address:

Insert address for Investigator

 [If Applicable]: A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

# 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,and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

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| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Printed name of subject** |  | **Signature of subject** |  | **Date** |

**If you are enrolling minors or individuals who have a legally authorized representative (LAR), include this section.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Printed name of person authorized to consent for subject (when applicable)** |  | **Signature of person authorized to consent for subject** **(when applicable)** |  | **Date** |

|  |  |
| --- | --- |
|  |  |
| **Relationship to the subject** |  |

**If you are enrolling minors, include this section.**

|  |  |
| --- | --- |
|  |  |
| **Name of child**  |  |

**Some studies may require signature of PI or research staff. This is an optional section.**

**Investigator/Research Staff**

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Printed name of person obtaining consent** |  | **Signature of person obtaining consent** |  | **Date** |