* **Language must be in plain language and match the IRB application, and protocol.**
* **Required language is in regular text highlighted in blue**
* **Blue language is required by Banner if conducting research at BUMC.**

**FOR ALL UNIVERSITY OF ARIZONA/Banner – Advarra ICF Preparation, the following is required:**

1. **The Banner-UA logo in the header on each page**
2. **The barcode, ON PAGE ONE (1) FOOTER ONLY**
3. **The HSPP box in the footer on EVERY page**
4. **All blue highlighted language below.**

**Consent to Participate in Research**

|  |  |
| --- | --- |
| **Sponsor / Study Title:** | **Sponsor Name / “Protocol Title”** |
| **Protocol Number:** | **Protocol Number** |
| **Principal Investigator:**  **(Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Additional Contact(s):**  **(Study Staff)** | **«AdditionalStaffMemberContacts»** |
| **Address:** | **«PiLocations»** |

Insert this language into the intro section of the ICF

## 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.

## 

If the study is using genetics, describe if any genetic testing will be conducted with the samples.

A federal law, called the Genetic Information Nondiscrimination Act (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 that the sponsor will get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that the sponsor will get 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 and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

**Insert into the Injury section of the ICF**

The University of Arizona and Banner-University Medical Center have no funds set aside for the payment of treatment expenses for this study.

**Insert into the compensation section of the ICF, if subjects are being compensated.**

Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

**Insert into the compensation section of the ICF, if subjects are being compensated or reimbursed for expenses.**

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

It is anticipated that 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 give 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, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups include:

# Office for Human Research Protections or other federal, state, or international regulatory agencies

* Food and Drug Administration

# *Banner University Medical Group and Banner Health*

# Advarra IRB

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

# The sponsor 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 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 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 or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

**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; and 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.

**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. The Principal Investigators address and telephone numbers is listed on the first page of this form.

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

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

**Will my data or specimens be stored for future research?  *(when defined in the protocol)***

Include a description of what information/specimens will be stored and whom they will be shared with (both internal or outside the institution). What research may be conducted with these data/specimens - including unspecified future research, genetics, disease specific, etc. The IRB prefers optional opt-in check boxes where subjects can agree to the various levels of research use.

Also include a description of how the information will be protected and stored. Explain if reconsent will be obtained from subjects for specific uses.

***This language is required under HIPAA when a study includes optional research activities or future use of PHI. Combine this language in the appropriate section describing these optional activities. Delete if not applicable.***

**Optional Research Activity *(when defined in the protocol)***

## 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 Study activity referenced above.

\_\_\_\_\_ Initials

**Future Use of PHI *(when defined in the protocol)***

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

## 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

# Who can answer my questions about this study?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects.  If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

* By mail:

Study Subject Adviser

Advarra IRB

6940 Columbia Gateway Drive, Suite 110

Columbia, MD 21046

* or call **toll free**:        877-992-4724
* or by **email**:              [adviser@advarra.com](mailto:adviser@advarra.com)

Please reference the following number when contacting the Study Subject Adviser: Pro000XXXXX.

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](mailto:BHResearchCompliance@bannerhealth.com).

To cancel your authorization for access to PHI you must notify the the study doctor listed on page one of this document.