VUMC Institutional Template Language for Sponsor Consent Template when VUMC IRB is the IRB of Record:

* This list is not all encompassing of optional/ “when applicable” language, but it includes the most commonly utilized language. Additional optional template language can be found on the HRPP website under “Template Language and General Guidance”
* If the Sponsor template includes the Sponsor’s version of Cost, Subject Injury, HIPAA language, etc., then the Sponsor’s language to be *removed* and *replaced* with the VUMC required language.
* When the Sponsor consent template is utilized, a tracked copy of the Sponsor consent template should be submitted that shows all of the changes made to the Sponsor template
* When the Sponsor consent template is utilized, the only changes that should be made are the changes to include VUMC institutional language. Formatting, layout, etc. should not be altered.

**Billing/Cost Language -REQUIRED**

This language must be included to inform participants whether they/their insurance may be billed throughout their participation in the study. Many studies, particularly clinical trials, overlap with the standard clinical care a patient is receiving, in which case the 2nd option will likely be used. If the PI/Sponsor determines that certain procedures fall under “standard clinical care”, the participant’s insurance may be billed for those procedures.

**Costs to you if you take part in this study:**

*If there is no billing to the participant or a third party payor, the following template should be used:*

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

**OR**

*If there is billing to the participant or a third party payor, the following template should be used:*

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

**Subject Injury Language -REQUIRED**

This language is specific to billing for **INJURY**. It does not correlate to the template Cost language. Subject Injury Language is required for all Greater than Minimal Risk studies and Minimal Risk studies with the potential for subject injury. Minimal Risk studies in which consent forms describe potential side effects should also use the institutionally approved subject injury language.

**Payment in case you are injured because of this research study:**

If it is determined by Vanderbilt and the Investigator [with Sponsor input] that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury.  You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt [or the Sponsor] to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

**HIPAA Authorization Language – REQUIRED**

This language must be included when patient medical records are being accessed during the study. Include this language within the body of the consent form before the consent signature lines. Study teams have 2 options. It is recommended (not required) that Option 2 be used for Sponsored studies in which the Sponsor template is being utilized. Sponsors tend to prefer Option 2 because they have the ability to make edits to the red template text.

**Option 1:**

**What information is being collected, used, or shared?**

To do this research, we will need to collect, use, and share your private health information.  By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study.  Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

**Who will see, use or share the information?**

The people who may request, receive or use your private health information include the researchers and their staff.  Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight.  By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center.    This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, insurance providers and other agents and contractors used by the study team.   We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others.  If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

**Do you have to sign this Authorization?**

You do not have to sign this Authorization, but if you do not, you may not join the study.

**How long will your information be used or shared?**

Your Authorization for the collection, use, and sharing of your information does not expire.  Additionally, you agree that your information may be used for similar or related future research studies.

**What if you change your mind?**

You may change your mind and cancel this Authorization at any time.  If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form.  Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

*[OPTIONAL: You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.]*

**If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.**

**Option 2:**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHIis your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked *[INCLUDE STUDY SPECIFIC INFORMATION: E.G. LABORATORY TESTS, X-RAYS, ETC.*], as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, *[ADD OTHERS AS APPROPRIATE, E.G., FOOD AND DRUG ADMINISTRATION, NATIONAL INSTITUTES OF HEALTH, REPRESENTATIVES OF {SPONSOR NAME}, CROs, IBC, SRC, INSURANCE COMPANIES FOR BILLING PURPOSES, ETC].*  Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished.  At that time, the research data that has not been put in your medical record will be kept for an unknown length of time*.* Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. [PI] in writing and let *[HIM/HER]* know that you withdraw your consent.  *[HIS/HER]* mailing address *is [ADDRESS]*.  At that time, we will stop getting any more data about you.  But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

[OPTIONAL: You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.]

**If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.**

**Communicable Disease Testing/Reporting- WHEN APPLICABLE**

Any Communicable Disease:

As part of this study you will be tested for [communicable diseases (ex: Hepatitis)].  If results show that you are positive for a [communicable disease] the study staff will tell you the results. We will talk with you before and after testing, and your test result will be given to you only in person. You should know that the study staff may be required to give your name to the Tennessee Department of Health if you test positive because this is the law.  It is important to seek medical care if you have a [communicable disease]. If you need a referral, please let the study staff know.

HIV Testing and Reporting:

You will be tested for HIV (AIDS virus) during this study. If test results show that you have the virus that causes AIDS, the study staff will tell you the results and refer you to the health department to confirm the test results and give you someone to talk to about this disease. We will talk with you before and after testing, and your test result will be given to you only in person. You should know that the study staff must give your name to the Tennessee Department of Health if you test positive because this is the law. If others find out you have this virus, it may cause mental stress, unfair treatment from other people, problems with being able to get insurance or find a job, or other unknown problems. It is important to seek medical care if you have HIV.

**Surrogate “Rider” – WHEN APPLICABLE**

I, \_\_\_\_\_\_\_\_\_\_ [name of decision-maker/surrogate],

am the \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ [state relationship to participant]

of \_\_\_\_\_\_\_\_\_\_ [state participant’s name]. I have read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to \_\_\_\_\_\_ [participant’s name]. I believe receiving such treatment would be in the interests of [participant’s name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend’s participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

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Signature of Health Care Decision-Maker/Surrogate Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_/\_\_\_/\_\_\_

Signature of Witness Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_/\_\_\_/\_\_\_

Name and Signature of person obtaining consent Date

**Certificate of Confidentiality Language – WHEN APPLICABLE**

If CoC language is included in the ICD, be sure to check that the study has some form of NIH funding (VICTR funding falls under this umbrella). Also, the CoC question in the IRB application should be answered “yes” if this language is included in the ICD.

*[Insert this language if the study receives any funding from the NIH]*

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality.  This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases.  The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

**Medical Record Language - REQUIRED**

Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

**Compensation/Payment Language – WHEN APPLICABLE**

**Payments for your time spent taking part in this study or expenses:**

*[Insert if you are a VUMC researcher and are providing any compensation*; *Insert a brief description of payments to participants and add the paragraph below, indicate no payments or delete if not applicable.]*

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws.  You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government‘s comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department’s Office of Foreign Assets Control’s Specially Designated Nationals (SDN) list of prohibited individuals.  You do not have to say why you choose not to be paid.

*Include this language for all studies with compensation unless it qualifies for one of the exceptions noted below:*

“We may ask you for your Social Security number and address before you are compensated for taking part in this study.”

*The language below should be included in all research consents that involve a compensation of $600 or greater in a calendar year.*

“You may receive up to (insert dollar amount or compensation) for taking part in this study. This amount may be taxable and will be reported to the Internal Revenue Service (IRS).”

**Exceptions**

For VUMC**:** It is not necessary to document SSN or request an SSN exception for studies compensating less than or equal to $100 ($50 for healthy volunteers) in a calendar year.

For VU**:** If participants will be compensated more than $300 in a calendar year, the study team must either plan to collect SSNs or request a waiver for the collection of SSNs. If the amount is less than $300 in a calendar year, the study team does **not** need to collect SSNs **nor** do they need the waiver.

**Additional Guidance**

SSN Exception Request and Approval: You may be contacted by CRFSS@vumc.org via email to provide additional information. If an SSN exception is requested, you may not compensate participants without collecting SSNs until you receive an email notification an SSN exception has been granted from [CRFSS@vumc.org](mailto:CRFSS@vumc.org) (separate from IRB approval).

If an SSN exception is requested as part of an amendment to a study, you must contact [CRFSS@vumc.org](mailto:CRFSS@vumc.org) upon amendment approval for the SSN exception request to be reviewed.

Reimbursement for participant costs (e.g., travel, meal expense, etc.) are not considered compensation and are not taxable.

For more information regarding participant compensation, refer to this link: <https://starbrite.app.vumc.org/research/crfss/participantcompensation>

**Radiation Risk Language – WHEN APPLICABLE**

* Study-specific VUMC research-related radiation risk language will be generated and provided to the study team based off the radiation procedures included in the Radiation Table in the IRB application. This language will be provided to the study team via a pre-review or CAL.
* In order for the IRB to provide the study team with accurate radiation risk language, the Radiation table in the IRB application **MUST** only contain the radiation procedures that will be occurring for research purposes (e.g. not standard of care).
* The HRPP analyst may ask for confirmation from the PI about research-related radiation procedures if the procedures entered into the IRB application’s radiation table does not appear to align with the amount/type of radiation procedures described in the Protocol.
* Remove all Sponsor radiation risk language. This includes any language that quantifies the risks from radiation procedures, such as “a small amount” and “low risk”

**Texting for Research Purposes – WHEN APPLICABLE**

**Texting or emailing for research purposes**: Required for all studies that will communicate Research Health Information (RHI) via text message or unencrypted email between KSP and research subjects.

[VUMC Policy: Electronic Messaging of Individually Identifiable Patient and Other VUMC Confidential, Private, and Restricted Data](https://sso.service.vumc.org/idp/SSO.saml2?SAMLRequest=fVJNT8JAEP0rm723pR9Q3NAmCDE2QSVQPXgx2%2b0Am7S7dWeL%2bu9diyZ4gGROk%2fcx72VmyNumY%2fPeHtQG3ntAS4plRt8gHMfpRHBvIuqpl8A49HjCay9O0opPkmpaJTeUvIBBqVVGI39ESYHYQ6HQcmXdahQlXhh60biMRiwO3fiOncZp%2bErJ2mirhW5upaql2me0N4ppjhKZ4i0gs4Jt5w8r5pRZdQIhuy%2fLtbd%2b2paUzBHBWGe%2b0Ar7FswWzFEKeN6sMnqwtkMWBEeuajCVbKzf6UaKLwvi4AvdBrW2CmygNHfRg0bvpfI5dp%2bUfLaNQjb0cv2q7jcCzWc%2faDbEN2f863T%2bF4DmF8%2bcBWfKJ5uOPTqpYrkegOROm5bby06hHw4bWXu7Acp6hR0IuZNQuxabRn8sDHALGbWmB0qC%2fOT6%2fyvybw%3d%3d&RelayState=%2fdotNet%2fdocuments%2f%3fdocid%3d34481)

**Note**: If the study team plans to communicate PHI via text messaging, a secure HIPAA-compliant platform must be used. **RHI**: Individually identifiable health information that is or has been collected solely for the purposes of research. **PHI:** Individually identifiable health information that is or has been collected or maintained by the covered entity in the course of providing healthcare that can be linked back to the individual participant.

The consent form must include a statement that informs the participant that they may receive communication via text message or unencrypted email and a statement that this form of communication is not secure.

**Suggested language (can use a variation of this as long as the same information is communicated):**

The study team may communicate with participants via text messaging or unencrypted email to send information such as study appointment reminders or survey links. These modes of communication may not be secure.

Optional:

The study team may communicate with me for research purposes via text messaging or unencrypted email.

Yes  No

**Genetic Screening/Testing “Rider” – WHEN APPLICABLE**

This language is not required word-for word. If the Sponsor template includes sufficient language regarding genetic testing, this language may not be needed; however, if the Sponsor consent does not include genetic testing language as robust as this language, then this language should be included.

**The following template language should be attached behind the signature page of the primary study consent form and be included in the consecutively numbered pages of the consent (i.e., primary consent page 1 of 5, 2 of 5, 3 of 5, genetic screening rider pages 4 of 5 and 5 of 5).**

**If the study is primarily designed for genetic testing, this template language should be included in the primary consent form rather than be presented as a rider.**

Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person’s risk for certain diseases and how they will respond to treatment.

You are being asked to give a *[Insert type of sample, e.g. blood, urine, etc.]* for genetic research. What we learn about you from this sample (will not be) or (may be) put in your health record. [*If applicable insert:* Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.]

A single [*blood sample of* *X teaspoons or tablespoons will be drawn from a vein in your arm using a needle; cheek swab sample will be obtained by (indicate method); urine sample will be obtained by (indicate method); extra biopsy tissue will be obtained by (indicate method); or other (indicate what) sample will be obtained by (indicate method.*] This will take about *X minutes/hour* of your time.

*If applicable insert:*

**Blood samples** – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

*Otherwise insert all risks, inconveniences or discomforts associated with specific type of sample collection*

[Insert if true, this may not be applicable for personalized medicine testing:] One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only (investigator’s name and/or other’s names) will have access to your name.

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 comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

[COMMERCIALIZATION LANGUAGE OPTION — INSERT THE FOLLOWING, IF APPLICABLE]:

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

[INSERT THE FOLLOWING STATEMENT IF TRUE]:

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

[Insert if genetic portion is optional]

Giving samples for research is your free choice and you may be in the study even if you do not want your samples used or stored for gene research.

At any time, you may ask to have your sample destroyed. You should contact [PI name or study staff] at [insert address/phone number] to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. [Insert if applicable: You will not be paid for the use of your samples.]

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

Yes  No

My blood/tissue sample may be stored/shared for future gene research in \_\_\_\_\_\_.

Yes  No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

Yes  No

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_