**Consent Form Template Language when Using a Non-Vanderbilt Consent Form**

When relying on an external IRB and not using the Vanderbilt consent form template, please include the following elements. The lanauge below provides local context and meets institutional requirements. Please use and adapt the language when modifying the consent and assent forms.

**General Guidance**

* The age of majority in Tennessee is 18 years. Minors who are pregnant or are parents are not automatically emancipated however minors who are married are emancipated.
* Legally Authorized Representatives can consent for cognitively impaired individuals. Absent a LAR, the Surrogate Consent Rider should be used to document a healthcare decision maker for research.
* VUMC does not allow changes to the subject injury language, it is a local policy.
* Typical reading level in Tennessee is 6-8th grade.

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| **The Heading:** | Add “Vanderbilt University Medical Center” or “Vanderbilt University” as part of the heading in the consent form. |
| **The Introduction:** | If not already listed in the heading, identify the name of the Vanderbilt Principal Investigator and name of department in the introductory paragraph. |
| **Reimbursement language (for all studies that provide compensation)**  Include one of the following options, if applicable, without revision or additions: | **Include this language for all studies 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> |
| **Payments for your time spent taking part in this study or expenses (for all studies that provide compensation)** | **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.” |
| **Billing language**  Include one of the following options, if applicable, without revision or additions: | 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 (greater than minimal risk only)**  Include one of the following options with edits only to the red bracketed text. | **Billing for Injury:**  “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.”  **No Billing for Injury:**  “If it is determined by Vanderbilt and the Investigator, with Sponsor input, that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.  There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.”  **Department of Defense (DOD) sponsored research:**  Use of the DOD subject injury language is required when the research is conducted at a DoD component facility- see Policy I.H and X.C.1 for additional guidance. |
| **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://vanderbilt.policytech.com/dotNet/documents/?docid=34481)  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:**  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 |
| **CoC Consent Language**  Required for all studies supported by the NIH or CDC **OR** for (non-NIH) studies that have been awarded a COC. | “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 or future research. Disclosures that you make yourself are also not protected.” |
| **Medical Record Information (for all consent forms)** | **Insert the following statement within the consent form:**  “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.” |
| **HIPAA Authorization language** | **If Protected Health Information (PHI) will be accessed, used, created or disclosed from Vanderbilt medical records:**  Use the standalone HIPAA authorization form on the VHRPP website under “Forms and Tools”  <https://www.vumc.org/irb/template-documents-and-tools> |
| **Contact Information:** | In the section that provides information about whom to contact with questions about the study, provide the Vanderbilt (local) PI’s contact information.  Note: Do not include the Vanderbilt HRPP IRB contact information. The participant should contact the reviewing IRB for concerns or questions about the research. |
| **Testing/Reporting**  **[Communicable Disease]**  For a complete list, visit:  <https://www.tn.gov/health/cedep/reportable-diseases.html> | **Insert reportable test in brackets, when applicable. This includes all communicable diseases. For example, if the study involves Hepatitis B and HIV testing, both tests can be inserted into the red bracketed text.**  As part of this study you will be tested for **[**communicable diseases].  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. |

**Healthcare Surrogate Rider:**

*Instructions: If your study may obtain informed consent from a healthcare decision maker, copy and paste the below information into the end of the consent document for IRB review and approval. For such studies, if the patient consents to enroll in the study, check the ‘not applicable’ checkbox during the informed consent discussion to document that this section is meant to remain incomplete for that participant.*

*This document should not be submitted to the IRB as a standalone document.*

**Surrogate Rider for the Consent Document**

**Not applicable** – This participant did not enroll utilizing a healthcare decision maker and the surrogate consent rider.

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

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Signature of Witness Date

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Name and Signature of person obtaining consent Date

Consent for Genetic Research:

*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: \_\_\_\_\_\_\_\_\_\_\_