JHM Consent/Assent Template Language: **JHM Will Rely on an External IRB**

JHM has agreed to rely on your institution as the Single IRB. Below is a list of language (mandatory and preferred) that must be included in the JHM site-specific versions of the consent/assent forms and waivers of documentation of consent. You may either a) send this language to the External IRB to be incorporated into the JHM site-specific version of the consent/assent form or b) provide us a JHM site-specific version of the consent/assent form with this language incorporated into the External IRB’s approved consent/assent template.

**Written Consent – Mandatory Language**

1. **Key Information**

***The Revised Common Rule requires that the consent form include a concise and focused presentation of information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This “key information” must be presented at the beginning of the consent form.***

1. **Financial Information**

***For studies that include a Prospective Reimbursement Analysis (PRA), you must include language about the Insurance and Research Participant Financial Responsibility Information Sheet.***

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet. This Sheet will give you the following information:

* The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

It may also include the following, if applicable for the study:

* The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

***You must also ensure that the consent includes a signature line:***

**I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.**

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Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

***If participants will be paid, include the following statement:***

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

1. **Future Use of Data and/or Biospecimens**

***The Revised Common Rule requires that the consent form include one of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:***

1. ***A statement that identifiers might be removed from the information or biospecimens and that, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future studies without additional informed consent being obtained.***
2. ***A statement that the information or biospecimens, even if identifiers are removed, will not be used or distributed for future research studies.***
3. **Local Contact Information**

***Please ensure that the JHM IRB version of the consent includes, as a minimum, JHM IRB email address and phone number. The IRB information is:***

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

***If this study includes participants at another site (e.g., KKI, JHCRN site), consult the JHM IRB consent template for the contact information and include the contact information in the consent form.***

***Please include a local emergency contact at each JHM-related site where the research will be performed.***

1. **Communicable Diseases and Requirements for Reporting**

***If applicable, add the following language:***

An HIV test will be done to document your HIV status. You may be asked to sign a separate state-issued consent form for this HIV test. If the HIV test is positive, it does not always mean you are infected with HIV. It does mean you will need further testing and you will receive counseling about this. The law requires us to report positive tests to the health department

As part of being in this study you will have a test for hepatitis (B or C or both). If the results of this test show that you have hepatitis (B or C or both), the law requires us to report this to the health department.

This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by applicable state law.  The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases

1. **Research-related information in the Electronic Medical Record (EMR)**

***<<This language is required for all studies that have a PRA and any study where inclusion of information in the EMR is possible. >>***

An Electronic Medical Record (EMR) is an electronic version of your medical chart. If you do not already have an EMR at Johns Hopkins, one may be created for this study. Some information from this study will be put in your EMR. (Examples include your consent form, test results, and scheduled procedures as well as any communications with the study team or assessments completed through MyChart, a portal used by patients to access their EMR). This information will be visible to any of your providers who view your EMR.

The information in your EMR may also be used and shared consistent with other medical information about you as described in the Johns Hopkins Notice of Privacy Practices.

Information within your EMR can be accessible to others (e.g., health insurance company, life insurance company, disability provider, third-parties specified in this consent). It is possible this information could be used to make decisions about coverage.

If you have any questions about what information may be added to your EMR from participating in this research, please ask the study team. If you do not want information from this research study included in your medical record you should not participate in this study.

1. **Conflict of Interest**

***If applicable, add the following language:***

**What does a conflict of interest mean to you as a participant in this study?**

A researcher has a financial or other interest in this study.

 ***<<For studies that also have an institutional conflict: >>***

A researcher and Johns Hopkins University have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins University. This financial interest has been reviewed in keeping with Johns Hopkins’ policies. It has been approved with certain conditions, which are intended to guard against bias in how the study is conducted, how the results are analyzed, and how participants are protected.

If you have any questions about this financial interest, please talk to *name and telephone number of non-financially interested designee*. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

1. **Subject Injury/Indemnification**

***<<Insert this heading and choose the appropriate section for your consent form:* >>**

What treatment costs will be paid if you are injured in this study?

***<<Insert the following language for all applicable studies except commercially sponsored studies with an IND/IDE held by the commercial sponsor:* >>**

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study.

***<<Insert the following language for studies sponsored by the federal government:* >>**

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

***OR***

***<<Insert the following language for commercially sponsored studies with an IND/IDE held by the commercial sponsor:* >>**

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The study sponsor, ***<<insert study sponsor name*>>**, has agreed to pay the usual and standard costs of treatment or hospital care you receive as a direct result of a study-related injury that are not covered by a health insurer (provided the costs are not the result of care required to treat your underlying disease or condition).

Any costs that are not covered by the study sponsor or a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

1. **Home Visits**

***If applicable, add the following language:***

The research team will comply with applicable state law and will tell the local or state authorities if they suspect abuse or neglect of a child or dependent adult.

1. **Genomic Data Sharing**

***<<Include this section if you will be submitting genomic data to an NIH designated repository>>***

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your health and your individual genes. This information will be sent to a National Institutes of Health (NIH) designated data repository that includes genomic and other data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that may:

* + Increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity);
	+ Affect the progress of a certain disease or condition;
	+ Affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We or our collaborators will remove direct personal identifiers (such as your name or date of birth) and instead code your information before sending it to the repository. The NIH will never receive this code or the personal identifiers we have removed.

The repository is a controlled-access repository. This means that your individual de-identified data is only available to researchers who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not always know what types of health-related research will be done with the data that are sent to the repository.

Genomic summary results (GSR) data for non-sensitive studies may be made available by NIH without controlled-access. GSR data does not include information about you as an individual, but consists of statistical information calculated using your data combined with data from other people.

What are the risks to your privacy?

There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in health insurance and employment.

Are there benefits to sharing your genetic information?

There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

1. **Signature Lines:**

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

**WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

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Signature of Participant (Print Name) Date/Time

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Signature of Person Obtaining Consent (Print Name) Date/Time

***<<If a physician is required to take part in the consent process and will conduct the entire consent process, then the physician should sign above as the person obtaining consent. If the physician will only discuss the risks, benefits, and alternatives, the physician must complete the second signature page and the non-physician consent designee discussing the remainder of the consent should sign above.* >>**

<<***Add any of the following that are applicable for this study and delete any that do not apply****>>*

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Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**FOR ADULTS UNABLE TO CONSENT**

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Relationship of LAR to Participant

(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

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Signature of Parent/Legal Guardian/Court-Appointed Representative (Print Name) Date/Time

**FOR CHILD PARTICIPANT**

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Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

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Signature of Parent #2 (Print Name) Date/Time

(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

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Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

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Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time

(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

**I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.**

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Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT’S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

***<<If a physician is required to take part in the consent process and will not be conducting the entire consent process, then this signature page must be completed and attached to the consent form.* >>**

**DOCUMENTATION OF PHYSICIAN/ADVANCED PRACTICE PROVIDER CONSENT PROCESS**

**My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.**

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Signature of Physician/Advanced Practice Provider (Print Name) Date/Time

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Signature of Participant (Print Name) Date/Time

<<***Add any of the following that are applicable for this study and delete any that do not apply****>>*

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Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

**FOR ADULTS UNABLE TO CONSENT**

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Relationship of LAR to Participant

(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

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Signature of Parent/Legal Guardian/Court-Appointed Representative (Print Name) Date/Time

**FOR CHILD PARTICIPANT**

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Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

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Signature of Parent #2 (Print Name) Date/Time

(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

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Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

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Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time

(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT’S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**Consent for study participants who are unable to read or write, are visually impaired, and/or have physical limitations that prevent them from signing the consent form on their own behalf**

The study participant is unable to sign the consent form on his/her own behalf because he/she has indicated to the study team that he/she is unable to read or write, is visually impaired, and/or has a physical limitation. The consent form has been read to the study participant and to their authorized representative, or to an impartial witness if an authorized representative has not been elected by the study participant or is not present, by a member of the research study team designated to obtain informed consent, and that member of the study team has discussed the information in the consent form with them. The study participant and their authorized representative, or the impartial witness, have been given an opportunity to ask questions and all of their questions have been answered to the study participant’s satisfaction. **The study participant has communicated his/her agreement to participate in the research study by making his/her mark on the participant signature line above, by verbally agreeing to join, or by some other means (e.g. nodding, blinking).**

I attest that the consent information was explained to the study participant and to myself, and that the study participant apparently understood the information, and informed consent was given freely.

**€**  **The participant agreed to join the study verbally or by some other means (e.g. nodding or blinking)**

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***<<Impartial Witness: A person who is independent of the study, who in the absence of an authorized representative for the participant attends the informed consent process, and who reads the participant information and informed consent form and any other written information supplied to the participant. >>***

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**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT’S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**

**Preferred Language**

***Please Note: Each of the following consent elements are required, but the language is preferred – not required. You may use your IRB’s language in lieu of the JHM language provided below.***

1. **HIPAA**

***<<If this consent form will be used at an international site, the appropriate privacy language can be found on the JHM IRB website in the HIPAA Authorization Form for International Research (HIPAA Form 1.1)* >>**

**HIPAA Authorization for Disclosure of Protected Health Information**

**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 Johns Hopkins Medicine 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 who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. 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 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.

**How will your information be protected?**

***<<If the research involves identifiable information, please include the specific steps you will take to minimize the risk of breach of confidentiality e.g. include details of where the data will be stored and analyzed, and who will have access to the data.*>>**

1. **Incidental Findings**

***<<If the research involves an imaging procedure conducted as part of a research protocol and will produce an image of clinical quality, the following incidental findings language should be included. If the image will be read by a centralized reading center, please verify the language aligns with the reading center process.* >>**

As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an “incidental finding.”

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding from an imaging procedure.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

* An incidental finding may cause you to feel anxious.
* Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company’s responsibility.

1. **Pluripotent stem cells**

This research is being done to....

***<<If cell lines will be created, include the following:>>***

Your tissue sample may be used to create a living tissue sample (called a “cell line”) that can be grown in the laboratory.  This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you. Each cell contains your complete DNA.

***<<If iPS cells will be created, include the following:>>***

We may use the cells taken from your [specify source of cells, e.g. skin] to create a type of cell known as a pluripotent cell.  This type of cell can be used to create different types of tissue, including [specify type of cells, e.g. cardiac, muscle, etc.] cells.  Your cells might be used in research involving genetic alteration of the cells.

***<<If organoids will be created, include the following:>>***

We may use the cells taken from your [specify source of cells, e.g. skin] to create what is sometimes called an “organoid”.  An organoid is an organized cluster of cells, grown in the lab, which are designed to mimic organ structure and function.  Organoids can be used to help understand diseases and treatments for them.

***<<If cells or organoids (if applicable) will be used in animal models include the following sentence:>>***

Your cells will *(if known)*/might *(if unknown)* be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

What you should know about the cell lines or organoids (if applicable) that will be derived in the course of this study?

* The cell lines created will be similar or identical to you genetically.
* The cell lines may be kept indefinitely.
* There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.
* The cell lines may be shared with researchers both inside and outside of Johns Hopkins, including our commercial partners.
* The cell lines may be used to develop treatments for a variety of diseases and conditions.

***Describe how the human biological materials will or might involve: (i) the introduction of the cells into humans; (ii) the introduction of the cells into the central nervous system of non-human primates; (iii) the introduction of the cells into non-human animals and whether there is a significant possibility of the cells giving rise to gametes; (iv) the derivation of gametes or embryos; (v) formation of embryo models derived from such cells; or (vi) in vitro culture of chimeric embryos (hPSCs introduced into non-human embryos).***

***Describe (i) whether the donated material will be coded or de-identified prior to research use; (ii) if the donors’ identities are retained (even if coded), whether donors can elect to be contacted to receive information through studies of the cell lines, (iii) that restricted and/or directed donation (e.g., to individuals or groups) are/is not permitted.***

1. **Future Use**

***This language would fulfill the requirement described in Item C: Future Use of Data and/or Biospecimens above (under Mandatory Language)***

***Option A (data only)***

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

We (Johns Hopkins) will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within Johns Hopkins.

If data are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data sharing could change over time, and may continue after the study ends.

The use and sharing of your data are required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

***Option B (data and biospecimens)***

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Examples of biospecimens include blood, tissue, saliva, urine, bone marrow, cells, etc. The specific types of biospecimens that will be collected in this study are described above. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

Future research may include:

* Genetic research: Study of human DNA to find out what genes and environmental factors contribute to diseases. Each cell contains your complete DNA.
* Gene sequencing: Gene sequencing of your DNA provides researchers with the code to your genetic material.
* Cell line creation: Cell lines can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.
* Xenotransplantation: There is the possibility that your cells or the created cell lines might be used in research that will involve genetic manipulation of the cells or the mixing of human and non-human cells in animal models.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way.

One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify, you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data/biospecimen sharing could change over time, and may continue after the study ends.

***<<If collecting/storing biospecimens for future use is mandatory, include the following statement:>>***

The use and sharing of your data and biospecimens are required for participation in this research study. If you are not comfortable with the use of your data/biospecimens in future research without further consent, you should not participate in this study.

***<<If the study would allow the option of not collecting/storing biospecimens for future use, then the following could be added:* >>**

The use and sharing of your data are required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

You can decline the collection and storage of biospecimens for future research.

Will you allow us to store and use the biospecimens we collect for this study for future research?

**Yes € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant

**No € \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Signature of Participant

1. Benefit to Participants

***State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there are no direct benefits, state:***

There is no direct benefit to you from being in this study.

***Describe the generalizable or societal benefits and use a sentence such as:***

If you take part in this study, you may help others in the future. ***Do NOT include financial rewards for participation in the study. Any payment to participants should be included in the “Will you be paid if you join this study” section. Results of tests given to participants and free medical care are not considered benefits. If results will be provided this should be explained in “What will happen if you join this study?***

1. **Radiation**

***For studies using < 0.3 rem***

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage cells, but at low doses, the body is usually able to repair these cells.

The radiation exposure that you will get in this research study is \_\_\_\_\_ rem (a rem is a unit of absorbed radiation). This is less than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food, and soil. The risk from the radiation exposure in this research study is very small.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other medical tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

***For studies using < 5.0 rem***

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays from natural or medical sources can damage the genetic material (DNA) in your cells. At low doses, the body is usually able to repair the damage.

The radiation exposure that you will get in this research study is \_\_\_\_\_ rem (a rem is a unit of absorbed radiation). This is more than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food and soil. It is less than the 5 rems of radiation that is allowed each year for people who are exposed to radiation in their jobs.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

***For studies using > 5.0 – 15 rem***

This research study includes exposure to radiation from x-rays or gamma-rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage the genetic material (DNA) in cells. At low doses, cells usually can repair this damage. There is some possibility that an incorrect repair may increase the risk of cancer in your lifetime. The normal lifetime risk of cancer is 25%. A radiation dose of 15 rems (a rem is a unit of radiation dose) would increase your lifetime risk to 25.6%.

The radiation exposure that you will get in this research study is \_\_\_\_\_ rem. To put that in context, the average person in the United States gets a radiation exposure of 0.3 rem per year from natural sources, like the sun, outer space, air, food and soil. People who work with radiation (for example, x-ray technologists) are allowed a maximum exposure of 5.0 rem each year. Although these levels of radiation are thought to cause an increased risk of cancer, studies in people who work with radiation have rarely shown a measurable increase in cancer risk.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor

1. **GINA**

***<<Insert this paragraph if genetic testing is being done in this study>>***

This study involves genetic testing on samples that you provide. The Genetic Information Nondiscrimination Act (GINA) is a federal law that helps reduce the risk of discrimination by health insurers or employers based on your genetic information. GINA does not protect you from discrimination if you apply for other types of insurance (such as life, disability or long-term care). GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Genetic information is unique to you and your family. Even without your name or other identifiers, it may be possible to identify you or other members of your family with your genetic information.

Johns Hopkins follows procedures so that people who work with your DNA information for research cannot discover it belongs to you, unless you have given consent. However, new techniques may be developed that in the future make it easier to link your genetic data to you, so we cannot promise that your genetic information will never be linked to you.

1. **CERTIFICATE OF CONFIDENTIALITY**

***For NIH-funded studies based in the U.S.***

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.

​​

***For international studies that will collect identifiable data***

This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

**Assent Language**

1. **Assent**

***Insert this statement if the study includes children, except when (a) the child is incapable of understanding the explanation: or, (b) the study intervention offers the prospect of direct benefit to the child that is only available through research.***

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

####

**Waiver of Documentation of Consent Script**

**Protocol Title:**

### <<REMOVE ALL THE INSTRUCTIONS IN RED BEFORE PRINTING>>

**The oral consent process must address all REQUIRED consent elements. Additional elements may be added, as applicable. Click** [here](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/waiver_documentation_consent) **for guidance.**

KEY INFORMATION

<<For applications initially approved after 1/21/19, this section is required.

The revised federal rule governing human subjects research (the “Common Rule”) includes the new element of “key information,” which must be presented at the beginning of the consent document.

The Common Rule defines key information as a concise and focused presentation that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.  Please see link [here](https://www.hopkinsmedicine.org/institutional_review_board/forms/JHMIRB_KeyInformation_Guidance_Dec2018.docx) for more guidance on key information. >>

PURPOSE

You are being asked to take part in a research study. The purpose of this study is…

<<In this section describe the study purpose. It is also a good idea to tell the subject why they are being asked to participate. >>

PROCEDURES

<<Describe procedures, and identify any procedures that are experimental. Include the expected duration of participation (i.e. 15 minutes to complete one survey). >>

<<If your study involves photographs or video/audio recordings, please include the following >>

**Photographs/Video/Audio recordings:**

As part of this research, we are requesting your permission to create and use [description of images and recordings] (e.g., photographs, video recordings, audio recordings) to help answer the research question. Any [insert description of images and recordings] will not be used for advertising or non-study related purposes.

You should know that:

* You may request that the (identify type of imaging/recording) be stopped at any time.
* If you agree to allow the (identify type of imaging and/or recording) and then change your mind, you may ask us to destroy that imaging/recording. If the imaging/recording has had all identifiers removed, we may not be able to do this.

<<Include the bullet below if the information is relevant for the study>>

* We will only use these (identify type of imaging and/or recording) for the purposes of this research.

<<Include the bullet below if the information is relevant for the study>>

* The audio recording will be transcribed by an outside company that has agreed to keep all data confidential.

<<If participants have the choice as to whether to allow the photographs or video/audio recordings and still take part in the study, please include the following>>

***Research Staff: Please indicate the participant’s decision below by checking the appropriate statement:>>***

\_\_\_\_\_\_I **agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use photographs/video recordings/audio recordings of me (or the participant I represent) for the purpose of this study.

\_\_\_\_\_\_I **do not agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use photographs/video recordings/audio recordings of me (or the participant I represent) for the purpose of this study.

RISKS/DISCOMFORTS

<<All research studies have some degree of risk or discomfort. Time burden and discomfort during interviews using sensitive questions are common risks and discomforts of minimal risk studies that use an oral consent process. Example text provided below. >>

**Interviews or questionnaires**

<<If the research involves interviews or questionnaires, include the following: >>

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

**Identifiable private information**

<<If the research involves identifiable private health information, include the following: >>

There is the risk that information about you may become known to people outside this study.

<<It is recommended to include a statement how confidentiality of records identifying participants is maintained. >>

BENEFITS

<<State the direct benefits, or the possibility of direct benefits, that are likely for research participants. >>

<<If there are no direct benefits to individual participants, state: >>

There is no direct benefit to you from being in this study.

<<If there is a potential for direct benefits to individual participants, state: >>

You may or may not benefit from being in this study.

<<Describe the generalizable or societal benefits and use a sentence such as: >>

If you take part in this study, you may help others in the future.

VOLUNTARY PARTICIPATION

You do not have to agree to be in this study. If you do not want to join the study, it will not affect your care at Johns Hopkins.

<<If participants are employees/students at Hopkins: >>

If you do not join, your employment/education at Johns Hopkins will not be affected.

<<Also include any alternative procedures or courses of treatment, if any, that might be advantageous to the participant>>

You can agree to be in this study now and change your mind later. If you wish to stop, please tell us right away. Leaving this study will not stop you from getting regular medical care.

PAYMENT

<<If there is payment for participation, include this separately from the benefits section here. >>

COSTS

<<If there are costs to participation, include those here. >>

IDENTIFIABLE INFORMATION IN FUTURE RESEARCH

<<If the research involves the collection of identifiable private information or identifiable biospecimens, select **ONE** of the following: >>

1. Identifiers (such as name, address, date of birth) might be removed from the information or biospecimens collected and, after such removal, could be used for future research studies or shared with another researcher outside this study team for future studies without additional informed consent.

<<If Option 1 is selected, please use this text>>

<<Include the following paragraphs if the study does not have a commercial sponsor>>

Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

Generally, when sharing information or biospecimens for future research we will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Data/biospecimen sharing could change over time, and may continue after the study ends.

<<Insert the following paragraph if the study has a commercial sponsor>>

By agreeing to be in this study, you allow the Sponsor to use study data/biospecimens for commercial purposes, and to use and share data/biospecimens from this study in the future. Johns Hopkins may also use and share study data for patient care, academic uses and publication, and when required by law.

1. Information or biospecimens, even if identifiers (such as name, address, date of birth) are removed, will not be used or shared for future research studies. Data/biospecimens collected through this study will only be used for this study and will not be used for any future research.

<<If Option 2 is selected, please use this text>>

We will only use data/biospecimens collected through this study for the purposes of this study. Data/biospecimens collected in this study will not be used for any future research, even if identifiers (such as name, address, date of birth, etc) are removed.

<<**Please note**, option 2 means no future research will be done with data/biospecimens collected from this study. If this option is selected, the IRB will NOT grant any future waivers of consent for use of data/biospecimens. >>

HIPAA DISCLOSURE

<<Where appropriate (studies that will collect PHI), add the following language to the script:

<<Include this sentence if you have not previously stated this. >>

We will collect information about you in this study.

<<Always include the following sentences. >>

People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information. The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory.

<<Include one of the following two paragraphs depending on whether this is a single-center, multi-center or sponsored study. >>

<<For single-center non-sponsored studies>>

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who need to make sure the study is being done correctly.

<<For multi-center or sponsored studies>>

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who are involved in the study or who need to make sure it is being done correctly. If the study has a sponsor, people at Johns Hopkins will send your information to that sponsor.

<<For HIPAA language, the following paragraphs are always included. >>

These people will use your information for the purpose of the study.

Your Authorization for the collection, use, and sharing of your information does not expire. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and do not want your information to be used for the study, you must contact the Principal Investigator by using the contact information provided in this document. 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.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.

###  <<If the study has a Certificate of Confidentiality, include the following: >>

### CERTIFICATE OF CONFIDENTIALITY

### 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.

<<If this is a clinical trial that will be registered in clinicaltrials.gov, include the following information>>

A description of this clinical trial will be available on [www.ClinicalTrials.gov](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.

CONTACT INFORMATION:

If you have any questions about this study, please feel free to contact the Principal Investigator <<Insert the PI’s name>> at <<Insert PI’s phone number>> or <<optional: insert PI’s email address>>.

The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.  You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.