**INSTRUCTIONS FOR DRAFTING AN ADULT CONSENT/AUTHORIZATION FORM**

This consent/authorization form template provides sample language for you to use. Your responsibility is to present study information in sufficient detail and to organize the information in a way that facilitates understanding. This is a Word Document; remove this instruction page and the all the *italicized/bolded* instruction language as you complete your form.

To make this form easier to use for most of our faculty and students (and to shorten the main part), we have changed the format. Instead of providing all possible consent form language and asking investigators to delete unnecessary sections, we have provided the basic sections and have taken 9 sections of specialized consent language and put them at the end of this form. If you need to use them, copy and paste the language into the parts of the form where indicated. The basic sections include ***suggested*** language; *you do not need to use the exact words*. When you finalize your form, delete *italicized language,* and all the pages following the Signature page. The 9 sections include:

1. Investigational drug/device/procedure language
2. Photo/video/audio recording language
3. What happens to the data and biospecimens you collect in this study?
4. Genomic Data Sharing
5. Certificate of Confidentiality
6. HIPAA Authorization for Disclosure of Protected Health Information
7. Conflict of Interest
8. Payment of treatment costs if participant is ill or injured in the study
9. Signature language associated with enrolling children in foster care

As you draft your language, consider the following tips:

* Use simple words and short sentences. It’s easier for participants to digest single concepts than multiple concepts in a string. Itemizing using bullet points or tables may also be helpful.
* Do not present information as a list of isolated facts.
* Think about what you, or one of your family members, would like to know if he or she considered joining the study.
* If you have multiple types of participants, consider drafting a consent form (or assent form for minors) that directly addresses each of their roles in the study. For example, there may be participants, participant’s caretakers, children, parents, teachers, etc. Label your document clearly with the identity of the person who will be providing consent or assent for the study.
* If your study involves study drugs, consider taking out the drug risks from the consent form and describing them on a separate form.
* Review the Informed Consent Elements Worksheet that is posted on our website. Include all the sections that are mandatory and select the sections from the “Optional” part of the form that are appropriate to include.
* Review signature lines to make sure they match the context of your study. If you are not enrolling adults who lack capacity to provide informed consent, delete the “LAR” lines; if you are not enrolling children, delete the parental signature lines.
* Use good document control practices to identify your document and its current version.

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**

**ADULT <<*insert participant type as needed*>> INFORMED CONSENT**

*<<include if relevant>>* **AND HIPAA PRIVACY AUTHORIZATION**

**Principal Investigator**:

**Study Title**:

IRB No.:

**Sponsor/Supporter/Funded By:** *<<Please choose the most appropriate descriptor for funded studies. Some funders require that entities providing monetary or material support be listed here. If there are multiple supporters, please list them and identify the type of support. Delete this line if not needed*>>

**PI Version Date:**

**Key Information about the Study**

***BEGIN WITH “KEY INFORMATION”, in the form of a concise (no more than 3 paragraphs) presentation of information most likely to help someone understand why a person might want to participate in the study, and why they might not want to participate. Use bullets to make it easier to read and access, but make sure the bullets connect in a logical way. The information in this concise summary does not need to be repeated in other parts of the document*.** ***The wording below is suggested, not mandated. You may adapt to suit your population****.*

Example:

* We are asking you to volunteer for a research study about *<< topic>>.* We want to learn *<< insert research objective>>. <<You may include collaborator names if you think that would be helpful.>>*
* You do not have to join the study; it is your choice and there is no penalty for not joining. Ask as many questions as you need to help you make your decision. Please review the details outlined in the rest of this consent document before deciding.
* <<*If relevant, explain how you learned about this potential participant and obtained their contact information*.>>
* You may be eligible for this study because you *<< insert eligibility criteria>>*. This study will *<<include something about the scope of the study.>>*
* If you join, we will ask you to *<<provide overview of study procedures. Provide basic details about how long participation will take, where procedures will occur, whether there will be any randomization, etc.- the who/what/where/when/how about procedures>>. <<For medical intervention studies, make clear how participation differs from the alternative standard care provided outside the study.>>*
* If you join the study, *<<describe possible benefits, including direct personal and societal benefits>>.* It is also possible that *<<summarize foreseeable risks, including discomforts, inconvenience, departure from standard care one might receive outside the study, and other reasons why someone might NOT want to join the study; then explain how you plan to reduce those risks and mitigate other concerns.>>*
* *<<Explain financial implications, if relevant – including payment for participation, cost of participation.>>*

**Details about the Study** *[This section should include information not already provided in the Key Information section; you do not need to repeat information. If you have nothing more to add about a particular subsection, just delete it.]*

**Why is this research being done?**

***Continue your description of the study objectives here. You might introduce this section by saying something like:***

As we mentioned earlier, this study is about *<<topic>>.* *<<Provide more information about what the study is designed to discover or establish. If this is a treatment study, describe how it differs from standard clinical care.>>*

***Possible Additional Language Insert << For investigational drug/device/procedures studies, see the special language provided at (1) following the Template’s Consent Signature page.>>***

**Who can join this study?**

***If you have additional information about study participants beyond what is in the Key Information Section, add here. If not, delete this section.***

**What will happen if you join this study?**

***You have already provided a brief introduction to the study procedures in the Key Information section. This is where you should provide more detail so that participants fully understand the commitment you are asking them to make. Do not simply provide lists of facts; do the best you can to make this information clear and accessible to participants.***

If you agree to be in this study, we will ask you to do the following things:

* *<<Describe the procedures chronologically using lay language, short sentences, and short paragraphs.*
* *Blood draw measurements should be provided in teaspoons/tablespoons, ounces, etc.*
* *Use subheadings and bulleted items.*
* *Use tables, flow-charts and other diagrams that might be a helpful visual aid in explaining procedures, visit structure and timelines.*
* *Distinguish which procedures are part of the study and which are standard clinical treatments.*
* *Clarify any change in participant’s care as s/he shifts from standard clinical care to the study intervention.*
* *Define and explain all medical and scientific terms in ordinary language.*
* *Specify the assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of procedures, etc.*
* *For research involving randomization, specify the randomization procedure. For two groups use language similar to “flipping a coin.” If your research includes more than two groups use language similar to “like drawing numbers from a hat.”*
* *For double-masked studies, include a statement that the masking can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out which drug or intervention you are assigned to receive.”*
* *For research involving the use of placebo, clearly define the term placebo. Use language like “A placebo is an inactive product that looks like the study drug, but contains no active drug.”*
* *If results are given to participants or their physicians, include here. >>*

***Possible Additional Language Insert*** *<<If your study involves photographs or video/audio recordings, please include here the special language at (2) following the Template’s Consent Signature page.>>*

**Will research test results be shared with you?**

***If this study involves testing that may generate clinically relevant results, include one of these statements. Otherwise, delete this section:***

This study involves research tests that may produce clinical information that could be useful to you. We will share this information with you. *<< Please be specific about the results you plan to share; clinical test results must come from a CLIA certified lab (U.S.) or national authority (if international). Indicate under what conditions these results will be disclosed. >>*

*OR*

This study involves research tests that we do not expect will be clinically useful for you. We will not share these results with you.

*OR*

It is uncertain if the research tests will produce clinically relevant results, so we will not share these results with you.

**How long will you be in the study?**

*Include this information if you have not already fully explained the time frame for study participation in “What will happen if you join this study?” above. Provide the expected duration (days, weeks or months) of participants’ participation. If not needed, delete***.**

***For the section below about Data, use the parts that are appropriate for your study and delete the rest. The idea is to give participants notice that their data will likely be shared and used beyond this specific study. We have drafted two versions, one for data only and a second for data and biospecimens. Use the version that is appropriate for your study. The section here is the “Data only” version.***

***Possible Additional Language Insert*** *If your study involves data and biospecimens, please replace this section with the “What happens to the Data and Biospecimens…” special language at (3) following the Template’s Consent Signature page.>>*

**What happens to data that are collected in the study?**

***In this section, we try to explain how data will be used and what identifiers will/will not be used or retained. Please include the use of the data for the current study and plans outlined for sharing or future use. These plans should be consistent with your research plan and funding documents.***

The data we collect from you will help advance science and public health. As a participant, you will not own your research data, and you will not benefit financially from any new product or idea that might arise from our work. Sharing of research data is often done to increase what scientists can learn. The data you provide us might be shared

• directly with other researchers, funders, government agencies, publishers of papers

• through government or other databases/repositories

We will do our best to protect the data you provide, and sharing of data would normally only be done anonymously (that is, the data would not be linked to your name, address, or date of birth). If data are shared with identifiers, further review and approval by an ethical review board might be required. *<< If relevant, include: If you are not comfortable with the use of your data in future research, you may not want to participate in this study.>>*

***Possible Additional Language Insert:*** *<<If your study involves depositing genomic data in an NIH GWAS repository, please include here the special language at (4) following the Template’s Consent Signature page.>>*

**What are the risks or discomforts of the study?**

***You have already identified in the Key Information section some of the reasons why someone might not want to join the study. You do not need to repeat what you have already said. In this section you should provide greater detail for risks that require more explanation.***

* *<<Identify each procedure with a subheading and then describe any reasonable risks, discomforts, inconveniences.*
* *Each medication/drug/device used must be listed in this document or in a separate “Study Drug Risk” document that you will go over carefully with the participants. Within subheadings, consider the use of bulleted items.*
* *In a study that poses potential therapeutic benefit, describe the risks associated with joining the study as compared with the risks associated with continuing standard clinical care.*
* *If this is a placebo-controlled study, include the risk that the participant may not receive any therapeutic benefit and the participant’s disease/condition may worsen.*
* *If the study includes a washout period, describe the possible risks of discontinuing medications.*
* *List risks in order of relative probability (e.g., “likely,” “less likely” or “unlikely,” and “rare but serious”). Always include risk of death where this risk exists. To the extent that probability can be quantified by percentages, please include when available.*
* *All drugs that are mandated (i.e., no substitutions permitted) by the protocol, even those that are standard of care, must be included in the procedures section, and the risks that are listed on their package inserts should be described in this section. If applicable, include a list of contraindicated medications.*
* *In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk for the loss of confidentiality of sensitive information. >>*

**Blood Draw**

***If the research involves blood draws, include language like the following:***

Taking blood may cause discomfort, bleeding or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

**Interviews or questionnaires**

***If the research involves interviews or questionnaires, include language like the following:***

You may get tired or bored while we ask you questions or you complete questionnaires. *<<If the questions may be sensitive, include:>>*Some questions may make you feel embarrassed or uncomfortable. Let us know if you feel distressed.

You do not have to answer any question you do not want to answer.

**Personal Privacy**

***If your study’s procedures include the risk of breaching a participant’s expectation of privacy, address how you will protect against such a breach. For example, you may need to protect the participant’s privacy when recruiting or collecting interview information to make sure other people do not hear your discussion.***

**Identifiable private information**

***If the research involves identifiable private information, include the following, and explain how you will mitigate that risk****:*

There is a risk that information about you may become known to people outside this study. We will protect your information to reduce the chance of this happening.

**How will the confidentiality of your data be protected?**

***If the research involves identifiable information, please include the study-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.***

***Possible Additional Language Insert*** *<< For NIH funded studies, see the special language on Certificates of Confidentiality provided at (5) following the Template’s Consent Signature page.>>*

***Possible Additional Language Insert*** *<<If your study involves Protected Health Information from a U.S. Covered Entity, and you need to ask the participant to sign a HIPAA Authorization, please include here the special language at (6) following the Template’s Consent Signature page.>>*

**What are the potential benefits to being in the study?**

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

*If there are no direct personal 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.

***Note: Do NOT include financial rewards for participation in the study as a benefit. Any payment to participants should be included in the “Will you be paid if you join this study” section. In general, standard test results given to participants and free medical care are not considered to be study benefits; however, in resource-poor settings where access to care is truly limited, this position may be reconsidered. If results will be provided this should be explained in “What will happen if you join this study?***

**What are your options if you do not want to be in the study?**

***This section is appropriate for studies that may involve a medical intervention; otherwise, delete.***

* *Describe any alternatives that should be considered before deciding whether or not to be in the study. If applicable, explain why certain procedures are being withheld. If there are no alternatives, state that an alternative is to not take part in the study.*
* *In a potentially therapeutic study, describe the option of continuing with standard clinical care and whether clinical care could include the study intervention proposed.*
* *Avoid suggesting that participation in the research is the only way to obtain medical care and attention.*
* *If other treatments are available to the participant, include the following:*

You do not have to join this study. Otheroptionsinclude*<<describe options, including routine care or dietary or lifestyle options, as applicable. Include a statement informing participants that alternatives should be discussed in detail with their doctor or other health care professionals* >>

*If relevant, end with the statement:*

If you do not join, your care at *<<Johns Hopkins/study partner>>* will not be affected.

*If participants are employees/students at Hopkins:*

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

**Will it cost you anything to be in this study?**

***This section is appropriate for studies that are associated with health services delivery; otherwise, delete.***

***Healthy Volunteer Studies: If billing will not be required, then state “No” as the answer to this question and do not include the text below****.*

*For JHM studies:*

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (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).
* 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.

**Will you be paid if you join this study?**

* *State whether the participant will be paid or offered other types of rewards (e.g., coupons, gift cards; if electronic, follow approved methods). If not, state: No.*
* *List rates of payment or other financial rewards (transportation, babysitting, etc.).*
* *List method and timing of payment, and provisions for partial payment if a participant leaves early.*
* *If U.S. participants will be paid more than $200/year for study participation, 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.

**Can you leave the study early?**

*If appropriate to the study, add some or all of the following statements:*

* You can agree to be in the study now and change your mind later.
* If you wish to stop, please tell us right away.
* Leaving this study early will not stop you from getting regular medical care.
* *<<If participants are Hopkins employees/students:* >> Leaving this study early will not affect your employment/education.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities*.*

***Note: If gradual withdrawal will be required for safety considerations, explain this and any unique procedure(s) required for timely and safe withdrawal****.*

**Why might we take you out of the study early?**

***Insert this heading and section if applicable.***

***If appropriate to the study, add some or all of the following statements:***

You may be taken out of the study if:

* Staying in the study would be harmful.
* You need treatment not allowed in the study.
* You fail to follow instructions.
* You become pregnant.
* The study is cancelled.
* There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities*.*

**Will the study require any of your other health care providers to share your health information with the researchers of this study?**

***Insert this heading and section if applicable.***

As a part of this study, the researchers may ask to see your health care records from your other health care providers*. <<Optional: You will be asked to give us a list of other health care providers that you use.>>*

***Possible Additional Language Insert*** *<<If your study involves a financial conflict of interest on the part of an investigator or JHU, please include here the special language at (7) following the Template’s Consent Signature page.>>*

***Possible Additional Language Insert*** *<<If your study involves potential payment of treatment costs if a participant is ill or injured as a result of participating in the study, please include here the special language at (8) following the Template’s Consent Signature page.>>*

**What other things should you know about this research study?**

***Include these statements if this study is a clinical trial and will be registered at clinicaltrials.gov:***

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

If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

***Include this statement for a blinded study or a study where medical information will not be available to participants until the study is completed:***

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

***The next two sections are important to provide participants with an avenue to obtain help if they need it. If working in settings where telephone access is problematic, or IRBs are not easily reached, provide alternatives. You could also provide contact information on a card instead of relying on a participant’s ability to locate their copy of the consent form. Describe your plan to the IRB in the research plan***

**What is the Institutional Review Board (IRB) and how does it protect you?**

This study has been reviewed by an Institutional Review Board (IRB), a group of people including scientists and community 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 410-955-3193 or jhsph.irboffice@jhu.edu.

**What should you do if you have questions about the study, or are injured or ill as a result of being in this study?**

Call the principal investigator, Dr. \_\_\_\_\_\_\_ at <<insert telephone number>>. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3193.

***<<Include this section if the research is more than minimal risk. A 24 hour number must be included if the research is more than minimal risk to ensure participants have access to a physician for an urgent medical problem>>.***

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Dr. \_\_\_\_\_\_\_ ***<<The Principal Investigator, or if the Principal Investigator is not a medical doctor, include designated physician>>*** at ***<<insert telephone number>>*** during regular office hours and at ***<<insert phone or pager number available 24 hours******>>*** after hours and on weekends. If this doctor is not available, the operator will page the “on call physician.”

**Documenting Participant Choices**

**Photographs/Video/Audio Recordings**

***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 language like the following (along with a checkbox or some other clear marking/coding/choice indicating the response. If they do not have the choice, make clear that they cannot join the study without providing this agreement.***

You may agree to or decline our request to make and use the recording/images described above. Please indicate your decision below by checking the appropriate box.

**Yes € No €**

**Collection/Storage of Biospecimens for Future Research Use**

***If the study would allow the option of not collecting/storing biospecimens for future use, then the following may be added. Include an explanation of how a participant can cancel consent and request biospecimen withdrawal, if that option is available. If the study involves collection of blood and urine, or other biospecimens, make clear which collection is required for study participation, and whether there are options for the future use of the different types of specimens.***

You may agree to <<or decline the collection and storage of biospecimens for future research. Please indicate your decision below by checking the appropriate box. ***<<You may/may not>>*** cancel this consent and request removal of your specimen from storage by contacting the investigator. If the specimen has been shared previously, or if the identifiers have been removed, that will not be possible.

**Yes € No €**

**Future Contact**

***If participants will be asked to allow future contact by the current research team, the yes/no option must include the full signature of the participant. If you include yes/no options, you must track the yes and no responses.***

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research. Please indicate your decision below by checking the appropriate box.

**Yes € No €**

**What does your signature on this consent form mean?**

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.

<<*Include unless you justify not providing a copy of the form>>*

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant (Print Name) Date/Time

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Signature of Person Obtaining Consent (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 NOT CAPABLE of GIVING CONSENT**

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Relationship of LAR to Participant Date/Time

(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 (Print Name) Date/Time

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

**For CHILD PARTICIPANT**

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Description of LAR’s authority under state or applicable local law to act as surrogate health care Date/Time

decision-maker for child research participant (for example, Legal Guardian, court-ordered 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)

**For JHM Only: I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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).**

**Special Language for Different Types of Studies: Use the language below as needed for your study; just cut and paste and insert the section where noted in the text above. Then DELETE this page and all following pages when you finalize your consent form.**

1. **Investigational Drugs/Devices/Procedures:**

**Are there any investigational drugs/devices/procedures?**

*If relevant: <<Broadly identify any drugs/devices/procedures that are investigational, e.g., not approved by the government authority or by an international authority like the World Health Organization (WHO). Details should be included below>>*

***If you are using a drug or device that is not approved for the proposed use by the FDA or the in-country regulatory authority (but which is being used in the study under an IND or IDE or something similar), state that the drug, combination of drugs, device, etc. are investigational and include the following:***

The use of “X” (study drug or device name) in this research study is investigational. The word “investigational” means that “X” is not approved for this use by the <<Food and Drug Administration (FDA)/Country Regulatory Authority.>> The <<FDA/Country Regulatory Authority>> is allowing the use of “X” in this study.

***If you are using a drug or device that*** *is FDA/Country Regulatory Authority - approved****, but will not be used in this study for its approved indications (and is being used in the study under an IND or IDE or the equivalent), include the following:***

“X” (drug or device name) is approved by the FDA/Country Regulatory Authority for the treatment of \_\_\_ (include disease/condition name(s)). It is not approved to treat \_\_\_ (disease/condition name(s)). The FDA/Country Regulatory Authority is allowing the use of \_”X” in this research study.

***If you are using a drug or device that is*** *FDA/Country Regulatory Authority* ***for marketing, but will not be used in this study for its approved indications (and is being used in the study without an IND or IDE, e.g. exempt determination made by the FDA, the in-country regulatory authority or the IRB), include the following:***

“X” (drug or device name) is approved by the <<FDA/Country Regulatory Authority>> for the treatment of \_\_\_ (include disease/condition name(s)). It is not approved to treat \_\_\_ (disease name(s)).

***If you are using a device that is not FDA-approved for marketing, but has been deemed non-significant risk (NSR) or IDE exempt by the FDA or the IRB, include the following:***

The use of “X” (device name) in this research study is investigational. The word “investigational” means that “X” is not approved for marketing by the <<FDA/Country Regulatory Authority>>.

1. **Photographs/Video recordings:**

As part of this research, we would like your permission to [photo, audio/video record images or voices] to help answer the research question. We will not use [insert description of images and recordings] for advertising or non-study related purposes.

You should know that:

* You may ask us to stop (identify type of imaging/recording) at any time.
* If you agree to allow the (identify type of imaging and/or recording) and then change your mind, just ask us to destroy that imaging/recording. If we have already removed identifiers from the imaging/recording, 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>>***

* Audio recordings need to be transcribed for analysis. We will use an outside company that has agreed to keep all data confidential.
1. **What happens to data and biospecimens that are collected in the study?**

*What testing or procedures may be done with your biospecimens?*

Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes ***<< Add the specific tests used in this study such as genetic testing, gene sequencing, cell lines, etc.>>***

***<<See separate Biospecimen Testing Guidance for language to include about specific tests used in this study.>>***

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens may include any of the following: blood, tissue, saliva, urine, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

If you join this study, 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 these efforts.

*How will your data and/or biospecimens be shared now and in the future?*

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:

* directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
* through government or other databases/repositories

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

We will do our best to protect and maintain your data/biospecimens in a safe way. However, when we share data, we limit the uses of the information and whether these data can be shared with another research team. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) new uses of the data/biospecimens do not need further review and approval by an IRB (ethics review board). If we share data/biospecimens with identifiers, new uses may need further IRB review and approval and the IRB will determine whether additional consent from you is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include cell line development, gene sequencing, and genetic testing. This future research may be unrelated to the current study and may include outside collaborators.

Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, we will ask the IRB to review and approve those new uses and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study.

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 identifiers (such as your name or date of birth) and will assign a code to your information before sending it to the repository***.*** The NIH will never receive the key to this code or the 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, for methods to protect the data, and for 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. Information from Johns Hopkins participants that is sent to the repository will only be shared with researchers at other not-for-profit organizations (for example, other academic institutions).

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; it consists only of pooled data -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 blood 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. **What is a Certificate of Confidentiality?**

***Insert this heading and section if the study will collect and store identifiable information if NIH funded, or if Certificate protections have otherwise been granted.***

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 NIH-funded international studies that will collect identifiable data and bring it to a U.S. “covered entity”, like JHM***

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

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

***If this consent form will be used at a U.S. covered entity, e.g., health care provider governed by HIPAA, and will collect Protected Health Information from that covered entity’s electronic medical records, include the following HIPAA Authorization language. Check the JHSPH IRB website for guidance on HIPAA.***

**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. 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.

***Insert this paragraph only if your study involves federally funded Cancer studies:***

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about you to track which groups of people participate in research.  You may contact the NCI if you have questions about how this information is used.

***Insert this paragraph if genetic testing of human DNA 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. **What does a conflict of interest mean to you as a participant in this study?**

***Insert this heading and wording if applicable.***

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 researchers and/or Johns Hopkins.

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

***Insert this heading and choose the appropriate section for your consent form for medical interventions:***

***<<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. *<<OR 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. **Consent form language re: Children in Foster Care**

If you plan to enroll children in Foster Care: add a statement before the parent/guardian/foster parent signature as follows:

“If your child is in the foster care system, additional approval and permission will be required from the Social Services Administration. The PI will apply for that approval and consent.”

**PLEASE CHECK THE LINE BELOW THAT BEST DESCRIBES YOUR ROLE WITH YOUR CHILD:**

**\_\_\_ Parent**
**\_\_\_ Legal Guardian**
**\_\_\_ Foster Parent**​

For school based studies with consent forms sent home with students, if you will exclude children in Foster Care, your parental permission document must include the following on the signature page of the document.

Consent Language: "This study is not open to children that are in foster care or otherwise in the custody of the Department of Social Services (DSS) and placed by DSS in your home.  Please check below and return this letter if the child is in foster care or otherwise placed in your home by DSS.

 ( ) the child is in foster care or placed in my home by DSS.

If you do not call us or check the above and return this letter, you are indicating that the child is not in foster care or DSS custody and you have authority to allow for the child to participate in the study.