March 2023 (doc)

COMBINED INFORMED CONSENT/AUTHORIZATION TEMPLATE

Instructions for developing informed consent/privacy authorization document

Please call the JHM IRB office (410-502-2092) if you have any questions

Drafting the Consent Form

Shaded Instruction Boxes:

Many sections of this document include brief instructions to provide a general overview of information required in the section. **Please delete all shaded instruction boxes before submitting your consent form to the JHM IRB for review.** To delete, select a shaded box and click the cut button on the Word toolbar.

Section Headings:

- 14 point font [Times New Roman is preferred font]
- Section headings marked *Insert if applicable* may be omitted if they do not apply to your study. If Sections are omitted, the paragraphs should be renumbered.

Text:

- 12 point font [Times New Roman is preferred font]
- Suggestions/hints for the text to be written under each heading are included and instructions are shaded blue.
- Please delete all shaded instruction boxes before submitting this form. To delete these shaded boxes, click the "cut" icon in the toolbar at the top of the document.

Header:

- To insert the date of the consent form, the Principal Investigator's name and the application number (for new studies the application number may not be available to you and can be left blank) into the Header, *go to the Toolbar, select View, select "Header and Footer." After inserting your information, select Close.*

Tips on Pagination:

- Once the text of the consent document is complete, format the page numbers. In Microsoft Word, start by clicking on File on the toolbar. Then, click on Print Preview. If, in Print Preview, the numbers do not reset appropriately, return to the document. *Make sure you are not in a "track and change" mode. Go to the toolbar, select View, select "Header and Footer", and then select the footer option. Highlight the page number, right click to select "Update Field."*

Protocol Description:

- The portions of the consent form that are specific to the study must conform to the protocol.
- Individuals taking part in the study should be referred to as participants, not patients.
- The use of the second person (e.g., "You will receive…") is generally required.
- The use of the first person (e.g., "I understand that…") is generally not allowed.
- Guidelines for avoiding common errors in consent forms are on page 3.

Required Paragraphs:

- The HIPAA Privacy Authorization developed by the General Counsel must be included in all consent forms.
- The required institutional boilerplate language is provided under "**What other things should you know about this research study?**"

Reading Level and Spell Checking:

- Your completed version of the informed consent document should be spell checked and proofread before being submitted.
- Investigators are expected to write consent forms in simple language. The preferred reading level is 8th grade.
- Please use the Spelling and Grammar feature of Microsoft Word or Word Perfect to check the reading level of the text of the document that you write (instructions for Microsoft Word are on pages 5 and 6 of this document).
- The standard required institutional boilerplate language under "**How will your privacy be protected?"** and "**What other things should you know about this research study?"** does not have to be checked.

Contact Information for PI or Other Study Team Members:

- Make sure that the address, telephone and fax information inserted into the consent form are current and accurate.

Signature Lines:

- The signature page of the informed consent document must include applicable signature lines for your study.
- Include time and date of signature.
- **DELETE SIGNATURE LINES THAT ARE NOT REQUIRED FOR YOUR STUDY.**

Approved Consent Forms: Only the approved consent form with the JHM IRB approval on the signature page or the JHM IRB Logo (for eIRB protocols) may be used to consent participants for research studies.

Questions or suggestions regarding the template should be sent to the JHM IRB office e-mail address (jhmirb@jhmi.edu).

FOR RESEARCH THAT INCLUDES CREATION OF CELL LINES OR PLURIPOTENT CELLS

FOLLOW INSTRUCTIONS BELOW AND/OR GO TO THE HUMAN PLURIPOTENT STEM CELL RESEARCH INFORMED CONSENT TEMPLATE ON THE JHM IRB WEBSITE FOR INFORMATION REQUIRED IN THE CONSENT FORM.

Section 2: Why is this research being done?

- *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.

- *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 cells 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 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.

Section 3: What will happen if you join this study?

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 there is a significant possibility of the cells giving rise to gametes; or (iv) the creation of gametes or 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.

Common Consent Form Errors

- Do not use “treatment” or “therapy” to describe an investigational drug, device or procedure. For investigational drugs use words like, “study drug” or “study product.” For an investigational device, use words like “study device” or “study product.” For an investigational procedure, use “study procedure” or “research procedure.”

- For investigational drugs or devices, state they are investigational and describe that term (e.g., the word "investigational" means the study drug is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies. Be consistent in using “investigational” throughout the consent form. **Do not describe investigational drugs, devices or procedures as “new.”** The word "medication" or "medicine" should only be used if the drug is commercially available for that particular condition.

- Do not use the term "treatment” or “therapy”" if one of the study arms will use a placebo. Clarify for the participant by using “study drug or placebo,” or “study product,” or “study substance.” Do not refer to a placebo as medicine or medication.

- Use "study doctor" (more understandable to a lay person) instead of “principal investigator."

- Use "research study," instead of "trial."

- Use the word "participant" in the consent form instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to his/her entering the study.

- Do not use the word “invite” (for example, “You are invited to participate in a research study.”) Instead use, “You are being asked to participate in a research study because (insert condition here).”

- When describing randomization for 2 groups use, “like the flip of a coin,” for more than 2 groups, use "like drawing numbers from a hat."

- Do not use e.g. or etc., use instead, "for example," "so forth."

- Spell out acronyms when first used.

- Do not use all capital letters (CAPS) or bold items unnecessarily.

- Use initial lines or check boxes for optional portions of the study (e.g., asking permission to store samples for future research).

- For double-blind studies, include a statement that the blind can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out to what study group you are assigned.”

Assessing Flesch-Kincaid Readability Using Microsoft Word 2013

1. Open the Microsoft Word document for which you would like to assess readability.

2. Select “FILE” in the upper-left hand corner. Then, choose ““Options”. A box opens. Click on “Proofing” on the left hand side of this box. Make sure that check box, titled “Show readability statistics” is selected under “When correcting spelling and grammar in Word” header.

3. Highlight/Select the text which you would like to assess. For consent form purposes, assess the study-related text leaving out any University boilerplate and HIPAA language.

4. Unless you know that your Microsoft Word is set for English (U.S.), then you should select “Review” on the top ”Ribbon”. Then, click on “Language” in the “Language” group and select “Set Proofing Language”.

5. A dialog box will appear. Use the list provided in this box to assure that the appropriate language is highlighted. Usually, this is “English (U.S.)”. Occasionally, studies are targeting a population using another language, or another type of English, such as U.K., Singapore, etc.

6. Once you have selected a language, make sure that the option within this box that reads, “Do not check spelling or grammar” is unchecked.

7. Next, click the “Ok” button at the bottom of this dialog box.

8. Now, select “Spelling and Grammar” icon visible in the “Proofing” group.

9. Microsoft Word will start guiding you through the Spelling and Grammar function. Use this chance to correct spelling/grammar errors that Word may have identified. (Use discretion. This function is not fool proof!)

10. Once Spelling and Grammar are complete, a dialog box will appear asking if you would like to continue checking the remainder of the document. Click “No.”

11. Once you click “No”, a box containing the readability statistics for the selected text will open.

12. The Flesch-Kincaid Grade Level is the last number listed under the Readability section in the dialog box.

13. Click “Ok” to exit Readability Statistics and to continue using this Word document.

Review of Required and Additional Elements

This checklist is provided to help you in the preparation of the consent form.
DO NOT SUBMIT THIS CHECKLIST WITH THE CONSENT FORM.

Verify that the informed consent document contains each of the eight required elements (45 CFR 46.116)

Yes	No	Item #	ITEMS
			8 REQUIRED ELEMENTS
		1a	a statement that the study involves research, and
		1b	an explanation of the purposes of the research, and
		1c	the expected duration of the participant ‘s participation, and
		1d	a description of the procedures to be followed, and
		1e	identification of any procedures which are experimental;
		2	a description of any reasonably foreseeable risks or discomforts to the participant;
		3	a description of any benefits to the participant or to others which may reasonably be expected from the research
		4	a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
		5a	a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and
		5b	if the research is subject to Food and Drug Administration (FDA) regulation, a statement that notes the possibility that FDA may inspect the records
		6a	for research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, and
		6b	an explanation as to whether any medical treatments are available if injury occurs and,
		6c	if so, what they consist of, or where further information may be obtained;
		7a	an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and
		7b	whom to contact in the event of a research-related injury to the participant;
		8a	a statement that participation is voluntary, and
		8b	a statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and
		8c	a statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, which of the following additional elements of information are provided in the consent form?

Yes	NA	Item #	ITEMS
			7 ADDITIONAL ELEMENTS
		1a	a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable; and
		1b	if the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable;
		2	anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent;
		3	any additional costs to the participant that may result from participation in the research;
		4	if this is a clinical trial, a statement that the research will be entered into the clinical trials.gov website;
		5a	the consequences of a participant’s decision to withdraw from the research; and
		5b	procedures for orderly termination of participation by the participant;
		6	a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant
		7	the approximate number of participants involved in the study.

Instructional Template

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title:

Application No.:

Sponsor: *Delete line if not applicable*

Principal Investigator: *Include name, address, phone and fax information*

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

Include this bullet if biospecimens will be collected in the study:

- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

Include these bullets if this study will be in 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 bullet 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 physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

Include this bullet if the study includes children and adults. If the study involves only children, then the term "your child" should be used in the consent form. A Parental Informed Consent/Authorization Template is available on the JHMIRB website for protocols only enrolling children.

- If children and adults can join this study, the word "you" in this consent form will refer to both you and your child.

Include this bullet if the study includes adults who are unable to consent:

- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

Start with an introductory sentence describing the primary purpose of the research as stated in the protocol:

This research is being done to....

- *State what the study is designed to discover or establish. If this is a treatment study, describe the nature of the experimental design and how it differs from standard clinical care (including, for example: projected differences in morbidity and mortality rates, consequent medication differences that might affect participants, what factors the PI considered in choosing the experimental design, etc.) Identify any procedures that are experimental.*
- *If cell lines may be created from tissue samples or iPS cells are used in this research, include the information on page 3 of this template.*
- *If you are using a drug or device that is investigational and is not approved by the Food and Drug Administration, 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 marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of "X" in this study.

If you are using an FDA approved drug or device, but not for an FDA-approved purpose, include the following:

"X" (drug or device name) is approved by the Food and Drug Administration (FDA) for the treatment of ___ (include disease name). It is not approved for use in ___ (disease name). The FDA is allowing the use of _"X" in this research study.

If the FDA may approve the study drug while the research study is in process, include information on whether participants will be responsible for paying for the study drug if it is approved.

Describe the basic eligibility criteria, but DO NOT state that the participant has been selected for the study:

People with _____ may join.

How many people will be in this study?

Include the approximate number of participants expected to take part. If this is a multicenter study, include the total number of participants at all sites, and the approximate number who will take part at Johns Hopkins.

3. What will happen if you join this study?

Start with the statement:

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.*
- *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. For example, volumes should be described in terms of teaspoons or tablespoons.*
- *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 "flipping a coin." If your research includes more than two groups use "like drawing numbers from a hat."

For research involving the use of placebo, clearly define the term placebo. Use language like "A placebo is an inactive substance that looks like the study drug, but contains no active drug"

If results are given to participants or their physicians, include here.

If participants will be asked to allow future contact or to allow optional procedures (e.g., additional blood draws), 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.

If your research will include genetic testing, insert the following:

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or health-related employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law does not apply to other types of insurance (such as life, disability or long-term care).

Despite the GINA protections and the best efforts of the research team to protect your information, you may still be at risk if information about you were to become known to people outside of this study.

If your research will include a request to store biospecimens for future research, include the following:

Request to collect and store biospecimens for future research

As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research. This research could include other diseases.

*If there is the possibility but not certainty that the future research will involve gene sequencing or the creation of cell lines, include the appropriate statement(s) below. If it is known that the study **will** include gene sequencing or the creation of cell lines, language provided on page 3 of this instructional template must be included in the consent form.*

The research may involve research tools such as gene sequencing or the creation of cell lines.

- Gene sequencing of your DNA provides researchers with the code to your genetic material.
- Cell lines are living tissue samples that can be grown in a laboratory. A cell line can provide an unlimited supply of cells in the future without requiring more samples from you. Each cell contains your complete DNA.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading *What happens to Data and Biospecimens that are collected in the study?*.

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

YES € _____
Signature of Participant

NO € _____
Signature of Participant

The following language should always be included for studies where the study team is likely to encounter reportable information as part of the study, e.g. home visits where the study team may observe abuse or neglect of elders or children, or questionnaires about suicidality

Reporting Requirements:

The research team will comply with applicable state law and will tell the local or state authorities if we suspect abuse or neglect of a child or dependent adult, or if we learn of possible harm to yourself or others.

If appropriate, state that the study will involve long-term follow-up.

How long will you be in the study?

Insert the expected duration (days, weeks or months) of participants' participation.

You will be in this study for _____.

4. What are the risks or discomforts of the study?

Identify each intervention with a subheading and then describe any reasonable risks, discomforts, inconveniences, and how these will be managed. Each medication used must be listed. Within subheadings, consider the use of bulleted items.

In a treatment study, 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's disease/condition may not be treated and that the participant's 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 in studies that involve serious underlying disease.

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.

If the research involves genetic material, include the following:

Genetic information is unique to you and your family, even without your name or other identifiers. Johns Hopkins follows procedures to prevent people who work with your DNA information from being able to discover it belongs to you. However, new techniques are constantly being developed that may in the future make it easier to re-identify genetic data, so we cannot promise that your genetic information will never be linked to you.

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.

If the research involves an intervention or the risk profile of any research procedures are not well known, end with the statement:

There may be side effects and discomforts that are not yet known.

5. Are there risks related to pregnancy?

- *Insert this heading and section if applicable.*
- *Describe foreseeable risks to a fetus.*
- *Describe any required pregnancy testing and actions that may be taken if the participant or a participant's partner becomes pregnant. This should also include the requirement of adequate birth control measures for women capable of having children.*
- *If the research involves pregnant women or women capable of having children, and the risk profile of the research procedures on an embryo or fetus are not well known, end with the statement:*

This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there 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 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?

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

- *Describe any alternatives that should be considered before deciding whether or not to be in the study. If applicable, explain why these procedures are being withheld. If there are no alternatives, state that an alternative is to not take part in the study.*
- *In a treatment study, describe the option of continuing with standard clinical care and whether clinical care could include the study intervention proposed.*
- *If the prospective participants are suffering from a terminal illness, and there are no alternative treatments available, you should say so, but you might include some palliative care language.*
- *If the prospective participants have a chronic, progressive disorder for which no treatment has been demonstrated to be safe and effective, say that as well.*
- *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:*

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments include *(describe treatments)*

End with the statement:

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

- *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.*
- *Studies only enrolling at international sites**:** Do not include the text below. Provide whatever cost information is applicable to your study.*

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.

We are required to collect information about your health insurance to register you in our medical record system as a participant and for billing, if applicable.

9. 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 certificates). 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 participants will be paid, include the following statement:*

Payment for research participation is considered taxable income and needs to be reported to the Internal Revenue Service (IRS) when you file your taxes. You may be required to provide your social security number to be paid for taking part in this study. If your total payments from Johns Hopkins exceed the IRS reporting threshold per year, Johns Hopkins will report these payments to the IRS and you will receive a 1099-MISC form from us.

10. 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 you leave 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.

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

11. 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.

12. How will your privacy be protected?

- *If sponsor would like to add further information in this section, you may do so and the JHM IRB will decide if the language is acceptable.*
- *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).*

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, reproductive health care, gender-affirming care, or mental health treatment).

The research team, who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory, will know your identity and that you are in the research study. Other people at Johns Hopkins, including your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. 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.

14. What if there is a Certificate of Confidentiality for this study?

Insert this heading and section if applicable.

<<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 NIH-funded 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.

15. 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, replace the first sentence with: A researcher and Johns Hopkins 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. 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 and to protect participants.

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 JHU SOM Office of Outside Interests (410-361-8667) for more information. This office reviews financial interests of researchers and Johns Hopkins.

16. 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:

Insert the following 3 paragraphs for all studies <u>except</u> 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.

For studies sponsored by the federal government, replace the first sentence with: ***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.***

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.

<u>For commercially sponsored studies with an IND/IDE held by the commercial sponsor, insert the following language:</u>

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.

The following section is required in this format on ALL consent forms.

17. What other things should you know about this research study?

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

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-502-2092. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

If this study is being done in the Johns Hopkins Clinical Research Network (Anne Arundel Health System Research Institute, Greater Baltimore Medical Center, Inova Health System, Peninsula Regional Medical Center, and/or Reading Health System) or if it may include participants at the Kennedy Krieger Institute, include the following:

If you are a participant at Anne Arundel Health System Research Institute, you may contact the AAMC IRB office at 443-481-1320.

If you are a participant at Greater Baltimore Medical Center, you may contact James Mersey, M.D. (Chairman of the GBMC IRB) at 410-828-7417.

If you are a participant at Inova Health System, you may contact the Inova Human Research Protection Program (IRB) at 703-776-3167.

If you are a participant at Peninsula Regional Medical Center, you may contact Timothy Feist, Vice President Performance Improvement/Patient Safety Officer at 410-548-7118.

If you are a participant at Reading Health System, you may contact Sharon House, R.N., IRB Manager at 484-628-5083.

If you are a participant at Kennedy Krieger Institute, you may contact Karen Cox, Vice President and Research Administrator at 443-923-9302.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. _____ at *insert telephone number*. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are 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 410-502-2092.

If this study may include participants at another site include the following:

If you are taking part at All Children's Hospital, call Dr. _____at *insert telephone number.*

If you are taking part at Howard County General Hospital, call Dr. _____ at *insert telephone number*.

If you are taking part at Sibley Memorial Hospital, call Dr. _____at *insert telephone number*.

If you are taking part at Suburban Hospital, call Dr. _____at *insert telephone number.*

If you are taking part at Anne Arundel Health System Research Institute, call Dr. _____at *insert telephone number.*

If you are taking part at Greater Baltimore Medical Center, call Dr. ____ at *insert telephone number.*

If you are taking part at Inova Health System, call Dr. _____at *insert telephone number.*

If you are taking part at Peninsula Regional Medical Center, call Dr. _____ at *insert telephone number*.

If you are taking part at Reading Health System, call Dr. _____at *insert telephone number.*

If you are taking part at Kennedy Krieger Institute, call Dr._____ at *insert telephone number.*

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call *Principal Investigator (If the Principal Investigator is not a medical doctor, include designated physician)* at *insert telephone number* during regular office hours.

A 24 hour number must be included if the research is more than minimal risk to ensure participant has access to a physician for an urgent medical problem.

If you have an urgent medical problem related to your taking part in this study, call *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 you insert a pager number, include the following instructions: **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

If this study may include participants at Anne Arundel Health System Research Institute, Greater Baltimore Medical Center, Inova Health System, Kennedy Krieger Institute, Peninsula Regional Medical Center and/or Reading Health System, include the following:

If you are taking part at All Children's Hospital and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Howard County General Hospital and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Sibley Memorial Hospital and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Suburban Hospital and you have a medical problem related to your taking part in this study, call Dr._____ at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Anne Arundel Health System Research Institute and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Greater Baltimore Medical Center and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Inova Health System and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Peninsula Regional Medical Center and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Reading Health System and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

If you are taking part at Kennedy Krieger Institute and you have a medical problem related to your taking part in this study, call Dr. _____at *insert telephone number.* If this doctor is not available, the operator will page the "on call physician."

d. What happens to Data and Biospecimens that are collected in the study?

If your study does not include biospecimens, you may delete that word from the heading and text

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

If consent for biospecimens is part of this informed consent, include the following:

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

18. Assent Statement

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.

Include the statement below if you will be submitting genomic data to an NIH designated repository

19. What is Genomic Data Sharing?

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 instead code your information before sending it to the repository**.** The NIH will never receive 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 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. 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, 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.

20. 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.

<<If you will enroll participants who cannot sign the consent form (unable to read or write, are visually impaired, and/or have physical limitations), use this additional signature page. If multiple participants are likely to need this signature page, add it to your consent form. For single cases, you may have the page approved as an addendum but do not need to add it to your consent form. You must receive IRB approval to use this form for your study. See instructions >>

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

Signature of Participant (Print Name) Date/Time

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS UNABLE TO CONSENT

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)

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

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

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)

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

Signature of Interpreter/Impartial 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)
<<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. >>

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).

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.

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

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

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS UNABLE TO CONSENT

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)

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

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)

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

Signature of Interpreter/Impartial 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)
<<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. >>

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).