**JOHNS HOPKINS UNIVERSITY**

**HOMEWOOD INSTITUTIONAL REVIEW BOARD (HIRB)**

**RESEARCH PARTICIPANT INFORMED CONSENT FORM**

* *Prepare your informed consent form(s) by editing this document. Instructions for each section are italicized and blue.* ***Delete the instructions when you are finished drafting your form.***
* *Before editing the document, save it with a name appropriate for the form you are preparing.*
* *Enter the date the form was prepared, principal investigator’s name, and application number in the header.*
* ***Use nontechnical language****. It is essential that the form be understandable to participants and should be written at approximately an* ***8th grade reading level.***
* *Most sections are required for all consent forms. A few of the sections — Circumstances That Could Lead Us To End Your Participation, Alternatives To Participation, Costs, and If You Are Harmed By Participating In The Study — should be included only if appropriate for your particular study, as specified in the instructions.*

**Study Title**:

Application No.:

**Sponsor/Supporter/Funded By: *<<Please choose the most appropriate header. It is required 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 applicable*>>**

**Principal Investigator**: ***<<Include name, JHU affiliation, address, email address, and phone information*>>**

***<<This is a required statement for all consent forms>>***

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

***<<Include this statement if cognitively impaired adults will be in the study:* >>**

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.

1. **Research Summary (Key Information):**

***<<This section is required to be completed. Include the following statement:>>***

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

* ***Please provide a concise and focused presentation of key information that is most likely to help potential participants understand why they might or might not want to participate in the study.***
* ***This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study and a statement as to whether there will be any costs associated with participation. The information presented in this section may be discussed in greater detail later in the consent form.***
* ***This summary of key information should be limited to one to three paragraphs, and the total length should not exceed one page.***
* ***Please see the guidance on the Homewood IRB website for further information and examples.***
1. **Why is this research being done?**

***<<Begin as follows:*** *>>*

This research is being done to....

***<<Describe the purpose in a way that makes the potential value of the study clear.>>***

***<<Describe the study population, but DO NOT state that the participant has been selected for the study:* >>**

People with \_\_\_\_\_\_ may join.

***<<OPTIONAL:>>***

We anticipate that about *[insert number]* people will take part in this study.

***<< If you choose to include this information, please make sure the enrollment number(s) match the enrollment number(s) listed in the application and/or protocol. Please note that if you revise your enrollment number(s) in the application and/or protocol, you will need to revise the information here.>>***

***<<If this is a multicenter study and you choose to add the number of participants, include the total number of participants at all sites, and the approximate number who will take part at Johns Hopkins University.*>>**

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

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.***
* ***Use subheadings and bulleted items.***
* ***Define and explain all technical and scientific terms in ordinary language.***
* ***Briefly describe what the participant will be asked to do, and identify any experimental procedures (e.g. non-standard instructional methods)***
* ***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.” >>***

***<<If collecting biospecimens, include: how the samples may or may not be used/analyzed; how long the samples will maintained/when they will be destroyed, who will have access to the samples, if participants can withdraw their samples, and if a link between identifying information and the samples be maintained in any way.>>***

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

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

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

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

Signature of Participant

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

Signature of Participant

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

**Photographs/Video recordings:**

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

You should know that:

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

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

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

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

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

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

Please indicate your decision below by checking the appropriate statement:

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

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

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

Participant Signature Date

(or Legally Authorized Representative Signature, if applicable)

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

***<<If this study involves testing that may generate clinically relevant results, include one of these statements :>>***

This study involves research tests that may produce information that could be useful for your clinical care. We will share this information with you. ***<< Please be specific about the results you plan to share. Indicate under what conditions these results will be disclosed. >>***

***OR***

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

***OR***

It is uncertain if the research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

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

You will be in this study for ***<<Insert the expected duration (days, weeks or months) of participants’ participation.* >>**.

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

***<<Identify any physiological risks/discomforts, and 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 blood draws, include 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.

***<<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 identifiable private information, include the following:* >>**

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

***<<If appropriate, include the following statement:>>***

Participation in this study may involve risks that cannot be foreseen at this time.

***<<For studies involving minimal risk, include the following statement, including or excluding the material in brackets as appropriate:>>***

The risks associated with participation in this study are no greater than those encountered in daily life [or during the performance of routine physical or psychological examinations or tests].

1. **Are there benefits to being in the study?**

***<<*** ***Describe any benefits to the participant that may be reasonably expected from the research. The description should be clear and not overstated.>>***

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

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

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

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

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

This study may benefit society if the results lead to a better understanding of [insert topic].

***<<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. Results of tests given to participants are not considered benefits. If results will be provided this should be explained in “What will happen if you join this study?”* >>**

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

Your participation in this study is entirely voluntary. You choose whether to participate.

***<<Describe any alternatives that should be considered before deciding whether or not to be in the study when (a) the participant may benefit from participating in the study and (b) the same or similar benefits may be obtained in some other way. For example, in the case of an educational study that provides special tutoring to participants, include this section if the same or similar tutoring is also available to students not taking part in the study. If there are no alternatives, state that an alternative is to not take part in the study.***

***<<End with the statement:* >>**

If you decide not to participate, there are no penalties, and you will not lose any benefits to which you would otherwise be entitled.

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

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

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

***<<*** ***Include this section if there are, or may be, any costs to the participant. You may state “No” as the answer to this question, if appropriate.>>***

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

***<<State whether the participant will be paid or offered other types of rewards (e.g., extra credit in a course, transportation reimbursement, coupons, gift cards). If not, state:*** No.

***<<List method and timing of payment, and provisions for partial payment if a participant leaves early or is taken out of the study. For example:***>>

If you satisfactorily complete the study, you will receive $000.00 to compensate you for your participation. $000.00 of this amount is a bonus for completing all of the sessions. If you end your participation before completing the study, you will be paid for your participation up to that time, at a rate of $000.00 per session. Payments are made by check at the end of the study.

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

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

1. **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, without any penalty or loss of benefits.
* If you wish to stop, please tell us right away.
* If you want to withdraw from the study, please [explain what the participant should do to withdraw].
* ***<<If participants are Hopkins employees/students:* >>** Leaving this study early will not affect your employment/education.
1. **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 fail to follow instructions.
* 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 information that it has already collected if the information is needed for this study or any follow-up activities*.*

1. **How will the confidentiality of your biospecimens and/or data be protected?**

**<<Describe to what extent the confidentiality of records identifying the participant will be maintained. For most studies, the following statement will be appropriate:>>**

Any study records that identify you will be kept confidential to the extent possible by law. The records from your participation may be reviewed by people responsible for making sure that research is done properly, including members of the Johns Hopkins University Homewood Institutional Review Board and officials from government agencies such as the National Institutes of Health and the Office for Human Research Protections. (All of these people are required to keep your identity confidential.) Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

**<<Some studies may require disclosure of information to other parties. For such studies, explain what information will (or may) be disclosed and to whom.>>**

**<<Describe how the study records and identifiable information will be created, stored, analyzed, and maintained to protect confidential information (e.g., who will have access to the data, data encryption, password-protection, use of code numbers rather than participants’ names on data sheets, keeping records in a locked file cabinet). >>**

1. **What is a Certificate of Confidentiality?**

***<<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.

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 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.

**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 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 410-516-6580 or hirb@jhu.edu.

**What should you do if you have questions about the study?**

**<<Begin with the following statement, inserting the name and phone number of the investigator or other appropriate contact. More than one contact may be provided if appropriate. For each contact, give his/her role in the study (e.g., Dr. John Smith, the director of the study).>>**

Call the principal investigator, <<insert PI name>> 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 410-516-5680.

You can ask questions about this research study now or at any time during the study, by talking to the researcher(s) working with you or by calling [insert name and role] at [insert phone number].

**<<End with this statement:>>**

If you have questions about your rights as a research participant or feel that you have not been treated fairly, please call the Homewood Institutional Review Board at Johns Hopkins University at (410) 516-6580.

**What should you do if you are harmed by taking part in this study?**

**<<Include this section if the research is of greater than minimal risk and research-related harm (physical, psychological, social, financial, or other) to the participant is possible.**

**Begin with the following statement, inserting the name, role, and phone number of the principal investigator or other appropriate contact:>>**

If you feel that you have been harmed in any way by participating in this study, please call [insert name and role] at [insert phone number]. Please also notify the Homewood Institutional Review Board at Johns Hopkins University at (410) 516-6580.

**<<Then state whether any compensation and/or treatment is available to participants who have been harmed and, if so, describe the compensation/treatment or indicate where further information may be obtained. Make clear whether treatment will be provided without cost to the participant or, instead, the participant will be required to pay.**

**If no compensation or treatment is available, include the following statement:>>**

This study does not have any program for compensating or treating you for harm you may suffer as a result of your participation.

1. **Optional Study Components:**
* ***<<We recommend (but do not require) any optional study components be added to this section of the consent.***
* ***If you choose to use this section, please include all details (procedures, risks, and signature lines) about any optional sub-studies that participants will be invited to take part in.***
* ***If you choose not to use this section, these optional components could be placed in Section 3 “What will happen if you join this study”, or as per preference by sponsor.***

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say “no” to this/these optional component(s).

**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 University from contacting you about other research.

**Please sign and date your choice below:**

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

Signature of Participant Date

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

Signature of Participant Date

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

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form, and you agree to join the study. You will not give up any legal rights by signing this consent form.

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

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

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)

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT.**