#### WAIVER OF DOCUMENTATION OF CONSENT SCRIPT

**Protocol Title:**

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

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

KEY INFORMATION

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

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

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

PURPOSE

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

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

PROCEDURES

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

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

**Photographs/Video/Audio recordings:**

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

You should know that:

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

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

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

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

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

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

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

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

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

RISKS/DISCOMFORTS

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

**Interviews or questionnaires**

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

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

**Identifiable private information**

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

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

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

BENEFITS

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

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

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

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

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

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

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

VOLUNTARY PARTICIPATION

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

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

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

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

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

PAYMENT

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

COSTS

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

IDENTIFIABLE INFORMATION IN FUTURE RESEARCH

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

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

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

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study.

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

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

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

Johns Hopkins protects research data/biospecimens by limiting the type of information that is shared and how it may be used, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups.

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

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

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

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

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

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

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

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

<<Click [**here**](https://www.hopkinsmedicine.org/institutional_review_board/forms/open_access_data_sharing_template_language.docx) for additional template language related to specific data sharing plans (e.g. sharing data for future “general” research use and sharing data via “Open Access”) >>

HIPAA DISCLOSURE

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

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

We will collect information about you in this study.

<<Always include the following: >>

People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information.

The people who may request, receive, or use your private health information include the researchers and their staff, who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory.

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

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

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

<<For multi-center or sponsored studies>>

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

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

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

Your Authorization for the collection, use, and sharing of your information does not expire. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and do not want your information to be used for the study, you must contact the Principal Investigator by using the contact information provided in this document. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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

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

CERTIFICATE OF CONFIDENTIALITY

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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

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

CONTACT INFORMATION

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

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