**\*\*\*REMINDER TO THE STUDY TEAM: ATTACH THE SEPARATE HIPAA FORM WHEN CREATING A PDF VERSION OF THE CONSENT FORM FOR LOCAL USE\*\*\***

**INSTRUCTIONS TO THE STUDY TEAM:** MAINTAIN ALL HEADERS AND TEXT FROM THE SPONSOR’S TEMPLATE. DO NOT INCLUDE THE WEB POSTING AND CRO STUDY # ON THE LOCAL VERSION, THE CRO WILL ADD IT BEFORE POSTING. ADD THE INFORMATION PROVIDED BELOW. INCORPORATE ANY STUDY-SPECIFIC ADDITIONS APPROVED SEPARATELY BY THE CIRB.

COPY THE FOLLOWING MRN BOX ONTO THE SPONSOR’S APPROVED TEMPLATE *BEFORE* THE SPONSOR’S STUDY TITLES:

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

INSERT THE FOLLOWING *AFTER* THE SPONSOR’S STUDY TITLE HEADER:

**JHM IRB Application No.:** <<IRB00xxxx>>

**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**: *<<Name>>*

*<<Mailing address>>*

*<<Email address>>*

*<<Phone information*>>

INSERT THE FOLLOWING *IN* THE ‘If Injured’ SECTION:

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people. The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you. By signing this form you will not give up any rights you have to seek compensation for injury.

INSERT THE FOLLOWING SECTIONS *AFTER* THE ‘More Information’ SECTION:

**What should you do if you have questions about being in the study at Johns Hopkins?**

Contact the Johns Hopkins Principal Investigator at the phone number or address provided on the first page of this consent form.

For more information about the costs of taking part in this study, you may contact the study doctor or research nurse. Contact information is provided on the first page of this consent form. You may also find more information in the “Information and Research Participant Financial Responsibility Information Sheet” provided to you with 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.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute’s Web site athttps://www.cancer.gov/about-cancer/treatment/clinical-trials/paying. You can print a copy of the “Clinical Trials and Insurance Coverage” information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

**What should you do if you are injured or ill as a result of being in this study at Johns Hopkins?**

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

***<<If this study may include participants at another Johns Hopkins site include the following language for each site:* >>**

If you are taking part at ***<<Site Name, i.e.: Johns Hopkins All Children’s Hospital, Howard County General Hospital, Sibley Memorial Hospital, Suburban Hospital>>*** and have questions or you have a medical problem related to your taking part in this study, call ***<<insert PI name>>*** at ***<<insert telephone number*>>** during regular office hours and at ***<<insert phone or pager number available 24 hours >>*** after hours and on weekends.

ADD ‘**Printed Name**’ AND ‘**Time**’ TO THE CIRB’s SIGNATURE LINES. For example:

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

Signature of Participant Printed Name Date/Time

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

Signature of Person Obtaining Consent Printed 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 Parent/Legal Guardian/Court-Appointed Representative Printed 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 Printed 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) Printed Name Date/Time

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

Signature of Interpreter/ Witness to Consent Procedures Printed Name Date/Time

*(optional unless IRB or Sponsor required)*

ADD THE FOLLOWING SECTION AT THE END, AS APPLICABLE:

**Physician/mid-level provider consent discussion**

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

Signature of Participant Printed Name Date/Time

ADD ANY OF THE FOLLOWING SIGNATURE LINES THAT ARE APPLICABLE FOR THIS STUDY AND DELETE ANY THAT DO NOT APPLY:

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Signature of Parent/Legal Guardian/Court-Appointed Representative Printed 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 Printed Name Date/Time

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

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

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

Signature of Interpreter/ Witness to Consent Procedures Printed Name Date/Time

*(optional unless IRB or Sponsor required)*

END WITH THE FOLLOWING:

**My signature below indicates that I have discussed the risks, benefits, and alternatives.**

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

Signature of Person Conducting the Discussion Printed Name Date/Time

**NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).**