NOTE TO CIRB: In addition to the standard boilerplate additions approved by the CIRB with our Institutional Worksheet, we are requesting the following statement(s)/section(s) be added to the study-specific consent form in the location(s) stated in the blue highlight instructions.

NOTE TO JH/ACH STUDY TEAM: Remove the instructions and any sections that do not apply to the study. Submit this document with the Study-Specific Worksheet request. After receiving CIRB approval of the Study-Specific Worksheet, incorporate the CIRB-approved institutional boilerplate additions and the approved sections below to create the local informed consent document.

INSERT THE FOLLOWING SUBSECTION(S) *IN* THE ‘Extra tests and procedures’ SECTION AT THE END OF THE SPONSOR’S TEMPLATE LANGUAGE:

***<<If your study involves communicable disease testing in Maryland (e.g. HIV, Hepatitis B and/or C), include the following>>***

**Communicable diseases:**

The law requires us to report positive tests to the health department.  This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by Maryland law.  The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

***<<If your study involves photographs or video/audio recordings, 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)*** 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>>***

Please indicate your 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.

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

Participant Signature Date

(or Parent/Legally Authorized Representative Signature, if applicable)

***<<If the research involves an imaging procedure conducted as part of a research protocol and will produce an image of clinical quality, the following incidental findings language should be included. If the image will be read by a centralized reading center, please verify the language aligns with the reading center process.* >>**

**Incidental Findings**

As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an “incidental finding.”

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding from an imaging procedure.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

* An incidental finding may cause you to feel anxious.
* Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company’s responsibility.

INSERT THE FOLLOWING *IN* THE ‘Risk’ SECTION AFTER THE SPONSOR’S TEMPLATE LANGUAGE:

***<<Copy the language from the Guidelines for Radiation Statements that is appropriate to the level of radiation exposure for the study. Include one of the following headers or provide an appropriate header relevant to the risk being included.* >>**

**Radiation Risks**

**Radiation Risks from CT-Guided Biopsies**

IF COMPENSATION IS PROVIDED, ADD THE FOLLOWING SECTION *AFTER* THE ‘Cost’ SECTION AFTER THE SPONSOR’S TEMPLATE LANGUAGE, AS APPROPRIATE:

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

* ***<<State whether the participant will be paid or offered other types of rewards (e.g., coupons, gift cards).***
* ***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:* >>**

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.

ADD THE FOLLOWING SECTION *BEFORE* THE ‘Signature’ SECTION:

**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.