**Sample Only (revised 11/14/19) – Cannot be used without IRB Approval**

 **TITLE** [***The repository title must match the title in your application and on your master protocol. Also, include the protocol/grant number if applicable***]:

**PRINCIPAL INVESTIGATOR:** [*PI Name*]

 [*PI Address*]

**CO-INVESTIGATOR(S):** [*Name(s*)]

[***TAKE NOTE****:*

* *A repository is being established when private information and/or biospecimens that will be, or have already been, collected will be stored for future research studies (in addition to, or separate from, any current objectives of any other study). If this is the case, then a separate repository consent form should be developed using this consent form template, and it should be submitted to the IRB for review. This template should also be used for exempt category 7 research studies involving storage, maintenance, and secondary research using identifiable private information or identifiable biospecimens that will be, or have already been, collected for another purpose.*
* *If you will not include any specimens, and your repository is solely for private information, simply delete the language below pertaining to specimens.*
* *You may not combine the repository consent form with the main consent form.*
* *The consent form should be written to conform to the UTHSC IRB template in regard to headings, format, and content. Additional content from the sponsor is allowable for review in the event that it is not repetitive of template content, and this content should be placed at the end of each applicable section.*
* *Lay terms or explanations must be used for all medical terms (consult our lay term glossary at* [*http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php*](http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php) *). Sentence structure should be simple. Do not use abbreviations such as “e.g.” and “i.e.”, difficult-to-understand prepositions such as “via”*, or *symbols such as “+”.*]

**1. KEY INFORMATION:**

[*If your repository includes ONLY children 7 years old and younger, simply write the consent form addressing the parent/legal guardian (ex: “your child”).*] A person who takes part in a research study or repository is called a research subject. In this consent form “your child” always refers to the research subject.

[***OR***]

[*If your repository includes any children 8 years old and older, OR any adults who cannot consent for themselves, edit and include the following:*] A person who takes part in a research study or repository is called a research subject. In this consent form, “you” refers to the research subject [and/or] [*choose:* parent/legal guardian and/or the legally authorized representative].

[***OR***]

[*If your repository does not include either of the above populations, no statement is needed as the consent form should be written in the second person addressing the adult subject as “you”.*]

[*All repositories should include the following 2 paragraphs:*]

You are being given the opportunity to contribute [*edit:* identifiable private information and/or indicate the type of specimen- blood, tissue, etc.] to a repository for research. A research repository is a place where [*edit:* identifiable private information, blood or indicate the type of specimen- blood, tissue, etc.] contributed by persons like you are stored for future research.

The purpose of this consent form is to help you decide if you want your [*edit:* information and/or specimen] to be in the repository.

[*Edit the following sentence to accurately reflect whether information and/or specimens have already been obtained and/or will be obtained, and the reason(s) why:*]

Your identifiable private information [and/or identifiable specimen] has/have already been collected [and/or will be collected], in order to diagnose or treat your illness [and/or for previous research purposes] [and/or for research purposes in the main study, entitled “[enter title]”, associated with this repository].

[*Describe the kinds of medical research for which it is anticipated that information/specimens from the repository will be used. This description must include sufficient detail such that reasonable persons would expect that their consent would permit the kinds of research that will actually be conducted.*

Your identifiable private information and/or identifiable specimen will be used in research studying….

**Procedures:**

[*If more than one visit is involved, or you will contact the subject to collect follow-up information, indicate how long the subject’s participation in the repository will be in hours, days, weeks, months, or years, and whether the visits are in-person, online, via telephone, etc. (When completing sentences, delete all blanks from this template.)*]

Your participation in this repository will last \_\_\_\_\_. You will be called every \_\_\_\_\_ months so that we can collect follow-up information about your health.

The following procedures are being performed for research purposes only:

[*List all procedures that would NOT performed if the subject were NOT participating in the repository, including how many ADDITIONAL blood draws, clinic visits, etc., are being performed for research purposes only. For example:*]

* Copying information such as your medical history, [etc.] from your medical record;
* 2 blood draws

[*The total amount of blood to be drawn solely for research purposes for the repository (in teaspoons/tablespoons) should be provided.*]

You will have a total of 10 tablespoons of blood drawn for research purposes.

[*In simple language, explain what researchers will have access to private information and/or* sp*ecimens from the repository (e.g., specimens might be available to investigators in a particular department, all faculty at the university, colleagues at other academic institutions, personnel from commercial entities, etc.). PLEASE NOTE: this content must accurately reflect what is described in the Confidentiality section of this consent form regarding with whom information/specimens are shared. For example:*]

Your [identifiable private information and/or specimens] from this repository will only be shared with investigators associated with this repository.

[***OR***]

Your [identifiable private information and/or specimens] from this repository may be shared with researchers at [other academic institutions or commercial entities].

[*If the materials will be shared with investigators outside the repository, explain whether these materials will be individually identifiable, coded, or de-identified. PLEASE NOTE: this content must accurately reflect what is described in the Confidentiality section of this consent form regarding with whom information/specimens are shared. For example:*]

Your [information and/or specimens] may be shared with investigators outside the repository, but these materials will be coded [or, will not contain any identifiers] so that outside investigators will not know your identity.

[*All repositories should include the following:*]

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

**Risks:**

[*Indicate in lay terms what the most common (highest in frequency) physical risks involved in collecting the specimens, which are not already associated with procedures being performed as part of the subject’s clinical care. If there are no additional physical risks, this should be stated. For example:*]

The potential risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, lightheadedness, and/or fainting are also possible, although unlikely.

[***OR***]

There are no additional physical risks associated with taking part in this repository, as we will be using a blood specimen that has already been obtained from clinical care purposes or previous research purposes.

[*If applicable, indicate any serious psychological, social, or economic risks. For example, if results of studies using the specimens are relevant to the health of subjects and may be returned to them, then indicate that disclosure of the results may have adverse psychological and social consequences*:]

If test results show that you are positive for \_\_\_\_\_ and you are made aware of this result, it may cause mental stress, unfair treatment from other people, or other unanticipated problems.

[***OR***]

Genetic testing may reveal that you are at increased risk for [breast cancer] compared to the general population. This may cause mental stress, unfair treatment from other people, or other unanticipated problems.

[*All repositories should include the following:*]

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

**Benefits:**

[*In simple language, indicate the possible benefit for both the subject and the ways in which the repository has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the repository, then this should be clearly stated.*]

There are no direct benefits to you for donating a specimen to this repository. Your participation in this repository may provide additional information regarding the possible causes of \_\_\_\_\_\_\_\_\_.

**Alternatives:**

[*In simple language, explain that prospective subjects do not have to participate in the repository. For example*:]

If you do not participate in this repository, none of the procedures described in this consent form will be performed.

[*For repositories associated with a main research study, explain whether subjects may participate in the main study without participating in the repository. For example*:]

You may take part in the main study without participating in this repository.

**Voluntary Participation:**

[*All repositories should include the following:*]

Your participation in this repository is voluntary. You may decide not to participate or you may leave the repository at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

[*For repositories that recruit in clinical care situations, also include the following statement:*]

Deciding to not take part in this repository will not change your regular medical care in any way.

[*If you will be recruiting potential subjects who are students, residents, or fellows (of UT/any school associated with this research) and/or employees (of UT/any institution/agency associated with this research) include the following statements*:]

If you are a student of [*school name*], participating or not participating in this repository will in no way influence your grade in any course. If you are a resident or fellow of [*school name*], participating or not participating in this study will in no way influence your academic standing. If you are an employee of [*name of institution/agency*], participating or not participating in this repository will not affect your employment status.

**2. DETAILED PROCEDURES TO BE FOLLOWED:**

[*Add the following statement only if this is an externally sponsored, multi-center repository:*]

Approximately \_\_\_\_\_ subjects will be participating in this repository at approximately \_\_\_\_\_ centers, and \_\_\_\_\_ subjects will be participating locally.

[***OR***]

[*Add the following statement only if this is a local or a one-site repository:*]

\_\_\_\_\_ subjects will be participating in this repository.

[*Include specific location(s) and the corresponding addresses at which the research procedures will be performed.*]

The repository procedures will take place at \_\_\_\_\_.

[*In simple language, explain the following:*

* *How the specimens will be collected, including the types and amounts of specimens, as well as any other interventions involved in the repository (e.g., use of questionnaires or concomitant review of medical records).*
* *How long the visit(s) will take; if research procedures will occur at a standard of care visit, then indicate how much additional time will be required due to the research procedures.*
* *The amount of blood to be drawn for research purposes at each visit should be given in teaspoons/tablespoons; if there are multiple draws, the total amount of blood to be drawn should also be provided in teaspoons/tablespoons.*

*For example*:]

If you choose to take part in this repository, approximately 2 tablespoons of blood will be drawn from your arm. [*If applicable, add:*]

In addition, the following information will be collected from your medical record:

* Date of birth
* Medical history
* A list of your current medications

You will also be asked to complete a 5-minute questionnaire about your quality of life.

All of this will take 30 additional minutes during your routine doctor visit.

[***OR***]

If you choose to take part in this repository, a small specimen [*provide lay terms for size of specimen*] of [*type of*] tissue will be removed during the surgery to remove the tumor.

In addition, the following information will be collected from your medical record:

* Date of birth
* Medical history
* A list of your current medications

[***OR***]

Leftover blood during your routine doctor visit will be obtained for the repository.

In addition, the following information will be collected from your medical record:

* Date of birth
* Medical history
* A list of your current medications

[*Describe the period of time that the identifiable (or de-identified) private information or identifiable (or de-identified) biospecimens may be stored and maintained (if the period of time could be indefinite, state this). Also describe the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (if the period of time could be indefinite, state this).*]

Your identifiable private information and blood specimen will be kept for 10 years and may be used for research purposes for 10 years.

[***OR***]

Your identifiable private information and blood specimen will be kept indefinitely and may be used for research purposes indefinitely.

[*For repositories involving biospecimens, when it is possible that genetic analysis may be performed, state whether the research will (if known) or might include analyses of the genetic makeup of subjects. This might include sequencing to determine the differences between subjects in terms of disease severity, likelihood of disease progression, and so forth; sequencing of genes that may indicate a disease susceptibility heretofore unknown to the subjects; sequencing to determine pharmacogenomic phenotypes; and whole genome sequencing, i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen. Include an explanation of what genes are and why they may be of interest to investigators. For example:*]

Your specimen [*choose:* will *or* may] be used for whole genome sequencing. Genes are like blueprints in each of your cells that determine traits that you inherit, like eye color and hair color. Genes may also influence what diseases you get and how you respond to treatment. DNA is the substance that makes up your genes. Whole genome sequencing involves learning about the makeup of all your genes.

[*If clinically relevant research results (e.g., general or aggregate information regarding the outcome of the research that could affect/change clinical care for a disease), OR individual research results (i.e., results specific to the subject and his/her health),* ***will not be*** *disclosed to subjects in* ***ANY*** *circumstances, include a statement that such results will not be disclosed to subjects. For example:*]

You will not be informed of any individual research results or general research results of future studies conducted with your [information and/or specimens] that may be relevant to your health.

[***OR***]

[*If at least some clinically relevant research results, including individual research*

*results, may be disclosed to subjects, indicate by whom (the study doctor, a genetic counselor, etc.) AND how (in the clinic, over the phone, by mail, etc.), AND provide a choice to the subject regarding receiving the results.*

*PLEASE NOTE: If you state here that you will return results to subjects, this must be consistent with your application. Further, if you will return results to subjects, future studies that request to use these repository materials will NOT qualify for IRB exempt status under the regulations.*

*For example:*]

If results of the studies conducted with your blood specimen may be relevant to your health, the study doctor will explain the test results to you in the clinic and what they may mean for your health.

Please check the appropriate box below indicating whether or not you want to receive such information:

\_\_\_\_\_ Yes, I do want to receive the results of the studies that are performed on my specimen.

\_\_\_\_\_ No, I do not want to receive the results of the studies that are performed on my specimen.

[*Add the following statement if the subject or parent/legal guardian or* *legally authorized representative will NOT be provided details about specific research studies, including their purposes and types of analyses performed. Specifically state*:]

You will not be informed of the details of any specific research studies that might be conducted using your identifiable private information and/or specimens, including the purposes of the research, and you may not have chosen not to consent to some of those specific research studies.

[*Indicate that subjects may discontinue their involvement by having their specimens and related information destroyed, without any loss of benefits to which they are otherwise entitled. Explain the procedures by which this can be accomplished, including who to contact. For example*:]

You may withdraw or take away your permission for your identifiable private information and identifiable specimens to be used for future research. You do this by contacting the investigator or repository staff and indicating your wishes. Your identifiable private information and identifiable specimens will be removed from the repository, but it will not be possible to secure their return from investigators to whom they have already been provided.

**3. RISKS ASSOCIATED WITH PARTICIPATION**:

[*Indicate in lay terms the physical risks involved in collecting the specimens, which are not already associated with procedures being performed as part of the subject’s clinical care. If there are no additional physical risks, this should be stated. For example:*]

The potential risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, lightheadedness, and/or fainting are also possible, although unlikely.

[***OR***]

There are no additional physical risks associated with taking part in this repository, as we will be using a blood specimen that has already been obtained from clinical care purposes or previous research purposes.

[*If your repository includes questionnaires/surveys with sensitive questions, then include the following:*]

**Questionnaires/Surveys:**

Completion of the \_\_\_\_\_\_\_\_\_ may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time.

[*If applicable, indicate any serious psychological, social, or economic risks. For example, if results of studies using the specimens are relevant to the health of subjects and may be returned to them, then indicate that disclosure of the results may have adverse psychological and social consequences*:]

If test results show that you are positive for \_\_\_\_\_ and you are made aware of this result, it may cause mental stress, unfair treatment from other people, or other unanticipated problems.

[***OR***]

Genetic testing may reveal that you are at increased risk for [breast cancer] compared to the general population. This may cause mental stress, unfair treatment from other people, or other unanticipated problems.

[*Include the following 2 sentences for all repositories:*]

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher’s computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

**4. CONFIDENTIALITY:**

**Research records/specimens**

[*If applicable,* *explain how paper research records will be maintained. For example:*]

All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[*If applicable,* *explain how electronic research records will be maintained. For example:*]

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[***OR***]

All your electronic research records will be kept on an encrypted computer where your information is replaced with a code and password only known to the research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[*If the repository involves the storage of specimens, then explain whether specimens will be labeled with a code while maintained at the local site. For example:*]

Your [*tissue, blood, etc.*] specimen will be labeled with a code.

[***OR***]

Your [*tissue, blood, etc.*] specimen will be labeled with your [*name, medical record number, etc.*].

[*If any individual research records or specimens will be transmitted during the study, explain whether or not the information will contain identifier or be sent using an encrypted method, and whether specimens will be labeled with a code. For example:*]

Your identifiable research records will be transmitted using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below. [***OR***] Your research records will be labeled with a code (will not contain any identifiable information about you) when transmitted.

Your [*tissue, blood, etc.*] will be labeled with a code when transmitted. [***OR***] Your [*tissue, blood, etc.*] will be transmitted in an identifiable form.

[*If coded research records or specimens will be sent to an external research site(s), explain whether or not the master key/list that links the subject’s name with the code will be maintained at the local investigative site*.]

A master key/list which links your name with the code on your [*research record and/or specimen*] will be maintained at [*name the location or site of the repository*].

[*For any repository that involves identifiable private information and/or identifiable biospecimens, add one of the following statements. NOTE that if this is an exempt repository, then the regulations require that the 2nd statement below MUST be included*.]

Identifiers might be removed from your [*choose one or leave both, as applicable:* private information or biospecimens], and after such removal, the information or biospecimens could be used for future research studies outside the objectives of this repository, or distributed to another investigator for future research studies without additional informed consent from you.

[***OR***]

Even if identifiers are removed from your [*choose one or leave both, as applicable:* private information or biospecimens] collected for the repository, these materials will not be used or distributed for research studies outside the objectives of this repository.

**Medical Records**

[*Explain whether documentation of the participation of the subject in the repository, such as a copy of the consent form or other notation will be placed in the subject’s medical record.* ***Note****: If the repository procedures will take place at Regional One Health, University Clinical Health, or Methodist/Le Bonheur facilities, these institutions require that a copy of the consent form be filed in the subject’s medical record. For example:*]

Information about your participation in this repository will be placed in your medical record.  As such, it may be available to your insurer.  However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

[***OR***]

Information about your participation in this repository will not be placed in your medical record.

**GINA**

[***For repositories whose objectives encompass genetic analysis that may reveal the genetic susceptibility of subjects or others to health problems of which they are currently unaware or from which they do not presently suffer, add the following paragraph.***]

A recent federal law, called the Genetic Information Nondiscrimination Act (GINA), provides additional protections for the genetic information about you that may result from this research. GINA makes it illegal for a health insurer to request or use any genetic information about you to make decisions about your eligibility for coverage or your premiums. The law also prevents employers with 15 or more employees from using genetic information to make decisions about hiring, promoting, or firing you. The protections of the law do not apply to insurers providing life, disability, or long-term care insurance.

**Presentations/Publications**

[*Explain whether or not individual subjects will be identified in any presentations or publications based on research performed with repository materials. For example:*]

While individual details about your case might be provided in publications or presentations about research performed with repository materials, they will not be discussed in a way that would allow you to be individually identified as a participant.

**Authorization to Use and Disclose Protected Health Information for Research Purposes**

[*NOTE: This must* ***not*** *be altered with sponsor language, as sponsors are not covered under the HIPAA regulations.*]

Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called “protected health information” or PHI). PHI collected for this repository may include information such as:

[*Edit this list as it applies to this repository:*]

* Past and present medical records
* Records about your repository visit(s)
* Records about phone calls made as part of this repository
* Previous research records

By signing this consent form, you are giving your permission for the investigator and the repository staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

[*Edit this list as it applies to this repository:*]

* The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
* [*if a multi-institutional repository, add*] Researchers at [*name of institutions*]
* [*if a cooperative repository, add*][*the name of the cooperative group*]
* [*if the repository is associated with an FDA-regulated study, add*] The US Food and Drug Administration (FDA)
* [*if applicable, add*] Department of Health and Human Services (DHHS) or other government agencies
* [*if applicable, add*] Governmental agencies in other countries
* [*if repository procedures are taking place at both Methodist and Le Bonheur, add*] Methodist Le Bonheur Healthcare
* [*if repository procedures are taking place at Le Bonheur Children’s Hospital add*] Le Bonheur Children’s Hospital
* [*if repository procedures are taking place at Methodist Hospitals, add*] Methodist Healthcare-Memphis Hospitals
* [*if repository procedures are taking place at Regional One Health, add*] Regional One Health
* [*if repository procedures are taking place at University Clinical Health, add*] University Clinical Health
* [*if repository procedures are taking place at a UT Le Bonheur Pediatric Specialists facility, add*] UT Le Bonheur Pediatric Specialists, Inc.
* [*if your repository has a sponsor, add*] [*name of sponsor*], which sponsors and provides funds for this repository
* [*if applicable, add*] [*name of CRO*], which has been hired by the sponsor to coordinate the repository
* [*if applicable, add*] [*name(s) of institutions and investigators (not already listed on this form) with whom you know you will share identifiable private information and/or identifiable specimens*]
* [*if applicable, add*] Other investigators or institutions that are not yet known

[*If you included a sponsor, CRO, or similar unaffiliated organization in the above bullet point list, add:*] However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

* To do future studies
* To study results of future studies
* To see if the studies were done correctly

[*Provide an expiration date for the authorization by choosing one of the following 3 statements*:]

Your PHI will be used for [*insert timeframe; e.g., 10 years*].

[OR]

[*If the repository is without a foreseeable end point, state*]Your PHI will be used indefinitely.

[***OR***]

[*if the repository is FDA-regulated, state*] Your PHI will be used for as long as the sponsor reports the results of research done with repository materials to the FDA.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the investigator.

When you withdraw your permission, no new PHI will be gathered after that date and your previously gathered PHI in the repository will be destroyed. However, information that has already been shared with investigators using the repository materials cannot be retrieved. The federal regulations allow you to review or copy your PHI that is used in this repository.

**Certificate of Confidentiality**

[*If your repository includes a federal Certificate of Confidentiality, add the following 4 paragraphs:*]

This research is covered by a Certificate of Confidentiality from [*name the federal agency granting the CoC, such as the National Institutes of Health*]. The researchers with this Certificate may not disclose or use information, documents, [*if using or collecting them in this study, add: or biospecimens*] that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, [*if using or collecting them in this study, add: or biospecimens*] protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except when: (1) there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases; (2) you have consented to the disclosure, including for your medical treatment; or (3) the materials are used for other scientific research, as allowed by federal regulations protecting research subjects.

[*Use the following language if this study is sponsored by a federal or state government agency, or is FDA-regulated:*] The Certificate cannot be used to refuse a request [*add the following if sponsored by a federal or state government agency:*] for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [*name the* *federal or state government agency*] which is funding this project [*add the following if FDA-regulated:*] or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

[*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws:*] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [*list what will be reported, such as child abuse and neglect, or harm to self or others*].

[*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants:*] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [*restate what will be disclosed, such as including research data in the medical record*].

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

**5. COMPENSATION AND TREATMENT FOR INJURY:**

[*All repository consent forms MUST include the statements in this section, even if you believe there is no potential for a physical or non-physical injury. If sponsors have different liability or reimbursement language, this can be added after all of UTHSC’s required liability language and can be separated by subheaders if preferable (e.g., “UTHSC’s statements”; “Sponsor X’s statements”.*]

[*All consent forms must include 1 of the 2 following paragraphs. If you are conducting your research at any of the additional sites/organizations in the list below, you must name all of them in each of the 3 sentences of the template paragraph, using only one paragraph. This language should NOT be edited otherwise.*

* *when both Methodist & Le Bonheur are involved, also include:* Methodist Le Bonheur Healthcare
* *when only Methodist hospitals are involved, also include:* Methodist Healthcare-Memphis Hospitals
* *when only Le Bonheur Children’s hospital is involved, also include:* Le Bonheur Children’s Hospital
* Regional One Health
* University Clinical Health
* UT Regional One Physicians
* UT Le Bonheur Pediatric Specialists, Inc.
* UT Methodist Physicians Group
* Methodist Medical Group

[*Use when NONE of the additional institutions in the above list is involved*:]

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee does not provide for treatment or reimbursement for such injuries.

***OR***

[*Use when ONE or MORE institutions in the above list is involved*]

You are not waiving any legal rights or releasing the University of Tennessee, [*name each additional institution*], or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and [*name each additional institution again*] do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and [*name each additional institution again*] do not provide for treatment or reimbursement for such injuries.

[*Edit the 2nd statement below to indicate whether the investigator will provide the medical treatment to subjects in case of a research related injury, provide acute treatment and then refer, or just provide a referral. For example*:]

If you are injured or get sick as a result of being in this repository, call the investigator immediately. The investigator will provide you with a subsequent referral to appropriate health care facilities.

[*For all repositories, include the following sentence. This language should NOT be edited.*:]

If you are injured or get sick as a result of being in this repository, you and/or your insurance will be billed for the costs associated with this medical treatment.

[*For all repositories, include the following sentence. This language should NOT be edited.*]

No compensation will be available to you for any extra expenses that you may have as the result of research related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc*.*

[*For all repositories, include the following sentence. This language should NOT be edited* .]

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

[*In addition to the UTHSC statements above, if the sponsor may reimburse part or all of these costs associated with the treatment of a research related injury, indicate this and any exceptions/limitations. (You may use a separate subheader above the sponsor statements if preferable.) For example*:]

If you have followed the instructions of the investigator, [name of the sponsor] will reimburse you, your insurance company, and/or the hospital for any costs related to a research injury.

**6. QUESTIONS:**

Contact [name] at [number(s)] if you have questions about your participation in this repository, or if you have questions, concerns, or complaints about the repository.

If you feel you have had a research-related injury, contact [name of the principal or co-investigator] at [must be a 24-hour/7-day telephone number(s)]. [***Note****: explain whether the 24-hour/7-day telephone number is an answering service, office number, pager, etc.*]

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the repository.

**7. PAYMENT FOR PARTICIPATION:**

[*If applicable, explain that participants will not be paid for participating in this repository. For example:*]

You will not be paid for contributing your private information and a specimen to this repository.

[*If payment will be made, explain the following:*

* *the amount of the payment, or of each payment if there is more than one*
* *the total possible payment*
* *in what form payments will be made, e.g., cash, check, or type of gift card*
* *when payments will be made*
* *whether payments will be made to the subjects OR their parent/legal guardian OR their legally authorized representative*

*For example:*]

You will receive a check for $\_\_\_\_ for contributing your private information and specimen to the repository. The check will be mailed to you after the visit where you provide your information and specimen for the repository.

[***OR***]

You will receive a $\_\_\_\_\_ gift card to [name of store or entity] for contributing your private information and specimen to the repository. You will be given the gift card at the visit where you provide information and specimen for the repository. If you are 12 and older, the gift card will be given to you; however, if you are under 12 years old, the gift card will be given to your parents for your use.

[*If applicable, if your repository might include subjects who are employees of UT and you are paying subjects using a check or cash, include the following sentence:*]

However, if you are an employee of the University of Tennessee, you will not receive a check or cash; your payment for participation will be added to your paycheck and will be subject to the standard taxes.

[*Indicate whether profit-making activities might result from commercialization of the information and/or specimens collected during the research study (e.g., the development of a marketable diagnostic test), and whether subjects will share in any profits deriving from these activities. For example*:]

Successful research using information about your health and your specimen (even if identifiers are removed) could result in commercial products, such as a drug to treat your disease. You will not share in any financial rewards associated with the development of these products.

 **8. COSTS OF PARTICIPATION:**

[*In simple language, state whether there are any costs to the subject or his/her parent/legal guardian or his/her legally authorized representative for donating a specimen to the repository. For example:*]

There is no cost to you for contributing your private infomration and specimen to this repository.

**9. CONFLICT OF INTEREST:**

[*Include this section in the consent form only if, with respect to the sponsor of the repository, one of the individuals among the key study personnel (including their spouses, parents, or children) has:*

* *Received remuneration from a publicly traded entity in the previous 12 months preceding the disclosure and/or possesses any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000; or*
* *Received remuneration from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when any individual among the key study personnel holds any equity interest in that entity; or*
* *Held intellectual property rights and interests (patents, trademarks, or copyrights) in the drug, device, or other article being tested, and income related to such rights and interest has been received.*

***If no conflict of interest exists, do not include this section in your consent form****.*

*If a conflict of interest exists, insert the following statement*:]

Some subjects want to know whether the investigators or other persons involved in conducting the research repository have a financial interest in the company sponsoring the repository. You should know that [*names(s) of key study personnel with conflict of interest*] [*insert a brief description of the financial interest; e.g., receives consulting fees from or holds the patent on the product being tested, or owns stock in (insert name of company), which provides funds for this repository*].

**10. FUTURE CONTACT:** [***Change this section to “9.” if you have no Conflict of Interest section***]

[*Include and edit the following paragraph if you wish to attempt to find subjects lost to follow up.*]

If we lose contact with you for any reason during the time your materials are stored in the repository (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

* The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the repository or the fact that you are/were participating in a repository.
* Certified mail will be sent to you requesting that you call us.
* A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the repository or the fact that you are/were participating in a repository.
* [*list any other ways that you stated in your application*]

Put your initials on one of the lines below:

\_\_\_\_\_\_\_We CAN attempt to find/contact you in the above ways.

\_\_\_\_\_\_\_We MAY NOT attempt to find/contact you in the above ways.

[*Include this section and EDIT the following paragraph if you wish to retain subjects’ contact information (and PHI) in order to contact them in the future regarding participation in other studies.*]

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about research studies in which you might be eligible to participate.

Put your initials on one of the lines below:

\_\_\_\_\_\_\_We CAN keep your contact information and health information to ask you about participating in future research studies.

\_\_\_\_\_\_\_We MAY NOT keep your contact information and health information to ask you about participating in future research studies.

**CONSENT OF SUBJECT:**

You have read or have had read to you a description of the research repository as outlined above. The investigator or his/her representative has explained the repository to you and has answered all the questions you have at this time. You knowingly and freely choose to contribute to the repository. A copy of this consent form will be given to you for your records.

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

**Signature of Research Subject (18 years +)** **Date Time**

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

**Printed Name of Adult Research Subject**

[***If you are utilizing a Legally Authorized Representative for an incompetent adult subject, then the following 3 lines must be included here, above the Person Obtaining Consent lines:***]

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

**Signature of Legally Authorized Representative Date Time**

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

**Printed Name of Legally Authorized Representative**

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

**Relationship of Legally Authorized Representative**

[***If the repository involves adolescents as research subjects between the ages of 14-17, then the 5 following lines must be included here, above the Person Obtaining Consent lines:***]

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

**Assent of Minor (Ages 14-17) Date Time**

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

**Printed Name of Minor Research Subject (Ages 14-17)**

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

**Printed Name of Minor Research Subject (Ages 0-7)**

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

**Signature of Parent/Legal Guardian Date Time**

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

**Printed Name of Parent/Legal Guardian**

**Check Relationship to Minor:**

* **Parent**
* **Court-Appointed Legal Guardian**

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

**Signature of Person Obtaining Consent** **Date Time**

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

**Printed Name of Person Obtaining Consent**

In my judgment, the subject [*or the parent/legal guardian or the legally authorized representative*] has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this repository.

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

**Signature of Investigator** **Date Time**

[***Note****:* ***If the repository involves children as research subjects between the ages of 8-13, include the following Assent Discussion page as the last page of the consent form. You MUST retain the Assent header on that page which identifies its use with children ages 8-13. If your lower age limit for subjects is greater than 8 and less than 13, please change both instances of “8-13” on the assent discussion page to your lower limit; for instance, “11-13.”***

***If the repository involves adults who do not have the ability to consent but may be able to provide assent, include the Adult Assent Discussion page as the last page of the consent form.***

***Delete the following pages if your repository does not involve children as research subjects between the ages of 8-13 or adults who do not have the ability to consent but may be able to provide assent.***

**A. Assent Obtained:**

The assent discussion was initiated on \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) at \_\_\_\_\_\_\_\_\_\_ (time).

The information was presented in age-appropriate terms.

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

**Minor Subject’s Printed Name (8-13 years) Minor Subject’s Date of Birth**

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

**Minor Subject’s Signature (8-13 years) Date Time**

**\* Please note that the parent/legal guardian must sign the consent signature page above.**

I hereby certify that I have discussed the repository with the minor subject and/or his/her parent/legal guardian. I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research subject was encouraged to ask questions and that all questions were answered.

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

**Printed Name of Person Obtaining Assent**

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

**Signature of Person Obtaining Assent** **Date Time**

**B. Assent Not Obtained, but Minor Subject was Enrolled:**

Assent of the minor subject was NOT obtained for the following reason:

[ ]  Minor is cognitively or emotionally unable to participate in an assent discussion (e.g., minor has either a psychiatric or developmental disorder; minor received narcotics within the last 4 hours; minor is sedated; etc.). [*delete section B if this option does not apply to your repository*]

**C. Assent Was Obtained, but Minor Subject was Unable to Sign:**

[ ]  The minor assented to participation, but has an incapacity that prevents applying a signature (e.g., the subject’s dominant hand is incapacitated, the subject is illiterate, etc.). The assenting subject’s inability to sign the assent document has been duly noted in the research record.

1. **Assent Obtained**

The assent discussion was initiated on \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) at \_\_\_\_\_\_\_\_\_\_ (time).

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

**Adult Subject’s Printed Name**

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

**Adult Subject’s Signature Date Time**

**\* Please note that the legally authorized representative(s) must sign the consent signature page above.**

I hereby certify that I have discussed the repository with the adult subject and/or his/her legally authorized representative(s). I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the research subject was encouraged to ask questions and that all questions were answered.

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

**Printed Name of Person Obtaining Assent**

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

**Signature of Person Obtaining Assent Date Time**

1. **Assent Not Obtained, but Adult Subject was Enrolled**

Assent of the adult subject was NOT obtained for the following reason(s):

[ ]  Adult subject is cognitively or emotionally unable to participate in an assent discussion (e.g., subject has a psychiatric, medical, or developmental disorder; subject received narcotics within the last 4 hours; subject is sedated; etc.). [*delete section B if this option does not apply to your repository*]

**C. Assent Was Obtained, but Adult Subject was Unable to Sign:**

[ ]  The subject assented to participation, but has an incapacity that prevents applying a signature (e.g., the subject’s dominant hand is incapacitated, the subject is illiterate, etc.). The assenting subject’s inability to sign the assent document has been duly noted in the research record.