**Sample Only (revised 2/23/21)– Cannot be used without IRB Approval**

**TITLE:** [***The study 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****:*

* *If you are gathering information about a* ***pregnant participant****, you may describe the data collection procedures for the pregnant participant and infant in the main consent form template. However, if you are gathering information about a* ***pregnant partner*** *and infant, you must use this template to create a separate consent form to be signed by the pregnant partner.*
* *If the protocol requires collecting identifiable information about the newborn infant after delivery for any amount of time after birth, then the infants are research subjects too. This means that the number of research subjects you provide in your IRB study application must account for the total number of: subjects who will participate in the main study, potential pregnant partner subjects, AND potential infant subjects.*
* *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:**

[*All studies should include the following:*]

You [*add if applicable:* and your infant] are being given the opportunity to participate in this observational pregnancy research study. The purpose of this consent form is to help you decide if you want to be in the observational pregnancy research study. In this consent form “you” refers to you and/or your infant.

You became pregnant while you or your partner were taking part in the research study named on the first page of this consent form. The research study is/was testing the experimental [drug, device, vaccine] named [X].

[*If you are using an investigational drug, drug combination and/or device, indicate what is FDA approved and what is investigational, and define the term “investigational”. If a drug is FDA approved but you are using it off-label, explain this as well.*]

[X] is an investigational [drug, device, vaccine]. An investigational [drug, device, vaccine] is one that has not been approved by the US Food and Drug Administration (FDA) as treatment for your/your partner’s condition.

[*State what effects, if any, are known on the developing fetus*]

The effects of [X] are not known on the developing fetus (unborn infant) in humans at this time. The [drug, device, vaccine] [X] that you/your partner is or has been taking may cause problems in your pregnancy or birth defects in the unborn baby you are carrying.

[*In simple language, explain the purpose of the observational pregnancy research study*]

The purpose of this observational pregnancy research study is to provide information about your pregnancy [*add if applicable:* and about your infant after delivery] to the study sponsor [X] (the company that provided the [drug, device, vaccine]) OR [name of institution or federal funding agency] OR study doctor.

[*All studies should include the following:*]

It is recommended that you receive routine prenatal (obstetric) care. Your regular obstetric care is not part of this research study. Your/your partner’s study doctor may need to disclose details of this study to the doctor taking care of you while you are pregnant.

The collection of information regarding your pregnancy and outcomes are for research purposes.

**Procedures:**

[*Describe the research procedures such as information collection, phone calls, and surveys/questionnaires. Indicate how long the subject’s participation in the observational pregnancy research study will be and indicate if participation will last up until the delivery and/or past the delivery date. For example:*]

This observational pregnancy study involves copying health information from medical records. If you agree to provide your health information, it will be copied from your medical record throughout your pregnancy until the delivery of your infant. [*edit if applicable*: If you agree to provide your infant’s information, it will be copied from your infant’s medical records until he/she is one year old.]

The collection of information regarding your pregnancy and outcomes are for research purposes. You [*add if applicable:* or your infant] will not be asked to undergo any additional tests for research purposes.

**Risks:**

[*Describe in lay terms the risks invovled. For example:*]

There is a risk that your [*add if applicable:* or your infant’s] 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 [add if applicable: or your infant’s] confidential information.

[*If surveys or questionnaires will be used, add:*] You may be asked questions about your pregnancy that make you feel uncomfortable. You are not required to answer these questions if you do not want to do so.

[*All studies should include the following paragraph:*]

The research may involve risks to you or to the embryo or fetus, which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**Benefits:**

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

There is no direct benefit to you [*add if applicable:* or your infant] for allowing your health information to be collected. However, this information will help doctors better understand the effects of [X] on the course of pregnancy and in human infants who may have been exposed to [X].

[***Note****: Do not list compensation for participation or free services as a benefit.*]

**Alternatives:**

[*All studies should include the following:*]

You do not have to participate in this research. If you do not participate, you do not have to share any information with the study doctor and/or [sponsor].

**Voluntary Participation:**

[*All studies should include the following:*]

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

If you decide to stop having your [*add if applicable:* or your infant’s] information collected, you should tell the study doctor. Deciding to not release information will not change your regular medical care in any way. If you decide to stop taking part in this research study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

[*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 statement(s)*:]

If you are a student of [*school name*], participating or not participating in this study 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 study will not affect your employment status.

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

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

The study will take place at \_\_\_\_\_.

[*All studies should include the following:*]

You are being asked to provide information on your health, pregnancy, and [*add if applicable:* about your infant’s health after delivery]. We are asking that you allow information concerning the outcome of your pregnancy to be collected and analyzed by [sponsor/institution/PI] to determine if [X] has affected your pregnancy or your unborn baby.

If you, your fetus [*add if applicable:* or newborn infant], experience a medical problem during this time, you may be requested to inform the study doctor, either directly or through your health care provider or obstetrician, until the problem is solved or becomes stable.

[*In simple language, using a bullet point format with headers or a table, explain the following:*

* *The tests and procedures that will be done (including medical record abstraction and all information which will be collected from the medical record)*
* *Which procedures are standard of care and which are for research purposes only. For example:*]

You [*add if applicable:* or your infant] will not be asked to undergo any additional tests other than those that your health care provider would normally perform in taking care of your pregnancy and your fetus [*add if applicable:* or newborn infant].

The medical information that will be collected for research purposes about your progress and outcome of your pregnancy and your unborn [*add if applicable:* or newborn infant] from you and your infant’s doctors includes:

* Your medical history including known history of hereditary diseases
* Previous pregnancy(ies) history and outcomes
* Details about your current pregnancy including date of conception and date of delivery
* Medications used during pregnancy
* Results of any tests taken prior to birth
* Details of any events or assessments that you have during or after birth
* Details of any complications during the pregnancy
* The progress and outcome of your pregnancy
* [*add if applicable:*] Health information about your infant after delivery

**3. CONFIDENTIALITY:**

**Research records**

[*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.).

[*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, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[*If any individual research records will be transmitted during the study, explain whether or not the data will contain identifiers, be sent using an encrypted method. For example:*]

Your identifiable research records will be transmitted to [name the investigative site, data center, etc.] 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 transmitted to [name the investigative site, data center, etc.] and will be labeled with a code (will not contain any identifiable information about you).

[*If coded research records will be sent to an external site(s) during the study, 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 will be maintained at [name the local investigative site].

[*For any research that involves the collection of identifiable private information, add one of the following statements*.]

Identifiers might be removed from your private information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

[***OR***]

Your private information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

**Medical Records**

[*Explain whether documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, will be placed in the subject’s medical record.* ***Note****: If the research study 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 study or the results of procedures performed in this study 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 study or the results of procedures performed in this study will not be placed in your medical record.

**Presentations/Publications**

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

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

[*For all government-sponsored, industry-sponsored, and investigator-sponsored clinical trials of drugs, biologics, or devices, include the following:*]

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**Limits to Confidentiality**

[*Explain any limits to confidentiality. For example:*]

Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

**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 in this study may include information such as:

* Past and present medical records
* Records about your study visits
* Records about phone calls made as part of this research
* Research records

By signing this consent form, you are giving your permission for the study doctor and the study 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 study:*]

* The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
* [*if a multi-institutional study, add*] Researchers at [*name of institutions*]
* [*if a cooperative study, add*][*the name of the cooperative group*]
* [*if the research involves an FDA-regulated drug/device/biologic, 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 research procedures will be billed to the subject’s insurance, add*] Your medical insurance provider
* [*if research procedures are taking place at both Methodist and Le Bonheur, add*] Methodist Le Bonheur Healthcare
* [*if research procedures are taking place at Le Bonheur Children’s Hospital add*] Le Bonheur Children’s Hospital
* [*if research procedures are taking place at Methodist Hospitals, add*] Methodist Healthcare-Memphis Hospitals
* [*if research procedures are taking place at Regional One Health, add*] Regional One Health
* [*if research procedures are taking place at University Clinical Health, add*] University Clinical Health
* [*if research procedures are taking place at a UT Le Bonheur Pediatric Specialists facility, add*] UT Le Bonheur Pediatric Specialists, Inc.
* [*if your study has a sponsor, add*] [*name of sponsor*], which sponsors and provides funds for this research
* [*if applicable, add*] [*name of CRO*], which has been hired by the sponsor to coordinate the study
* [*if applicable, add*] A Data and Safety Monitoring Board (DSMB)

[*If you included a sponsor, CRO, DSMB, or similar unaffiliated organization in the above bullet point list, you must 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 the research
* To study the results
* To see if the research was done correctly

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

Your PHI will be used until the study is completed.

[***OR***]

[*if the research is FDA-regulated, state*] Your PHI will be used for as long as the sponsor reports study information to the FDA.

[***OR***]

[*if the research is without a foreseeable end point, such as a repository or a registry, state*]Your PHI will be used indefinitely.

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 study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

[*If the research study includes treatment of subjects, add the following sentences.*]However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

**Certificate of Confidentiality** [*If your study 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 or documents 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 or documents 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.

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

[*All studies utilizing a main consent form 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***

[***Example*** *for 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 study doctor will provide the medical treatment to subjects in case of a research related injury, provide acute treatment and refer, or just provide a referral. For example*:]

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

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

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

[*For all studies, 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 studies, 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 study doctor, [name of the sponsor] will reimburse you, your insurance company, and/or the hospital for any costs related to a research injury.

**5. QUESTIONS:**

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

If you feel you have had a research-related injury [*or a reaction to the study drug*], 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 research.

**6. PAYMENT FOR PARTICIPATION:**

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

You will not be paid for participation in this *observational pregnancy research study*.

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

* *the amount of each payment*
* *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*
* *whether subjects will receive a bonus payment if they complete the entire study*

*For example:*]

You will receive a check for $\_\_\_\_, mailed to you after each completed study visit. If you complete all the study visits, you will receive a maximum payment of $\_\_\_\_\_\_. If you do not complete the study, you will be paid for the visits you have completed.

[***OR***]

You will receive a $\_\_\_\_\_ gift card to [name of store or entity] at the completion of each study visit. If you complete all the study visits, you will receive a total of \_\_\_\_\_ gift cards worth $\_\_\_\_\_\_. 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 study 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.

**7. COSTS OF PARTICIPATION:**

[*Explain whether there are any costs to the subject. If there are, explain whether insurance will be billed and who will pay if insurance does not.*]

There are no costs to you for participating in this observational pregnancy research study.

The study sponsor and the study doctor will not be responsible for the costs related to you pregnancy, delivery, or care of your infant.

**8. CONFLICT OF INTEREST:**

[*Include this section in the consent form only if, with respect to the sponsor of the research, 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 study have a financial interest in the product being tested or the company sponsoring the research. You should know that [*name(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 research project*].

**9. 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 during the study for any reason (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 study or the fact that you are/were participating in a study.
* 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 study or the fact that you are/were participating in a study.
* [*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 and edit the following paragraph if applicable to your study, such as with investigational drug and device studies.*]

Please note that if we lose contact with you and there is new information about your participation in the study that could affect your/your infant’s safety, we will attempt to find you or make contact with you in any way possible.

[*Include and edit the following paragraph if you wish to retain subjects’ contact information and PHI, including screening results, 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 other 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 [*add if applicable:* , as well as your infant’s health information,] to ask you about participating in future studies.

\_\_\_\_\_\_\_We MAY NOT keep your contact information and health information [*add if applicable:* , as well as your infant’s health information,] to ask you about participating in future studies.

**10. CONSENT OF SUBJECT/PREGNANT PARTNER:** [***Change this section to “9.” if you have no Conflict of Interest section***]

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. 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 research study involves the collection of identifiable information about the infant upon or past the date of delivery, then the 3 following lines must be included here, above the Person Obtaining Consent lines:***]

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

**Printed Name of Infant if known**

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

**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 legally authorized representative*] has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

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

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

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 research project 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 if option does not apply to your study*]

Adult subject refused to provide assent; however, the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the adult subject and is available only in the context of the research. [*delete if option does not apply to your study*]

**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.