**Boilerplate Language for Consents**

**The following are main areas of boilerplate language that must be considered:**

1. **Use of UTHSC letterhead**
2. **Authorization to Use and Disclose Protected Health Information for Research Purposes (if the UTHSC IRB will act as the Privacy Board for the study)**
3. **Participant injury**
4. **Contact information**
5. **Signature lines**

**Instructions are in italics and highlighted in yellow. Delete the highlighted instructions and information that is not applicable for your specific study before submitting to an IRB**.

1. **Use of UTHSC Letterhead**

[*The consent form must be prepared on UTHSC letterhead according to the current UTHSC IRB consent form template*.]

|  |  |
| --- | --- |
|  | https://brand.uthsc.edu/wp-content/uploads/uthsc-campus-logo-stacked.jpg |

1. **Authorization to Use and Disclose Protected Health Information for Research Purposes (if the UTHSC IRB will act as the Privacy Board for the study)**

**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.

1. **Participant Injury**

**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 sub-headers if preferable (e.g., “UTHSC’s statements”; “Sponsor X’s statements”.*]

[*Choose one of the following 8 paragraphs; however, if you are conducting your research at several of the sites/organizations mentioned 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.*:]

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*** *when Regional One Health is involved*]

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

[***OR*** *when both Methodist & Le Bonheur are involved*]

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

[***OR*** *when Methodist hospitals are involved*]

You are not waiving any legal rights or releasing the University of Tennessee, Methodist Healthcare-Memphis Hospitals, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Methodist Healthcare-Memphis Hospitals do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Methodist Healthcare-Memphis Hospitals do not provide for treatment or reimbursement for such injuries.

[***OR*** *when Le Bonheur is involved*]

You are not waiving any legal rights or releasing the University of Tennessee, Le Bonheur Children’s Hospital, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Le Bonheur Children’s Hospital do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Le Bonheur Children’s Hospital do not provide for treatment or reimbursement for such injuries.

[***OR*** *when University Clinical Health is involved*]

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

[***OR*** *when UT Regional One Physicians is involved*]

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

[***OR*** *when UT Le Bonheur Pediatric Specialists, Inc. is involved*]

You are not waiving any legal rights or releasing the University of Tennessee, UT Le Bonheur Pediatric Specialists, Inc., or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and UT Le Bonheur Pediatric Specialists, Inc. do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and UT Le Bonheur Pediatric Specialists, Inc. do not provide for treatment or reimbursement for such injuries.

[*Edit the 2nd statement 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.

1. **Contact Information**

**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.

1. **Signature Lines**

**CONSENT OF SUBJECT:**

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 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 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 research study.

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

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

**Assent Discussion for Subjects 8-13 Years of Age:**

[***Note****:* ***If the research study 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 study 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 study 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 research project 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 if option does not apply to your study*]

[ ]  Minor 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 minor and is available only in the context of the research [45 CFR 46.408(a)]. [*delete if option does not apply to your study*]

**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.

**Assent Discussion for Adult Subjects**:

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.