**Boilerplate Language for Consents**

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

1. **Use of UTHSC or UTCOMC letterhead**
2. **Participant injury**
3. **Contact information**
4. **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 [*or UTCOMC if at the Erlanger/UTCOMC Campus*] 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  [*OR if at the Erlanger/UTCOMC Campus, the consent form must be prepared on UTCOMC letterhead*  *according to the current UTCOMC consent form template]*  C:\Documents and Settings\hendrisb\Local Settings\Temporary Internet Files\Content.Word\COMChattCentered (4).jpg |  |

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.

[***OR*** *when Erlanger Health System is involved*]

You are not waiving any legal rights or releasing Erlanger Health System or UT College of Medicine or its agents from liability for negligence. In the event of physical injury resulting from research procedures, Erlanger Health System and UT College of Medicine do not have funds budgeted for compensation either for lost wages or for medical treatment.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

[*Edit the 2nd statement to indicate whether the study doctor will provide the medical treatment to participants 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.

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 participant, or if you have questions, concerns, or complaints about the research.

*[OR if at the Erlanger/UTCOM Campus, use the following contact information for the UTCOM IRB instead*:]

Questions about your rights as a research subject: You may contact the UT College of Medicine Institutional Review Board (IRB) at 423-778-3818. The IRB is a group of people that reviews studies for safety and to protect the rights of study subjects.

1. **Signature Lines**

A line must be inserted for the research participant’s initials or initials of the LAR (\_\_\_\_\_) at the bottom of all pages except the signature page (where the line for initials is permitted but not necessary).

**CONSENT OF PARTICIPANT:**

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

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

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

**Printed Name of Adult Research Participant**

[***If you are utilizing a Legally Authorized Representative for an incompetent adult participant, 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 participants 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 Participant (Ages 14-17)**

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

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

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

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

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

**Printed Name of Parent/Legal Guardian**

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

**Relationship to Minor (Parent or Court-Appointed Legal Guardian)**

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

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

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

**Printed Name of Person Obtaining Consent**

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

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