

Social Behavioral Consent Form**Sample Only (created 11/14/19)– 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 your study will include any biomedical or physical procedures, such as drawing blood, collecting saliva, performing an EKG, conducting genetic testing, using drugs/devices, etc., you must use the UTHSC main consent form template. The social behavioral template is ONLY intended for use in studies employing interviews, surveys/questionnaires, focus groups, individual/group counseling, behavioral interventions, diaries, educational testing, medical record review, etc.*
- 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>). 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 “+”.*
- You may not combine a repository consent form with the social behavioral consent form. A repository is being established when identifiable private information 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).]*

1. KEY INFORMATION:

[Insert Preparation Date]

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Subject Initials _____
[OR]

Subject or Parent/Legal Guardian Initials _____
[OR]

Parent/Legal Guardian Initials _____
[OR]

Subject/Legally Authorized Representative Initials _____

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[If your study 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 is called a research or study subject. In this consent form “your child” always refers to the research subject.

[OR]

[If your study 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 is called a research or study subject. In this consent form “you” refers to the research subject **[and/or]** **[choose:** the parent/legal guardian **and/or]** the legally authorized representative].

[OR]

[If your study 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 studies should include the following:]

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

[In simple language, explain why the research is being done and what the experimental components are.]

The purpose of this study is to...

Procedures:

[Provide in lay terms a basic description of the design of your study.]

In this study, we will be collecting data from your medical record as you complete visits for your clinical care. We will also be asking you to complete some additional questionnaires about your quality of life.

[OR]

In this study, we will randomize subjects between different treatment groups to compare their efficacy and safety.

[If the study involves randomization choose from one of the following statements. If the study does not involve randomization, delete the following three paragraphs.]

[If subjects will be randomized in a 2-arm trial where only 1 arm is experimental, explain the following:]

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You will be randomly assigned (like the flip of a coin) to receive [treatment group A, experimental] or [treatment group B]. You have a ___ in ___ chance of receiving [treatment group A], the experimental treatment. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. It is not known whether the experimental treatment is as good as, better than, or worse than the standard treatment.

[OR]

[If subjects will be randomized in a 2-arm trial where both arms are standard treatment, explain the following:]

You will be randomly assigned (like the flip of a coin) to receive [standard treatment group A] or [standard treatment group B]. You have a ___ in ___ chance of receiving [standard treatment group A or B]. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. It is not known whether [standard treatment A] is as good as, better than, or worse than [standard treatment B].

[Indicate how long the subject's participation in the research study will be in hours, days, weeks, months, or years.]

Your participation in this study will last _____.

[Indicate also (if applicable) whether you intend to collect follow-up information and how long this will be done, e.g., for 6 months after the last study visit]

[Indicate how many total visits there are, how often the visits are, and whether the visits are in-person, online, via telephone, etc.]

The following procedures are being performed for research purposes only:

[List all procedures that would NOT be performed if the subject were NOT participating in the study, including how many ADDITIONAL 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 group counseling sessions; and
- 3 questionnaires.

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[All studies should include the following:]

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

Risks:

[Describe in lay terms the most common (highest in frequency) risks of the research procedures and the most serious risks (greatest in magnitude), even if the latter rarely occur. For example:]

Some of the most common side effects from study participation are uncomfortable feelings during the questionnaires and tiring during the group sessions. Discussing the sensitive questions that are asked in group could also cause you to experience and dwell on feelings of sadness, anger, or anxiety (such as with posttraumatic stress disorder), but this does not occur often.

[All studies 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 study has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.]

Your *[name of condition and/or name specific symptoms]* may improve while you are in this study; however, this cannot be promised.

The results of this study may help people with *[name of condition]* in the future by *[insert ways]*.

[OR]

You will not receive any direct benefits from being in this study. The results of this study may help people with *[name of condition]* in the future by *[insert ways]*.

[OR]

[For active controlled trials: The discussion of potential benefits should distinguish between subjects receiving standard therapy and those receiving experimental therapy. For example:]

If you are randomized to receive standard therapy, it is likely to be as safe and effective in treating *[name of condition and/or name specific symptoms]* as it is when given outside the research setting. If you are randomized to receive *[experimental therapy]*, its safety and effectiveness in treating *[name of condition and/or name specific symptoms]* may be the same as, better than, or worse than standard treatment. The benefits of the *[experimental therapy]* are less certain because it is still being tested for the treatment of your condition.

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The results of this study may help people with [name of condition] in the future by [insert ways].

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

Alternatives:

[**For treatment studies**, include the following 3 paragraphs.]

State whether subjects may receive the treatment(s) used in the research without participating in the study. For example:]

You may receive [study procedure] without participating in this study.

[**OR**]

You cannot receive [study procedure] without participating in this study.

If you decide not to enter this study, there are other choices available. These include: [list the major ones such as attending group sessions outside of this study]. Ask the study investigator to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

[Briefly explain whether subjects will receive treatment for their condition whether or not they participate in the study. For example:]

You will receive treatment for [the subject's condition] whether or not you participate in the study.

[**For non-treatment studies**, include the following statement.]

If subjects have a medical condition being studied (but not treated within the study) by their regular doctor or by the facility at which they receive care, briefly explain if they will receive medical treatment for their condition whether or not they participate in the study (1st example sentence below). If not, include the 2nd example sentence below.]

You will receive medical treatment for [medical condition] whether or not you participate in the study.

[**OR**]

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

Voluntary Participation:

[All studies should include the following:]

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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.

[For therapeutic trials, also include the following statement:]

Deciding to not take part in this research study 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 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:

[Add the following statement only if this is an externally sponsored, multi-center study (when completing sentences, delete all blanks from this template):]

Approximately _____ subjects will be participating in this study at approximately _____ centers, and _____ subjects will be participating locally.

[OR]

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

_____ subjects will be participating in this study.

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

The study will take place at _____.

[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)
- Which procedures are standard of care and which are for research purposes only
- If research procedures will occur at a standard of care visit, indicate how much additional time will be required to complete the research procedures
- Estimate the time required of the subject for each visit

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For example:]

Day 1/Visit 1 (this will take an additional 45 min. at your routine visit):

- Information such as your age, weight, height, and medical history such as [previous heart attacks, etc.] will be copied from your medical record
- You will take a questionnaire about the quality of your life
- You will participate in a group session discussing _____

Day 2/Visit 2 (2 hours 30 min.):

- Complete a questionnaire
- You will participate in a group session discussing _____

Your participation in this research study may be stopped by the study investigator [*or the sponsor*] without your consent for any of the following reasons:

[if the protocol lists specific reasons, insert the specific reasons for discontinuation listed in the protocol]

- If you do not show up for visits
- If you do not follow the study investigator's instructions

[For therapeutic trials, add the following paragraph:]

If you decide to stop taking part in this research study, you should tell your study investigator, and any information that you have already provided will be kept in a confidential manner. *[If applicable, add the following 2 sentences]* In addition, the study investigator will discuss further treatment options with you, and you will be asked to return to the clinic to have all the final clinical evaluations completed.

[OR]

[For non-therapeutic trials, add the following paragraph:]

If you decide to stop being part of the study, you should tell your study investigator, and any information that you have already provided will be kept in a confidential manner.

3. RISKS ASSOCIATED WITH PARTICIPATION:

[In simple language and in simple bullet format (whenever possible), explain the possible risks and discomforts, including:]

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- Potential risks of investigational procedures and treatments, as well as known risks of comparative procedures and treatments used in the study;
- If applicable, psychological, social, or economic risks; and
- Only include the risks associated with procedures and/or treatments being performed solely because the subject is participating in this research study. Risks of standard of care procedures that would normally be performed even if the subject were not participating in this research study should not be included in the consent form. However, if randomizing to a standard of care treatment when other standard of care treatments/alternatives exist, the risks of the standard of care treatment should be included because the patient may not incur these particular risks outside of the study.].

Include the following 2 paragraphs for all studies:

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.

The research may involve risks to you [*if applicable, add: or to the embryo or fetus, if you are or may become pregnant,*] 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.

If any of the following procedures will be performed only for research purposes, use the following template language:

Drug Screening:

You will undergo screening for illicit (street) drug(s). If others find out you have tested positive for illegal drugs, it may cause mental stress, unfair treatment from other people, problems with getting insurance or finding a job, legal difficulties, or other unknown problems. It is important to seek medical care if you have a drug abuse problem. [*Edit the following sentence according to your current procedure; i.e., indicate whether results will or will not be placed in either record.*]

The information about your test result will be placed in your medical record and in your research record.

[*If the subject is a minor and the result of the drug test will be shared with the parent/LAR, include a statement using simple terms regarding the potential psychological distress and*

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familial conflict that may occur as a result of receiving the results of a positive drug test, and if applicable, indicate that referrals for counseling will be provided.]

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

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 during the study.

Individual/Group counseling:

Participating in the _____ counseling may make you feel uncomfortable or cause troublesome feelings or emotions. You may take a break or end the session at any time during the study.

Discussing the sensitive questions that are asked could also cause you to experience and dwell on feelings of sadness, anger, or anxiety (such as with posttraumatic stress disorder), but this does not occur often.

Videotaping/Photography/Audio Recording: *[Edit the following sentence according to which procedure(s) you will include in your study:]*

Having your photograph taken, your voice recorded, and being videotaped may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who views your video and photograph or listens to your audio recording might identify you.

4. 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:]

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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, and whether it will be labeled with a code. 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,*

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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.

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

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By signing this consent form, you are giving your permission for the study investigator 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 is FDA-regulated, 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 you included a sponsor, CRO, 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

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- 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 investigator. 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 (CoC), 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

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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 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]

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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 study investigator 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 investigator immediately. The study investigator will provide acute medical treatment and will provide you with a subsequent referral to appropriate health care facilities.

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

If you feel you have had a research-related injury, contact [name of the principal or co-investigator] at [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.

[Insert Preparation Date]

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Subject Initials _____
[OR]

Subject or Parent/Legal Guardian Initials _____
[OR]

Parent/Legal Guardian Initials _____
[OR]

Subject/Legally Authorized Representative Initials _____

Social Behavioral Consent Form

7. 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 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.

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

[Insert Preparation Date]

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Subject Initials _____
[OR]

Subject or Parent/Legal Guardian Initials _____
[OR]

Parent/Legal Guardian Initials _____
[OR]

Subject/Legally Authorized Representative Initials _____

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Successful research using information collected from your participation in this study could result in commercial products. You will not share in any financial rewards associated with the development of these products.

8. COSTS OF PARTICIPATION:

[Explain whether there are any costs to the subject or his/her parent/legal guardian or his/her legally authorized representative. 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 study. *[If applicable, include the following statements:]* [Sponsor Name] will provide the [study interventions] free of charge during this study. Tests and procedures that are done only for research purposes will not be billed to you or your insurance company.

[OR]

You or your insurance company may be billed for:

- [list costs as necessary]

[If some or all of the costs associated with procedures being performed for research purposes only will be billed to insurance, add:]

You may want to talk with your insurance company about its payment policy for medical care or procedures performed as part of a research study. If your insurance company does not pay, you may be billed for those charges.

9. 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*

[Insert Preparation Date]

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Subject Initials _____
[OR]

Subject or Parent/Legal Guardian Initials _____
[OR]

Parent/Legal Guardian Initials _____
[OR]

Subject/Legally Authorized Representative Initials _____

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- *Held intellectual property rights and interests (patents, trademarks, or copyrights) in the product/intervention 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]*.

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 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.

[Insert Preparation Date]

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Subject Initials _____
[OR]

Subject or Parent/Legal Guardian Initials _____
[OR]

Parent/Legal Guardian Initials _____
[OR]

Subject/Legally Authorized Representative Initials _____

Social Behavioral Consent Form

_____ We MAY NOT attempt to find/contact you in the above ways.

[Include and edit the following paragraph if applicable to your study.]

Please note that if we lose contact with you and there is new information about your participation in the study that could affect your 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 to ask you about participating in future studies.

_____ We MAY NOT keep your contact information and health information to ask you about participating in future studies.

[Insert Preparation Date]

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Subject Initials _____
[OR]

Subject or Parent/Legal Guardian Initials _____
[OR]

Parent/Legal Guardian Initials _____
[OR]

Subject/Legally Authorized Representative Initials _____

Social Behavioral Consent Form

11. CONSENT OF SUBJECT: *[Change this section to "10." 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 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)

[Insert Preparation Date]

Social Behavioral Consent Form

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

[*Insert Preparation Date*]

**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:

[Insert Preparation Date]

Assent Discussion for Subjects 8-13 Years of Age

- 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

A. 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

B. 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.

[Insert Preparation Date]