***Template***

***Consents submitted to IRB should use all black font. Delete instructions (blue, green and red text) from final version***

**Instructions**

**Insert requested information**

New language required by the Revised Common Rule

**Consent to Take Part in a Research Study**

**Title: Insert**

**Principal Investigator: Insert**

**The goal for all patient materials is 7th grade reading level or below. The use of tables is encouraged to explain study procedures. If appropriate, the table should specify which procedures are routine care and which are additional for the research.**

New language required by the Revised Common Rule **for federally funded studies ONLY**: **Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. The example below in** red **should be modified to fit the study.**

**Example:**

The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patient with ABC. Participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to UT Medical Center fitness center three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months. The greatest risk of this study include the possibility of injury during the physical therapy program and loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

Include only if Applicable: If you are the parent/guardian of a minor child or the legally authorized representative of an adult unable to sign for themselves “you” in this consent refers to the patient or research subject or you as their representative.

You are being asked to take part in a research study. This information is provided to tell you about the study. Please read this form carefully. Your participation is voluntary. Saying no will not affect your rights to health care or services. You are also free to withdraw from this study at any time. [Optional statement, include only if true for this study] You will be notified if new information becomes available about the risks or benefits of this research. Then you can decide if you want to stay in this study.

**What is the purpose of the study?**

The purpose of the study is to **(insert purpose).**

**How long will I be in the study?**

You will be in the study for **(insert length of time).**

**What will happen to me during the study?**

The following tests or procedures that are required in this study for research purposes are **(insert test, procedures and identify any that are experimental)**.

**What side effects or risks can I expect from being in the study?**

The potential risks to you include **(insert all risks)**. **Separate out by “Likely”, “Less Likely” and “Rare but Serious”.**

**Are there benefits to taking part in the study?**

The potential benefits to you include **(insert benefits**).

* 1. The possible benefits to you from this study are… **or**
  2. You may not benefit personally from this study… **or**
  3. The possible benefits to society may include…

**What other choices do I have if I do not take part in this study?**

If you choose not to participate in the research, alternative procedures or treatments include **(insert alternatives other than participation)**.

**How many people will be in the study?**

About xx people will be in this study at UT Medical Center (UTMC) and about xxx people will be in this study throughout the U.S. (or throughout the world).

**What will it cost me to be in the study?**

**List any cost that will be billed to the subject or their insurance.**

**Will I be paid for taking part?**

**If the subject will be paid list the total amount to be paid and how it is calculated; for example: The most you will be paid is $250.00 if you complete all study visits. If you withdraw before finishing the study, your payment will be calculated at $25.00 per visit based on the number of visits completed.**

**Is the Investigator paid to do this study?**

**Yes, the investigator is being paid by the sponsor to enroll and monitor people in this study. OR No, the investigator is not being paid to enroll people in this study.**

**What if I am injured in this study?**

You will get medical treatment if you are injured as a result of taking part in this study.  You and/or your health plan will be charged for this treatment.  The study will not pay for medical treatment.  **(If this is not true for your study, replace this paragraph with an explanation of how injuries will be handled.)**

**Please note: Language to the effect of “If you are injured in this study [Sponsor Name] will pay for the reasonable costs of medical treatment that are not covered by your medical insurance or other programs” creates a Medicare Secondary Payer problem. Medicare considers the sponsor the primary payer and as such, you cannot bill Medicare in such a situation. Clarify this with the sponsor and reword it to say that the sponsor will pay the bills. [Remove this note from completed consent]**

It is important that you tell your study doctor, (insert name of PI) if you feel that you have been injured because of taking part in this study.  You can tell the doctor in person or call him or her at (insert phone number).

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 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.

**Who do I call if I have questions about the study?**

Questions about the study: PI Contact Info…

Questions about your rights as a research subject: You may contact the UT Graduate School of Medicine Institutional Review Board (IRB) at 865-305-9781. The IRB is a group of people that reviews studies for safety and to protect the rights of study subjects.

**Can I stop being in the study?**

You may withdraw from the study at any time. Your treatment, payment or enrollment in any health plans or eligibility for benefits will not be affected if you decide not to take part.

**Could I be removed from the study?**

You may be withdrawn for the study for any of the following reasons:

* + - The sponsor may stop the study
    - The doctor in charge of the study may feel it is in your best interest to change treatments
    - If you do not take your medication as instructed, or keep you appointments as scheduled you may be removed from the study.

**Identifiable private information or identifiable biospecimens:**

**Include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:**

i. Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative (if this might be a possibility); ***or***

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

**Will my medical information be kept private?**

All reasonable efforts will be made to keep your protected health information (PHI) private and confidential. PHIis health information that is, or has been, collected or maintained and can be linked back to you.  Using or sharing (“disclosure”) of such information must follow federal privacy guidelines. By signing the consent document for this study, you are giving permission (“authorization”) for the uses and disclosures of your personal health information. A decision to take part in this research means that you agree to let the research team use and share your PHI as described below, for the purpose of this research.

As part of the study, [name of PI] and [his or her] study team may share the results of your [List information to be collected: e.g. laboratory tests, x-rays, ECG etc.]. These may be study or non-study related. They may also share portions of your medical record, with the groups named below:

* The Federal Government Office for Human Research Protections,
* The University of Tennessee Graduate School of Medicine Institutional Review Board,
* [Add others as appropriate, e.g., food and drug administration, national institutes of health, representatives of {sponsor name}, CROs, insurance companies for billing purposes, etc].

Federal privacy regulations may not apply to these groups; however, they have their own policies and guidelines to assure that all reasonable efforts will be made to keep your personal health information private and confidential.

**[OPTIONAL**: The sponsor may give your personal health information, not containing your name, to others or use it for research purposes other than those listed in this form. In handling your personal health information, the sponsor, [PI] and associated staff will keep your information in strict confidence, and shall comply with any and all applicable laws regarding the confidentiality of such information.]

The study results will be retained in your research record for at least six years after the study is completed.  At that time, the research information not already in your medical record will be [INFORM PARTICIPANT WHAT WILL HAPPEN TO THE RECORD AT THAT TIME]. Any research information entered into your medical record will be kept indefinitely.

Unless otherwise indicated, this permission to use or share your PHI does not have an expiration date. If you decide to withdraw your permission, we ask that you contact [PI] in writing and let

[him/her] know that you are withdrawing your permission.  The mailing address is [ADDRESS].  At that time, we will stop further collection of any information about you.  However, the health information collected before this withdrawal may continue to be used for the purposes of reporting and research quality.

**[OPTIONAL**: You have the right to see and copy your personal health information related to the research study for as long as the study doctor or research institution holds this information.

However, to ensure the scientific quality of the research study, you will not be able to review some of your research information until after the research study has been completed.]

**ADDITIONAL ELEMENTS: Add if applicable to the study**”

* A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
* The subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

**CERTIFICATE OF CONFIDENTIALITY:**  **If you are obtaining a federal Certificate of Confidentiality, insert the following. If your research is NIH-funded, you are automatically covered by a Certificate of Confidentiality and you must include this language in the consent form.**

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

* To a member of the federal government who needs it in order to audit or evaluate the research.
* To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly
* To the federal Food and Drug Administration (FDA), if required by the FDA.
* To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
* To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others

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

**STUDENT PARTICIPATION:** Your participation or discontinuance will not constitute an element of your academic performance nor will it be a part of your academic record at this Institution*.*

**EMPLOYEE PARTICIPATION**: Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this institution.

**ASSENT OF MINORS:** If participants include those under 18 years of age: 1) The subject's parent or legal guardian will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides his/her assent.

**CONSENT OF SUBJECT: (when all subjects are adults)**

I have read or have had read to me the description of the research study. The investigator or his/her representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts and side effects as well as the possible benefits (if any) of the study. I will receive a copy of this form after it is signed.

I freely volunteer to take part in this study.

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Printed Name of Subject Signature of Subject or Date & Time

Authorized Representative

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Printed Name of Representative Relationship to Subject

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Printed name of person Signature of person Date

Obtaining Consent Obtaining Consent

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Printed name of Investigator Signature of Investigator Date

(Signature lines for studies containing minors are on the next page and should be deleted if not applicable to your study.)

**CONSENT OF SUBJECT: (If some or all of subjects will be minors)**

I have read or have had read to me the description of the research study. The investigator or his representative has explained the study to me and has answered all of the questions I have at this time. I have been told of the potential risks, discomforts, and side effects as well as the possible benefits (if any) of the study. I freely volunteer to take part in this study.

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Printed Name of Adult Subject Signature of Subject Date & Time

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Printed Name of Minor Subject Assent/Signature of Subject Date & Time

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Printed Name of Parent/ Signature of Parent/ Date & Time

Legal Guardian Legal Guardian

**Check Relationship to Minor:**

* Parent
* Court-Appointed Legal Guardian

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Printed name of person Signature of person Date

Obtaining Consent Obtaining Consent

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Printed name of Investigator Signature of Investigator Date