Template

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

Instructions

Insert requested information

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.

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 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 East Tennessee Children Hospital 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 includes 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**).

a) The possible benefits to you from this study are… **or**
b) You may not benefit personally from this study… **or**
c) 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 East Tennessee Children Hospital (ETCH) 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 East Tennessee Children Hospital or its agents from liability for negligence. In the event of physical injury resulting from research procedures the East Tennessee Children Hospital 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?

For questions about the study or if you have a research-related problem or if you think you have been injured, you may contact PI Contact Info….

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Office of Patient Experience at (865) 541-8586.

If you have questions about your rights as a research participant or any problems that you feel you cannot discuss with the investigators, or have any research related issue, you may reach the Chairman of the Institutional Review Board of East Tennessee Children's Hospital, through the secretary, at (865) 541-8477. The Institutional Review Board is a group of people who review the research study to protect your child's rights.

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.

What if new information is learned during the study that might affect my decision to participate?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

Will I be given individual results from the research tests?

If there is potential for incidental findings, describe how incidental findings will be managed and whether findings will or will not be communicated to participant.

Generally, tests done for research purposes are not meant to provide clinical information.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by _____ {specify review by a special committee, an expert consultant} to determine if it is in your best interest to contact you.

If so, _____ {the repository, your primary/clinical care provider} will contact you using the information you provided. With the help of a {medical specialist, a genetic counselor}, they will present possible risks or benefits of receiving the information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this, call _____ {list person to contact} at_____{list the phone number/email etc.}

OR

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ **Yes** ☐ **No** **Initials**_____

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to _____ {provide phone and mailing address}.

Will I be contacted with my information about participating in future studies?

If you are planning to contact these research subjects in the future regarding their potential participation in additional research studies, their permission to do so is recommended. If you do not plan to contact these research subjects regarding participation in additional studies, DELETE this section. Please note that if you are planning on creating a subject pool, a separate IRB application should be submitted.

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to {specify frequency} times per year.

Do you give your permission to be contacted in the future by _____(insert investigator or staff) regarding your willingness to participate in future research studies?
☐ **Yes** ☐ **No** **Initials**_____

Will my information (or specimen samples) be used for future research?

Include ONE of the following statements if this study collects ANY identifiable samples or ANY identifiable private information:

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

If above statement selected, delete the **statement and collapsed future use** section below.

OR

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

Include this section if storing and/or sharing for future use and delete the first statement indicating information or samples will not be used for future research.

Storing and sharing your information or specimen samples for future use:

We would like to store, use, and share {specify what will be stored for future use, e.g., your leftover specimens, extra tissue samples, blood samples, other biologic samples, health information, etc.), for future research. Having information/samples from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information/samples to learn more about _____ (cancer, diabetes, and other health problems) or research additional scientific questions.

(Specify if requesting current and future access to the medical record) We also would like to have permission to look at your medical records from (specify frequency). We would collect general information related to your health such as test results, treatments, and doctor's notes. The confidentiality section below provides details about how we will keep your information private.

(Include if applicable) We may use the genetic material (genes, DNA, RNA) in your sample to learn about the role genes play in heath and disease. Genetic studies help explain why traits or diseases are passed down in families. Results of genetic studies may also reveal information about your family members.

(Include if applicable) Researchers may use your sample to create a "cell line" which is cells grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

(Include if applicable) The genetic testing may include whole genome sequencing. This means a researcher would map your entire set of genetic instructions. Genetic instructions are what make you unique. These tests involve scanning the genomes from many different people and looking for markers that scientists can use to predict the presence of a disease. Data obtained from analyzing your genomic information and your medical information may be put into scientific databases along with information from other research participants. (If placing data in "unrestricted access" database) We will remove your name and other information that could be used to identify you before placing the genomic data in public databases. (If placing data in "controlled access" database) We will place the analyzed data in databases that require researchers to apply for and get permission to use the data for a specific research project.

Where will information or specimen samples be stored and for how long?

The information will be stored at _____ {describe location/facility} _____ {indefinitely, for no longer than XXX years/months}.

Are there risks from allowing my information or specimen samples to be stored for future research?

Physical:

There is no additional physical risk from collecting leftover tissue from a procedure that is being done as part of your clinical care.

Include if additional blood is being collected as part of the research via venipuncture:

Risks associated with blood sampling are generally slight, but may include soreness, bruising,

pain, infection, possible fainting, bleeding.

Include if additional tissue will be collected during a clinical procedure:

When we collect extra tissue during your procedure, we will limit the amount so that there is no significant increase in risk to you {OR describe specific additional risks associated with additional tissue collection}.

Privacy and Social/Psychological:

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

Include if genetic or genomic testing is possible:

Even without your name or identifiers, genetic information is unique to you making it possible for someone to trace it back to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

Unknown:

There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

How will you share my information or specimen samples with other researchers?

Indicate what is required in order to provide data to recipient researchers.

The researchers requesting access to information/samples must (specify, complete an application process; sign an agreement). The researchers who receive your information/sample will sign an agreement to use the data responsibly.

Before sharing your information or samples, we will remove identifiers such as (e.g., your name, medical record number, or date of birth). Your de-identified information or samples may be shared with other East Tennessee Children Hospital (ETCH) researchers and researchers outside of ETCH, without your additional informed consent. We will use _____ (a process, software, barcodes) to track information shared without releasing your identity.

What if I change my mind and want to withdraw your information or specimen samples?

You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to _____ {insert address}.

We will destroy any remaining information and samples that have been stored. In addition, it

may be possible to destroy the code that links you with your information and specimen samples. However, we cannot withdraw the information and samples that have already been used.

Will I receive any commercial profit from future research discoveries?

The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

Will I be given individual results from the future research tests?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

If storing for your future use is optional, include the signature box below. Otherwise, remove signature box.

OPTIONAL FUTURE USE:

Do you give permission for (insert investigator name) to store your (specify information and/or specimens) for future research? □ Yes □ No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored for this investigator's future research.

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.

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: Name of the Subject _____

I have been given a copy of all _____pages of this Consent form.

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 that 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 agree to take part in this study.

_____ _____
Participant Date

_____ _____ _____
Parent/ Legal Guardian (Relationship with patient) Date

_____ _____ _____
Parent/ Legal Guardian (Relationship with patient) Date

_____ _____
Assent of minor (if subject is 14-17 yrs. old) Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Signature of Interpreter (if used) Date

_____ _____
Signature of Witness Date

_____ _____
Physician/ PNP obtaining consent Date

_____ _____
Signature of Physician/ Investigator obtaining Assent
(7-17) years old Date