Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Consent Form - Key Information

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Key Information

[45 CFR 46.116(a)(5)(i)]

"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."

Key Information

- It aims to facilitate understanding in Informed Consent
- Does not necessarily include each element of informed consent as specified in the regulations
- Must be presented in a ***concise and focused*** manner
- Information must be presented in ***sufficient detail*** and ***organized*** way that facilitates subject's or their LAR's understanding of why one might or might not want to participate

*LAR – Legally Authorized Representative

Informed Consent Elements Checklist: Key Info

The first 9 items of the consent elements checklist should be presented concisely in the beginning of the document:

1. Study involves “research”
2. Purpose
3. Voluntary participation
4. Study procedures
5. Identification of the experimental procedures
6. Duration
7. Risk or discomforts
8. Benefits to participants or others
9. Alternative procedures or course of treatment

Key Information (cont.)

Key Info: Sample Format 1

UNIVERSITY OF GEORGIA
CONSENT FORM
Osteoarthritis Prevention Study (OPS)

Researcher's Statement

We are asking you to take part in a research study. The information in this form will help you decide if you want to be in the study. Please ask the researcher(s) below if there is anything that is not clear or if you need more information.

Principal Investigator: AyAr Bee, PhD, ATC
Department of Kinesiology
Email: irb@uga.edu
Phone: 706.542.3199

- Study Purpose: Individuals with a history of anterior cruciate ligament reconstruction (ACLR) are at increased risk for developing knee osteoarthritis. The increased risk of osteoarthritis may be caused by too little force applied to the knee throughout the day as a result of lack of physical activity. Therefore, the purpose of this study is to see if increasing daily steps will change knee joint health.
- Study Eligibility: You are being asked to be in the study because you are between the ages of 18-40, have torn ACL and had it surgically reconstructed within 6 to 24 months, and have completed all other forms of formal physical therapy and therapeutic exercise regimens.
- Your involvement in the study is voluntary, and you may choose to stop your participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- Study Procedures: You will wear a physical activity monitor on your waist for 7 days, undergo magnetic resonance imaging (MRI) of their surgical knee, walk on a treadmill, undergo walking biomechanics and thigh muscle strength assessment, and fill out surveys about their knee.
- Study Duration: 2 to 4 visits ranging from 30 minutes to 3.5 hours.
- Potential Risks: There is an unlikely risk of pain, soreness or injury from the MRI or biomechanical testing.
- Potential Benefits: You may learn about your health information. The study may help us in finding ways on how to mitigate Post-traumatic Osteoarthritis (PTOA) in patients with ACLR.
- Another option to get the benefit: You may get your health information from your primary healthcare provider if you don't want to participate in the study.

If you are interested in participating in the study, please read the additional information on the following pages, and feel free to ask questions at any point.

Key Info: Sample Format 2

APPENDIX: A HYPOTHETICAL CLINICAL TRIAL

Title: A trial to evaluate the use of product X to treat health condition Y

Key Information You Should Know Before Agreeing to Participate

The key information that follows can help you learn more about this clinical trial. It can also help you decide whether or not to take part in the trial. **Please read the entire consent form or have someone read it with you.** If there is anything that you do not understand, please talk to the trial doctor or team to have your questions answered before signing the consent form.

Voluntary Participation and Right to Discontinue Participation

We are asking you to consent to participate in this research study. Your participation is voluntary and should be based on what is important to you. It is your choice to participate in this trial. If you agree to participate, you may leave at any time without penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

The purpose of the trial is to find out if product X, the product that is being studied, is safe and effective in treating adults like you who have health condition Y.

Key Reasonably Foreseeable Risks and Discomforts (see page #)

- If you take product X, you have a chance of side effects, such as fever or rash.
- Nausea or vomiting may be related to your health condition and is a rare but serious side effect of product X. If product X is suspected to cause these or other symptoms, product X may be stopped.
- We do not know if product X will help you. There is a chance that product X could worsen condition Y.
- More information on risks is available in the consent form.

Reasonably Expected Benefits (see page #)

- Prior research suggests product X may improve condition Y.
- Researchers are studying product X in this trial to learn more about whether product X will improve condition Y.
- If you are randomly assigned to take product X, product X may improve your health condition Y. If you are randomly assigned to take the inactive pill, you will not receive product X and will not benefit directly.
- By participating in this trial, you will help researchers learn how product X may help people with condition Y.

– MORE –

Helpful Links

- 45 CFR 46.116: General Requirements for Informed Consent
- Key Information – 45 CFR 46.116 (a)(5)(i)
- Key Information Requirements (October 17, 2018)
- Draft Guidance – Key Information and Facilitating Understanding in Informed Consent (Federal Register Notice - March 1, 2024)
- What's New in Informed Consent: Revisions to the Common Rule
- Checklist 409 – Informed Consent Elements Checklist

Thank you!