INFORMED CONSENT FORM

Title of Protocol
Study # or Protocol #

Sponsor Name: Sponsor Name

Sponsor Address: Sponsor Address

Site Name: Site Name

Site Address: Site Address

Study Related Phone Numbers: Study Related Phone Numbers

Principal Investigator: Name

Introduction

You are being asked to voluntarily participate in a study being undertaken by company name, and conducted by name. The United States Food and Drug Administration (FDA) regulations require the investigator to obtain your signed agreement (consent) to participate in this project. In order for you to decide whether or not to participate in this study, you should understand the study procedures, risks and benefits so that you can make an informed judgment. The purpose of this informed consent form is to provide you with this essential information. In addition, you have the right to have your questions answered by study personnel. You will be given a copy of this form to take with you.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Purpose of the Study

The purpose of the study is to describe study

Study Procedures

Provide description of what will occur during the study.

Inclusion Criteria

Provide a list of inclusion criteria

Exclusion Criteria

Provide a list of exclusion criteria

Risks and Discomforts
Describe risks and, if applicable, state: Please keep out of the reach of children.

During the study, if you think you are experiencing a problem with a test product, call Dr. name at site immediately, day or night, at phone #

Benefits
Describe expected benefits.

Cost to Subjects
Detail any possible cost to the subject, or state that there is no cost to the subject.

Compensation
Indicate the compensation and, if applicable, the following statements: There is no compensation for missed visits. There is also no compensation for the screening visit.

Alternative Treatments
If any. Or, if none, then the statement that your alternative is not to participate in the study.

Confidentiality
You have a right to privacy, and any information obtained in this study that can be identified with your name will remain confidential as far as possible within state and federal law. The United States Food and Drug Administration (FDA), the Argus Independent Review Board or the sponsoring drug company may inspect and copy your medical records relating to this study, and the results of the study may be reported to the FDA and other health authorities.

Medical Care for Injury Related to This Study
If your use of the test products provided in this research project directly results in physical injury to you, medical treatment will be available at no cost to you. There is no compensation available to you for such injury. For information about the treatment of injury, call Dr. name at site phone #. You do not waive your legal rights by signing this form.

Information
If you have any questions about this research project, you may ask Dr. name or his associates at site. If you have any questions about your rights as a research subject, you

may call the ARGUS Independent Review Board Chairman at (520) 298-7494. ARGUS IRB is an ethics committee that is established to help protect the rights and welfare of study subjects.

Voluntary Participation

Your decision whether or not to participate in this study is strictly voluntary. Refusal to participate will not involve penalty or loss, or affect your future relationship with site or your doctor. You are free to discontinue participation at any time. You may be discontinued from the study without your consent for safety reasons, or if you fail to comply with the conditions of the study. Site reserves the right to discontinue the study prior to inclusion of the intended number of patients, but intends only to exercise this right for valid scientific or administrative reasons. Any significant new findings developed during the course of this study that may relate to your willingness to continue to participate will be provided to you.

Photographic Consent (If applicable)

As explained above, photographs of describe location on the body will be taken throughout the study. These photographs may be used for promotional purposes, and/or in teaching and research. By signing this form, you are providing consent for your study photographs to be used as described above. There will be no further compensation for any photographs used.

Authorization (example)

I have read and understood the information provided. I have been given the opportunity to discuss this information with my doctor and study personnel, and have had my questions answered in language I understood. I meet all the study criteria. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I freely agree to participate in this study.
I understand that my participation is voluntary and that I may withdraw from the study at any time after signing this form without penalty. I also understand that I may be withdrawn from the study for non-compliance, or if it is determined that it is in my best interests to do so. I agree to abide by all subject instructions, reminders, and precautions given to me before and during the study.

Subject Name (Please Print Full Name)		
Signature of Subject	Date	Time (24 hr clock)
Signature of Investigator/Representative	Date	Time (24 hr clock)
Signature of Witness	Date	Time (24 hr clock)

Read and Understood (Your Initials)_____