**Study Title:**

**Sponsor:**

**Principal Investigator:**

**Address:**

**Telephone #**

This consent form may contain words that you do not understand. Ask the study doctor or study staff to explain any words or information that you do not clearly understand.

**INTRODUCTION:**

You are being asked to volunteer for a medical research study. You have the right to know about the procedures and possible risks and benefits of this study to assist you in making an informed decision about whether or not you will participate in this study.

This consent form contains important facts to help you decide if it is in your best interest to take part in this study. If you have questions that are not answered in this consent form, one of the research staff will be happy to give you further information.

**BACKGROUND:**

Include how many people will be included in the study

**PURPOSE:**

The purpose of this study is to determine\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PROCEDURES:**

List procedures to be followed. i.e., number of visits, physicals, blood draws, etc.

How long will you be in the study?

**RISKS:**

List all possible risks. i.e., allergic reactions, physical symptoms and possible side effects.

Are they reproductive risks?

**BENEFITS:**

Participation in this study may or may not \_\_\_\_\_\_\_\_\_\_\_\_. You may benefit from the close supervision of your general health and the information from this study will benefit patients in the future who have the same condition as you.

Your will be reimbursed at the rate of $\_\_\_\_ per visit for time and expenses, payable at the end of your participation in the study. [if applicable]

All expenses related to procedures or treatment required in this study will be provided at no cost to you.

**ALTERNATIVE PROCEDURES OR TREATMENT:**

If you choose not to participate in this study, there are alternative treatments for your condition. Treatment with medications already on the market such as \_\_\_\_\_\_\_\_\_\_.

**COMPENSATION FOR MEDICAL TREATMENT:**

If you suffer any adverse drug experience resulting directly from the study medication, (sponsor/organization) will provide reimbursement for the reasonable costs of medical treatment to the extent such costs are not covered by your medical or hospital insurance or by third-party or governmental programs providing such coverage. No other form of compensation is available. If you have any questions concerning availability of compensation/medical care or if you think you have experienced a research related illness/injury, you should contact Dr. \_\_\_\_\_\_\_\_\_\_ at phone number.

**CONFIDENTIALITY:**

Information from this study will be submitted to (sponsor/organization) and made available to the Food and Drug Administration (FDA). Medical records which identify you and the consent form signed by you will be inspected by the sponsor and may be inspected by the FDA and the Southwest College Institutional Review Board. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

**TERMINATION OF STUDY:**

Your participation in this study is voluntary. You may refuse to participate, and you are free to withdraw at any time. Neither of these actions will result in the loss of any benefits to which you are otherwise entitled, nor will it prejudice your doctors against you in any way.

However, if you withdraw from this study, you will be required to contact the investigator immediately. It will be your responsibility to contact your personal physician for alternative therapy if you withdraw. Your participation in this study may also be ended without your consent by the study physician or the sponsor (1) if the study physician feels it is not in your best interest to continue in the study, (2) if you fail to keep the scheduled appointments or fail to follow instructions given by the study staff, (3) you experience an adverse reaction to study drug that requires medical treatment, or (4) the sponsor stops the study for any reason. At study termination, you will be required to return all unused study medication. You may be asked to cooperate in having whatever laboratory tests and physical examinations the study physician considers necessary. You may also be asked about your experience with the study drug.

New information, which may affect your willingness to continue participation, will be communicated to you.

**WHOM TO CALL FOR ANSWERS TO QUESTIONS:**

If you have any questions about a research related injury, this study, or medical questions you may call \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_.

If you have questions about your rights as a research subject, you may contact Dr. Yasmin Abusamra, Chair, Southwest College of Naturopathic Medicine Institutional Review Board at (480) 222-936, email j.bain@sonoran.edu.

**PARTICIPANT’S ACKNOWLEDGEMENT:**

I, or my legally authorized representative, have read, understand and I have been sufficiently informed about the description of this study including the purpose and nature of this research, the procedures to be followed, reasonably foreseeable risks and discomforts, benefits, alternative procedures or treatments, and release of my medical records.

I understand that participation in this research study is voluntary and refusal to participate will involve no penalty or loss of benefit to which I am otherwise entitled. Further, I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled.

I understand that my doctor has the right to discontinue the research at any time without regard to the consent if he or she feels that it is in my best interest.

I will receive a signed copy of this consent form.

Having thoroughly read, reasonably understood, and had full explanation of the above information; my legally authorized representative or I voluntarily consent to participate in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Subject's Name Signature Date

(Typed or Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Authorized Representative Signature Date

(Typed or Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Name of person obtaining consent Signature Date

(Typed or Printed)

STATEMENT FOR PARTICIPANT WHEN ENGLISH IS NOT THE FLUENT LANGUAGE:

I have explained the above study to the potential participant in his/her native language. He/She voluntarily consents to participate in this study. He/She has had an opportunity to ask questions and understands that future questions he/she may have about the research or about participants' right will be answered by one of the investigators listed above.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Subject's Name Subject's Signature Date

(Typed or Printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_

Interpreter's Name Interpreter's Signature Date

(Typed or Printed)

Affiliation of Interpreter: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_