

## Samples Risks

Text	Sub-Heading
There are no anticipated risks to you of participating in this study.	No risk
The only risk to you of your involvement in this study is the inconvenience of giving 15 minutes of your time to evaluate a questionnaire. The study has been designed to minimize any risk to you from your participation in this study. You will not be asked to provide personal information about yourself.	Inconvenience
There are no anticipated risks to you of participating in this study. You may be deceived about some procedures during the study.	Deception
The harm or discomfort involved in the psychological testing is some stress typical when answering questions about one's self.	Psychological Testing
<p>The information being requested in this study may be of a sensitive and personal nature. Because of the sensitive nature of the information that you are being asked to provide, you may experience discomfort.</p> <p>There will be counseling available to you free of charge after the study upon request. You may call xxx-xxxx to arrange an appointment for a counseling session with a staff psychologist of the Department of XXXXXXXXX during normal business hours. You may identify yourself as a participant in Dr. XXX?s hospital survey. You do not need to identify yourself by name to arrange an appointment if you do not wish to reveal this information.</p>	Sensitive Topics
Your involvement in this study will involve sleep deprivation. The amount of sleep deprivation involved in this study is not known to cause any serious side effects or health problems. The known side effects include the following: shakiness, muscle aches, lightheadedness, headache, blurred vision, loss of appetite, increased appetite, weight loss, weight gain, apathy, irritability and fatigue. You are likely to experience some or all of these symptoms. These symptoms are expected to stop as soon as you resume a normal sleep schedule. You should report any symptoms that are severe, or any symptoms that are unexpected (any symptoms not described here) to the study director as soon as possible.	Sleep Deprivation
Your involvement in this study will involve some food restriction for a period of two weeks. If you agree to participate in this study, you will be agreeing to refrain from eating any food product that contains yeast. A daily dietary supplement will be given to you while you are participating in this study to ensure that you receive the necessary nutrients that you may be obtaining in your normal diet through eating products that contain yeast. The information from similar studies involving the	Diet Restriction

<p>elimination of yeast products suggests that the elimination of yeast products from a normal, healthy person's diet for the period of this study (two weeks) will not have any effect on your health. You may, however, find it difficult and inconvenient to eliminate certain foods from your diet for this period of time. You will also be given a list of commonly eaten food that will need to be eliminated from your diet during your involvement in this study. If you have questions about a food item that is not on either list, you may call the investigator at XXX-XXXX to find out if the food item can be eaten while you are participating in this study.</p>	
<p>Research information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, may inspect research records and learn your identity if this study falls within its jurisdiction. Your MRI will be interpreted and the results will be shared with you or a physician you may name. Your MRI report will be maintained as part of the clinical database at the hospital (name of hospital).</p>	<p>Clinical Database- Loss of Confidentiality</p>
<p>The potential that you may reveal involvement in illegal activities involves the risk to you of criminal penalties and/or prosecution if your identity were to be revealed. The investigator would not normally reveal your identity or identifying characteristics to anyone outside the research team, but can be compelled to do so by a court of law. In order to protect the investigator against the possibility of being compelled to disclose the identity of any research participant, the investigator has obtained a <a href="#">Certificate of Confidentiality</a> from the National Institutes of Health. This certificate protects the investigator against being compelled to disclose your identity or identifying characteristics in any legal proceeding.</p>	<p>Criminal or Civic Liability - Illegal Activities</p>
<p>Once the sample is taken, it will forever be separated or unlinked from your name. This will protect your identity and preserve anonymity. However, once you donate the sample, you will not be able to withdraw your tissues from the research project because the samples will not be traceable.</p>	<p>Medical - Tissue Sampling or Banking</p>
<p>Results reported to subject: Your tissues will be stored under your name. Your name will not be included in any data shared with other investigators or in any publication. If you wish, you will be told the results of the testing on your tissue sample. The possible risks of knowing the test results include: anxiety, other psychological stress, and the possibility of insurance and job discrimination. The possible risk of not knowing the test results is your not being aware of the need for treatment. Please circle [yes or no], depending on whether or not you wish to be told the test results.</p>	<p>Medical - Tissue Sampling or Banking</p>
<p>Results not reported to subject: Your tissues will be</p>	<p>Medical - Tissue</p>

<p>stored under your name. Your name will not be included in any data shared with other investigators or in any publication. The investigator will use the results of the testing on your tissue for research purposes only, and will not include your test results in your medical record. This precaution is being taken to protect you from potential discrimination on the basis of your disease or genetic information.</p>	<p>Sampling or Banking</p>
<p>If you are receiving course credit for participating in this study: You have the right to withdraw from this study at any time without penalty. If you want to withdraw from the study, tell the interviewer and leave the room. You will still receive course credit for the study.</p>	<p>Students Rights to Withdraw Without Penalty or loss of course credit</p>
<p>The risks of having blood drawn include soreness and bruising at the puncture site, and sometimes there may be discomfort during the procedure. Occasionally people feel lightheaded or faint. There is a small risk of infection whenever blood is drawn or when a plastic catheter (tube) is placed in the vein. The amount of blood to be taken is not considered to be a significant amount, and is therefore not expected to have any significant risk to you.</p>	<p>Medical - Blood Draw</p>
<p>There may be risks to life associated with involvement in this study. Approximately 20% of patients have some degree of lung tissue damage after receiving the study drug (name of drug). This is greatest in patients who have previously received medications which cause lung tissue damage or who have underlying lung problems. The effects range from shortness of breath to lung failure or collapse. This study may also have other risks that cannot be determined or known at this time. Because this treatment is considered to be investigational, side effects may be overlapping and/or side effects may occur of which your doctor is not yet aware. A physician will be present at all times for the duration of the study to provide medical care to you if needed. You will be closely watched during all study procedures, and your blood pressure and heart rate will be continuously monitored. You will be told of any potential risks that may be discovered while you are participating in this study and other new findings that may affect your willingness to participate in this study.</p>	<p>Medical - Physical Injury - Risk to Life</p>
<p>We do not know the effect this drug may have on an unborn fetus. Because of the potential risk of harm to an unborn fetus, all heterosexual sexually-active men and women who are able to have children must use a highly effective form of contraception (birth control) while taking the study drug. Highly effective methods include, injectable contraceptives, IUDs, or a vasectomized partner. Oral contraceptives (the pill) must not be used, as the effect of the study drug on these contraceptives is also not known. Women must not breastfeed while taking</p>	<p>Medical - Physical Injury - Pregnancy Risk</p>

<p>the study drug. There is still a risk that pregnancy could occur despite the responsible use of a reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which will result in your being withdrawn from the study. If you become pregnant, you will be asked to follow-up with the study team until the end of the pregnancy and up to thirty days after delivery. The newborn infant will be examined for any sign of congenital abnormalities (birth defects).</p>	
<p>The standard drug that is administered for the treatment of herpes B is xxxxxxx. The purpose of this study is to judge the effectiveness of the alternative drug xxxxxxx in the treatment of herpes B. Therefore, you will be given the alternative drug xxxxxxx and the standard treatment of herpes B (with the drug xxxxxx) will be withheld from you. There is a risk that the alternative drug will not be as effective a treatment as the standard one. You will be given information during the course of your taking the study drug comparing the effectiveness of the study drug that you will be receiving with that of the standard study drug. If during the course of taking the study drug, there are significant new findings discovered which might influence your willingness to continue in this study, you will be informed of these developments.</p>	<p>Medical - Standard Treatment Withheld</p>
<p>Participation in this study requires that you postpone receiving your artificial limb for two weeks longer than would be normal if you were not in this clinical trial.</p>	<p>Medical - Standard Treatment Postponed</p>
<p>The research drugs that you will be receiving may involve risks to you that are currently unforeseeable.</p>	<p>Medical - Unforeseeable - General Medical</p>
<p>This is the first time that the study medication has been given to people with diabetes. Early safety results from a previous study in which healthy volunteers received a single dose of medicine (from 100-1500 mg) show that it is well tolerated at all doses tested. The most common side effect was headache, which occurred in 10 of the 75 people in the study. Of these 10 people, 7 were receiving the study medication and 3 were receiving a placebo (pretend treatment with no drug in it). Less common side effects included in local skin irritation, muscle cramps, muscle aches and lightheadedness. All side effects reported were mild or moderate and resolved completely once the study medication was stopped.</p> <p>The study medicine has been given to animals at very high doses and caused shakiness, convulsions, involuntary movement, decreased appetite, weight loss, chills and fatigue. These are also possible risks to humans taking the study medicine.</p>	<p>Medical - Unforeseeable - Clinical Trials</p>

Because this drug is experimental, there may be additional risks that are currently unknown or that cannot be determined at this time.

