

AVANDIA® (ROSIGLITAZONE) PARTICIPANT CONSENT FORM

You are being asked to participate as a participant in the research study entitled, Influence of Rosiglitazone (Avandia®) on Cognitive Function in Patients Convalescing from Traumatic Brain Injury, under the direction of Lisa Kreber, Ph.D. and colleagues, Centre for Neuro Skills®(CNS), 2658 Mt. Vernon Avenue, Bakersfield, CA, 93306.

PURPOSE OF THE STUDY

The purpose of this study is to look at how effective Avandia® is in improving cognitive function. Avandia® is an FDA-approved medication that is used to treat patients who have Type 2 Diabetes Mellitus. Individuals who participated in these diabetes trials also experienced improvement in cognitive function (such as thinking, calculating and remembering).

You are being asked to participate because you are recovering from traumatic brain injury, which can damage cognitive function.

PROCEDURES

Before start of the study:

If you decide to participate in the study and you meet all of the qualifications, you will have your blood pressure checked and will have blood drawn (about one tablespoon) from a vein in your arm to make sure that it is safe for you to participate in the study; you will have a comprehensive neuropsychological evaluation which includes evaluation of your intellectual function (how well you process information) and your academic achievement (how well you do at school work). These evaluations take 3 hours or less to complete.

You will be randomized (like the flip of a coin) to receive one of two possible treatments – Avandia® or placebo (no active medication -- like a sugar pill). You will have a 50% chance of receiving Avandia® 4 mg, twice daily for 12 weeks or a 50% chance of receiving placebo, twice daily for 12 weeks. Neither you nor the investigators will know whether you are receiving active medication (Avandia® 4 mg, twice daily) or placebo. However, this information is available to your study doctor in case of emergency.

During the study:

You will be asked to take the study medication or placebo twice daily for a period of 12 weeks. You will be seen by your study doctor every 4 weeks during the study. You will have your blood pressure and pulse checked and you will have your blood drawn (about one tablespoon) from a vein in your arm for a routine safety check to make sure it is safe for you to continue to participate in the study. At the end of 12 weeks you will have an evaluation of your cognition and mood. These evaluations take 3 hours or less to complete.

After completing the 12 weeks, you will then stop taking the study medication or placebo.

During the entire 12 weeks of the study you will have a total of 30 ml (approximately 8 tablespoons) of blood drawn for your safety.

You will continue with any current medical treatments and therapies at Centre for Neuro Skills[®] (CNS) that have been ordered by your doctors.

During the study you will be asked to report all changes in your physical condition, whether or not you feel they are related to the study. You will also be asked about any side effects you may have experienced and any new medications you may be taking. Please report any unexpected changes in your weight or any new swelling in your feet or hands.

PROCEDURES RELATED ONLY TO THE RESEARCH

Informed consent, medical history, physical examination, blood pressure, pulse, measurement of height and weight, and blood draws are routine procedures; however these procedures listed above in this project are necessary to conduct the study. The study medication, Avandia[®], is an approved drug in the United States for people who have Type 2 Diabetes Mellitus. However, Avandia[®] is experimental for the purposes of this study and is not approved by the FDA for use in improving cognitive function.

RISKS OF PARTICIPATION

Like many medications, Avandia[®] may cause unwanted effects. Common side effects include weight gain, peripheral edema (swelling of the feet and hands) and low glucose (low blood sugar).

You should not participate in this study if you are hypersensitive or allergic to Avandia[®], if you have liver disease, severe diabetes or low blood sugar or CHF

(Congestive Heart Failure), or if you are pregnant or planning to become pregnant or breastfeeding your child during the course of this study.

You should know that the study medication may lower your blood sugar and can make you feel nauseated. You should know that if you take insulin or any other medication that is used to reduce your blood glucose (sugar in the blood) in combination with the study medication, this can reduce your glucose to very low levels which can be dangerous. Common symptoms of low blood sugar are: nausea, weakness, feeling faint, severe sweating, and headache. You should notify your doctor and study doctor if you are taking any of these medications. If you have any of the previously noted symptoms while in the study, notify Dr. Kreber as indicated on page 6.

NUMBER OF SUBJECTS PARTICIPATING AND THE DURATION OF YOUR PARTICIPATION

The anticipated number of subjects involved in the study will be 30 subjects from Centre for Neuro Skills[®]. The length of time for your participation is approximately 12 weeks and you will need to visit your study doctor every 4 weeks during the study for a total of 8 visits. Each visit will last approximately one to three hours.

BENEFITS TO THE SUBJECT

You understand that the potential benefit of being in this study is that you may experience improved cognitive function. However, you should know that you might not benefit in this study and that no guarantees have been made to you.

BENEFITS TO SOCIETY

This study may also benefit others who suffer with traumatic brain injury now or in the future by helping doctors to learn more about the study medication, Avandia[®] and how it affects people with traumatic brain injury.

ALTERNATIVE TREATMENT

You do not have to participate in this study. There are currently no other medications on the market that improve cognitive function. If you chose to not participate in this study, you can continue with your current therapy as prescribed by your doctor. Your study doctor is able to discuss available alternatives and answer any questions you may have.

REIMBURSEMENT FOR EXPENSES

You will not be reimbursed for your participation in this study.

COMPENSATION FOR RESEARCH-RELATED INJURY

If you are physically injured because of any substance given to you or procedure performed during this study, Centre for Neuro Skills® will reimburse you for reasonable medical expenses for the treatment of those injuries.

No other forms of compensation are available. However, you are not waiving any of your legal rights by participating in this study.

COSTS OF PARTICIPATION

All study-related costs associated with your participation will be paid by Centre for Neuro Skills®. You and/or your insurance company will not be charged or held responsible for the costs of the study procedures.

REASONS FOR THE STUDY INVESTIGATOR TO STOP YOUR PARTICIPATION

Your study doctor may discontinue your participation in this research study for any reason without your consent. The study may be discontinued by the U.S. Food and Drug Administration or this site's Institutional Review board at any time.

Your study doctor can withdraw you from the study at any time (with or without your consent) if it is in your best interest or if you are unable to comply with all the requirements of the study. You may also stop your participation in this research study at any time.

PROCEDURES FOR WITHDRAWAL

If you withdraw voluntarily or are withdrawn involuntarily, you may be asked to return to the clinic to have any final laboratory tests and examinations that your study doctor thinks are necessary. If you withdraw your consent to participate in the study, your consent for your data to be processed is still valid unless you specifically withdraw permission to use your data.

USE AND DISCLOSURE OF YOUR HEALTH INFORMATION

Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) provide safeguards for privacy, security, and authorized access of your records. These regulations require the Centre for Neuro Skills® to obtain an authorization from you for the use and disclosure of your health information. By signing this consent form, you are authorizing the use and disclosure of your health information for the purpose of completing the research study.

Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Centre for Neuro Skills®. For records disclosed outside of Centre for Neuro Skills®, you will be assigned a unique code number. The key to the code will be kept in a locked file in the study coordinator's office.

As part of the study, Dr. Kreber and her study team may report the results of your study-related laboratory tests to the following recipients: the IRB or study personnel. You also grant study-related personal health information about you obtained during this study to be made available to authorized representatives of the national and foreign government agencies.

While other recipients may understand the importance of protecting the confidentiality of your health information, Centre for Neuro Skills® cannot guarantee the confidentiality of your health information or protect from further disclosures once these recipients receive your health information.

If you sign this form, you are giving us permission to collect, use and share your personal health information. You do not need to sign this form. If you decide not to sign this form, you cannot be in the research study. We cannot do the research if we cannot collect, use and share your health information. Whether or not you agree to the research project or give us permission to collect, use or share your health information will not affect the care you will be given at Centre for Neuro Skills®.

Dr. Kreber will use and disclose your study-related test results both to treat you and to complete the research study. These would include laboratory tests such as your blood counts to measure the function of your liver and kidneys. These test results will be recorded in your medical record and will be recorded in a case report form that does not identify you by name. You may see or receive a copy of any research information that will be included in your medical record. For all other health information we collect on you that will not be included in your medical record, you may not be allowed to access or receive a copy of the information until the conclusion of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include, for example, representatives of the Food and Drug Administration, and Centre for Neuro Skills®. This authorization for the use and

disclosure of your health information as described above expires upon the conclusion of the research study.

If you change your mind later and do not want us to collect or share your health information, you need to contact the researcher listed on the attached consent form in writing. You need to say that you have changed your mind and do not want the researcher to collect and share your health information. We may still use the information we have already collected.

ADDITIONAL REQUIRED CLAUSES

1. Informed consent is required of all persons in this project. Whether or not you provide a signed informed consent for this research study will have no effect on your current or future relationship with Centre for Neuro Skills®.
2. The principal and alternative procedures, including the experimental procedures in this project, have been identified and explained to you in language that you understood.
3. The risks and discomforts from the procedures have been explained to you.
4. The expected benefits from the procedures have been explained to you.
5. An offer has been made to answer any questions that you may have about these procedures. If you have any questions before, during or after the study, or if you need to report a research related injury, you may contact Dr. Kreber at 661-872-3408 extension 1513, or if after normal office hours, 661-335-1458.
6. Your participation in this study is completely voluntary and you have been told that you may refuse to participate or stop your participation in this project at any time without prejudice and without jeopardizing your medical care at Centre for Neuro Skills®. If you decide to stop your participation in this project and revoke your authorization for the use and disclosure of your health information, Centre for Neuro Skills® may continue to use and disclose your health information in some instances. This would include any health information that was used or disclosed prior to your decision to stop participation and needed in order to maintain the integrity of the research study. All new findings during the course of this research that may influence your desire to continue or not to continue to participate in this study will be provided to you as such information becomes available.
7. If you are injured or have an adverse reaction because of this research, you should immediately contact one of the personnel listed in Clause #5 above. Agreeing to this does not mean that you are giving up any legal rights that you may have.

8. If you have any questions regarding your rights as a subject participating in this study, you may contact Ms. Velda Bryan, Institutional Review Board contact, at (661) 872-3408.
9. You have a right to privacy, and all information that is obtained in connection with this study and that can be identified with you will remain confidential as far as possible within state and federal law. However, information gained from this study that can be identified with you may be released to no one other than the investigators, your personal physician, and the Centre for Neuro Skills® Institutional Review Board. The results of this study may be published in scientific journals without identifying you by name.

The purpose of this study, procedures to be followed, risks and benefits have been explained to you. You have been allowed to ask questions and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. You have read this consent form and voluntarily agree to participate as a subject in this study. You are free to withdraw your consent, including your authorization for the use and disclosure of your health information, at any time. You may withdraw your consent by notifying Dr. Lisa Kreber at (661) 872-3408 extension 1513. You will be given a copy of the consent form you have signed.

Print Name	Sign Name	Date & Time
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Authorized Representative Name <i>(if applicable)</i>	Signature of Authorized Representative	Date & Time
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Witness Name <i>(if applicable)</i>	Witness Signature	Date & Time
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Print Name of Person Conducting Consent Interview	Signature of Person Conducting Consent Interview	Date & Time
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Using language that is understandable and appropriate, I have discussed this project and the items listed above with the participant and/or his/her authorized representatives.

Signature of Principal Investigator or Sub-Investigator	Date & Time
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