UNIVERSITY OF CALGARY

FACULTY OF MEDICINE

Department of Paediatrics
Alberta Children's Hospital
Telephone: (403) 229-7365
Fax: (403) 543-9100
Email: kaplan@ucalgary.ca

CONSENT FORM

Title: Open Trials of a Nutraceutical Treatment for Mental Disorders in Adults
Investigators: Bonnie Kaplan, Ph.D., _____

Severed under Section 24(1) of the FOIP Act

This consent form, a copy of which has been given to you, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

There is much interest lately in nutritional approaches to problems such as those you are experiencing. We are studying some nutritional supplements which consist primarily of trace minerals. Although the supplements we are studying show some promise, there is no solid scientific data yet in existence to prove their value for these problems. We are inviting you to participate in an *open trial* of the supplements: that means that you will be taking the real supplements and not a placebo.

If you decide to participate, your physician will first do an initial assessment of your problem, and then will monitor your condition at least once a week while you take the supplements. In addition to the physician's weekly assessment, we will also ask you to record information every day about your symptoms. The supplements must be taken four times each day; there is no cost to you. If you benefit from the supplements, the manufacturer has promised to give them to you free for 12 months.

Although we have no reason to suspect that the supplements can harm you in any way, we also have no proof of their benefit. In previous research here at the University of Calgary, blood samples, heart rate, and blood pressure were monitored in 12 children, and no one was found to experience any problems while taking the supplements. These types of supplements have been used by many people for many years without any unpleasant results reported. Here in Alberta we know of many people who have been taking them, and we have not heard of any problems with side effects.

Your psychiatrist and/or family physician will be responsible for your ongoing care. It is possible that your medication will have to be adjusted as a result of taking the supplements; in some cases, people have no longer felt it necessary to take any of their medication. *Your physician will make this decision, based on a weekly assessment of your condition.*

All the information you provide will be handled confidentially. Some of the data will be stored on a computer at the Behavioural Research Unit at the Alberta Children's Hospital, where it will be entered by a code number and not your name. Only the research assistants and the investigators will have access to the computer-stored data. If the results of any open trials are published, participant data will be anonymous.

If you decide not to participate in this open trial, or if you decide part-way through that you want to stop, you are certainly free to do so. This decision will not influence your ongoing health care in any way.

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In the event that you suffer injury as a result of participating in this research, no compensation or treatment will be provided for you by the University, the Calgary Regional Health Authority, . or the Researchers. You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages.

Severed under Section 4(1)(b) 24(1) of the FOIP Act

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information through your participation. If you have further questions concerning procedural matters related to this research, please contact Dr. Bonnie Kaplan at 229-7365. If you have questions regarding your mental condition, please contact your physician. If you have any questions concerning your participation in this open trial, you may also contact the Office of Medical Bioethics, University of Calgary, at 220-7990.

_____ _____

Participant or Legal Guardian Date

_____ _____

Investigator Date

_____ _____

Witness Date

A copy of this consent form has been given to you to keep for your records and reference.