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FACULTY OF MEDICINE

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CONSENT FORM

Title: Nutraceutical Treatment of Mental Disorders in Adults: an RCT with Bipolar Disorder
Investigators: Bonnie Kaplan, _____

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.

Purpose and Significance
You are invited to participate in a study that will evaluate a nutrient supplement (primarily minerals) in the treatment of patients with Bipolar Disorder. There is much interest lately in nutritional approaches to problems such as those you are experiencing. 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 a randomized controlled trial (RCT) of the supplements. This means that if you participate, you may receive the actual supplements or you may receive a placebo (fake) supplement. The decision as to which you receive will be made with a table of random numbers.

The Supplement
The supplement that we are evaluating consists mainly of minerals, with a few vitamins and other nutrients. If you participate, you will be asked to take 32 gelatin capsules per day, divided however you like into 3 or 4 doses.

Benefit/harm
Although we have no reason to suspect that the supplement can harm a physically healthy adult in any way, we also have no proof of its 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 supplement. This type of supplement has 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. While there are no reliable guidelines, at least one of the supplement ingredients (vitamin A) is present in quantities that are potentially unsafe for a developing baby. Therefore, women who are pregnant or who are thinking of becoming pregnant should not take this supplement as we do not know if it is safe for a fetus.

Study Procedures
If you choose to participate, you will be randomly assigned into one of 2 treatment groups, active or placebo supplements. You will not know which group you were in, until the study has been completed (expected completion date: September 2002). Your regular physician or psychiatrist will be responsible for your ongoing care, and will see you once a week for the first two months of the study, and once every two weeks for the remaining four months of the study. In addition, one of the members of the study team will assess you at entry, after one month, after three months, and after six months. Those assessments will include the completion of the following questionnaires: the Brief Psychiatric Rating Scale, the Clinical Global Index, the Hamilton Depression

Rating Scale, an Outcome Questionnaire, and the Young Mania Rating Scale. In addition, you or your caregiver/supporter will be asked to make a brief phone call every night to report a symptom score to an answering machine. You or your caregiver/support will be instructed by a Dietician and asked to fill out a record of all the foods and beverages you consume for 7 days at the beginning and near the end of the study.

In addition, a small sample of your blood (10 ml, which is less than a tablespoon) will be drawn by a qualified technologist at the beginning of the study and again at the end, when you have concluded your participation. The blood will be evaluated for a variety of nutrients. There is a minor risk of fainting or some discomfort and redness in the arm from where blood samples are taken.

The study will last six months, so during that time you will see your regular physician approximately 16 times, and you will see a member of the study team 4 times. It will be your regular physician who continues to monitor (and possibly modify) your medications. Your physician will be informed as to which group you are in, in order to make wise decisions about any potential medication adjustments, but he or she will not be able to disclose that information to you or your family. You will be asked to not try any alternative medicines or other forms of therapy until you have completed your involvement in this study.

Confidentiality

All information about you that is collected in this study will be held in the strictest confidence. The only people who will have access to the information required for this research project are the study investigators and designated staff. The final results will be reported as part of a large group as numbers and percentages. Your name will never appear in any reports related to this study. During this study, it will be necessary for a member of the research team to look at your previous medical records. You are assured that this will also be handled in a confidential manner.

Liability and Compensation

As health care professionals, it is our responsibility to place patient well being above all else. It is with this in mind that we have undertaken this research project. We do not anticipate any harm will come to you as a result of our questions and treatment. However, in the event that you do have problems resulting from participating in this research project, no compensation will be provided for you by The University of Calgary, the Calgary Regional Health Authority, Dr. Bonnie Kaplan, the other members of the research team, or [redacted]. You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages.

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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 clinical 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. Similarly, the study's investigators might choose to end your participation in the study at any time for any reason.

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 as a subject. 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 without jeopardizing your health care. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation. If you have further questions concerning matters related to this research, please contact Dr. Bonnie Kaplan at 229-7365. If you have any questions concerning your rights as a possible participant in this research, please contact the Office of Medical Bioethics, Faculty of Medicine, 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.