CONSENT FORM FOR OPEN TRIAL

Title: Open trials of nutritional supplements for the treatment of children with anxiety/mood problems
Investigators: Bonnie Kaplan, Ph.D., Severed under Section 24(1)(e.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 complementary medicine approaches to problems such as those experienced by your child. Although the supplements we are currently studying show some promise, there is no solid scientific data yet in existence to prove their value for these problems.

You have agreed to give your child a nutritional supplement consisting primarily of trace minerals.

The reason you have made this choice is because of the following symptoms:

_____

Although we have no reason to suspect that the supplements you are trying can harm your child in any way, we also have no proof of their benefit. The reason we would like you to keep a daily checklist during your open trial is so that all of us can learn more about the potential benefit of the supplements. The supplements consist of small amounts of minerals and vitamins. In previous research here at the University of Calgary, blood samples, heart rate, and blood pressure were monitored 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 the only problem encountered thus far has been that some children have difficulty swallowing pills.

We will ask you to record information about your child's symptoms. For instance, you may be asked to complete a weekly or daily checklist to indicate the severity of some symptoms. You may also be asked to fill in some questionnaires occasionally or answer some interview questions about some symptoms.

We will assign your child a code number, and all of the data we collect will be identified only with that code and not your name. All our data will be stored on a computer at the Behavioural Research Unit at the Alberta Children's Hospital (ACH). If your child does not already have a hospital number, we will assign one so that your involvement in the study can appropriately be entered in the hospital records. The hospital requires this summary for all study participants. Only one research assistant 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 or your child 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.

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 matters related to this research, please contact Dr. Bonnie Kaplan at 229-

7365. If you have any questions concerning your participation in this open trial, you may also contact the Office of Medical Biocthics, University of Calgary, at 220-7990.

Participant	Date
Investigator	Date
Witness	Date

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

For the participation of children: The investigator has explained to your child the research and his or her involvement, and has sought the child's ongoing cooperation throughout the project.

Investigator