SAMPLE LETTER OF CONSENT

(Place on Department or Faculty Letterhead)

(Insert Date)

Dear *(Insert Potential Research Participant's Name)*:

You are being invited to participate in a research study on people's experience on psychosis. In particular, we are interested in how psychosis may have mystical and/or spiritual aspects to it, and how some people experience recovery from psychosis.

This research will require about 1-2 hours of your time. During this time, you will be interviewed about your experiences with psychosis. The interviews will be conducted wherever you prefer (e.g. in your home), and will be tape-recorded.

There are no anticipated risks or discomforts related to this research. The person interviewing you, however, can give you the name and telephone number of some counseling and/or mental health services, if you wish this information.

You may also find the interview to be very enjoyable and rewarding, as many people who experience psychosis do not get to share their experiences with a skilled and nonjudgmental interviewer, as you will. By participating in this research, you may also benefit others by helping people to better understand what it is like to experience psychosis, and how some persons can recover from psychosis.

Several steps will be taken to protect your anonymity and identity. While the interviews will be tape-recorded, the tapes will be destroyed once they have been typed up. The typed interviews will NOT contain any mention of your name, and any identifying information from the interview will be removed. The typed interviews will also be kept in a locked filing cabinet at the University of Lethbridge, and only the two main researchers and a research assistant (sworn to confidentiality) will have access to the interviews. All information will be destroyed after 5 years time.

Your participation in this research is completely voluntary. If you decide to participate, you will receive $30 cash for your time and trouble. However, you may withdraw from the study at any time for any reason. If you do this, all information from you will be destroyed, and you will be allowed to keep your $30.

The results from this study will be presented in writing in journals read by counselors and mental health professionals, to help them better understand the experience of psychosis. The results may also be presented in person to groups of counselors or mental health professionals. At no time, however, will your name be used or any identifying information revealed. If you wish to receive a copy of the results from this study, you may contact one of the researchers at the telephone number given below.

If you require any information about this study, or would like to speak to one of the researchers, please call *(Insert Researcher's Name)* at *(Insert Researcher's Phone Number)* at the University of Lethbridge. If you have any other questions regarding your rights as a participant in this research, you may also contact the Office of Research Services at the University of Lethbridge at 403-329-2747 or research.services@uleth.ca.

I have read (or have been read) the above information regarding this research study on the experience of psychosis, and consent to participate in this study.

_____ (Printed Name)

_____ (Signature)

_____ (Date)

SAMPLE LETTER OF CONSENT

(Place on Department or Faculty Letterhead)

(Insert Date)

Dear *(Insert Research Participant's Name)*:

You are being invited to participate in a research study on motor development in infants. In particular, we are interested in the motor development of skilled limb movements and corresponding neural development. That is, we are interested in studying how motor behaviours, such as reaching-to-eat, develop in infants, and how the development of the movement interacts with the development of the brain.

This research will take a maximum of 9 months. During this time we will require to meet with you and your infant for about 0.5-2 hour sessions, between 1 to 4 times each month, for 9 consecutive months. At each session, your infant will be videotaped while breastfeeding, while lying down and presented with objects, and sitting upright (supported until they can sit unsupported) and presented with objects. The objects that will be presented to your infant will be selected from your own infant's regular toys. At the first session, you will also be asked to fill out a brief and confidential questionnaire. These sessions can be conducted in your home, or at the University of Lethbridge - wherever you prefer.

There are no anticipated risks or discomforts related to this research. However, if you feel uncomfortable with any part of this study at any time, you have the right to terminate participation without consequence.

You may find participation in this study enjoyable, as it is a chance to have your infant videotaped throughout his/her early development. By participating in this research, you may also benefit others by helping scientists to better understand healthy motor development in infancy. This information can be useful in identifying abnormal motor development thus potentially allowing for early diagnosis of a variety of childhood disorders.

Several steps will be taken to protect your anonymity and identity. Firstly, your head and face will not be videotaped when videotaping your infant during breastfeeding. Second, your and your infant's name and personal information will be kept confidential. Names will be translated into ID codes and all data collected, will be labeled with the ID codes rather than your names. This information and the videotapes will be kept in the researcher's locked office at the University of Lethbridge. The only person, other than the researcher and yourself, who will view the raw data (videotapes) will be the researcher's PhD supervisor, who is the co-researcher of this study.

Your participation in this research is completely voluntary. Although we cannot offer you any compensation, we can provide you with a copy of all the videotapes taken of you and your child in this study. We hope that you will decide to participate in this study. If you choose to participate and then change your mind, you may withdraw from the study at any time for any reason. If you do this, you will have the choice of having the information contributed removed from the study and destroyed, or allowing the information contributed until the time of withdrawal to be included in the study, and that no more information or data will be collected from you from that point on. Again, there will be no consequences to any decisions you make.

The results from this study will be reported in general terms in the form of speech, writing, photograph or video that may be presented in manuscripts submitted for publication in scientific journals, or oral and/or poster presentations at scientific meetings, seminars, and/or conferences. Any photograph or video

selected for potential presentation will be carefully selected and edited in order to conceal your, and your infant's, identity. Furthermore, the use of photograph and/or video will only be used for such presentations if you provide permission after you are given the opportunity to view the selected photographs/videos. Your personal information, including your, and your infant's name, will be kept confidential and not be distributed in any way. At no time, will your name be used or any identifying information revealed. If you wish to receive a copy of the results from this study, you may contact one of the researchers at the telephone number given below.

If you require any information about this study, or would like to speak to one of the researchers, please call *(Insert Researcher's Name)* at *(Insert Researcher's Phone Number)* at the University of Lethbridge. If you have any other questions regarding your rights as a participant in this research, you may also contact the Office of Research Services at the University of Lethbridge at 403-329-2747 or research.services@uleth.ca.

I have read the above information regarding this research study on the development of skilled limb movements, and consent to participate in this study. I also provide consent for my infant to participate in this study.

_____ (Printed Name)

_____ (Signature)

_____ (Date)

_____ (Infant's Printed Name)

_____ (Mother's Signature)

_____ (Date)

The following has been quoted from the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Section 2 – Free and Informed Consent:

D. Informing Potential Subjects

D1. General Conditions

Article 2.4

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective subjects with the following:

a. Information that the individual is being invited to participate in a research project;

b. A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;

c. A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

d. An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and

e. The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

Under the normal process of obtaining written consent, the prospective subject should be given a copy of the consent form and any relevant written information. The consent of the participants shall not be conditional upon, or include any statement to the effect that, by consenting, subjects waive any legal rights.

In light of (b) and (c), Research Ethics Boards (REB) may require researchers to provide prospective subjects with additional information, such as that detailed in Table 1.

Article 2.4 indicates the requirement to give prospective subjects the information they need to give an informed consent on whether to be involved in the research project. In a research team, the principal researcher is ultimately responsible for the actions of those acting with delegated authority.

Research subjects, whether inside or outside Canada, may have cultural values different from those of the researcher. Thus, as Articles 2.4 (a-c) indicate, researchers must clearly explain the nature and goals of the research and other essential information, in a manner appropriate for the prospective subjects' cultural settings. With some cross-cultural research projects, it may not be possible to offer an adequate translation of the researcher's understanding to prospective subjects. REBs should proceed cautiously in such cases and require stringent protection for the interests of subjects, such as appointing an individual

to act in an independent advocacy role. On the other hand, REBs should not assume an unnecessarily protective role which suggests that those who do not share the culture of the researchers, particularly those in foreign countries, are incapable of making rational decisions in their own interest.

Articles 2.2 and 2.4 (d) help to ensure that a prospective subject's choice to participate is voluntary. Pre-existing entitlements to care, education and other services shall not be prejudiced by the decision on whether to participate. Accordingly, a physician should ensure that continued clinical care is not linked to research participation, and teachers should not recruit prospective subjects from their classes, or students under their supervision, without REB approval. Nothing in this Section should be interpreted as meaning that normal classroom assessments of course work require REB approval. Article 2.4 (d) also requires that researchers specifically ascertain continuing consent from subjects on the basis of new information.

Table 1

Additional information that may be required for some projects:

1. An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation;

2. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;

3. Information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;

4. An indication as to who will have access to information collected on the identity of subjects, descriptions of how confidentiality will be protected, and anticipated uses of data;

5. An explanation of the responsibilities of the subject;

6. Information on the circumstances under which the researcher may terminate the subject's participation in the research;

7. Information on any costs, payments, reimbursement for expenses or compensation for injury;

8. In the case of randomised trials, the probability of assignment to each option;

9. For research on biomedical procedures, including health care interventions: information about (a) foregoing alternative procedures that might be advantageous to the subject, (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and, (c) particularly in trials of therapeutic interventions, the care provided if the potential subject decides not to consent to participation in the study;

10. The ways in which the research results will be published, and how the subjects will be informed of the results of the research.

Article 2.4 (e) reminds researchers of relevant ethical duties that govern potential or actual conflicts of interest, as they relate to the free and informed consent of subjects. To preserve and not abuse the trust on which many professional relations reside, researchers should separate their role as researcher from

their roles as therapists, caregivers, teachers, advisors, consultants, supervisors, students or employers and the like. If a researcher is acting in dual roles, this fact must always be disclosed to the subject. Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project. Conflict of interest matters are further elaborated in the Tri-Council Policy Statement.

Table 1 also indicates other information that researchers may be required to provide in some areas of research for the purpose of obtaining free and informed consent. Item 2 refers to the qualified designated representative who is usually someone on the research team. When the research poses more than minimal risk, it may be advisable to have a person who is independent of the research team in this role. Item 3 acknowledges that some institutions may decide either to name an ombudsman for research subjects, or designate, with the agreement of the researcher, a resource person to handle queries, receive complaints, and transmit them to the REB. Item 7 is intended to prevent the development of a payment structure for research participation that might place undue pressure on research subjects either to join or remain within a research project. It does not imply that subjects should be paid for their participation in research. In research projects where subjects will be compensated, REBs should be sensitive to the possibility of undue inducement for participation, such as payments that would lead subjects to undertake actions that they would not ordinarily accept. REBs should pay attention to issues such as the economic circumstances of those in the pool of prospective subjects, and to the magnitude and probability of harms. Item 10 of the Table indicates that subjects have the right to know whether they will be identified directly or indirectly in publications resulting from the research. Rushing the free and informed consent process or treating it as a perfunctory routine violates the principle of respect for persons, and may cause difficulty for potential subjects. The time required for the free and informed consent process can be expected to depend on such factors as the magnitude and probability of harms, the setting where the information is given (e.g., hospital or home) and the subject's situation (e.g., level of anxiety, maturity or seriousness of disease). In some circumstances, witnessing the signatures on the consent form may be felt to be appropriate. In law, the role of a witness is only to attest that the person actually signed the form; a witness is not responsible for certifying such factors as the signature being obtained under defined conditions or that the signers were competent. However, a court might subsequently seek the opinions of the witness on such issues.