Lake of the Woods District Hospital

ETHICS COMMITTEE/
ETHICS RESEARCH SUB-COMMITTEE

RESEARCH ETHICS PROTOCOL

Application for Review of Research Project Involving Human Participants or Data on Human Participants

- *Research Ethics Review Guidelines*
- *Questionnaire*
- *Guidelines for Preparation of Consent Forms*
- *Research Ethics Agreement Form*

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RESEARCH ETHICS REVIEW GUIDELINES

The Ethics Research Sub-committee of Lake of the Woods District Hospital (LWDH) adheres to the following guidelines in reviewing all projects and recommending ethics clearance. These guidelines are reflected in our review questionnaire and we ask that you complete it thoroughly.

It is hoped that these guidelines will help in the preparation for ethical review. Investigators should feel free to contact the Research Coordinator (LWDH) to obtain clarification, additional information or to discuss the ethical aspects of their research. Additional information and application forms may be obtained by contacting the Research Department (LWDH) (807) 468-9861 ext. 463.

1. INFORMED CONSENT

An individual should generally be accepted as a research participant only after he/she or, where necessary, the legal authorized guardian or next-of-kin has consented to participation in the research. The individual's right of free choice must be respected. This requires that the decision to participate be made in the light of adequate and accurate information. It also should be made clear that the individual has the right to withdraw consent without penalty at any time. The consent must be voluntary and no form of coercion, direct or indirect, explicit or implicit should be employed. The individual should understand the risks, if any, involved and, where appropriate, be aware that the research may not be of personal benefit. Instructions for the preparation of a consent form accompany the application for review form.

2. RESEARCH IN WHICH FULL DISCLOSURE IS NOT GIVEN OR DECEPTION

The Ethics Research Sub-committee of LWDH generally does not find lack of full disclosure or deception acceptable. Any proposal involving such will be carefully scrutinized and examined. A special meeting with the applicant is held in which all factors are carefully examined. It is very likely that such proposals will be required to be revised in a major way if ethics clearance is to be given.

3. STATEMENT OF RISKS AND BENEFITS

A participant is considered to be "at risk" if any aspect of the research exposes him/her to **physical, physiological, social or other hazards**. The investigator should specify these risks and make it clear that the participants are also to be fully informed. The steps taken to minimize risks and the reasons why they cannot be avoided should be indicated. Where risks are involved, the possible benefits accruing from the research which may offset the dangers also should be noted. It is realized, especially in the case of basic research, that this may have to be speculative.

4. MAINTENANCE OF CONFIDENTIALITY

Every person has a right to privacy as regards most aspects of life, which only that person (or in certain cases a guardian or next-of-kin) can give permission to violate. When the possibility exists that others may have access to information gathered from research participants, it is required that this possibility, with the plans for protecting confidentiality, be explained to the participants as part of the procedure for obtaining informed consent. Similarly, statistical data must appear in publications in a manner which prevents individuals from being identified.

5. PERSONAL HEALTH INFORMATION

The Personal Health Information Protection Act (PHIPA) (2004), outlines requirements that must be set out in research plans. Section 4(1) of the Personal Health Information Protection Act (PHIPA) (2004), defines personal health information as follows:

"Personal health information" means identifying information about an individual in oral or recorded form, if the information:

- Relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family;
- Relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual;
- Is a plan of service within the meaning of the Long-Term Care Act, 1994 for the individual;
- Relates to payments or eligibility for health care in respect of the individual;
- Relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance;
- Is the individual's health number; or
- Identifies an individual substitute decision-maker (2004, c 3, Sched A, S. 4 (1).)

QUESTIONNAIRE

Lake of the Woods District Hospital Ethics Committee

APPLICATION FOR REVIEW OF RESEARCH PROJECT INVOLVING PARTICIPANTS OR DATA ON PARTICIPANTS

Please submit one typed copy of this form or a facsimile thereof along with a copy of any documents requested in the Research Guidelines to the address below at least four (4) weeks before a proposed review date. Two (2) copies of the original Research Proposal will be required.

Donna Makowsky
Chair, Ethics Committee
Lake of the Woods District Hospital
21 Sylvan
Kenora, Ontario
P9N 3W7

SECTION A

1. Title of Research Project

_____

_____

_____

2. Principal Investigator

Name: _____

Address: _____

_____

Phone #: _____ Fax: _____ E-mail: _____

3. Has this proposed research project been reviewed by any other Ethics Committee?

↑ Yes ↑ No If yes, please provide the name of the Review Board

_____

_____

_____

4. **Please provide a timeline from proposed beginning to completion for the Research Project submitted for review.**

_____

_____

_____

_____

5. **Source of Project (check one)**

- ↑ Lake of the Woods District Hospital (LWDH)
- ↑ External Organization or Individual
- ↑ University/College Thesis or Dissertation
- ↑ Other (specify) _____

6. **Research Sponsor (if applicable)**

_____

_____

7. **Status of Funding (check one)**

- ↑ Applied for
- ↑ Secured
- ↑ Not Applicable

8. **Participants/Clinical Records Format**

I will need access to (check the appropriate box):

- ↑ Human Participants
- ↑ Hospital Records
- ↑ Both of the above
- ↑ Other (specify): _____

9. **Please provide a description of the personal health information required and the potential sources where you will assess this information.**

_____

_____

_____

10. **What percentage of your sample is needed from LWDH (approximately)?**

_____

_____

11. **Do you intent to publish this research (check the appropriate box)?**
    ↑ No ↑ Yes _____

12. **What cooperation will be necessary from LWDH staff for your research to be done (procedures, time commitment, training, meetings, etc.)? Please be specific.**

_____

_____

_____

13. **Please describe, in detail, who will be working on the research project and have access to the personal health information collected through the study. Include job descriptions and credentials of individuals.**

_____

_____

_____

_____

14. **Have you contacted the appropriate authorities in LWDH Clinical and/or Records Department where you hope to gather data (i.e. is the study feasible at LWDH and will the departments cooperate fully with your procedure pending ethics clearance)?**

    i) **Contact**: _____

    Result of Contact: _____

    _____

ii) **Contact:** _____

Result of Contact: _____

_____

iii) **Contact:** _____

Result of Contact: _____

_____

SECTION B

1. Summary of Proposed Research

a. State the purpose of the research in the space provided below

b. Describe in detail what will be done to the participant

c. How will the personal health information be used in the research and if applicable, how will it be linked to other information in the study.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

d. Do any of the procedures involve invasion of the body (e.g. touching, contact, attachment to instruments, withdrawal of specimens)?

↑ No ↑ Yes

If yes, describe and specify: _____

_____

_____

_____

e. Can the research be completed without accessing personal health information?
If applicable, is the linking of health information necessary to successfully complete the research?

_____

_____

2. Participants Involved in the Research

a. Describe the salient characteristics of participants – number, age, range, sex, institutional affiliation or where located.

b. Describe how participants are to be recruited.

c. Describe the relationship between the investigator(s) and the participants(s).

_____

_____

_____

_____

_____

3. Estimate the Risks of the Proposed Research

	No	Yes
b. Do you deceive them in any way?	↑	↑
c. Are there any physical risks?	↑	↑
d. Are there any social risks (possible loss of status, privacy and/or reputation)?	↑	↑
e. Are there any psychological risks (might a participant feel demeaned, embarrassed, worried or upset)?	↑	↑

If the answer is "Yes" to any of the above, please explain alternative approaches involving less risk cannot be used. Procedures for reversing reversible harm should be stated.

_____

_____

_____

4. Estimate the Benefits of the Proposed Research

a. What are the proposed benefits to the participants, the scientific community and/or society that would justify asking participants to participate?

b. What inducement is offered to participants?

_____

_____

_____

_____

5. Plan for Obtaining Informed Consent

Please refer to "Guidelines for Preparation of Consent Form (Appendix 1)

a. Describe the explanation to be given to participants before they agree to become participants in the project. For surveys circulated by mail, please attach a copy of the explanatory letter to the participants.

_____

_____

_____

b. Are participants capable to consent?
↑ Yes ↑ No **If "No"** describe the alternate source of consent.

_____

_____

c. Do participants have the right to withdraw at any time during and after the research project?
↑ Yes ↑ No

d. Are participants to be informed of this right?
↑ Yes ↑ No

If the answer to "c" and/or "d" is **No**, please explain.

_____

_____

e. What procedures will be followed for participants who wish to withdraw at any point during or after the study?

_____

_____

f. Is the consent form witnessed? ↑ Yes ↑ No
If **"No",** please explain.

_____

_____

PLEASE ATTACH A COPY OF THE INFORMATION LETTER AND CONSENT FORM YOU WILL USE IN THE RESEARCH WITH PARTICIPANTS

6. Steps to be Taken to Ensure Confidentiality of Data

a. Will the data be treated as confidential? ↑ Yes ↑ No
If "Yes", explain the steps that will be taken to ensure confidentiality of the data.
If "No", explain why not.

_____

_____

b. Where will the data be stored and who will supervise access to the data?

_____

_____

c. Is information, obtained on individual subjects, disclosed to third parties?

_____

d. Will information on your subjects be obtained from third parties?

_____

7. Participant Debriefing
Will participants be debriefed at the end of the research project?
↑ Yes ↑ No
If "Yes", explain how this will be done. If "No", explain why not.

_____

_____

_____

Signature: _____ _____
Principal Investigator Thesis Advisor (if applicable)

Date: _____

APPENDIX 1

GUIDELINES FOR PREPARATION OF CONSENT FORMS

Consent forms should be written in a simple, direct style using terms and language which the participant understands and should incorporate the following information:

1. Identities of the researchers and sponsoring institutions;

2. Statement of general purpose(s) of the study;

3. Statement that data gathered will be used only for stated purposes of the research;

4. Description of the procedure(s) involving the proposed participant including their purpose, nature, duration and frequency;

5. Description of any physical risks such as side effects, discomforts and inconveniences and psychological or social discomforts which might be attendant to participation;

6. Description of any recording devices to be used;

7. Statement of provisions for confidentiality;

8. Statement of whether or not research findings will be available to the participants;

9. Details of any scheme of remuneration, if any, and in the case of long-term projects, the manner in which compensation is to be given if the participant withdraws from the study prior to its completion but after partial participation;

10. Statement that the participant has the right to withdraw without penalty from the study at any time and/or to refrain from answering whatever questions he/she prefers to omit.

RESEARCH ETHICS AGREEMENT

RESEARCH PROTOCOL TITLE

Approval by Lake of the Woods District Hospital (LWDH) Ethics Research Sub-committee to conduct research at LWDH is limited to the conditions and details outlined within the Protocol **(date)**, Information Letter/Consent **(date)**.

I agree to abide to the Ethical Guidelines and Procedures of LWDH Ethics Research Sub-committee and my professional standards. I am aware of my responsibility to be familiar with these standards.

I agree:

- That all confidential information received or exchanged will be held in strict confidence. Confidential information will be extracted in the way described and approved in the protocol. Confidential information will not be used for any purpose other than for the project for which it was provided. The data will be shared only with those individuals listed who are working directly on the project. Confidential information will be kept in a secure physical location to which access is given only to the individuals listed. The confidential information disclosed will in no way be used for computer linkage to any other existing database(s) unless specified and approved by LWDH.

- That approval from Ethics Research Sub-committee must be granted prior to any departures from this protocol or consent. The principal investigator assumes full responsibility for this study as detailed and will notify the Ethics Committee should any unexpected results, serious adverse events or complaints arise. Any new information learned about potential risk must also be communicated (e.g. information concerning risks learned from new publications or from other current research projects).

- There will be notification to the BEC should there be any change in the methodology or status of the research project during the life of this research.

- To submit a progress report in writing to the BEC annually and upon completion of the research project.

Date Annual Report required by: _____
(Date)

The undersigned hereby agrees to these terms:

_____ _____
(Signature of Principal Investigator) (Date)

_____
(Print Name of Principal Investigator)

Please send completed form to the Chair, Ethics Committee at LWDH