For IRB Use Only:
Application Number _____

Lakeland University
Application for IRB Review

Cover Sheet

Project Title: _____

_____

Primary Research Investigator: _____

Program/Department: _____ **Campus Address:** _____

Campus Phone: _____ **Home Phone:** _____

E-mail address: _____

Check status: ☐ **Faculty** ☐ **Student** ☐ **Staff Member**

If a student project,

Research Advisor's Title & Name: _____

Program/Department: _____ **Campus Address:** _____

Campus Phone: _____ **Home Phone:** _____

E-mail address: _____

Date Application Submitted: _____

Project Start Date: _____

Expected Duration of Project: _____

CERTIFICATION STATEMENT

By making this application, I certify that I have read and understand the University's policies and procedures governing research activities involving human subjects. I agree to comply with the letter and spirit of those policies. I acknowledge my obligation to:

1. Accept responsibility for the research described, including work by students under my direction.
2. Obtain written approval from the Institutional Review Board of any changes from the originally approved protocol **BEFORE** implementing those changes.
3. Retain signed consent forms in a secure location separate from the data for at least **three** years after the completion of the research.
4. Immediately report any adverse effects of the study on the subjects to the Chairperson of the Institutional Review Board, Dr. Alan Mock, Lakeland University, W3718 South Dr., Plymouth, WI 53073; Phone: 920-56-1000 x2348, Email: mocka@lakeland.edu.

_____

Primary Investigator Signature Date

_____

Research Advisor Signature (required for all student projects) Date

FORM A — EXPEDITED REVIEW (Tier I)

The following questions pertain to potential risks to subjects. Answer items 1-4 & item 15 on a separate sheet of paper. Please be sure to number your responses appropriately. Similarly, if you need to provide additional information/explanations for any of items 5-14, please do so on the separate document as well. Indicate the appropriate question number with the explanation.

1. **PURPOSE:** Describe the general purpose of the study.

2. **Describe your POTENTIAL SUBJECT POOL**.

3. **RECRUITMENT OF SUBJECTS: How will you recruit subjects?**

4. **Where is the LOCATION OF RESEARCH:** Exactly where will research be conducted (e.g., Old Main 26, subject's home, via mail, etc.)? If research will be conducted in a classroom or service delivery setting, will it require any activity that is not part of the normal class or service delivery?

5. If subjects will not be identified from public sources, will signed approval to recruit subjects, conduct the study, or use existing data be obtained from the designated authority prior to conducting the research?.....☐N/A☐YES ☐NO
Explain

6. Is there a pre-existing dual relationship between the researcher and subject (eg. Teacher-student, counselor-client, intern-client)? ……☐N/A☐YES ☐NO
Explain

If yes, explain the nature of the relationship & how you will arrange to have a third party solicit subjects' participation in your study.

7. If research will be conducted in a classroom or service delivery setting, will it require any activity that is not part of the normal class or service delivery?... ☐N/A☐YES ☐NO
Explain

8. Will a consent form or a cover letter be provided to participants?..... ☐YES ☐NO
Explain

9. If subjects are minors, will parental consent be obtained for participation? .. ☐N/A☐YES ☐NO
Explain

10. Will subjects be told that participation is voluntary and they are free to withdraw **at any time?**.....☐YES ☐NO
Explain

11. Will subjects receive compensation for participating in the research (e.g., money, extra credit toward grades)?..... ☐YES ☐NO
Explain

FORM A — EXPEDITED REVIEW (Tier I) continued

12. If extra course credit will be given, will students who choose not to participate in the research have alternative opportunities to earn credit?.....☐N/A☐YES ☐NO
Explain

13. Will the data be recorded in such a way that the individual subjects cannot be linked to the data?..... ☐YES ☐NO
Explain

14. At the completion of the study, will you destroy or erase any materials (e.g., data sheets, audio/video tapes) that identify individual subjects?.....☐N/A☐YES ☐NO
Explain

15. (Note: This question MUST be completed.) Describe procedures IN DETAIL. Include exactly what will be done with the subjects and what measurements will be taken. Provide an electronic copy of any material that will be used during the research study (e.g., recruitment scripts, consent forms, cover letters, questionnaires, interview protocols, surveys, etc.). Each participant **must** be provided with a cover letter or consent form that explains the study. The next page provides the required elements of cover letters and consent forms.

Lakeland University
Institutional Review Board

REQUIRED ELEMENTS OF THE COVER LETTER AND/OR INFORMED CONSENT FORMS

To facilitate review of your application, be sure to include all the following elements in your cover letter, consent form, instructions to the subjects, or phone script.

1. A statement explaining your **affiliation with Lakeland University.**

2. A statement that the study involves **research** and an explanation of the **purpose of the research** in terms the potential subjects can readily understand.

3. A description of the **procedures to be followed** and approximately **how long participation in the study will take**.

4. A brief statement of the **criteria for subject selection**.

5. A statement concerning the **voluntary nature of the study** or a statement such as, "Completion and return of this survey indicates voluntary consent to participate in this study."

6. A statement describing the extent, if any, to which **confidentiality of records** that identify the subject will be maintained and the precise means of maintaining confidentiality. The confidentiality statement should incorporate all of the following items that apply to your project:

   a. If a coding system will be used, you need to describe it and explain the purpose for keeping the list of
   subjects' names. **NOTE:** If you assign a number, it must **not** be the Social Security number.

   b. If you will keep a sheet that matches the random number with any identifying information, state that the code listing and the data will be kept in separate and secure locations.

   c. State who will have access to the code list and the gathered data.

   d. State what will happen to the code list upon completion of the study (i.e., whether it will be destroyed. If not, how will it be kept secure?)

   e. Include a statement such as "We will take all reasonable steps to protect your identity."

7. A statement of **whom to contact** for answers to questions about the research. **Students must include the name, title, address, and telephone number of the faculty member who is supervising the project, as well as their own information.**

1. 8. **The Institutional Review Board approval statement:** "This project has been reviewed and approved by the Lakeland University Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Committee Chairperson, Dr. Alan Mock, Lakeland University, W3718 South Dr., Plymouth, WI 53073; Phone: 920-56-1000 x2348, Email: mocka@lakeland.edu.

SEE FORMATTING SUGGESTION BELOW:

- Place the IRB statement at the very bottom of the cover letter/consent form.
- You may use a smaller font than used in the rest of the document.
- Do not combine this statement with researcher or advisor contact information.

REQUIRED ELEMENTS CONTINUED

9. **If children will participate in the research**, provide both a consent form for the parent to read and sign and an appropriately phrased assent form for the child.

10. **If subjects will be audio/videotaped**:

    a. Include a statement describing the recording procedures.

    b. Indicate how confidentiality will be maintained and what will happen to the tapes upon completion of the study.

    c. Include a statement similar to: "I agree to participate in this activity and know that my responses will be recorded on audio/video tape." If you want to quote subjects in your report, include a sentence at the end of the consent form requesting permission to attribute quotes to them. Subjects must be given the right to agree or to refuse to be quoted. For example: "I agree ___I disagree___that Dr. XXX may quote me in her paper."

    d. Each subject must sign the consent form, indicating approval for the taping.

    e. If taping is planned in a group setting, the consent of all members of the group must be obtained for taping to take place.

    f. Describe how the tapes will be stored, who will be allowed to hear/view the tapes, and when the tapes will be erased.

    g. If the tapes will **not** be erased:
        - Get the subjects' written permission to keep the tapes.
        - State where the tapes will be kept.
        - State who will hear/view the tapes.
        - State how the tapes will be used in the future (e.g., future research, valuable historical data).

11. **If an e-mail survey will be used**, add the following information:
    a. The "from line" should be the researcher's name.
    b. The "subject line" should be "Research Request".
    c. The message should state at the outset where the e-mail addresses were obtained.
    d. Include **either** a statement saying there will be no future e-mails **or** an opt-out message that permits addressees to have their names removed from any future mailings.
    e. **If** you plan future e-mails, add the statement, "If you do not respond to this survey or return the opt-out message, you will be contacted again with this request X times during the next X weeks."
    f. The IRB's e-mail address (mocka@lakeland.edu) after our phone number in the last sentence of the IRB approval statement.
    g. Use a blind copy format so that the list of recipients will not appear in the header.

12. **If research involves using focus groups** the following language should be included in the consent form:

"All reports based on this research and written by the researcher will maintain the confidentiality of individuals in the group. Only group data will be reported and no names will be used. Since a focus group involves a group process, all members of the group will be privy to the discussions that occur during the session; therefore, absolute confidentiality on the part of the participants, themselves, may be difficult to ensure."

REQUIRED ELEMENTS CONTINUED

13. If you plan to access subjects' **private health information,** recent federal law has changed the procedures for releasing health records. Our website [insert URL] has information about the Health Insurance Portability and Accountability Act (HIPAA). However, you should contact the agency that has the health records and ask them what procedures they require before they will release subjects' private health information.

The following elements may also be required for research requiring Intermediate or Full review.

1. All tier II and III research require that the **subject sign the consent form**, and all consent forms should include a statement similar to: "I have read the material above, and any questions I asked have been answered to my satisfaction. I understand a copy of this form will be made available to me for the relevant information and phone numbers. I realize that I may withdraw without prejudice at any time."

2. A statement of any **foreseeable risks or discomforts** to the subject or a statement that the risks are minimal.

3. A **description of any benefits** to the subject or to others which may reasonably be expected from participation in the research.

4. For projects that may involve **physical risk** to the subject, include:

   a. The following paragraph, verbatim: "The Department of Health and Human Services requires that you be advised as to the availability of medical treatment if a physical injury should result from research procedures. The researchers do not have funds specifically dedicated to compensate you for any adverse effects that you may experience by participating in this research. Nevertheless, you retain all your legal rights to seek compensation in the event of injury or other adverse event. If you are a registered student at Lakeland University, you are eligible to receive medical treatment at the Student Health Center. If you are not a registered student at the University, immediate medical treatment is available at usual and customary fees at Aurora Memorial Medical Center, Sheboygan, Wisconsin.***** In the event you believe you have suffered any injury as a result of participating in the research program, please contact the Chairperson of the Institutional Review Board, who will review the matter with you. Phone (920) [insert appropriate number]."

      *****(Note that the name of the hospital or other health care facility should be appropriate to the location where the study will be conducted.)

   b. A statement that a medical questionnaire must be completed and that subjects may be excluded from participation based on their responses.

   c. If blood is to be withdrawn, include a statement indicating the amount of blood to be withdrawn and potential complications, including possible bruising, inflammation, and infection at the site of the puncture. Name the individual who will withdraw the blood, state his/her qualifications, and assure subjects that care will be taken to avoid any complications.

IRB APPLICATION CHECKLIST

Did you attach the appropriate documents to your completed IRB application?

All applicants should attach…

a) Screening Questions

b) Project Cover Sheet

c) The appropriate proposal form (A or B)

d) Copies of data collection instruments (written questionnaires, interview questions, instructions to participants, observational coding sheets, datasheets, recruitment scripts, interview protocols, etc.)

…and appropriate documentation of consent to participate (which could include…)

a). A copy of the written consent form to be signed by participants and/or their legal guardians or representatives.
b). A copy of the written assent form to be signed by participants who are between the ages 7-17.
c) A copy of the cover letter accompanying a confidential or anonymous survey indicating that continuation and subsequent participation in the research project will be deemed "consent". (The cover letter should also include all content required of informed consent statements).
d). A copy of the transcript of any oral presentation used in the place of a written consent statement, accompanied by the statement which participants or representatives, and an auditor-witness sign indicating their agreement to participate in the study described orally.

Additionally, *IF* your project involves….

a) …a Primary Investigator (PI) who is NOT an Lakeland University employee or student, attach a copy of the application submitted to the IRB at the PI's sponsoring institution. If the application was approved, also submit a copy of the approval letter with any contingencies listed.

b) …access to participants at cooperating institution(s), provide documentation from the appropriate sponsoring individual(s) or body from that institution.

c) …access to health care, legal, or educational records, provide documentation of approval to access these records.

d) …use of archival data, and they are not publicly available, provide documentation of your authorization to access and use these data.

e) …use of deception, attach a copy of the debriefing protocol and/or materials.

f) …use of audio or videotaping of participants, attach a separate consent form to be signed by participants, identifying the recording medium and describing the disposition of recordings after completion of the project.