

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: 920-565-1000, ext. 2348; Email: mocka@lakeland.edu.

Primary Investigator Signature Date

Research Advisor Signature (required for all student projects) Date

FORM B- INTERMEDIATE & FULL REVIEW (Tiers II & III)

Please provide (on additional pages) the information requested below. Refer to the same Roman numerals and capitalized key words as used in the outline below. Your responses should be concise and, insofar as possible, be in non-technical language. Items that do not apply to your research should be designated “N/A” for “Not Applicable.” Do not submit more than 5 additional pages, excluding attachments. Do not send copies of a prospectus.

- I. PURPOSE:** Describe the general purpose of the study.
- II. INFORMATION ABOUT POTENTIAL SUBJECTS:**
- A. Describe your **POTENTIAL SUBJECT POOL.**
- B. **IDENTIFICATION:** Describe specifically how potential subjects’ names will be obtained (e.g., from what membership lists, class lists, telephone books, etc.) and how you will have access to these lists. If subjects will not be identified from public sources, you should get signed approval from the designated authority to recruit subjects, conduct the study, or use existing data prior to conducting the research. Include a copy of any advertisement(s) to be used.
- C. **RECRUITMENT:**
1. After subjects are identified, how will they be recruited (i.e., by mail, phone, classroom presentation, personal contacts, etc.)?
 2. Who will recruit subjects (researcher, third party, clinic secretary, etc.)?
 3. If you are associated with the subjects (e.g., your students, employees, clients, patients), explain the nature of the association and how you will arrange to have a third party solicit their participation in your study.
- D. **INCLUSION CRITERIA:** Outline what determines your choice of subjects, justifying the involvement of any special populations. If the project will involve another institution or business, you must obtain letters of permission or cooperation—on the institution’s letterhead—to use their facilities and interact with personnel there. The letter must be sent to the Institutional Review Board Committee prior to beginning your study.
- III. 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?
- IV. CONFIDENTIALITY:** How will data be recorded to ensure anonymity/confidentiality of subjects (e.g., substituting numbers for names, keeping data in locked files, not identifying individuals in reports, etc.)? **NOTE:** If you assign a number, it must not be the Social Security number.
- A. Will you keep a sheet that will match the random number with any identifying type of information? If you will, the code listing and data must be kept in separate and secure locations.
- B. Will you destroy the code list upon completion of the study?

FORM B CONTINUED

- C. Who will have access to the code list and the gathered data? Include this information in the cover letter/consent form.

NOTE: You cannot guarantee confidentiality. Use a statement such as “We will take all reasonable steps to protect your identity. Do not confuse confidentiality with anonymity. Anonymity applies only when subjects’ identities cannot be known.

- V. **FOLLOW-UP:** Is a subject follow-up anticipated? If it is, state for what reason and include this information in the cover letter/consent form. Attach A copy of all materials used in the follow-up.

VI. **METHODOLOGY:**

- A. Describe any form of **COMPENSATION** to subjects (e.g., money, grade, extra credit, etc. If extra credit or grade is given to subjects who participate in the project, what alternative opportunity for extra credit or grade is provided to students who choose not to participate?)
- B. What do you **INTEND** to do with the data collected (e.g., publish data, present paper)
- C. Describe what **SUBJECTS** will be asked to do.
- D. Describe all **MEASUREMENTS/ PROCEDURES**. Attach a copy of any questionnaires, measurement instruments, and interview protocols to be used. Describe the procedures that the researcher will use with the subjects. If you have more than one group in the study, how many subjects will be in each group? Will any group receive less than standard practice? Will the test results be disseminated to the subjects (and/or their parents or guardians)? If so, explain the qualifications of the person(s) interpreting the results.
- E. Describe any type of **ELECTRICAL EQUIPMENT** that will be connected to the subjects. Attach a signed and dated letter from the individual who checked the equipment for electrical safety. The letter must include the person’s name and qualifications and the types and results of the safety checks performed.
- F. If the project involves **AUDIO/VIDEO TAPING**, provide an explanation of the need for taping, the location where tape(s) will be stored, the specific intended uses of the tape(s), the person(s) who will have access to the tape(s), and when or if tape(s) will be erased.

You should include a sentence at the end of the consent form that reminds subjects that their signatures give the researcher permission to audio/video tape the research sessions. 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.

- G. If the project involves procedures that are considered to be **MORE THAN MINIMAL RISK** (e.g., obtaining blood samples, information on sensitive issues such as illegal drug use, treatment involving drugs, psychological manipulation, more than moderate exercise, etc.), describe these procedures in detail, including the qualifications/certification of the person(s) who are administering/assisting with the data collection.

FORM B CONTINUED

- VII. CONSENT:** Describe how consent will be obtained (i.e., how, where, and when the study will be explained to the subjects) and how subjects will indicate their consent. If your subject pool includes special populations who lack the capacity to give valid/legal consent, a substitute consent form should be provided for guardians. A copy of the consent form or, in the case of a mailed survey, a cover letter explaining the project, must be offered to each subject. If you are requesting a waiver of the written/signed consent, describe the alternative method you plan to use to obtain consent.
- VIII. EXISTING DATA:** If you are using existing/secondary data, describe how you have obtained permission to access these data and include a letter from an authorized individual stating that you have permission to access these data. If the subject's personal files (school, medical, etc.) will be read, where are the files kept and who will gather the information? Has permission been obtained to gather this information? Do the subjects (and/or their parents or guardians) know that these files will be read? If not, explain.
- IX. RISK ASSESSMENT:**
- A. Describe any **RISKS TO THE SUBJECT** that might arise from participation in the study. Subjects should be protected against injury and invasion of their privacy, and their dignity should be preserved. Risks fall under the following categories: physical, psychological, social, economic, legal, and other. Please assess the risks involved in this research.
 - B. When visual or auditory stimuli, chemical substances, or other measures might affect the health of subjects, a **STATEMENT FROM A PERSON QUALIFIED TO EVALUATE RISKS FOR SUCH CONDITIONS** will be required by the Institutional Review Board
 - C. Describe **STEPS** you will take **TO MINIMIZE RISK**, as well as **PROTECT SUBJECTS' RIGHTS, WELFARE, AND PRIVACY**, including how subjects will be informed of the risks to which they will be subjected.
- X. ATTACH A COPY OF EXACTLY WHAT THE SUBJECTS WILL BE TOLD/READ PRIOR TO INVOLVEMENT IN THE STUDY (i.e., verbal script, handout, etc.).**
- XI. ATTACH CONSENT FORM.** If project involves minors, attach parental consent form.
- XII. ATTACH COVER LETTER** to be sent to prospective subjects – if needed for subject recruitment.
- XIII. ATTACH SEPARATE CHILDREN'S ASSENT FORM** – if project involves minors.
- XIV. ATTACH DEBRIEFING STATEMENT** – if project involves deception. Also describe the nature of the deception, why it is necessary, and how subjects will be debriefed. Include any feedback—educational or otherwise—that subjects will receive.

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.**
4. 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: 920-565-1000, ext. 2348; Email: mocka@lakeland.edu.

SEE FORMATTING SUGGESTIONS 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.