Lakeland College Institutional Review Board
Application for Intermediate or Full Review (Tiers II & III)
Form B

Please provide 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 send copies of a prospectus or research proposal. Answer the questions in the space provided.

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

2. INFORMATION ABOUT POTENTIAL SUBJECTS:

   2.1. Describe your POTENTIAL SUBJECT POOL.

   2.2. 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.

   2.3. RECRUITMENT:

      2.3.1. After subjects are identified, how will they be recruited (i.e., by mail, phone, classroom presentation, personal contacts, etc.)?
      2.3.2. Who will recruit subjects (researcher, third party, clinic secretary, etc.)?
      2.3.3. 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.

   2.4. 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.

3. LOCATION OF RESEARCH: Exactly where will research be conducted (e.g., Old Main 26, subject's home, via mail, and 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?

4. 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 of the subject.

   4.1. 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.

   4.2. Will you destroy the code list upon completion of the study?

   4.3. 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.

5. 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.

6. METHODOLOGY:

   6.1. Describe any form of COMPENSATION to subjects (e.g., money, grade, extra credit, etc.)

   6.2. 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?)

   6.3. What do you INTEND to do with the data collected (e.g., publish data, present paper)

   6.4. Describe what SUBJECTS will be asked to do.

   6.5. 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.

   6.6. Describe any type of ELECTRICAL EQUIPMENT that will be connected to the subjects.

   6.7. 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.

   6.8. If the project involves AUDIO/VIDEO RECORDING, provide an explanation of the need for recording, the location where recording(s) will be stored, the specific intended uses of the recording(s), the person(s) who will have access to the recording(s), and when or if recording(s) will be destroyed.

   6.9. 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 recording 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.

   6.10. 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.

7. 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.

8. 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.

9. RISK ASSESSMENT:

    9.1. 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.

    9.2. 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.

    9.3. 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.

10. ATTACH A COPY OF EXACTLY WHAT THE SUBJECTS WILL BE TOLD/READ PRIOR TO INVOLVEMENT IN THE STUDY (i.e., verbal script, handout, etc.).

11. ATTACH CONSENT FORM. If project involves minors, attach parental consent form. (See Cover Letter and Informed Consent Required Elements instructions.)

12. ATTACH COVER LETTER to be sent to prospective subjects – if needed for subject recruitment. (See Cover Letter and Informed Consent Required Elements instructions.)

13. ATTACH SEPARATE CHILDREN'S ASSENT FORM – if project involves minors.

14. 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.

Attachment Checklist

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

All applicants should attach…

1. Screening Questions

2. Project Cover Sheet

3. The appropriate proposal form (A or B)

4. 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 copy of the written consent form to be signed by participants and/or their legal guardians or representatives.
- A copy of the written assent form to be signed by participants who are between the ages 7-17.
- 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).
- 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….

1. A Primary Investigator (PI) who is NOT a Lakeland College 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.

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

3. Access to health care, legal, or educational records, provide documentation of approval to access these records.

4. Use of archival data, and they are not publicly available, provide documentation of your authorization to access and use these data.

5. Use of deception, attach a copy of the debriefing protocol and/or materials.

6. 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.