

Lakeland College Institutional Review Board

Cover Letter and Informed Consent Forms Required Elements

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

1. A statement explaining your affiliation with Lakeland College.
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 the subjects' names. NOTE: If you assign a number, it must not be the Social Security number of the subject.
 - 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.
8. The Institutional Review Board approval statement: "This project has been reviewed and approved by the Lakeland College Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the IRB Committee Chairperson, Lakeland College, P.O. Box 359, Sheboygan, WI53082; Phone: 920-565-1290; E-mail: IRB@Lakeland.Edu"

FORMATTING SUGGESTION:

- 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.
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 media.” 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 that in her paper, -- OR -- ☐ I disagree that in her paper, Dr. XXX may quote me.” (Note: Use the appropriate title for the investigator Dr., Mr., Miss., Ms., Mrs., Prof., etc.)
 - D. Each subject must sign the consent form, indicating approval for the recording.
 - E. If recording is planned in a group setting, the consent of all members of the group must be obtained for recording to take place.
 - F. Describe how the recordings will be stored, who will be allowed to hear/view the recordings, and when the recordings will be destroyed.
 - G. If the recordings will not be erased:
 - Get the subjects’ written permission to keep the recordings.
 - State where the recordings will be kept.
 - State who will hear/view the recordings.
 - State how the recordings 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 (IRB@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.”

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 College, you are eligible to receive medical treatment at the Student Health Center. If you are not a registered student at the College, immediate medical treatment is available at usual and customary fees at Aurora Memorial Medical Center or St. Nicholas Hospital, 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) 565-1290.”

*(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.

Sample Participant Cover Letter for Mailed Questionnaire

Respondent
Address
City, State ZIP Code

Dear Respondent,

I am a [student/faculty/staff member] at Lakeland College, and I am conducting a study examining mental health court participants' perceptions of the mental health court experience. Mental health courts are new and innovative, and there is little research that has examined court participants' perceptions of the experience. The results of this study will hopefully improve the operations of mental health courts. It is my understanding that you are currently, or have participated in the Tarrant County Texas Mental Health Court.

I am interested in your experiences in the mental health court, so I have enclosed a questionnaire which asks you to respond to a series of statements and questions. The items in the questionnaire focus on your decision to enter the mental health court and how you thought you were treated by the judge while participating in the court program. Items also ask you to report how often you were compliant in taking prescribed medications, attending treatment sessions and meeting with the judge for court appearances and other program requirements. Finally, the questionnaire includes statements evaluating how helpful you think the court has been across a number of mental health, social service and quality of life areas.

I want to stress that your participation in this study is voluntary and all efforts to protect your identity and keep the information confidential will be taken.

I have enclosed a consent form for your review. Please read the form and feel free to contact me if you have any questions about the study. If you choose to participate, please sign, initial and date the consent information form and return it along with the completed questionnaire in the self-addressed envelope. I look forward to learning about your experiences in the mental health court. Your participation will be greatly appreciated.

Sincerely,

Name
Lakeland College
P.O. Box 359
Sheboygan, WI 53082-0359
Phone Number(s)

This study was reviewed and approved by the Institutional Review Board (IRB) of Lakeland College. Questions concerning your rights as a participant in this research may be addressed to the IRB Chairperson (IRB Chairperson, Lakeland College, P.O. Box 359, Sheboygan, WI 53082; Phone: 920-565-1290; E-mail: IRB@Lakeland.edu)

Sample Informed Consent Form

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. It describes the procedures, benefits, risks and discomforts of the study. It also describes your right to withdraw from the study at any time.

Purpose of the Study

Mental health courts are a fairly new development. There is growing evidence that mental health courts do a better job than traditional courts in helping persons with mental disorders. However, there remains a need to understand how and why mental health courts work. This study will examine mental health court participants' perceptions of the mental health court experience. The study will focus on participants' decisions to enter a mental health court and how they felt they were treated by the judge as well as self-reported program compliance and satisfaction with the court and services provided.

Procedures Involved in the Study

The researcher will attempt to contact participants for a phone interview and asked to respond to statements using options provided by the phone interviewer. For example, some items ask about the percentage of time (0% - 100%) participants engaged in treatment and program requirement behaviors while other items ask the extent to which participants agree with a statement (strongly disagree to strongly agree). The phone interview will take approximately 15-20 minutes. As a secondary procedure, participants will receive a notification letter, the consent form and a copy of the questionnaire to complete and return in a self-addressed envelope [In the event that phone numbers have been disconnected, the information provided to the researcher is incorrect, the researcher has been unable to reach participants via phone, or contacted participants would prefer to complete a paper-pencil survey].

Confidentiality of Research Records

- Only the researcher has access to contact information and responses
- Your personal identifying information will only be used to contact you. Your responses will be recorded on a form that contains a code number created by the researcher.
- After interviewing you or if you decline to participate, the researcher will take a black marker and cross through your name and information. At the end of the study, the contact sheet will be shredded, leaving no possible way to match code numbers/responses with your name.
- Your personal/individual responses will not be given to the judge or court personnel
- During the study, all data will be kept in a locked, secure, filing cabinet
- By using code numbers, in the event that the results were subpoenaed, your individual responses could not be singled out

Potential Risks and Discomforts:

- No physical, social or economic risks are posed to participants.
- *Participating in the study will not affect your current legal status, services provided or status in the program.* For participants in the study who are currently enrolled in the mental health court, your participation in this study will in no way alter the level or type of services you are receiving from the court or change your legal status in the court. For example, reporting medication noncompliance to the researcher will not result in a program violation. The information that participants provide will remain confidential and the researcher is under no legal obligation to report program non-compliances, such as usage of alcohol or drugs, medication noncompliance and treatment non-attendance to the judge or other court personnel. If you have already completed the mental health court program or were terminated from the program, your results are also confidential and will in no affect the previous outcome/disposal of your case.

- *Breaking confidentiality and mandatory reporting.* If a participant provides detailed information about crimes committed that are unknown to the court (a crime that you were not caught, charged or convicted of) the researcher will be legally obligated to report the crime to the court or appropriate authorities. Similarly, if participants discuss plans to harm themselves or others during the phone interview, and the interviewer perceives the threat to be real and imminent (going to happen soon), the researcher is obligated to report the threats to the appropriate authorities. To reduce the likelihood of this risk, the researcher will instruct the participant to refrain from providing information about specific criminal behaviors and to only respond using the response options for questions provided in the phone interview.

Potential Benefits

By participating in this study, you will get an opportunity to provide information about how you felt you were treated in the mental health court; identify positive and negative aspects of mental health courts; and potentially improve the services provided to mental health court clients. This is a participant's chance to give the research community and the mental health court important feedback on the operations of the court. The research community often overlooks client perceptions and experiences in the criminal justice system and in new programs. Your responses are highly valued and could possibly explain what makes mental health courts different from standard courts and why mental health courts are effective or ineffective in helping persons with mental disorders.

Voluntariness & Withdrawal from Study

Your participation in this study is strictly voluntary and will not affect your current legal situation or result in adverse reactions from the mental health court. Neither the judge nor court personnel will know who has or has not participated in the study. If you choose to participate in the phone interview, you may end the interview at any time.

This study was reviewed and approved by the Institutional Review Board (IRB) of Lakeland College. Questions concerning your rights as a participant in this research may be addressed to the IRB Chairperson (Lakeland College, P.O. Box 359, Sheboygan, WI 53081; Phone: 920-565-1290; E-mail: IRB@Lakeland.edu.)

I have read the material above, and understand the purpose, risks and benefits associated with the participating in this study. 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.

Respondent's Signature

Date