

2016 Sample Informed Consent Documents

Sample Informed Consent Document #1 [Reading level 8.0]

October 11, 2016

Jane Q. Student is conducting a study called The Effects of Noise on Thinking. About 100 people will be asked to read a passage in a noisy room, and then answer three questions about it. This should take about 10 minutes.

An experimental study is being conducted to determine the effects of noise on thinking. Experimental procedures will be used as participants will be randomly assigned to conditions. No more physical or mental risks or discomforts than would be ordinarily found in daily life will result from participating. You may not benefit, but your participation may help others.

Your name will not be revealed. Any data you share will be recorded in a way that keeps your name confidential. Only the researcher will have access to the data. Data will be kept in a locked box at the University. All participant data will be added together when reported.

Your participation is completely voluntary. You may change your mind about participating at anytime. Just tell Jane you want to quit. No penalty or loss of benefits will occur if you leave the study or if you choose not to participate.

If you have questions about the research, contact Jane Q. Student at 814 555-1234. If you have questions about your rights as a research participant, contact [the chair of Institutional Review Board Committee for Protection of Human Subjects] at 814 555-5555 or xxx@gannon.edu.

You will be given a copy of this form to keep.

I volunteer to participate in this study. I have had the opportunity to ask questions.

Participant signature _____ Date _____

Witness signature _____ Date _____

Check here to see the results when the study is over.

Using language that is understandable and appropriate, I have discussed this research with the above participant.

Researcher signature _____ Date _____

Sample Informed Consent Document #2

Title: Comparison of Test Scores before and after a Program Change

Researcher: Jane Q. Student, Teacher at X School, Student at Gannon University
Address
Phone

Research Purpose: This study involves research. The purpose is to evaluate results of program change on test scores. None of the research methods are experimental.

Duration: Participants have already spent one year in the new program. Participants will not be asked to spend more time.

Procedures: Scores on achievement tests administered 2 years ago and entered into school records will be compared with scores on achievement tests administered most recently. The tests were part of the normal curriculum. The researcher is asking for permission to use previously recorded scores for study. Data has been stored on the school record keeping system.

Risks: Since the testing has already been completed, there are no known risks.

Benefits: There are no benefits to the participants. Future students may or may not benefit. There will be no payment for participation.

Confidentiality: The researcher alone will have access to students' names. Names will be removed before analysis. Findings will be presented in group form. Individual scores or names will be impossible for anyone to discover when the study is complete.

Contacts: If you have questions about the research, contact Jane Student at 555-1234 or Gannon University faculty sponsor at 814 555-4321. If you have questions about your rights as a participant in research, contact IRB Chairperson at 814 555-5555 or xxx@gannon.edu.

Rights: Your consent to allow your child's scores to be used is voluntary. No penalty or loss will occur if you do not allow participation. You may withdraw participation any time before the data is compiled by contacting the researcher. If you agree, your child will be asked to agree also.

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.....

I permit my child [_____] to participate in the above research, if my child agrees to participate.

Parent Signature: _____
Date: _____

Sample Informed Consent Document #3 –*Information Sheet* [Reading level 7.7]

Date

Dear Participant;

You are invited to enter a research study. The title of the study is [title]. The study is conducted by [name] at Gannon University for the purpose [state here]... Your participation will help me gain a better understanding of [the topic]. Physical or mental risks from participating are no greater than would be found in daily life. No experimental procedures will be used.

Those who participate will be asked to [answer a 10 question survey]. This should take 15 minutes. Do not put your name on the survey. Any information obtained will remain confidential. No individual answers will be reported. Only grouped data will be published. Surveys will be scanned to a computer in the researcher's office at Gannon University for storage.

Your participation is voluntary. If you don't want to participate, don't submit your survey. Since no name is on the form, it will be impossible to withdraw your data from the study after the survey is turned in.

Ask questions about the research of [researcher] at (555) 555-5555. Ask questions about your rights as a participant of [the chair of Institutional Review Board Committee for Protection of Human Subjects] at 814 555-5555 or xxx@gannon.edu.

You may keep this form. Signing or returning it is not needed. Thank you.

Signed,

Name
Principal researcher

Sample informed consent document #4—*Script* [Reading Level 7.6]

Sample situation:

The script below is to be read aloud to prospective participants gathered in one place to attend a lecture. The script will be read to as many groups as needed to gather 400 surveys.

Sample script

May I have your attention, please?

I ask you to volunteer to participate in a research study. To be eligible to volunteer, you must be at least 18 years of age. If you decide to volunteer, you will be asked to answer a 15-item survey questionnaire that is printed on the papers in my hand. I estimate this to take about 10 minutes.

The research project is called “The effect of lighting on ease of reading”. The purpose is to evaluate participant’s preferences regarding lighting in a classroom.

Procedures to be followed

You will be given a survey and a pen. Please DO NOT put your name on the survey. After you have looked over the survey, you may mark answers on it or not. Please put the survey in the box located on the table by the door. You may keep the pen. Answers will be tabulated by the researcher and results will be compiled for possible publication. None of these procedures are experimental.

Possible concerns

Your participation is anonymous. No name has been collected. Since no names are collected it will be impossible to withdraw from the study after you have submitted the survey. There is no penalty for not answering the questions. You may not benefit from participating. Your responses may benefit others. There are no more risks, either physical or mental, than you would find in every day life.

Contact persons

If you have questions, business cards for persons who will answer them are available next to the collection box. George Washington, the principal investigator, will answer questions about the research study and Dr. Georgia Bush, the researcher’s adviser, will answer questions about your rights as a participant.

Thank you for considering participation in this project.

SAMPLE CHILD ASSENT

For Children Between 7 and 12 Years of Age

My name is XXX. I am a student in the Department of XXX Gannon University. I would like to invite you to take part in my research study. A research study is a special way to find out about something. I am trying to learn more about what makes a good friend.

If you agree to be in this study, you will be asked to meet with me privately and you will be asked to answer questions about why you like your friends and why they like you. The questions will take about 15 minutes to answer. Some of the questions will be personal and you can stop at any time. We don't know if being in this research study will help you. But you may be helping us to understand children and friendship or what makes a good friend.

If you agree to help us, your teacher and classmates will not know what you have said. If you decide to be in the study or if you decide to say "no" your choice will not affect your grades or whether people like you.

When we are done with the study, we will write a report about what we found out. We won't use your name in the report.

Please talk this over with your parents before you decide if you want to be in my study. I will also ask your parents to give their permission for you to be in this study. But even if your parents say yes you can still say no and decide not to be in the study.

If you don't want to be in this study, you don't have to be in it. Remember, being in a study is up to you and no one will be upset if you don't want to be in it. If you decide to stop after we begin that is okay too. Remember that no one else, not even your parents will know what you have told me.

You can ask any question that you have about the study. If you have a question later that you didn't think of now, you can call me or ask your parents, teacher or a friend to call me at 814-XXX-XXXX.

Signing here means that you have read this paper or someone read it to you and that you are willing to be in this study. If you don't want to be in this study, don't sign.

Printed Name of Participant

Date

Signature of Participant

Printed Name of Investigator

Date

Signature of Investigator