

WESTERN CONNECTICUT STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT GUIDELINES

The Federal Guidelines offer the following definitions of Informed Consent.

Definition: [45 CFR 46.116]

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

A. CHECKLIST: The following is a list of information that should be included in letters of consent, when obtaining such consent is relevant or appropriate for your research. Letters should be written in a normal letter format. See the sample informed consent letters at the end of this document.

1. Introduce the project as "research," give the title and explain the purpose of the experiment.
2. State that the project has received approval from the Institutional Review Board, which is the University's human subjects research protections review committee. AND for student research state the course title and number, the name of the professor/instructor, and specific course requirements this project meets.
3. Give a description of the research: outline the hypotheses or research questions being studied and the research procedures being used.
4. List the possible risks and benefits the research may offer and state the precautions being taken to protect human subjects. **NOTE:** If participation in the research involves physical, psychological, and/or social **risk** to the subject, **the informed consent form must say so in bold type.**
Usually, if there is some risk of psychological distress to participating subjects, the WCSU IRB recommends that subjects be provided with a referral source in case they wish to seek assistance dealing with this distress. An appropriate and available referral source is the WCSU Counseling Center, extension 8690.
5. Address the efforts being taken to maintain confidentiality of all data collected. If survey data, records of interviews or other data records are being kept by the researcher, please describe how these records are being kept in a secure manner.
6. If incentives are being used in the study, they should be clearly described.
7. If deception is being used in the study, subjects should receive an explanation of the purpose of the deception during a debriefing.
8. Make it clear that participation in the research is completely voluntary.
9. Establish who may be contacted and how they may be contacted should the

subject have any questions or concerns at any time, or if they should want to receive a final report of the research results.

10. Include a statement that the subject has been informed and understands the experiment, that they consent to participate and that they are at least 18 years of age. (No undergraduate student projects may involve minors under 18; any faculty or graduate student projects that involve minors must receive signed consent from a parent/guardian).

11. Paginate the Informed Consent letter and have the subject initial each page if multiple pages are used.

12. Mention that a copy of the consent form is provided to each subject enrolled in a research study.

B. Copies of the Informed Consent Statements

The Principal Investigator (PI) must keep the original of each consent form signed by subjects enrolled in the research protocol. It is the responsibility of the principal investigator to assure that a copy of the consent form is provided to each subject enrolled in a research study.

C. IRB Waiver of Signed Consent Form requirement

From [45 CFR 46.117 c]

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than the minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

D. Sample Informed Consent forms (on following pages).

A. Sample Informed Consent Example, Lab research.

B. Student Research Example, letter format.

C. Sample of Informed Consent for Minors and/or person with legal guardian(s).

WESTERN CONNECTICUT STATE UNIVERSITY
Danbury, CT

A. SAMPLE INFORMED CONSENT

This is an example of an actual Informed Cosent statement used in a psychological research study conducted at WCSU. Highlighted areas should be replaced by the content of your research.

I. Purpose of the Experiment

By signing this form and completing the attached questionnaires, I consent to participate in the study "Psychological Effects of Participation in Violent Video Game Play". This study is designed to examine the psychological and emotional effects of participating in online video game play on the player.

II. Description and Precautions

There are no expected individual benefits to me from participating in this study, but my participation may help the researchers understand what happens to people emotionally and cognitively when they play violent video games.

I understand that there are no known physical risks associated with participating in this study. I understand that research has indicated that players who play video and computer games containing violence may experience some short-term increases in negative feelings such as anger and frustration. Research indicates that these feelings usually go away after a few hours.

If I still feel upset, angry, or frustrated or if I feel that I need to talk to someone about these feelings, I know that I can contact the Principal Investigator

Bob Smith, Ph.D. Psychology Department WCSU 203-837-XXXX.

for suggestions. Also, the WCSU Counseling Center is available for students who seek counseling or guidance. They can be contacted at: 203-837-8690

I am aware that I may decline to participate in this study, or withdraw from this study at any time without penalty, and that non-participation or withdrawal will in no way affect my grades or prejudice my future interactions with the Psychology department or faculty.

I agree that the investigators and noone else may have access to the information needed to evaluate the study data. I understand that all research and evaluation materials will be confidentially maintained; that my name on this form will not be linked in any computer database with the questionnaires I complete; and that my name will never be used in any presentations or reports of the data. All data from this study will be reported in group form only. I also know that I may direct relevant questions about the research or the rights of research subjects to:

Bob Smith, Ph.D. Psychology Department WCSU 203-837-XXXX.

(If you do not agree to the above terms and do not wish to have your data included in the study, or are less than 18 years of age, please return these forms unsigned to the investigator, and thank you for your time.)

If you have any questions concerning the IRB research application process, please call the WCSU Office of Sponsored Programs and Research at (203) 837-8944.

I understand that this project has been reviewed by the WCSU Human Subjects Review Committee, the University's Institutional Review Board.

I acknowledge that I have been informed of and understand the nature and purpose of this study and my rights regarding participation. I acknowledge that I am at least 18 years of age and that I freely consent to participate in the study. I have received a copy of this Informed Consent statement.

Signed _____

Date _____

Name of Student (print) _____

Your age _____

Project Director, **Bob Smith, Ph.D.**

WESTERN CONNECTICUT STATE UNIVERSITY

B. Sample Informed Consent Letter Student Research Example

Instructions: Replicate this letter with the appropriate information filled in wherever there is highlighting – do not use all caps. Proofread your Informed Consent letter carefully.

Dear Potential Interviewee,

I am taking a course on XXX ENTER COURSE TITLE. You are invited to participate in my student research project for this course. The title of my research project is XXX ENTER PROJECT TITLEXXX. You are being asked to participate in this research study because XXX STATE WHY & KEEP IT SIMPLE AND RESPECTFUL XXX. It is hoped that this interview will help to clarify XXX ENTER YOUR RESEARCH OBJECTIVE – KEEP IT GENERAL AND TO THE POINT XXX.

If you consent to this interview, I will ask you a series of questions. You are not required to answer any of the questions asked. ***FOR NOTE TAKING PURPOSES ONLY, I WOULD LIKE TO RECORD THIS INTERVIEW. I WILL STOP THE RECORDER AT ANY TIME UPON YOUR REQUEST. – or just state – I WILL BE TAKING NOTES DURING THE INTERVIEW.*** All of your responses and your identity will be kept confidential. A pseudonym (not your real name) will be used in the write up of this project.

Possible benefits from participation in this research include DESCRIBE ANY POSSIBLE BENEFITS HERE. Possible risks from participation include DESCRIBE POSSIBLE RESEARCH RISKS HERE.

If you have any questions about this research, please call my professor who is the student project director, XXX ENTER YOUR PROFESSOR'S NAME AND PHONE NUMBER. This research project has been reviewed and approved by the WCSU Institutional Review Board. If you have any questions concerning the IRB research application process, please call the WCSU Office of Sponsored Programs and Research at (203) 837-8944.

You will receive a copy of this form.

I am 18 years of age or older.

Signed: _____

Name (please print): _____

Date: _____

Thank you for assisting with this study.

Sincerely,

(LEAVE SPACE FOR YOUR SIGNATURE)

XXX (YOUR NAME) XXX

Student – **XXX ENTER COURSE NUMBER AND TITLE**

(LEAVE SPACE FOR YOUR PROFESSOR'S SIGNATURE)

XXX ENTER PROFESSOR'S NAME AND CREDENTIALS

Project Director

XXX ENTER YOUR PROFESSOR'S TITLE

Department of **XXX ENTER DEPARTMENT NAME**

Western Connecticut State University

181 White ST

Danbury, CT 06810

XXX ENTER YOUR PROFESSOR'S EMAIL ADDRESS

(203) 837- **XXX ENTER YOUR PROFESSOR'S PHONE NUMBER**

WESTERN CONNECTICUT STATE UNIVERSITY

C. SAMPLE OF INFORMED CONSENT FOR MINORS AND/OR PERSON WITH LEGAL GUARDIANS

Date

Dear Parent or Guardian,

- (1) The (name of the program) is a research project developed by (name the researchers and/or agencies involved) to (describe the nature of the project).
- (2) The (name of the project) has the approval of (name all institutions and boards such as school districts, businesses involved, etc.). It has also been approved by the Institutional Review Board at Western Connecticut State University, which is the University's human subjects research protections review committee.
- (3) (Describe data that will be collected.) For example: Student information will include achievement test scores; school and program attendance records; number and/or quality of performances and/or projects; results from student identification procedures; student grades; students progress in the program (achievement in mathematics, science, and writing; self-regulation and confidence; habits of mind); student perceptions of the program and of how they are doing in school.

As a Parent/guardian, you will be asked to complete surveys about how your son or daughter is doing in school and in the (name) program. This information will be used to (describe the benefits). (Also describe any risks).

This information will be collected throughout the program and will be reported based on group results, not individual student results. Please be assured that any information that you provide will be held in strict confidence by the researchers.

In order to improve my child's school program, I understand that information will be collected about how my child is doing in school and in the (name) Program. I understand that participation in the data collection is voluntary and that I may decide to withdraw my child from the data collection process at any time. If I withdraw my child from the data collection process, this will not change my child's school program in any way or affect my child's grades in school.

I know that I can contact the Project Director at any time and that I can receive a final report of the research results in aggregate form upon request to the Project Director, (name, address, phone at work, rather than at home).

(NAME OF PROJECT)

If you agree to have this information collected about you and your child, please complete the following information. Your signature indicates that the research study has been explained to you, that your questions have been answered, and that you agree to take part in this study.

PRINT YOUR CHILD'S NAME	SCHOOL	GRADE LEVEL
PRINT YOUR NAME (PARENT/GUARDIAN)	<u>YOUR SIGNATURE</u>	DATE

Subject's name (please print): (if minor can sign).

Signature of subject: _____

I acknowledge that the signer of this consent form has been informed of and understands the nature and purpose of this study and freely consents to participate.

Signature of Person Who Obtained Consent: _____

**Please return this form to: YOUR CHILD'S CLASSROOM TEACHER
AT HIS OR HER SCHOOL**

A copy of this form has been included for your records.

This research project has been reviewed and approved by the WCSU Institutional Review Board. If you have any questions concerning the IRB research application process, please call the WCSU Office of Sponsored Programs and Research at (203) 837-8944.