

CONSENT DOCUMENT

(Project Title)*

Patient Professional Relationships

(Explanation of Procedures)*

Professor Mary Smith, of the Department of Sociology in the University of Wisconsin Oshkosh, and her student, William Jones, are conducting a study of how medical professionals relate to patients. We would appreciate your participation in this as it will assist us in making recommendations for improving the teaching of health professionals and the way they treat you.

As part of this study, we would like to observe your visits during the next month with your doctor, nurse, and health technicians. To do this, a trained health researcher will be present in the room to take notes. We will only observe your office visit with your doctor and the office staff. We will not observe your treatment in the examining room. We would also like to ask you questions on a questionnaire after each visit. Our study will not interfere with your treatment at any time.

(Alternative Procedures)*

Although we could study this question by just interviewing your doctor and the office staff, we feel that speaking patients is the best way to find out if they are receiving good medical treatment.

(Risk and Benefits)*

We do not anticipate that the study will present any medical or social risk to you, other than the inconvenience of extra time require for you to answer the questionnaire. Participation in this study may not benefit you directly.

(Safeguards)*

The information we gather through observation or that you give us in the questionnaire will be recorded in anonymous form. We will not release information about you to your doctor or to anyone else in a way that could identify you.

(Freedom to Withdraw)

If you want to withdraw from the study at any time, you may do so without penalty. The information collected from you up to that point would be destroyed if you so desire.

(Offer to Answer Inquiries)*

Once the study is completed, we would be glad to give the results to you. In the meantime, if you have any questions, please ask us or contact:

Dr. Mary Smith
Department of Sociology
UW Oshkosh
Oshkosh, WI 54901
920/424-xxxx

(Third Party Referral)*

If you have any complaints about your treatment as a participant in this study, please call or write:

Chair, Institutional Review Board
For Protection of Human Participants
c/o Grants Office
UW Oshkosh
Oshkosh, WI 54901
920/424-1415

Although the chairperson may ask for your name, all complaints are kept in confidence.

I have received an explanation of the study and agree to participate. I understand that my participation in this study is strictly voluntary.

PRINTED NAME SIGNATURE DATE

[If minors are involved include a separate line for parent or guardian signature.]

PRINTED NAME SIGNATURE DATE

This research project has been approved by the University of Wisconsin Oshkosh IRB for Protection of Human Participants for a 1-year period, valid until (one year from the IRB approval date).

Omit Parenthetical Notes*

B. Short Form Written Consent

This is an example of the consent form that would be signed by the prospective research participant when the short form informed consent procedure is being used. A copy of this document, as well as a copy of the Summary of Research Project (see "C" below) that has been presented to the prospective participant is to be given to the person signing the form.

UNIVERSITY OF WISCONSIN OSHKOSH
SHORT FORM CONSENT DOCUMENT

I, the undersigned, have had presented to me a description of the research study, (TITLE), which explained the study's scope, aims, and purpose; the expected duration of my participation; the procedures which will be used (including experimental procedures); the reasonably expected benefits to myself or others; the reasonably foreseeable discomfort and risk of harm which could result from my participation in this project; and other information required under procedures for informed consent.

I have been provided with a copy of the summary that was presented to me.

I agree to participate in this study.

_____ Date

Signature of Research Participant or
Participant's Legally Authorized
Representative

(Print) Name of Research Participant or
Participant's Legally Authorized
Representative

I, the undersigned, have witnessed the presentation of the description of the research study to the above named research participant (or participant's legally authorized representative).

Signature of Witness

(Print) Name of Witness

C. Information Sheet

This is an example of a written summary that would be presented to the prospective research participant when the research has been determined to be exempt. It contains all of the elements of the Informed Consent Sample in "A". A copy of this document is to be given to the participant.

SUMMARY OF RESEARCH PROJECT

The purpose of this summary is to describe the research study, (TITLE)... and to explain the study's scope, aims, and purpose.

1. The reasonably expected benefits of the project include:
 - a. The benefit to yourself of.... (Description)....
 - b. The benefit to society due to the acquisition of knowledge that may eventually lead to improved.... (E.g. - medical care, health status, quality of life)....
2. The procedures that will be used involve.... (Description)... including the experimental procedures.... (Description)....
3. It is reasonably foreseeable that you will experience.... (Describe).... discomfort. The risk of harm that could result from your participation in the project is.... (level of risk)
4. The alternative procedures that could have been used in this study include.... (Describe)....
5. The expected duration of your participation is.... (time period)
6. Your participation in the study is completely voluntary--you do not have to participate and you can stop at any time. If you refuse to participate now, or withdraw from the study later, it will have no effect on any regular services or benefits available to you at the University of Wisconsin Oshkosh.
7. Any personal information used in this study will be treated confidentially. Information which identifies you as an individual will not be released, without your consent, to anyone for purposes which are not directly related to this research study.
8. If you have any question about this study, or your rights, you may call or write:

Name	Address	Phone
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9. You will be given a copy of this statement, which serves to acknowledge the fact that you have been informed about the project and that you have voluntarily agreed to participate.

Notes:

If the research involves more than minimal risk, add the following:

"The research involves more than minimal risk, in that...(describe).... Compensation in the amount of .(\$)., as well as medical treatment consisting of...(describe)..., is available to you if injury occurs. Contact...(name) ..., ...(address)..., ...(telephone number)..., in the event of a research-related injury."

Where appropriate, add statements such as the following to the Consent document:

"The research may involve risks to yourself (or to the embryo or fetus, if you are or become pregnant) which are currently unforeseeable."

"Your participation in the research may be terminated by the investigator without regard to your consent if ... (reasons)...."

"If you wish to withdraw from the project at a later date, contact ... (name)..., ... (address) ..., ... (telephone number)"

"Any significant new findings developed during the course of the research, which may relate to your willingness to continue participation in the project, will be provided to you."

"Approximately ... (#) ... participants are involved in the study."