

GUIDELINES FOR WRITING INFORMED CONSENT

An informed consent form outlines the research study and expectations for potential participants. This document should be written in layman terms and typed on Delaware State University letterhead. If a technical term must be used, define it the first time it is used. Also, any abbreviation should be spelled out the first time it is used. The title of the research project must be on the informed consent. Each consent form should include the following elements:

Purpose - Include a statement that the study involves research, an explanation of the purposes of the research procedure and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures that are experimental.

Risks and Discomfort - Describe any reasonably foreseeable risks or discomforts-- physical, psychological, social, legal or other associated with the procedure, and include information about their likelihood and seriousness.

Discuss the procedures for protecting against or minimizing any potential risks to the subject. Discuss the risks in relation to the anticipated benefits to the subjects and to society.

Benefits - Describe any benefits to the subject or other benefits that may reasonably be expected from the research. If the subject is not likely to benefit personally from the experimental protocol note this in the statement of benefits. Discuss the risks in relation to the anticipated benefits to the subjects and to society.

Alternative procedures - Include a disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous.

Costs and Payments - It is assumed that there are no costs to subjects enrolled in research protocols. Any anticipated costs to the subject for tests/procedures performed specifically for the study, experimental procedures or use of equipment must be stated.

Any payments to be made to the subject (e.g., travel expenses, stipends) must also be stated, including when the payment will be made.

Confidential information - Provide a statement describing the extent, if any, to which confidentiality or records identifying the subjects will be maintained, and note the possibility that the Food and Drug Administration or drug company supplying the experimental drug may inspect the records.

Compensation - For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs, and if so, what they consist of or where further information may be obtained.

Inquiries - Explain whom the subject should contact for answers to questions about the research or research-related injuries (usually the PI) and the research subject's rights (IRB - Human Subjects Protection Committee chairperson).

Voluntary Participation - Include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits.

Required signatures - Each research subject or the surrogate decision-maker must sign an informed consent form prior to entering the research protocol unless a protocol was specifically exempted because of the nature of the study. Provide a statement of consent written in the first person, i.e., "I hereby consent," etc.

Signature lines for the following should be included on the informed consent form:

- a) The subject or the subject's legally authorized representative.
- b) The witness of both the oral presentation and execution of the written consent.
- c) The investigator or the person obtaining the subject's consent form.

Each subject (or authorized representative) should be given a copy of the signed informed consent. Include such a statement on the informed consent form.

For further information, please contact the Office of Sponsored Programs, 857-6810.

DELAWARE STATE UNIVERSITY
INFORMED CONSENT AND HUMAN SUBJECTS RESEARCH

Research investigators are responsible for obtaining informed consent from human subjects (or their legally authorized representative). The consent information must be in language understandable to the subject or the subject's representative. Wording should not include conditional language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or release the research investigator, the sponsor, the institution or its agents from liability for negligence.

Avoid the person/tense used in the wording of the consent form. Statements interchanging "I," "you," and "one" can be very confusing to the reader.

An effort should be made to be precise. As in our sample, the entire copy may be produced on one side of paper.

A. BASIC ELEMENTS OF THE INFORMATION NECESSARY FOR "INFORMED CONSENT" INCLUDE:

1. Statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation. Use the word "research" to make this element clear.
2. An invitation to participate--worded perhaps as "You are invited to participate in a study of We hope to learn"
3. Why the subject was selected--if this is appropriate to the project.
4. A description of the procedures to be followed and identification of any procedures which are experimental.

5. A description of any reasonably foreseeable risks or discomforts.
6. If any benefits can be reasonably expected, they should be described.
7. A disclosure of any appropriate alternative procedures that might be advantageous for the individual.
8. Aspects of confidentiality of information--if data is in form of tape recordings, photographs, movies or videotapes, researcher should describe period of time they will be retained before destruction. Showing or playing of such data must be disclosed, including instructional purposes.
9. An explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of research-related injury to subject. This is usually the researcher or the faculty advisor.
10. An explanation of whom to contact concerning issues on human subjects rights. This is IRB - Human Subjects Protection Committee Chair or the Office of Sponsored Programs.
11. If subjects are paid a fee or receive some service in lieu of financial compensation for participating, this should be described.
12. A statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits. If the subject is receiving some form of course "credit" for his/her participation, the effect of withdrawal from the experiment on "credit received" should be explained.

13. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if any injury occurs and, if so, what they consist of, or where further information may be obtained.

14. Concludes with statement of acceptance to participate in the research study including the signature of the subject or responsible agent, unless nature of research is such that signed consent forms are unnecessary.

B. DOCUMENTATION OF INFORMED CONSENT

1. Research investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form approved by the IRB - Human Subjects Protection Committee and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB - Human Subjects Protection Committee. A copy of the signed consent form is given to the person signing the form; the original signed consent form is retained by the research investigator.

2. The requirement for the investigator to obtain a signed consent form may be waived by the IRB - Human Subjects Protection Committee if it finds that either:
 - a. the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality.

- b. the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

 - 3. When the IRB - Human Subjects Protection Committee waives the documentation requirement, it may require the investigator to provide subjects with a written statement about the research, generally including the relevant elements of informed consent. In all cases, a written statement describing the informed consent procedure shall be provided to the IRB - Human Subjects Protection Committee.
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PLEASE NOTE THAT THE FINAL FORM ADMINISTERED MUST BE APPROVED BY THE IRB - HUMAN SUBJECTS PROTECTION COMMITTEE BEFORE IT CAN BE LEGALLY ADMINISTERED; SAMPLE COPIES OF THE FORM MUST BY LAW BE RETAINED BY THE IRB - HUMAN SUBJECTS PROTECTION COMMITTEE.

Sample Subject's Consent Forms are attached. **NOTE:** Three samples are shown, a comprehensive form, a cover letter format and oral consent--investigators should develop a consent form appropriate to the type of subject and the nature of the proposed research. Please remember to write at the educational level of the intended subject population.

SAMPLE COVER LETTER FOR CATEGORY I/II PROJECTS

(When signed consent form is not required or appropriate,
e.g., anonymous research involving minimal risk, non-sensitive data, etc.)

Dear (potential subject pool, e.g., student, teacher, manager):

You are invited to participate in a research study [state what is being studied]. We hope to learn [state what the research project is designed to discover or establish]. You are being asked to participate in this study because [state why person is appropriate subject].

If you decide to participate in the project [describe the procedures to be followed, e.g., please complete the attached survey and return it in the enclosed envelope] -- [describe confidentiality conditions].

If you have any questions about this research, please call [name of faculty advisor/investigator]. If you have questions concerning the rights of subjects involved in research studies, please call the Office of Sponsored Programs at 302-857-6819 or 6811.

Your voluntary completion of the survey constitutes consent to participate. Thank you for assisting us with this study.

Sincerely,

Name of faculty/student researchers and University affiliation

e.g., John Smith

Joan Brown

Students in Management 689

Obtaining Oral Consent: If oral consent is necessary due to limited literacy or language comprehension, the subject or his/her legal representative will be asked to sign a short form stating that the basic consent form elements have been orally presented. Both the short consent form and the oral presentation must be approved by the IRB - Human Subjects Protection Committee. A witness must also be present for this presentation and must sign both the short form and a written summary of the oral presentation. The subject or his/her legal representative must be furnished with a copy of both signed documents.

SAMPLE ORAL CONSENT

HELLO--I am a [describe who you are, including university affiliation, e.g., student in (Department) at Delaware State University]. We are conducting research [describe project and method of data collection, e.g., telephone survey, etc.].

Your are being contacted because [explain why you are calling, e.g., random survey, resident of Dover, listed in yellow pages].

If you agree, I would like to ask you some questions about [describe nature of survey]. The survey should take [specify amount of time]. Your responses are [confidential] and will be grouped with other people who are called.

Do you have any questions about the research project? May I proceed with the first question?

Sample Subject Consent Form/Statement

Project Director or Principal Investigator:

Title of Project:

You are invited to participate in a research study of [state what is being studied]. We hope to learn [state what the study is designed to discover or establish]. You were selected as a possible participant in this study because [state why the subject was selected].

If you decide to participate, we [or: Dr. _____ and associates] will [describe the procedures to be followed, including their purposes, how long they will take, and their frequency]. [Describe the discomforts and inconveniences. An estimate of the total time required must be included]. [Describe the risks reasonably to be expected]. [Describe any benefits reasonably to be expected. If benefits are mentioned, it is advisable to add:] We cannot and do not guarantee or promise that you will receive any benefits from this study.

[Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.]

[A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.] If you give us your permission by signing this document, we plan to disclose [state the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure.]

[If the subject will receive a fee for participating, or services in lieu of a fee, describe the amount or nature.] [If there is a possibility of additional costs to the subject because of participation, describe it.]

[For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs, and if so, what they consist of or where further information may be obtained.]

Your decision whether or not to participate will not prejudice your future relations with [(Institution) and the named cooperating institution, if any]. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

Before you complete and sign the form, please ask questions on any aspect of the study that is at all unclear to you. If you have any additional questions later, Dr. _____ (give a phone number or address) will be happy to answer them. If at any time you have questions concerning your rights as a research subject, you may call the Office of Sponsored Programs, 302-857-6819 or 857-6811.

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

I acknowledge that I have received a personal copy of this consent form.

Copy received: _____ (initial) _____

Date

Signature

Time AM/PM

Relationship to subject

[This line should not appear on forms that will be given to subjects consenting for themselves.]

Signature of Witness

Signature of Investigator

Informed Consent Form

Principal Investigator: Dr. Hank N. Lewis

Title of Project: To Assess Students' Perception of Career Choice and Income

You are invited to participate in a research study of "*To Assess Students' Perception of Career Choice and Income*". We do you hope to learn how well the faculty curricula are informing students relative to the work world. This study will be of benefit to others by enabling faculty to understand the extent to which student perceptions are consistent with reality. This kind of clarification can lead to meaningful changes in curricula to enable students to have a more informed view of the world of work.

You were selected as a possible participant in this study because you are a graduating senior or a graduating masters level student at Delaware State University.

If you decide to participate, Dr. Hank Lewis will ask that all graduating students report to the research station where a research assistant will provide each student with the informed consent "Signature Sheet". Students will be asked to take two minutes to read and sign the sheet. After students have signed the sheet, they will be given the 2-page, 15 item survey instrument to complete. The instrument has been field tested and it is confirmed that the average student should complete the instrument within 10 to 15 minutes. Combined with the two minutes for reviewing the informed consent "signature sheet", the total time to complete the survey process is estimated at a minimum of 12 minutes and a maximum of 17 minutes. Considering that this study is based on student perception and there are no invasive procedures or information requested, no discomforts or risks can be identified. This study has minimal risks attached to it relative to the participants. Therefore, issues such as medical care and compensation are not active concerns. This study will be of benefit to others by enabling faculty to understand the extent to which student perceptions are consistent with reality.

Student participants are asked to read and sign a separate signature sheet to address informed consent. These documents will be kept in my research mentor's office in a locked file until the data is analyzed and the report is generated. These forms will then be shredded under the supervision of the research mentor when the written report is accepted. There is no identification included in the survey instrument. So there will be no way of identifying responses with the respondents.

If you give us your permission by signing this document, we plan to disclose this study in a formal paper submitted to my research mentor and the director of the McNair Program.

Your decision whether or not to participate will not prejudice your future relations with Delaware State University. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice. Before you complete and sign the form, please ask questions on any aspect of the study that is at all unclear to you. If at any time you have questions concerning your rights as a research subject, you may call the Office of Sponsored Programs at 302-857-6810.

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

I acknowledge that I have received a personal copy of this consent form. Copy Received: _____
(initial)

Date _____ Signature _____

Signature of Investigator _____