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HSRP Forms

Office of Human Subject Research Protection

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Template 1: format for signed informed consent document

Office of Human Subject Research Protection, Northeastern University

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Template 1 Format for Signed Informed Consent Document

Northeastern University, Department
Investigator Name
Title of Project

Informed Consent to Participate in a Research Study

We are inviting you [or your child] to take part in a research study. This form will tell you about the study, but the researcher will explain it to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, the researcher will ask you to sign this statement and will give you a copy to keep.

Why am I being asked to take part in this research study?

Explain if the person is being recruited because of special or clinical characteristics.

Ex: *We are asking you to be in this study because you are a Gulf War veteran*.

Why is this research study being done?

State the purpose of the study in lay language.

Ex: *The purpose of this research is to develop a survey that will be useful in measuring whether people with arthritis are doing better or worse after treatment*.

Is preferable to:
The purpose of this research is to develop a psychometrically valid and reliable instrument that will provide quantitative data that can be analyzed to support treatment and management decisions for people with arthritis.

What will I be asked to do?

If you decide to take part in this study, we will ask you to _____.
Describe all the tasks that the person will be asked to do, or describe what will be done to them. Provide sufficient detail so the person understands what his/her role entails. If it involves questionnaires, provide a brief description. If it involves unfamiliar equipment, explain how it will be used. Use lay language rather than technical/professional terms. Use bullets or timetables for research that has multiple visits or tasks.

Identify and describe any procedures that are experimental.
If applicable, differentiate between research procedures and routine procedures. For example, if you wish to add a research component to a regularly scheduled (non-research) program, clearly identify the tasks that are program-related and those that are research-related. Be clear that the person may continue with the regular program even if they decide not to participate in the research component.

If the study is randomized, explain randomization.

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Where will this take place and how much of my time will it take?

Tell the person where each part of the study will be conducted and how long each part will take.

> **Ex**: *You will be interviewed in your own home or at a time and place that is convenient for you. The interview will take about one hour. Three months later, we will mail you a follow-up questionnaire with 25 questions that will take 20- 30 minutes to complete. You can mail it back to us in the stamped envelope we will provide.*

Will there be any risk or discomfort to me?

Identify any reasonable foreseeable risks, harms, discomforts or inconvenience that the participant may experience. Indicate the likelihood that it may occur as well as the seriousness. Consider legal, financial, social, psychological, physical, etc. risks. Describe the precautions you will take to minimize the risks, discomforts or inconvenience. Describe follow up for any adverse event (anxiety, physical injury). If there is no foreseeable risk or discomfort, state that.

Will I benefit by being in this research?

Describe any personal benefits that the participant may reasonably expect from their participation. If there is no direct benefit, state that. Payment for participation is not considered a benefit.

> **Ex**: *There will be no direct benefit to you for taking part in the study*. You may add, "*However, the information learned from this study may help ...."*

Who will see the information about me?

If the participant's identity **WILL NOT** be matched to their responses:

> **Ex:** *Your identity as a participant in this study will not be known. That means no one, not even the researchers, will know that the answers you give are from you.*

If the participant's identity **WILL** be matched to their responses:
Explain who will have access to information and in what form.

> **Ex**: *Your part in this study will be confidential. Only the researchers on this study will see the information about you. No reports or publications will use information that can identify you in any way.*

Describe the procedures you will use to protect personal information. If codes are used, describe coding procedures. Explain how data will be maintained, and when/if data will be destroyed. Audiotapes and videotapes are considered identifiable information, even if no names are included.

Describe any limits to confidentiality. For example, identify any legal reporting requirements, e.g., child abuse. Specify what information must be reported, under what circumstances, and to whom. Also, explain official oversight or monitoring that may be done by NU, government agencies, sponsors, etc.

> **Ex***: In rare instances, authorized people may request to see research information about you and other people in this study. This is done only to be sure that the*

research is done properly. We would only permit people who are authorized by organizations such as Northeastern University or [FDA, OHRP, sponsor] to see this information.

If I do not want to take part in the study, what choices do I have?

For treatment studies, alternatives to participation must be identified and described. For example, if the person does not want to participate in an experimental physical therapy program, inform the person about standard physical therapy or other appropriate health care.

If your study does not involve treatment or other potential benefit, the participant's option is to not participate. In that case, you may omit this section.

What will happen if I suffer any harm from this research?

If research-related injury (i.e. physical, psychological, social, financial or otherwise) is possible in research, provide an explanation of whatever compensation or treatment will be provided. If physical injury is possible, explain whether any medical treatment is available, what it consists of, and where further information may be obtained.

When appropriate, you may use wording such as, *No special arrangements will be made for compensation or for payment for treatment solely because of my participation in this research.*

Can I stop my participation in this study?

Ex: *Your participation in this research is completely voluntary. You do not have to participate if you do not want to. Even if you begin the study, you may quit at any time. If you do not participate or if you decide to quit, you will not lose any rights, benefits, or services that you would otherwise have [as a student, employee, etc].*

Who can I contact if I have questions or problems?

Include the name and viable contact information of one or more appropriate people. If there is a possibility of an emergency, be sure an immediate response is available.

Who can I contact about my rights as a participant?

Ex: *If you have any questions about your rights as a participant, you may contact Nan C. Regina, Director, Human Subject Research Protection, 960 Renaissance Park, Northeastern University Boston, MA 02115 tel. 617-373-7570, email: irb@neu.edu. You may call anonymously if you wish.*

Will I be paid for my participation?

If participants will be paid or given a gift, state what the payment is and when it will be given.

Ex: *You will be given a $5 gift certificate to Chicken Lou's as soon as you complete the Nutritional Quality of Life Survey.*

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Will it cost me anything to participate?

State any costs that may be incurred by the participant for the study, e.g., parking.

Is there anything else I need to know?

Include any pertinent information that may not be stated elsewhere.

Ex: *You must be at least 18 years old to participate unless your parent or guardian gives written permission.*

Ex: *This research is paid for by Boston Police Dept; XYZ Pharmaceuticals; Internal Revenue Service*

I agree to [have my child] take part in this research.

_____ _____

Signature of person [parent] agreeing to take part **Date**

_____

Printed name of person above

_____ _____

Signature of person who explained the study to the participant above and obtained consent **Date**

_____

Printed name of person above

``

Depending upon the nature of your research, you are required to provide information about one or more of the following if it is applicable:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new finding(s) developed during the course of the research which may be related to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.