

Informed Consent Agreement for Participation in a Research Study

Investigator:

Contact Information:

Title of Research Study:

Sponsor:

Introduction (recommended)

You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: (In a few sentences, describe the overall purpose of the study. For this section, and all sections of the consent form, use simple, plain English. This section is required.)

Procedures to be followed: (Here describe the research procedures to be followed, including duration of the subject's participation. Experimental procedures must be identified. This section is required.)

Risks to study participants: (Describe any reasonably foreseeable risks or discomfort to the subject. This section is required.)

Benefits to research participants and others: (Here describe benefits, if any, to the subject or to others which may reasonably be expected from the research. Do not list compensation, if any, as a benefit. If there are no benefits to the subject, indicate that there are none. This section is required.)

Alternative procedures or treatments available to potential research participants: (Here list any appropriate alternative procedures or courses of treatment that might be advantageous to the subject. If none are known, omit this section.)

Record keeping and confidentiality: (Describe record keeping procedures, including who will have access to records, whether and how confidentiality will be maintained, and what information is expected to be reported. Include the following statement, "Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you." This section is required.)

Compensation or treatment in the event of injury: (If the research involves more than minimal risk of injury or harm, explain whether any compensation or whether any medical treatment is available in the event of injury. Explain the nature of any compensation or treatment, and where further information may be obtained. Include the following statement, “You do not give up any of your legal rights by signing this statement.” This section is required.)

Cost/Payment: (Describe amount and type of subject compensation, if applicable. If none, omit this section.)

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: (Fill in your contact information or make reference to information provided at top of page. In addition, include the contact information for the IRB Manager (Ruth McKeogh, Tel. 508 831-6699, Email: irb@wpi.edu) and the Human Protection Administrator (Gabriel Johnson, Tel. 508-831-4989, Email: gjohnson@wpi.edu). This section is required.)

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit. (This section is required.)

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

Study Participant Signature

Date: _____

Study Participant Name (Please print)

Signature of Person who explained this study

Date: _____

Additional clauses to add to Consent Agreements, as appropriate:

The treatment or procedures used in this research may involve risks to the subject (or to an embryo or fetus, if the subject is or may become pregnant), which are currently unknown or unforeseeable.

Additional costs to the subject that may result from participation in this research include: (list).

Significant new findings or information, developed during the course of the research, may alter the subject's willingness to participate in the study. Any such findings will be promptly communicated to all research participants.

Should a participant wish to withdraw from the study after it has begun, the following procedures should be followed: (list). The consequences for early withdrawal for the subject and the research are: (list).

Special Exceptions: Under certain circumstances, an IRB may approve a consent procedure which differs from some of the elements of informed consent set forth above. Before doing so, however, the IRB must make findings regarding the research justification for different procedures (i.e. a waiver of some of the informed consent requirements must be necessary for the research is to be "practicably carried out.") The IRB must also find that the research involves "no more than minimal risk to the subjects." Other requirements are found at 45 C.F.R. §46.116.