

SAMPLE CONSENT TO PARTICIPATE IN RESEARCH

[Insert title of the study]

[Insert 24 hour phone # for studies involving more than minimal risk]

CONSENT TO PARTICIPATE IN RESEARCH

[If the study involves using different consent forms for different populations, identify the population group as the subtitle of the study.]

You are asked to participate in a research study conducted by [insert names and credentials or student status, e.g. doctoral candidate], from the [insert department affiliation] at Trident University International. [If student, indicate that results will be contributed to a dissertation] You were selected as a possible participant in this study because [explain succinctly and simply why the prospective subject is eligible to participate].

PURPOSE OF THE STUDY

[State what the study is designed to assess or establish.]

PROCEDURES

If you volunteer to participate in this study, you will do the following things:

[Describe the procedures chronologically using simple language (8th grade reading level for an American native-English speaking population), short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. Identify any procedures that are experimental.]

[Specify the subject's assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of the procedures to be done, etc.]

POTENTIAL RISKS AND DISCOMFORTS

[Describe any reasonably foreseeable risks, discomforts or inconveniences, and how these will be managed.]

[If there are significant physical, psychological, economic or social risks to participation that might cause the researcher to terminate the study, please describe them.]

POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY

[Describe benefits to subjects expected from the research. If the subject will not benefit from participation, clearly state this fact.]

[State the potential benefits, if any, to science or society expected from the research.]

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PAYMENT FOR PARTICIPATION

[State whether the subject will receive payment or other form of incentive. If not, so state. If subject will receive payment, describe remuneration amount, when the payment is scheduled, if there is a pro-ration schedule, so state, in case the subject decides to withdraw or is withdrawn by the investigator.]

EMERGENCY CARE AND COMPENSATION FOR INJURY

[Note: The following is a required element of informed consent for research involving more than minimal risk. If this does not apply to your research, please omit this entry and delete the heading:]

"If you are injured as a direct result of research procedures not done primarily for your own benefit, [... describe the form of professional medical advice or treatment you will make available.]

CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law.

[If information will be released to any other party for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.]

[If activities are to be audio- or videotaped, describe the subject's right to review/edit the tapes, who will have access, if they will be used for educational purposes, and when they will be erased.]

PARTICIPATION AND WITHDRAWAL

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. Participation or non-participation will not affect your [Note--choose appropriate term: grade, treatment, care, employment status, etc,] or any other personal consideration or right you usually expect. You may also refuse to answer any questions you don't want to answer and still remain in the study. The investigator may withdraw you from this research if circumstances arise that in the opinion of the researcher warrant doing so. [Note: If you are providing a benefit to subjects or an incentive payment, and if you know or can anticipate the reasons for withdrawing a subject, you should state them briefly. These reasons should relate to the original eligibility requirements in your protocol. Do not include reasons which are crimes or otherwise covered in penal codes; these are covered in your authority over the research.]

IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about the research, please feel free to contact [identify research personnel: Principal Investigator, Faculty Sponsor (if student is the P.I.), Co-

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Investigator(s)]. Include day phone numbers for all listed individuals. For greater than minimal risk studies, include night/emergency phone numbers.]

RIGHTS OF RESEARCH SUBJECTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, contact the Institutional Review Board for the Protection of Human Subjects at Trident University International, 5757 Plaza Drive, Suite 100, Cypress, California 90630; Telephone: (714) 226-9840.

During this study, if the researchers discover any new information that might cause you to change your mind about participating, the researchers will share this new information with you.

SIGNATURE OF RESEARCH SUBJECT (AND) OR LEGAL REPRESENTATIVE [Note: Use "and" when both required.]

I understand the procedures and conditions of my participation described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

Name of Subject

Name of Legal Representative (if applicable)

Signature of Subject or Legal Representative Date

Name and signature of witness where appropriate

STATEMENT and SIGNATURE OF INVESTIGATOR [Note: The IRB will normally require that the investigator sign the following statement when the risk to subjects is greater than minimal or when physically invasive procedures will be used or when there is a probability* of some subjects being of diminished autonomy.

* Probability in this situation means at least one standard deviation greater than mean statistical possibility.]

In my judgment the subject is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

Signature of Investigator Date