

SAMPLE CONSENT FORM FOR GREATER THAN MINIMAL RISK

This format is provided as a **SAMPLE FORMAT** for greater than minimal risk to assist you in writing an informed consent form. The form must be typed and the **first page must be on Hope College letterhead (or official stationary of the site where the research is being conducted)**. All pages of the form must be numbered, e.g. Page 1 of 6.

RESEARCH SUBJECT INFORMATION AND CONSENT/AUTHORIZATION FORM

TITLE OF PROJECT: _____

NAME OF PRINCIPAL INVESTIGATOR: _____

PRINCIPAL INVESTIGATOR'S PHONE: _____

SPONSOR: (if applicable) _____

"CONFLICT OF INTEREST" STATEMENT: [Choose an applicable statement. If assistance is needed, contact the Chair of HSRB, inman@hope.edu]

Hope College and/or Dr. _____ are (is) being paid by the sponsor of this research study for conducting services related to the protocol. However, neither Hope College nor the investigator has a significant financial interest in the sponsor of this research study.

or

Both Hope College and Dr. _____, the investigator conducting this study sponsored by _____, have a significant financial interest in the sponsoring company.

or

Dr. _____, the investigator conducting this study, has a significant financial interest in _____, the company sponsoring this study.

or

Hope College has a significant financial interest in _____, the company sponsoring this study.

or

This study is funded by _____ [agency or foundation name], a public agency/private not-for-profit foundation], which is supporting the costs of conducting the research. Neither Hope College nor _____ [Principal Investigator's name] will receive any financial benefit based on the results of the study.

CONSENT FOR PARTICIPATION IN A RESEARCH INVESTIGATION

INTRODUCTION

I, _____ agree to participate in a research study entitled,
_____ (name of participant)
” _____” which has
been given approval by the Hope College Human Subjects Review Board (HSRB) for the use of
human participants in the study.

PURPOSE OF THE STUDY

The purpose of the study is _____ (Write a short paragraph explaining in easy to understand layman's language the purpose of the study. Do not use scientific jargon or abbreviations.)

DESCRIPTION OF RESEARCH PROCEDURES

The procedure involves... _____ (Describe in lay terms what the participant is expected to do and what the participant can expect to be done to him/her. Include disclosure of all surveys, testing, questioning, or recording.)

The study continues for _____ (Give an overall time involvement of subject.)

RISKS/DISCOMFORTS

You may experience _____ (List any discomforts, embarrassments, ill effects, inconveniences, and other possibilities of unforeseen risks.)

COSTS (sample statements - select the applicable statement)

There will be no cost to you if you participate in this research.

or

The following cost will be incurred by you if you participate in this research.

NOTE: The HSRB strongly discourages the submission of research protocols in which any costs directly related to research participation are borne by the study subjects, because this may result in inequitable access to the research based on income.

BENEFITS

Benefits that may occur from this study are said to include...(State realistic benefits. Do not include monetary benefits if subjects are being reimbursed for their time and expense. Monetary matters are discussed below under Compensation.)

or

There may be no personal benefit to you but the knowledge received may be of value to humanity.

RIGHTS

Your participation is voluntary. Refusal to participate will not result in any penalty or loss of benefits to which you might otherwise be entitled. You can withdraw your consent and discontinue participation in the study at any time without affecting your relationship with your teacher or Hope College and without loss of any benefits that you may otherwise be entitled. In the event that you withdraw from the study, the study investigator may ask your permission to continue study follow-up as it relates to the study.

New information developed during the course of the study which might affect the understandings in this consent and willingness to continue to participate will be brought to your attention.

Your participation in this study may be ended by the principal investigator or the sponsor if they feel it is in the interest of safety.

No guarantees have been made as to the results of your participation in the study.

COMPENSATION

[If there is reimbursement for study participation, include statement pertaining to the reimbursement, e.g., "You will receive up to \$ _____ total for completion of this study. This is for your time and travel costs related to the study."]

For research involving more than minimal risk, include an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, who will pay for these treatments, and where further information may be obtained.

CONFIDENTIALITY

I understand that the following procedures will be used to maintain my anonymity in analysis and publication/presentation of any results: (1) Each participant will be assigned a number, names will not be recorded. (2) The researchers will save the data file and/or any video or audio recordings by participant number, not by name. (3) Only members of the research group will view the files in detail. (4) The recordings and files will be stored in a secured location by Professor _____. (5) Only the investigators and research team will have access to these files.

Optional Permission: I understand that the researchers may want to use a short portion of any video or audio recording for illustrative reasons in presentations of this work in the classroom or

at professional meetings. I give my permission to do so provided that my name and face will not appear.

_____ YES _____ NO (Please initial here ____)

I understand that in signing this consent form I give Professor _____ and his/her associates permission to present this work in written and/or oral form for teaching or presentations to advance the knowledge of science and/or academic without further permission from me.

CONTACT INFORMATION

If you have any questions about this study, you should feel free to ask them now or anytime throughout the study by contacting:

Professor _____
Department Name
Address
Phone
E-mail

You may report any objections to the study either orally or in writing to:

Dr. Mary Inman, HSRB Chair
Hope College Psychology Department
1162 Schaap Science Center
E-mail: inman@hope.edu
616-395-7148

For any questions pertaining to your rights as a research subject, you may contact the HSRB chair above.

UNDERSTANDING OF PARTICIPATION

I have read all _____ (indicate the exact number of pages) pages (if more than two, note how many pages, e.g., Page 1 of 6) of this form and understand and agree to the material contained thereon. I will receive a copy of this form.

I agree to participate.

SUBJECT SIGNATURE (relationship, if kin or guardian signs for subject) DATE

WITNESS: _____ DATE: _____

