Model Consent Form for Adults

This model consent form is meant to be a guide for you as you write your own consent form. Note that this example is for illustrative purposes only. The length of and detail in each category will depend on the individual study and its potential risk to human participants.

The language should be written in language appropriate for the audience. Only adults can legally give informed consent (sign consent forms). When your study involves minors, you must obtain written permission from the parent/guardian and verbal or written assent from the participant.

Directions and suggestions are in *italics* and sample language is highlighted.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Project:

Principal Investigator(s):

Include the investigator's name, title, and university or (when appropriate) other work contact information.

Ms. Sally Jones
Graduate Student
College of Education
Some University
jones@someuniversity.edu

Co-Investigator(s):

Identify all co-investigators. When the co-investigator is a faculty sponsor, identify as such. You may delete this heading if there are no co-investigators.

Mr. Abdullah Shamrani
Graduate Student
College of Business & Technology
Some University
shamrani@someuniversity.edu

Faculty Sponsor:

Dr. John Smith
Assistant Professor
College of Business & Technology
Some University
smith@someuniversity.edu

918-444-XXXX

Purpose of the Study:

Explain in 1-2 sentences why this study is being done.

Procedures to be Followed:

Describe what the participant will be asked to do, and what you and others involved in the study will do, if they agree to participate. Be specific—walk them through the process. Explain the participants' tasks in chronological order.

If the information is collected during a class period, be sure and state that those who do not participate will have an alternative activity and that non-participation will not affect their grade.

You are being asked to participate because you are currently taking a health or physical education course at Some University. You will be asked to complete a series of questions about your thoughts, beliefs, and attitudes about physical activity, healthy behaviors, social anxiety, and self-esteem and asked to report your height and weight. You will complete this questionnaire during one of your health or athletics classes. You will be asked to complete this consent form and the questionnaire, place them in separate sealed envelopes provided for you, and put them in separate boxes at the front of the room. You will have an alternative activity to complete if you do not wish to participate in this study.

Participation or non-participation in this study has no impact on your grade in your Health or Physical Activity class. You are welcome to place the blank documents in the envelopes and place them in the box if you do not wish to complete them.

Describe the qualifications to be in the study, if applicable. You must be at least 18 years of age to participate.

State who will be administering the tests and their qualifications, if applicable.

Discomforts and Risks:

Describe any discomfort and/or risks the participant may have. The following are two examples—the first is for a participant who is being asked to complete a survey and the second is for the participant using an experimental drug.

There are no risks in participating in this research beyond those experienced in every day life. Some of the questions are personal and might cause discomfort.

You may have side effects while participating in this study. You will be observed and watched carefully for any side effects. However, the investigators do not know all the side effects that could potentially occur. Side effects may range from mild to very serious. The investigators may give you medications to help decrease the side effects. Some side effects may occur initially and then go away after you are taking the drug. Serious side effects may be long lasting and/or may never go away.

You should speak with your investigator immediately should any side effects occur during this study.

Known risks and side effects related to this drug include…

You should not become pregnant or father a baby while participating in this study. The drug you are taking may affect an unborn baby. Women should not breastfeed a baby while participating in this study. You should use birth control while participating in this study. Check with the investigator about what kinds of birth control methods to use and how long to use them. Some methods may not be approved for use in this study.

Pregnancy testing may be required.

If there is the potential for injury, give details about what to do and what will happen if this occurs. Provide contact information.

If you are injured as a direct result of research procedures, you will receive reasonably necessary medical treatment at no cost. The university does not provide any other form of compensation for injury. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

If applicable, you may need to include that there is a risk of death.

Benefits:

Describe any anticipated benefits of participating in this study to the individual and/or the benefits of the research to society. Be careful not to overpromise results. The following are examples of what you might say.

The information we get from this study may help us to…

You may enjoy sharing your (experiences, opinions).

You might learn more about yourself by participating in this study.

You might gain a better understanding of your behavior relating to (physical activity, health, social aspects, self-esteem…)

Studies that involve drugs or interventions:
You may not benefit from taking part in this research.

Costs or Compensation:

Tell the participant if there are any costs for taking part in the study.

There is no charge for participation in this study. Neither you nor your insurance carrier will be charged/billed if you take part. All costs will be paid by the sponsor(s) of this study.

Is there compensation for participating in the study? If there is, describe the payment they will receive for participating. You can pro-rate for those who withdraw early, though you should not make completion a condition of payment. If there is no compensation, simply state that there is no compensation.

Samples or information taken during this study may be used for research and development purposes not related to your treatment or condition. You will not have property rights or ownership interest in products or data which may be derived from your samples or participation.

Duration:

It will take approximately 30-45 minutes to complete this survey.

You will turn in your exercise log once per month throughout the six month study period.

Describe any follow-up activities in this section.

You will take the pre-test now, then take a post-test one month later.

After the six month study period, the investigator will ask you to visit the clinic for follow-up exams for at least three months.

The researcher would like to ask questions about your experience three months after you complete the survey.

Statement of Confidentiality:

Tell the participant how you will keep their information confidential before, during and after the study. Include information on when and how you will dispose of the data.

This study is anonymous. That means that we will not collect any information that will identify which answers/data belong to you.

Only the persons in charge will know that you participated in this study. The fact that you participated in the study will not be shared with anyone.

This information will be kept in the investigator's files for (?) months/years and then destroyed.

Right to Ask Questions:

Inform the participant that they have the right to ask questions at any time during the process. Provide the information for the person(s) they need to contact to ask questions about the study as well as contact information for the IRB.

Please contact the principal investigator if you have questions about this study.

This project has been approved by Northeastern State University's Institutional Review Board (IRB). Contact the IRB Chair, Dr. Sophia Sweeney, if you have questions about your rights as a participant study or want to talk to someone not directly involved in this study. Dr. Sweeney can be reached at 918-444-3719 or sweeney@nsuok.edu, or you can visit the IRB web site for more information at http://offices.nsuok.edu/irb/

Voluntary Participation and Right to Withdraw:

Tell the participants that they have the right to withdraw at any time without consequence or penalty.

Survey: Participation in this study is voluntary. You may withdraw at any time and may also decline to answer any questions that you do not want to answer. You can end your participation at any time by telling the persons in charge/the investigator(s).

Online survey: Participation is this study is voluntary. You may skip any question that you do not wish to answer. If you wish to withdraw from the study, simply close the browser window.

Classroom example: Participation in this study is voluntary. You may choose to either take part or not to take part in the study. You may end your participation at any time by telling the person(s) in charge/the investigator(s). Participation, non-participation, or ending your participation will not affect your grade in any way.

Drug treatment example: Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. *(Include the following, if applicable.)* No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

Informed Consent

Add a statement that describes what action constitutes giving informed consent.

Avoid using the wording, "I understand that…" as this language may be considered exculpatory. Please refer to the Definition of Informed Consent at http://offices.nsuok.edu/irb/Policies/InformedConsent.aspx for more information.

Electronic form: Click on the button below to indicate that you agree to participate in this study.

Consent form: My signature indicates that I have read the information above and that I agree to participate in this study. I can ask for a copy of this consent form.

Your completion and return of this form/survey/questionnaire implies your consent to participate in this study.