

Written Consent Format

A written consent form must contain all the required information (see Elements of Consent checklist in Appendix E) and it must be capable of being fully understood by the individuals expected to read it. All the relevant information should be included. It is not sufficient to say, “Dr. Jones has explained” such things as the procedure or risks and discomforts. You should put these explanations in the written consent form or else use the short form consent (see Appendix G) that requires a script of the accompanying oral presentation about the procedure, risks, etc. One way or the other, the IRB needs to know *what* the subjects will be informed of, not merely that they *will* be informed. Technical material and the purpose of the study must be explained in lay terms. Procedures should be explained from the point of view of what will happen to the subject in the course of the study.

A general rule of thumb used by federal regulators is that consent forms aimed at the general public should be written at a 7th grade reading level. Adjustments up or down from that standard can be made depending on the target population of subjects. Short sentences and the use of smaller words help to achieve lower reading levels. The Flesch-Kincaid grade level estimate is available by clicking on Tools, Options, Spelling & Grammar in Microsoft Word. It may be helpful but is only an aid for writing at the appropriate level. Common sense is sometimes a better guide. Example 1 below is a consent form written for the general public. The Flesch-Kincaid grade level is 6.7. Example 2 is written for college students and has a grade level of 11.4.

The purpose of a consent form is to help the investigator protect *subjects* by *informing* them about the research and their rights as human subjects. It is not supposed to be a legal document that somehow protects the *researcher*. In fact, courts have ruled that a signed consent form that is too difficult for the subject to understand neither constitutes consent nor protects the investigator and the institution from liability. Therefore, pseudo-legal language such as “hereby”, “aforementioned”, etc should be avoided on the grounds that it detracts from communication. Federal regulators also suggest that, in order to facilitate communication, consent forms need to be written in the second person and avoid phrases such as “I understand that...” because they add nothing meaningful beyond the subject’s signature.

Texas Tech University does not have a model consent form and the examples of consent forms below are just examples. The IRB believes that subjects’ rights will be better protected if investigators have to think about the best way to inform subjects rather than simply filling out a form. Any format (e.g., the question-and-answer format used by TTUHSC) is acceptable as long as it serves its intended purpose and includes the elements of consent. Investigators should craft consent forms that clearly include the elements of consent but which are specific to their own research program and to particular projects. It may be a good idea for each researcher to create a model consent form or template that can be modified for specific projects.

Example 1 Consent Form

We are asking you to be a subject in a research project called “A Longitudinal Investigation of the Relationship between Work and Leisure Activities”. Dr. P.I. Magnum of the Department of Herpetology at Texas Tech is in charge of the study. His phone number is 742-XXXX.

The purpose of this project is to see how the things we do at work relate to the things we do in our time off. If you agree to be a subject, we will give you a survey that asks some questions. There are questions about how you feel about your job and your boss and what you like to do in your free time. Some of the questions are a little bit personal. It is good for us if everyone answers all the questions. But if there is a question you don't want to answer, it is ok to skip it.

There are about 80 questions. It will take you about 20 minutes to finish the survey. In one year, we will call and ask you to do the same survey again.

Some of the questions might be a little embarrassing to some people. But we don't think there will be any harm to you from answering the questions.

You will be given a coupon good for one cheeseburger at McDonald's each time you do a survey. It is our way of thanking you for doing a survey.

No one but Dr. Magnum and his assistants will see your answers. They will be kept in a locked file cabinet in his offices at Texas Tech. Your answers will be put into a computer without your name. So no one else from work or from your family will ever know what your answers were.

Doing these surveys is completely up to you. No one can force you to do them and you won't lose anything if you don't do them. Also, you can quit anytime you want and you won't lose anything. You keep the MacDonal'd's coupons even if you quit.

Dr. Magnum will answer any questions you have about the study. For questions about your rights as a subject or about injuries caused by this research, contact the Texas Tech University Institutional Review Board for the Protection of Human Subjects, Office of Research Services, Texas Tech University, Lubbock, Texas 79409. Or you can call (806) 742-3884.

If you sign this sheet, it means that you read this form and that all of your questions were answered.

Signature of Subject

Date

This consent form is not valid after September 30, 2004.

Example 2 Consent Form

You are invited to be a subject in a research project entitled “Exercise, Heat Stress, Lung Function, Cognitive Problem Solving and Their Relationship to Academic Achievement”. Dr. Inves Tigator of the Department of Phrenology at Texas Tech is in charge of the study. Her phone number is 742-XXXX. You can also contact R. A. Sisstant, who is responsible for carrying out the procedures for the study at 742-YYYY.

Purpose

This study is part of a research project that has the aim of understanding the relationship between exercise and the ability to solve problems. In this particular study we are attempting to assess the possible role of lung functioning and stress on the body due to heat in this process. The results of this study may help us to understand some of the effects of stress from heat on both physical (e.g., lung functioning) and cognitive functions (e.g., solving complex problems). Also, in order to better understand the results of the cognitive tests, we will compare the test performance with academic records, including GPA and entrance test scores.

Explanation of the Tests

In the first step in this research, you will fill out a questionnaire about your health and be interviewed about your health by trained professionals before any tests. In the course of the interview they will determine if there are any reasons that would make it unsafe for you to take the test. Consequently, it is important that you provide complete and accurate answers to the interviewer. Any failure to answer completely and honestly could lead to possible unnecessary injury during the test. Also, if you think there is any reason you should not participate in a study that involves physical stress in hot conditions, you must inform the interviewer.

The second step, which will take place today, is a set of tests of your lung functioning. To start, standard pulmonary function testing will be performed to demonstrate normal lung function. To do these tests you will have to inhale and exhale into a tube several times as hard as you can. Second, a graded exercise test on a stationary bicycle will be performed. You will continue to exercise until you tell the operator that you feel fatigue, shortness of breath, or chest discomfort. During the test, expired respiratory gases will be collected in order to determine your maximal oxygen consumption. Your blood pressure will be taken prior to and during the test with a standard blood pressure cuff. Your heart rate and rhythm will be monitored during the test with a standard electrocardiograph. This requires attaching electrodes to your chest with tape. During the test itself, a trained observer will monitor your responses continuously and take frequent readings of blood pressure, the electrocardiogram, and your statements about your effort. A true determination of your exercise capacity depends on continuing the test to the point of fatigue (when you tell the operator to stop) or reaching a pre-determined exercise stopping point (when the operator tells you to stop) It is important to remember to tell the operator to stop the test at any point if you feel unusual discomfort or fatigue. Following the test, you will be monitored for approximately 10 minutes to insure the heart rate and blood pressure have returned to pre-test levels. The questionnaire and interview should take about 30 minutes and the exercise test about 45 minutes for a total of about an hour and 15 minutes.

The third step in the research will take place in another session two days from today. You will be asked to ride the exercise bike for endurance at about 55-60% of the exercise intensity that you reached on the first test. This level of exertion should produce respiratory muscle fatigue (labored breathing) but will fall short of the level of exertion you got to in the first test. You will perform this second test in either hot (100 degrees Fahrenheit, 45% humidity) or normal (70 degrees Fahrenheit, 45% humidity) conditions. Otherwise this second test will be exactly like the first test. It will end when you are no longer able to breath at 85% of your maximum oxygen consumption.

The last step in the research will be a test of your performance on a test of thinking ability. Immediately after you finish the exercise, you will sit at a computer and do a series of tasks that require you to do such things as respond quickly to identify characteristics of words, or find associations between words, or determine whether briefly presented strings of letters are words or not. During this test your breathing, heart rate, and blood pressure will continue to be measured just as they were during the exercise test. The second session should take about an hour and a half altogether, 45 minutes for the exercise task and 45 minutes for the cognitive tests.

Finally, because we want to compare your performance on the cognitive tests with your academic record, we are asking you to give us permission to obtain information on your grade point average and your entrance test scores.

In summary, in today's session you will fill out a health questionnaire and be interviewed. If there is no reason why you should not do these tests, you will be hooked up to the monitoring devices and perform the exercise test to your maximum level. Two days from today you will return for the second session and do the exercise test again at about 55-60% of your maximum level. You will also do the cognitive tests on the computer.

Risks

There are a number of possible of negative effects of these tests. Due to the extensive exercise, you will feel tired and may experience muscle soreness. The blood pressure cuff and attaching or removing the electrodes from your skin may make you uncomfortable. During the actual exercise tests there is a very small possibility for healthy individuals of more serious effects. These could include abnormal blood pressure, fainting, disorders of heart rhythm, stroke, and, in very rare instances, heart attack or even death. Every effort will be made to minimize these occurrences by precautions and observations taken during the test. Oxygen and trained CPR personnel will be available on site during all exercise tests. You should consider these risks when you decide whether or not be a subject in this research.

Benefits

If you participate in this research project you will be learning something about exercise testing. In addition, if you are enrolled in ESS 3304, you will receive 5 extra points on the third examination. The instructor will offer you a chance to earn the same credit in an activity that involves about the same time and effort but that does not involve research.

Confidentiality

All the data and your academic records will be seen only by Dr. Tigator and her assistants. All the records will be kept in Dr. Tigator's laboratory in a locked file cabinet. Only those working on this project will have access to that cabinet. Once all the data are recorded and entered into a computer, you will be identified only by a code and anything with your name on it, except a copy of this consent form, will be destroyed. If any of the findings from this study are published, your name will not be used.

Your Rights and Information About Your Consent

You do not have to participate in this research. It is entirely voluntary. You will not lose anything to which you are entitled by refusing to participate. Also, you can withdraw from the study any time you want, even in the middle of a test. If you do withdraw, and you are an ESS 3304 you will receive proportionate credit toward your grade on the third examination.

The research staff may discontinue your participation in this study at any time if they believe that there is a risk to you based on their observations or measurements. You will be referred for medical examination and treatment if this occurs. If **you** decide to withdraw from the study, you may be required to keep the monitoring equipment in place for enough time for the staff to ensure that you have not been harmed by the tests.

The particular tests used in this research may involve risks to you that are currently unforeseeable. If we obtain information during this study that changes our assessment of the risks involved or if we find any other information that might affect your willingness to continue with the study, we will inform you.

Dr. Tigator (742-XXXX) will answer any questions you have about the study. For questions about your rights as a subject or about injuries caused by this research, contact the Texas Tech University Institutional Review Board for the Protection of Human Subjects, Office of Research Services, Texas Tech University, Lubbock, Texas 79409. Or you can call (806) 742-3884.

If this research project causes injury (physical, psychological, financial, etc.), Texas Tech University or the Student Health Center, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Kathleen Harris, Associate Vice President for Research, (806) 742-3884, Room 203 Holden Hall, Texas Tech University, Lubbock, Texas, 79409.

By signing this sheet, you certify that you have read this form and that all of your questions have been answered. Your signature also gives us permission to obtain your academic records from the Texas Tech Registrar's Office.

Signature of Subject

Date

This consent form is not valid after September 30, 2004.