

Purdue IRB Consent Form Suggested Language*

The IRB reviews consent documents for adequate information about procedures and risks. When common procedures are used, the IRB has language that should help researchers build their consent form.

Note that some procedures may require the researcher to fill in information or expand upon potential risks or descriptions. The Text below should be used as a base template for guidance.

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If your study will use a procedure listed in this column:	Add this Text to the Consent Form under: “What will you do if you choose to be in this study?”	Add this Text to the Consent Form under : “What are some of the risks and discomforts that may happen to people who are in this study?”
Biopsy	During a biopsy a small piece of skin or muscle is removed from _____ (site) and looked at under the microscope. This research project is looking for _____ (condition, disease, or trait) . Any biopsy material you provide is for research and not for a medical diagnosis or treatment.	The biopsy may cause some pain and discomfort. It is possible, but not likely that you could get an infection. In very rare cases, people might have an allergic reaction to the numbing medicine. The allergic reaction could include rash/hive, flushing of the face, itching, wheezing and tightness in the throat. There will be a small scar from the biopsy.
Blood Draw/Venipuncture	You will have (amount) of blood taken (number of times drawn, and frequency) . The blood will be taken from (name the location, i.e., arm). The total amount of blood taken for the whole study will be (amount in teaspoons or tablespoons). The blood you provide is for research and not for a medical diagnosis or treatment.	The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a risk of fainting.

Bone Scan	During a bone scan you will be injected with a radioactive substance in your vein. A short time later, a machine measures how much radiation has been taken into the bones. The test should not hurt but you may have to stay in a certain position to get a good picture. You may have to agree to separate consent or safety forms that are required for services performed as part of this procedure.	This risk of exposure to radiation is small. The contact with radiation in this study is thought to be _____ (NUMBER OF UNITS AND COMPARISON TO KNOWN QUANTITY SUCH AS DENTAL X-RAYS OR CHEST X-RAY). However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease. Before agreeing to participate in this study, think about your past and future contact with radiation.
Bone Densitometry (Dual-energy x-ray absorptiometry [DEXA])	A DEXA is a type of x-ray used to measure bone strength. During this test, X-ray pictures of your body will measure how much fat and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of the body. This test will last about (FILL IN THE TIME) minutes.	This risk of exposure to radiation is small. The contact with radiation in this study is thought to be _____ (NUMBER OF UNITS AND COMPARISON TO KNOWN QUANTITY SUCH AS DENTAL X-RAYS OR CHEST X-RAY). However, the effects of radiation add up over a lifetime. It is possible that having several of these tests may add to your risk of injury or disease. Before agreeing to participate in this study, think about your past and future contact with radiation.
Caliper (Body Fat) Test	A tool called a caliper (like a pincher) grasps a small fold of flesh on the back of the arm, shoulder blade, or waist to measure the amount of body fat.	You may experience a little pain or discomfort from a pinch with a caliper.
Electroencephalogram (EEG)	An electroencephalogram (EEG) measures the electrical activity in the brain (brain waves) using electrodes (small metal discs or sensors) placed on the head with gel. The test does not hurt and usually takes about (FILL IN THE TIME) minutes.	The gel used to put the discs on your head in an EEG is sometimes sticky and the EEG discs may scratch.
Electrocardiogram (EKG)	An electrocardiogram (EKG) is a test that gives us a measure of the heart's electrical activity. You will be asked to lie flat on a table and several small electrode pads (like stickers) will be placed on the body. This test takes about 10 minutes.	The EKG test may cause some redness or itching where the pads are placed.

<p>MTurk (Amazon Mechanical Turk)</p>	<p>Amazon MTurk can potentially be linked to information available on your Amazon public profile page through the Worker ID that the researchers access. You can choose what is available on your Amazon public profile settings using their settings. The researchers will only be collecting the answers you provide, and will not be accessing other information about you that may be part of your Amazon public profile.</p>	<p>Please be certain that you have read and agree to Amazon’s Mechanical Turk participant and privacy agreements prior to participation in this study.</p>
<p>Online Survey Platforms Using Validity Questions <i>If you are using an online platform such as MTurk and will be embedding rejection criteria e.g., minimum or maximum time to completion, or validity questions, you must tell participants in the risk section of the consent form that their survey may be rejected and the reason(s) for the rejection. You do not have to provide specifics of the rejection, e.g., minimum time to completion or what the validity questions are.</i></p>	<p>You will complete a survey on (FILL IN METHOD paper, computer) about your attitudes, beliefs or personal history. These will help our research team answer questions about (ENTER YOUR RESEARCH QUESTION).</p>	<p>This survey has been pilot tested to determine the average time it takes to complete it if the respondent fully reads and answers each question. Marked deviation from this average time could result in rejection of your completed survey.</p> <p>OR</p> <p>This survey has a number of questions embedded in it as validity checks to insure that you are not a robot and are in fact fully reading and answering each question. A unique combination of answers to those questions may result in your survey being rejected.</p>
<p>Surveys (those not considered exempt under the regulations)</p>	<p>You will complete a survey on (FILL IN METHOD paper, computer) about your attitudes, beliefs or personal history. These will help our research team answer questions about (ENTER YOUR RESEARCH QUESTION).</p>	<p>You may feel uncomfortable thinking about your personal attitudes. You may skip questions that make you uncomfortable. There is also a risk of breach of confidentiality, but steps have been taken to avoid such a breach. If you do not wish to answer a question, you may skip it and go to the next or stop.</p>
<p>Spirometry Test</p>	<p>Spirometry tests how your lungs work by measuring how much and how fast air moves out of your lungs. You will wear a nose clip and forcefully blow into a tube hooked to a machine.</p>	<p>Spirometry may make you cough or feel lightheaded. This should go away shortly after the test is finished.</p>

Ultrasound¹	<p>Ultrasound (or sonography) is a test that uses high-frequency sound waves to show what is inside your body. You will lie on a cushioned table and gel will be applied to your skin; the gel acts as a conductor. Ultrasound is often used to see internal body structures. A hand-held device that sends and receives ultrasound signals, is moved over the area of your body being imaged. Images are seen on a monitor and sent to a specialist to review and interpret. The test will take about (FILL IN THE TIME) minutes.</p>	<p>The gel may be sticky but the test should not cause any pain or discomfort. There are no known side effects associated with this type of ultrasound examination, and it causes no physical discomforts. It is possible that you may feel some slight discomfort from remaining seated for a long period of time. Ultrasound involves no radiation exposure.</p>
X-rays or Fluoroscopy (Standard)	<p>This procedure uses x-ray radiation to take images of various body parts. You may be asked to remove clothing and/or jewelry and wear a supplied gown for this procedure. You may have to stand or sit still or follow instructions during the procedure.</p>	<p>The dose from this procedure is approximately (FILL IN THE CALCULATED DOSE) millirem and equivalent to (FILL IN CALCULATED DOSE) days of exposure to natural background radiation. The risk (radiation dose) from any one of these procedures is small and is not expected to result in any adverse health effects over your lifetime. Any effects from radiation may add up over your lifetime and not become apparent until many years later. When deciding whether or not to enter this study you should consider past and possible future radiation exposures.</p>

References

*Thank you to Northwestern University IRB for providing permission to utilize much of the base language.

¹Excerpts adapted from: Epstein MA, Clin Linguist Phon 2005 Sep-No; 19(6-7): 567-72