

**Table 1. Examples of Informed-Consent Text Provided by Institutional Review Boards at U.S. Medical Schools.\***

Readability Level	Voluntary Participation	New Information about Risks	No Direct Benefits	Involuntary Removal
4th Grade†	“You don’t have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor’s attitude toward you will not change.”	“We may learn about new things that might make you want to stop being in the study. If this happens, you will be informed. You can then decide if you want to continue to be in the study.”	“There is no benefit to you from being in the study. Your taking part may help patients in the future.”‡	“You may be taken out of the study if: 1. Staying in the study would be harmful. 2. You need treatment not allowed in this study. 3. You fail to follow instructions. 4. You become pregnant. 5. The study is canceled.”‡
6th Grade†	“Taking part in this study is your choice. If you decide not to take part, this will not harm your relations with your doctors or with the University.”	“We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.”	“You may receive no direct benefit from being in this study. However, your taking part may help patients get better care in the future.”	—§
8th Grade†	“Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.”	“We will tell you about new information that may affect your willingness to stay in this study.”	“There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.”	“The study doctors have the right to end your participation in this study for any of the following reasons. It would be dangerous for you to continue. You do not follow study procedures as directed by the study doctors. The sponsor decides to end the study.”
10th Grade†	“Your participation in this study is voluntary and you are free to withdraw at any time. Participation or withdrawal will not affect any rights to which you are entitled.”	“We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.”	“There is no guarantee that you will receive direct benefit from your participation in this study.”	“The study doctor, or the sponsor, may stop my participation in this study without my consent.”
12th Grade¶	“Your participation in this study is strictly voluntary. You have the right to choose not to participate or to withdraw your participation at any point in this study without prejudice to your future health care or other services to which you are otherwise entitled.”	“You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate. If new information becomes known that will affect you or might change your decision to be in this study, you will be informed by the investigator.”	“There may be no direct benefit to me, however, information from this study may benefit other patients with similar medical problems in the future.”	“You may be terminated from this study without your consent if you have serious side effects, you fail to follow your doctor’s instructions, your disease gets worse, or the sponsor closes the study. If this should happen, your doctor can discuss other available treatment options with you.”
College¶	“You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the University.”	“During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.”	“The research physician treats all subjects under a specific protocol to obtain generalizable knowledge and on the premise that you may or may not benefit from your participation in the study.”	“Your participation in this research project may be terminated by your doctor without your consent if you are not benefiting from the treatment/procedure, or if the treatment/procedure is determined to be inappropriate to your case. You may also be terminated from participation at any time, at the study physician’s discretion, for any reason he/she deems appropriate.”

\* All the examples are taken directly from medical-school Web sites unless otherwise noted.

† The readability level is based on the Flesch–Kincaid readability scale.

‡ The passage was modified to present key concepts at a 4th-grade reading level.

§ No passage was found at this reading level.

¶ The readability level is based on the Fry readability formula.