

■ TABLE 4.1 Information to Include in a Consent Form

Purpose of the research along with a description of the procedures to be followed and the length of time it will take the participant to complete the study

A description of any physical or psychological risks or discomforts the participant may encounter

A description of any benefits the participant or others may expect from the research

A description of any alternative procedure or treatment that might be advantageous to the participant

A statement of the extent to which the results will be kept confidential

Names of people the participant may contact with questions about the study or the research participant's rights

A statement indicating that participation is voluntary and the participant can withdraw and refuse to participate at any time with no penalty

A statement of the amount and schedule of payment if participants are to be paid for participation

The information should be written at an eighth-grade reading level; in cases targeting specific populations, a sixth-grade reading level might be appropriate

For additional tips on preparation of the consent form, go to <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm>.