Informed Consent

Participating in Clinical Studies

By Sheila Sprague, BSc;
Beate P. Hanson, MD, MPH; and
Mohit Bhandari, MD, MSc, FRCSC

The case of Leo

Leo, 25, presents to the emergency department (ED) following a car accident. He has a broken tibia. He will require an operation to fix his broken bone. Leo notices a poster in the ED that states, "Do you have a tibial fracture? Ask your physician about enrolling in a research study to improve results after fracture surgery." He inquires about whether he's a candidate for this research?

After reviewing the eligibility criteria for the trial, you confirm that he is eligible and should consider participating. Leo requests more information.

Ms. Sprague is a research coordinator, OKATT Research Group, McMaster University, Hamilton, Ontario.

Dr. Hanson is director, AO-Clinical Investigation and Documentation, Davos, Switzerland.

Dr. Bhandari is a fellow, department of clinical epidemiology and biostatistics, McMaster University, Hamilton, Ontario.

What is informed consent?

Informed consent is the process by which a patient voluntary confirms his or her willingness to participate in a clinical trial. Prior to giving consent, the study investigator or delegate must inform the patient of all aspects of the trial (Table 1).

Informed consent must be documented in a written form, signed, and personally dated by the patient or by the patient's legally acceptable representative, and by the person who conducted the informed consent discussion.

How much time do I need?

Conduct the informed consent discussion in a quiet room and allow adequate time for questions. During the discussion, it is vital to communicate in non-technical language and to take into account any language barriers.

Do patients have rights?

Patients who participate in research trials have many rights and they need to be informed of these rights during the informed consent discussion. Three of the most fundamental rights are:

Table 1

What patients need to know before paticipating in clinical research

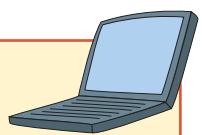
- The purpose of the research
- The trial treatment(s) and the probability for random assignment to each treatment
- The trial procedures to be followed, including all invasive procedures
- The subject's responsibilities
- Any aspects of the trial that are experimental
- The reasonably foreseeable risks and benefits
- Any alternative treatment(s) that may be available
- Any compensation available to the patient in the event of a trial-related injury
- The anticipated payment or expenses, if any, to the patient for participating in the trial
- The patient's participation is voluntary and the patient may refuse to participate or withdraw from the trial at any time without prejudice
- Who will have access to their original medical records
- The records identifying the patient will be kept confidential
- If the results of the trial are published, the patient's identity will remain confidential
- The patient will be informed if information becomes available that may be relevant to the patient's willingness to continue to participate in the trial

Table 1
Cont'd

- The person to contact for additional information on the trial
- The foreseeable circumstances or reasons under which the patient's participation in the trial may be terminated
- The expected duration of participation
- The approximate number of patients involved in the trial

1. The patient's participation in the research trial is voluntary.
2. The patient has the right to refuse to participate or withdraw from the trial without providing a reason. Refusing to participate or withdrawing from the trial will not affect his/her subsequent medical care.
3. The patient will be informed of any new findings that may affect his/her willingness to continue participating in the trial. Dx

Surf your way to...



1. Health Canada's Good Clinical Practice Consolidated Guidelines summarize the information that should be included in the discussion and the written consent form: *www.ncehr-cnerh.org*