

# Clinical trials

by Mavis Young

**New drugs hold great hope. But before they reach the pharmacy they must be tested in people with HIV to make sure they're safe and effective. If you volunteer to participate in a clinical trial, make sure you know exactly what you're signing up for.**

**Y**ou may be invited at some point to participate in a clinical trial. Clinical trials evaluate new ways of treating disease, either by testing new, experimental medications or by trying already approved and licensed drugs in new ways or at different doses.

## The long road to drug approval

A clinical trial is the final step in the process of development and approval of a new drug before it can be sold on prescription. A promising new drug is synthesized by researchers, tested against the HIV virus in the laboratory, then tested at various doses in animals, in healthy humans and finally in volunteers infected with HIV. Every drug has to undergo thorough testing before being approved by the Therapeutic Products Directorate (TPD) of Health Canada. The arsenal of powerful anti-HIV drugs on the market today is available only because HIV-infected positive individuals volunteered to test new drugs and combinations.

## Becoming a research participant

For the participant, the clinical trial process starts in the doctor's office. He or she, being familiar with your medical history, your CD4 count and viral load and knowing what medications you've already tried, may let you know about a clinical trial underway that targets patients with your profile. He or she can provide you the information to contact the clinical trial researchers.

If you agree to participate, an appointment will be made for you to see the study nurse or coordinator, who will explain the study to you

and give you an "Informed Consent Form" (see box below).

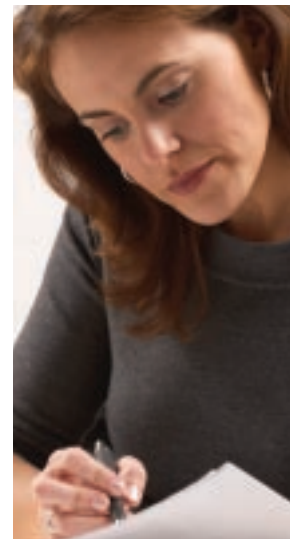
## What do blinded, placebo controlled and randomized mean for you?

Some clinical trials involve testing a new drug by comparing it to a 'placebo,' an inactive pill, which resembles the study drug but doesn't contain the active ingredient. Neither study staff nor participants know who gets the study drug and who gets the placebo because a computer randomizes or assigns participants to one or the other. This is referred to as double-blinding. If the study is placebo-controlled, randomized and/or blinded, be aware that you won't necessarily get the new study drug. Usually both groups receive, in addition to the study drug or the placebo, an approved, standard effective anti-HIV therapy. So what's being measured by the trial is the potentially additional anti-HIV activity of the new drug under study.

## Research ethics

Before a clinical trial can begin, its design must be reviewed by a Research Ethics Board. You should be given the telephone numbers of people who can be reached if you want to discuss your rights as a participant, or if you feel you've been injured as a result of your participation. Even though you've signed a consent form and agreed to participate in the trial and are informed about potential risks, this doesn't mean you've given up the right to take legal action in case of injury. If you have lingering questions, talk to someone at an AIDS service organization (see listing p. 8-9) near you. **R**

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## The informed consent form will tell you:

- why the study's being done
- why you're being asked to participate
- participation is voluntary
- you're free to withdraw from the study at any time without reason
- information about any experimental drug (study drug)
- whether there's a "placebo" arm
- eligibility requirements: CD4 cell count; viral load; treatment-experience etc.
- study procedures such as visits, tests, restrictions
- whether you'll continue to get the drug after the study's over
- any risks to participants
- how your confidentiality will be protected