

## The Patient's Rights in Clinical Trials

By Tina Soulis, B.Sc.Ph.D, Clinical Project Leader

All clinical trials are run to world ethical and scientific guidelines. This means that all institutions running clinical trials must run that trial according to certain rules and regulations. Running of clinical trials in this way ensures that both the patient as well as the institution are protected. This article aims to discuss your rights as a patient in a clinical trial and the obligations of the institution taking part in the clinical trial to you, the patient.

### The Declaration of Helsinki and ICH/GCP

**"It is the mission of the physician to safeguard the health of the people"**

The Declaration of Helsinki was first put into place in 1964 to outline the principles of biomedical research. The declaration led to the development of guidelines on running clinical trials known as Good Clinical Practice (GCP). Many countries set up their own guidelines. The objectives of the guidelines is to help safeguard the interests of subjects, sponsors, the institutions running the trials and society by ensuring that only adequately planned and conducted clinical trials are performed. In more recent times, many countries including Australia have harmonised their country specific GCP guidelines. This new set of guidelines is known as the International Committee of Harmonisation (ICH) and has become law in some countries. Today, most countries work with both sets of guidelines. In Australia both GCP and ICH are used by the sponsor companies as well as government authorities

### The Ethics Committee and The Patient

Before a trial is initiated, foreseeable risks and inconveniences must be weighed against the benefit of taking part in the trial for the patient. A trial should only be initiated and continued only if the participated benefits justify the risks. In addition, there should be information both non clinical as well as clinical to adequately support the conductance of the trial. Before the clinical trial starts, a clear and detailed protocol is written. This is basically a plan of how the trial will proceed. The protocol includes a background section on the product with references. The protocol also includes the schedule of the trial and every procedure that the trial involves such as the number of blood tests on any given day.

This protocol is brought before the institution's Ethics Committee. Each institution running the trial will usually have it's own Ethics Committee. This committee's members include clinical people, a lawyer, a religious representative as a well as a members of the public. This committee then assesses the protocol and decides if it will benefit patients. The trial can only go ahead once it has received Ethics Committee approval.

Once the trial is up and running, the Ethics Committee requires formal periodical reports that show the number of patients, whether the trial is still running or has fulfilled the number of patients. Most importantly, the committee is interested in any serious adverse events that may have been experienced by patients on the trial. These reports are required whether the trial drug was the suspected cause or not. For example, if a patient on an IBD trial was hospitalised with exacerbation of their disease, the committee usually requires a report within 24 hours. Equally if any of the details of the protocol change the institution running the clinical trial must report the changes to their ethics committee. As you can see already, a lot of work is put into setting up the trial in order to protect the patient. At all times the ethics committee should have up to date information about the status of the trial not only in their institution but also around the world if this is the case.

## The Rights Of The Patient

When you are invited to take part in a clinical trial you will be handed a Patient Information Sheet. This sheet describes the trial including why the trial is being run, what the side effects might be, what procedures will take place (eg. blood tests), and how long you are expected to take part in the trial. This Patient Information Sheet has been approved by the Ethics Committee. You should be given adequate time to think about your participation in the trial and even take a copy to your local GP for their review. As a patient taking part in a clinical trial, you can withdraw from the trial at any point for any reason without prejudicing your future treatment. Participation is purely voluntary. In fact before anything related to the trial can be carried out, you must sign a Patient Informed Consent form. This is usually attached to the Patient Information Sheet. You should be given a copy of the above documents to take home after you have dated and signed them in front of a witness. You should also be told of any new information that arises during the trial about the drug used. This whole procedure is called Informed Consent.

## Access To Your Medical Records

Informed Consent also involves allowing clinical trial staff and representatives of the study sponsor to have access to your medical records. The sole purpose of this is to make sure that what is in your medical records matches up with what has been written in the study forms that need completing. Your identity remains confidential and in fact, the forms for the trial only contain your initials and a specific study number assigned to you. It is the institution's responsibility to keep the medical records arising from a patient's participation in a clinical trial for at least 15 years in a secure, locked place. In the case of children the records must be kept for 23 years.

## Randomisation and Placebo

In order to see the true effect of any drug treatment in a clinical trial, the study must be unbiased. This means that in a well-designed clinical trial the patient and the doctor and study personnel do not know which of the treatments being looked at that the patient is on. This procedure is called "blinding". Patients are usually randomly assigned into the different treatment groups of the trial by "chance" much like tossing a coin. In case of an emergency, the treatment information is available to the doctor.

## Medical Care Whilst On The Trial

The medical care given to and the medical decisions made on behalf of the patients on any clinical trial should always be the responsibility of the doctor that is looking after the patient on the trial. Equally, each individual involved in conducting the clinical trial should have suitable education, training and experience. This means that all members of the institution's clinical trial team must be suitably trained as well as trained in the specifics of the study-taking place. By taking part in a clinical trial you are also obtaining access to new treatment, free of charge that is not available to everyone else. You also generally get to see your doctor on a more regular basis and are monitored very closely. The clinical trial team must make sure that they keep timely and accurate medical records for each patient on the trial.

## What This Means To Patients In Australia

Patients with IBD in Australia can now have access to the very latest of therapies and be involved with cutting edge research. You also are able to take the drugs involved free of charge and you get to see your doctor and thus be closely monitored for your IBD on a very regular basis.