

MELANOMA INSTITUTE AUSTRALIA

CLINICAL TRIALS & RESEARCH STUDIES

PATIENT INFORMATION



HELPING SOLVE THE MELANOMA PROBLEM

Having been diagnosed with melanoma you may be offered participation in a clinical trial or research study.

Clinical trials are conducted to help find better ways to prevent, screen, diagnose or treat a disease or to improve the quality of life of those who have this disease.

CLINICAL RESEARCH

Clinical research started at Melanoma Institute Australia, formerly known as the Sydney Melanoma Unit, in the late 1960s. Since then, the large number of patients willing to participate in clinical trials has enabled Melanoma Institute Australia and these patients to make major contributions to many critically important clinical research programs, several of which have resulted in changes to the daily management of melanoma patients in Australia and throughout the world.

Unfortunately, many questions about melanoma remain unanswered, hence clinical trials continue at Melanoma Institute Australia. Current trials are assessing the value of surgery, radiotherapy, chemotherapy, immunotherapy treatments and quality of life studies.

Clinical trials are conducted worldwide by universities, hospitals, research institutions or drug companies. They vary in size from single centre studies to studies conducted at multiple centres in several countries. Teams of doctors, nurses, scientists, research assistants, data managers, pharmacists and other health professionals supervise participants throughout the trial process.

Trials are very strictly regulated and each one follows an approved, carefully-controlled protocol. A protocol is a study plan that ensures the safety of participants in the trial and is designed to answer specific research questions. Before the trial can begin, the protocol must be reviewed and approved by a Human Research Ethics Committee (HREC), made up of medical and scientific professionals and the general public. It is the HREC's responsibility to ensure the protection of the rights, safety and well-being of people involved in a trial.

INFORMED CONSENT

Choosing to participate in a clinical trial is an important decision. Informed consent is the process of gathering and understanding the information about a trial in order to make an informed decision on whether or not you want to be a part of the trial.

You will always receive written information, the "Information for Participants" and the Consent Form for the specific trial you are being asked to consider, and you will be given ample opportunity to discuss that trial with your doctor and trial staff. The "Information for Participants" document includes details about the trial such as the aim, procedures involved, duration, alternative treatment options, risks, benefits, costs and key contact details.

When you feel that you are fully informed, you can decide whether to participate or not. If you choose to participate you will be required to sign the Consent Form. A signed copy of this form will be given to you to take home. Informed consent is also a continuing process throughout the trial providing participants with any new information that may affect their continuation in the trial.

During the trial you and/or your doctor may decide it no longer suits your need. You can withdraw from trial treatment at any time without concern that it will affect your future care.

TRIAL TYPES AND PHASES

TYPES

The U.S. National Institutes of Health (NIH) classify clinical trials into five types:

- Treatment trials are the most common type of trial, testing experimental treatments, new drug combinations or new approaches to surgery or radiotherapy.
- Prevention trials test new ways to prevent disease in people who have never had the disease or to prevent the disease from returning in those previously treated.
- Screening trials test the best way to detect a disease.
- Diagnostic trials are conducted to find better tests or procedures for diagnosing a disease.
- Quality of Life trials (or Supportive Care trials) explore ways to improve the comfort and quality of life for people with a disease.

NEW TREATMENTS MUST GO THROUGH THREE “PHASES” OF TRIALS BEFORE THEY CAN BE CONSIDERED FOR USE;

A **PHASE I** trial is the first study of the experimental treatment that involves humans. Safety and dosage range are tested and side effects identified. Only a small number of people are involved.

A **PHASE II** trial involves a more detailed evaluation of effectiveness and safety. A larger number of people are required for a Phase II trial.

A **PHASE III** trial involves formal comparison of the experimental treatment with the current standard treatment to work out which is better. This requires a much larger group of participants to be involved.



Clinical trials staff will explain the risks and benefits of taking part in a trial, provide you with written information, and answer your questions about the trial.

People who consent to the trial are randomly selected to receive the experimental treatment or the current standard treatment. In a Phase III trial, random treatment allocation is necessary so that each group has a similar mix of people to ensure the treatments can be compared without bias. Neither you nor the trial staff can choose which treatment you will receive. If the trial involves a new drug, it is possible that you and the trial staff might not be told which treatment group you are in; this is known as blinding and is used to prevent bias. In some trials experimental treatments are compared with a placebo, an inactive pill, liquid or powder that has no treatment value. You will be informed if the trial you are considering is blinded or placebo-controlled. If it is required for your safety or future care, 'unblinding' can be done to allow you and your treatment team to know what treatment you were on. The decision to 'unblind' your treatment allocation will be made by your treating doctor if it is required for your safety or future care.

WHY SHOULD I JOIN A TRIAL?

People choose to participate in trials for different reasons. There are benefits and risks involved in joining any trial.

THE BENEFITS ARE:

- You have an active role in your own healthcare.
- You can access new research treatments.
- You may experience a treatment benefit.
- You will possibly help others including your own children and grandchildren by contributing to medical research.
- You will experience increased personalised care and attention.
- You will increase your knowledge about melanoma and its treatment.
- You may find some of your treatment costs are covered.

THE RISKS ARE:

- The experimental treatment may not be effective for you.
- You may experience side effects of the experimental treatment.
- The trial may require more of your time and attention including more trips to the study site, more treatments and more investigations.

Please remember that clinical trial participation is voluntary. You may withdraw from a trial at any time without affecting your ongoing care at Melanoma Institute Australia. Please contact the clinical trial staff if you require further information.



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