

IS A CLINICAL TRIAL RIGHT FOR YOU?



Clinical trials aim to find ways to improve care and quality of life for people affected by cancer and other illnesses. This information sheet will guide you through the process of joining a clinical trial and help with questions to ask your treating team.

What are the advantages of taking part in a clinical trial?

- Access to treatments or tests that are not yet available.
- Treatments being tested may work better than the current options available to you.
- Close clinical trial monitoring, care and support from a specialist team of clinical trial doctors, nurses and coordinators.

What are the disadvantages of taking part in a clinical trial?

- You may experience unpleasant, serious or life threatening side effects to experimental treatments.
- The treatment being tested may not work better than your current available options.
- You may need to make extra visits for reviews, tests and scans.

What is informed consent?

Your clinical trial team will give and discuss all the information about the clinical trial with you. This information will also be on your '**patient informed consent form**'. To help decide if the clinical trial is right for you, we encourage you to:

- Discuss the '**patient informed consent form**' with a family member or your general practitioner (GP).

- Use the attached '**Please Ask Us**' checklist to think about questions that you may want to ask at your next appointment.

After this, if you decide to take part in the clinical trial, you will be asked to read and sign a '**patient informed consent form**' before taking part. This means you:

- Are **informed** about the clinical trial, by being given all the information you need to help decide whether a clinical trial is right for you, in a language you understand.
- Give **consent** to take part in the clinical trial, after understanding all the information on the clinical trial.

What happens if you say, "No, I don't want to take part"?

You can say "no" to taking part in the clinical trial. Saying "no" will not affect your treatment or relationship with your doctor.

What happens if you say, "Yes, I want to take part"?

If you say "yes" to taking part in the clinical trial, then the clinical trial doctor will ask you to sign the '**patient informed consent form**'.

What is eligibility?

All clinical trials have a set of eligibility criteria that patients need to meet before joining a clinical trial.

Eligibility criteria may include age, medical history and current health status.

These criteria are put in place to make sure that patients who are more likely to experience serious side effects are **not put at risk**.

Once you have signed your 'patient informed consent form', we have your permission to perform tests or scans to see if you are eligible.

Signing the 'patient informed consent form' does **not** guarantee you will be able to take part in the clinical trial. You must meet all the eligibility criteria before you can receive treatment on the clinical trial.



If you have any questions about clinical trials, please speak to your doctor. If you or your family would like more information about available clinical trials, please contact us via email: research@monashhealth.org or phone: **9594 4611**.



PLEASE ASK US...

Asking questions is an important part of 'informed consent'.

We have provided some questions you may wish to ask your clinical trial team. You may also have questions of your own that you can write over the page.

Ask your doctor...

- What is this clinical trial about?
- Are other clinical trials available to me?
- Can I get the clinical trial treatment without taking part in the clinical trial?
- If I do not take part, what treatment will I get?
- What are the advantages in taking part in this clinical trial?
- What are the disadvantages or risks of the clinical trial treatment?

What happens if I get trial treatment?

- What is already known about the clinical trial treatment?
- What kinds of treatment are offered on this clinical trial?
- Will I know what treatment I am getting?
- How will my clinical trial treatment be given?
- Can I continue to use the treatment after the clinical trial has finished?
- What happens if I become unwell or something goes wrong on the clinical trial?
- What happens if the clinical trial treatment is not helping me?
- Can I continue to take my current prescribed medications or alternative therapies?

Ask your nurse or coordinator...

- Who will be my treating team on the clinical trial?
- Who can help me with questions or concerns while I am on the clinical trial?
- What happens to my clinical trial results?
- Are the results made public?

What happens to my personal information?

- How is my privacy protected?
- Will my name be used with my clinical trial information?
- Who will see the information I provide as part of the clinical trial?
- What happens to my information if I quit the clinical trial?

What will happen to me if I take part?

- If I join a clinical trial but later change my mind, how can I stop?
- What time commitment is involved?
- Will I need to do any extra tests or procedures?
- Will there be extra costs for me if I take part in the clinical trial?
- Can I have the clinical trial treatment or procedures closer to my home?
- Is it safe for me or my partner to breast feed or get pregnant while taking part?
- Am I required to use contraception while taking part?

