Genetic Support Network of Victoria

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Participating in Clinical Trials Factsheet

1. What is a clinical trial?

Clinical trials are medical research studies that trial experimental treatments, prevention methods, diagnostic or screening techniques. These trials aim to discover a better way of managing, treating or diagnosing a certain condition by assessing how people respond to new drugs, surgical procedures, vaccines, tests or lifestyle changes.

2. Why do clinical trials?

Clinical trials aim to determine the best way to treat, manage or detect a certain condition or symptom in an effort to improve the way patients in the future will be treated. Their goal is to discover whether a method, drug or procedure is effective by observing how lots of people respond to it*. It is important to remember that their goal is not to improve your health but to improve the health of the community by observing your response, unlike a GP whose goal is to improve your personal health.*

3. How are clinical trials carried out?

Clinical trials involve allocating participants into two groups; those who will undergo the new treatment or receive the new drug, and those who will receive what is the current standard for treatment or a placebo. A placebo is an *inactive* treatment, for example a sugar pill. This ensures that any benefits measured from the treatment group are more than psychological effects. A placebo is only given when it is considered to be ethical. For example in a clinical trial testing a new cancer drug, giving a placebo (an inactive drug) to one group would be unethical as their cancer will be left untreated. In cases like this, this group of participants would be given the current standard of treatment instead of a placebo.

The group of participants who are given the new treatment are compared to the group of participants that receive the current standard treatment or the placebo (the control group). The treatments, drugs or procedures being tested will only be considered for future use if they prove better than the current standard of treatment.

4. Who can participate in a clinical trial?

You can participate in a clinical trial if you satisfy all of the inclusion and exclusion criteria set out by the researchers and once you have given your informed consent. Criteria may include consideration of aspects such as age, gender, type of condition, stage of disease or previous treatment.

5. **What is informed consent?**

Informed consent is a requirement of all participants of any research and means that you are aware of certain things about the research and have agreed to participate knowing all the risks, benefits and requirements of taking part.

Informed consent requires you to have knowledge of:

- The aims and purposes of the research
- The anticipated outcomes of the research
- The options available in participating or not participating
- The expected outcomes if you participate or don't participate
- The success rates for each option
- The incidence of side effects in each option (i.e. how likely is it that this side-effect will occur?)
- What you will be required to do
- Possible benefits and harms to yourself in taking part in the research
- Possible benefits and harms to others, the environment or society due to the research
- Your right to refuse to participate
- Your right to withdraw from the research at any time and what will happen if you do
- How your anonymity and confidentiality will be upheld

6. **What are the benefits of participating in clinical trials?**

Clinical trials can provide you with access to:

- The latest research treatments before they are made available to the general public
- Leading medical experts for advice and treatment
- The most up to date medical facilities

Clinical trials may also provide:

- Greater understanding of your condition
- The chance to have an active role in your own healthcare and treatment
- The chance to be more closely monitored than others receiving standard treatment

7. **Could I be harmed by participating in a clinical trial?**

There are some risks involved with participating in clinical trials. These could be physical, psychological or emotional risks and may include:

- Unknown immediate or long term side effects
- You may be inconvenienced by more treatment, tests or hospital visits than those receiving standard care
- You may have to follow a more complicated medication plan or keep a symptom or medication diary
- Treatment may not be effective for you
- Implications to relatives, your insurance or employment if undergoing genetic testing as part of the research (*See our 'Participating in Genetic Research' Factsheet)*

To minimise the chance that you are harmed by participating in a clinical trial, speak with your health care provider (GP or specialist) as well as the researchers conducting the trial to make sure that you are aware of the risks involved in participating.

8. How do I know if the clinical trial has been approved by an appropriate body?

All good clinical trials will have been approved by the Human Research Ethics Committee (HREC) of their governing hospital or research organisation and this should be detailed on your consent form. To be approved by their HREC, researchers must have submitted an application document detailing and explaining:

- Why they believe their research should be carried out
- How their research will benefit the medical community
- How they plan to carry out their research
- How they will protect the privacy and confidentiality of participants
- How they will avoid or manage possible risks to participants
- How they will be analysing their data

You may have to ask the researchers or search the internet for the contact details of their HREC if you would like more information regarding their ethics approval.

9. What else should I know before participating?

To ensure you are well informed when agreeing to participate in a clinical trial, you may wish to discuss the following with the researchers:

- Does the research aim to cure my condition, manage it or change policy surrounding the treatment of people with my condition?
- Has the research been approved by an appropriate body?
- Does the research have ethics approval?
- Who can I contact for support and information during the research process?
- Will I be inconvenienced? Will I be contacted multiple times, have to make multiple visits to a hospital or undergo various tests?
- How might the research affect me and my family?
- What will my responsibilities be during the research?
- Will I have to travel to participate? Will there be costs involved in this travel?
- Will I be paid/reimbursed for my time?
- If there a complications as a result of the research, who will be responsible for treating me and paying for the cost of treatment?
- Is there a long term commitment? Will I be contacted at a later date or do I have to have long term follow up care?
- How can I access the results of the research? (Outcomes of the research should be made available to you in a timely manner)
- How will my privacy be protected?
- Has the treatment been tested before?
- Is there a control treatment? Is the control the current standard for treatment or a placebo? Will I know what treatment I am receiving?

- What tests will I have to undergo?
- How long will the trial last?
- Can I continue with my normal lifestyle?
- Will I have to pay for the treatment? How much will it cost?

If the clinical trial will involve genetic testing, you may also wish to discuss the following with the researchers:

- Will I be told my test result? How will I be told and who will tell me?
- Will I have access to genetic counselling afterwards?
- How will my family members be affected by my test result?
- What will a positive result mean?
- What will a negative result mean?
- How accurate is the testing?

Written by Amy Schneider and Emily Higgs, Master of Genetic Counselling students, reviewed by Dr Jan Hodgson, Research Coordinator and Senior Lecturer, University of Melbourne and Murdoch Childrens Research Institute.

Sources:

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