

## Information about participating in research

This information has been prepared for people who are thinking about participating in research into the causes, effects and treatment of motor neurone disease (MND). MND is a progressive, degenerative disorder of certain nerve cells in the spinal cord and brain called motor neurones. Loss of these cells results in weakness and wasting of the muscles.

### **Understanding the causes, effects and finding treatments for MND**

Australia researchers are working towards understanding MND. This research contributes to increasing knowledge about the causes, diagnosis, treatment and management of the disease and is often dependent on the participation of people with the disease.

### **Types of research being undertaken**

Research into MND is usually clinical science research. This involves human research with specific clinical tests and investigations. Clinical science research may involve the collection of information about you (places you have lived, your work and leisure activities, food and drugs you may have consumed and your health history); observations about you (such as the function of your nerves, limbs and speech); samples of your blood or tissue (which may or may not involve the extraction of your DNA); your organs (such as your brain, in much the same way as you would donate your organs for transplantation).

Clinical science research may also involve the trial of treatments and interventions such as the administration of drugs or specific exercise. It may also involve giving access to information others hold about you, such as information collected by your neurologist or general practitioner.

Research is also undertaken into the effect of MND on a person's life, such as the financial and emotional impact of MND, equipment needs and carer related issues. This usually involves the collection of information about your life now and may include information about how you feel about having MND or caring for someone with MND.

Researchers also work on basic science research which can contribute to scientific knowledge generally. This may include studies involving animals or may involve observational studies, such as studies related to tissue growth.

### **Research and ethics**

Human research makes an important contribution towards increasing knowledge. The Australian Government, through the National Health and Medical Research Council (NHMRC), publishes information for researchers undertaking human research in Australia (NHMRC 2009). Generally human research in Australia needs to have merit; be conducted with integrity; be fair and just, for example, not exploit participants; have likely benefits that would justify any risks of harm or discomfort (and be suspended if the risks are no longer justified); and have due regard for consent, confidentiality, privacy, cultural sensitivities and personal beliefs. Additionally, some human research is subject to Commonwealth and State or Territory statutory regulation. Some, but not all, research proposals are reviewed by a university or health care institution Ethics Committee. The committee reviews the researcher's plan against the framework provided by the NHMRC.

### **Consent**

Before you participate in research you will be asked to provide your consent. This should be a voluntary choice and consent should only be given after you have been provided with enough information to understand the proposed research and the risks or benefits of your participation (NHMRC 2009). If you don't want to participate, you don't need to provide any reasons for your decision and should not suffer disadvantage as a result of your decision. Even if you do give consent, you can withdraw it at any time.

## **Databanks, human tissue collection and genetic research**

There are special requirements for researchers involved in data banks, the collection of human tissue and genetic research. These include how information and samples are collected and stored; confidentiality; and specific information that needs to be provided to you for consent. For example, such information would include whether identifiable information about you will be stored with the sample and who will have access to this information.

### **Issues to consider**

#### *Individual risk*

While most research is reviewed by an ethics committee, all potential research participants need to think about any risk of harm, discomfort or inconvenience that could occur as a result of their participation in the research. You may need to ask questions to make sure you get all the information you need. Once you know about the risks, you need to weigh these up against how you feel about the benefits of participating. Although most human research provides no immediate individual health benefit to research participants, you may find out information about yourself that you otherwise would not have known, for example, genetic information.

#### *Interventions and treatments*

If you are participating in research that involves an intervention or treatment you may not actually receive the intervention or treatment. For example, if you agree to participate in a drug trial, you may be allocated to an intervention group (who receive the treatment) or to a control group (who receive a 'fake'/placebo treatment or a 'usual' treatment). You will have no control over your group allocation.

#### *Your family*

It is important that you talk to your family about how you feel about becoming involved in any research project. Your involvement may also have some effects on them, for example, you may need transport for extra appointments or you may find out that you carry an MND-related gene. Also, some MND researchers are seeking the participation of people without MND. Your family may like to participate.

#### *Inclusion and exclusion criteria*

Researchers often limit their investigations to people with MND who have or don't have other specific characteristics, for example, by age-range or years since diagnosis, and you may feel disappointed to be excluded. Some research studies only accept participants who live near where the research is being undertaken, while others accept participants from all over Australia. Some projects have funds available to reimburse travel expenses.

#### *Keep your medical care provider involved*

You should let your neurologist or general practitioner know if you are thinking about participating in research. Your doctor will be able to support you through your decision-making. Sometimes, the involvement of your doctor can ensure your involvement in the research. For example, if you decide to donate your brain to research, your general practitioner will be able to assist your family make sure your wishes are honoured. However sometimes your doctor may form part of the research team. You can always ask to speak to another doctor who is not involved in the research project. If your doctor is involved and you decline to participate, this should not affect your care or treatment.

### **Further Reading**

NHMRC 2009. *National Statement on Ethical Conduct in Human Research (2007)* incorporating all updates, National Health and Medical Research Council. Publication number E72. Australian Government. Canberra. Available free online at [www.nhmrc.gov.au/guidelines/publications/e72](http://www.nhmrc.gov.au/guidelines/publications/e72)

### **More information**

The Motor Neurone Disease Association of NSW is an advocate and funder for the advancement of MND research. However, individuals need to carefully consider and determine if participation is right for them. You can find information about current research projects at [mndnsw.asn.au](http://mndnsw.asn.au) or contact the MND NSW Info Line ph. 1800 777 175.