

## Participant Information Sheet: TIME Study - Genetic Study



Study title:  
Brief title:  
Name of Researcher:

**Principal Investigator:** Professor Tom MacDonald

**Contact for queries:**

If you have any queries about this study, you can contact:  
Professor Tom MacDonald or Dr Isla Mackenzie  
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**Treatment In Morning versus Evening (TIME) Study**  
**TIME Study**  
**Professor Tom MacDonald**

You are being invited to take part in an additional genetic sample collection in this research study. Before you decide it is important for you to understand why the genetic research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like further information.

### **Why is this part of the study being done?**

We hope that we can help future research into the prevention, treatment and diagnosis of illness. We can look at genes by studying DNA, which carries the genetic blueprint of individuals handed down through generations. If you agree, we would like to store a mouth swab sample for such future genetic tests studies to see if there are any genetic factors that predispose to the side effects or beneficial effects of treatment. This may help in the future to make medicine better and safer.

There is a separate genetic consent form for TIME STUDY so if you do not wish to have a genetics sample stored you can still take part in the main study. You are receiving this information sheet because you indicated that you may be willing to provide a mouth swab genetics sample.

### **What will happen to any samples I give?**

The sample collected from you will be stored and anonymised, meaning that although the genetic information can be linked to your clinical information, personal details allowing you to be identified will be masked. Clearly however, in the future we may discover important new information relating to particular genes and in this situation it may be helpful to be able to directly identify you for instance to do further tests, and therefore we would like to keep the genetic samples to test theories that arise either from the trial or subsequently. Any further tests that will be done would not be linkable back to you. If we did want to do tests that were not acceptably anonymised in this way we would write to you again to seek your consent to do this. An independent Ethics Committee will approve all future genetic research on these samples.

### **What about confidentiality?**

Any information we obtain from you will remain strictly confidential. To ensure confidentiality is maintained we will:

- allocate a code to your stored sample
- keep your personal details separate from your stored sample but linked by that code.
- make sure that researchers only have access to that code.
- hold all information in a secure database, which can only be accessed by research staff directly involved in the study.

### **What would you need to do?**

To help us in this research, we would need you to provide a mouth swab sample for storage for further study tests. If you agree to have such a sample, we will post a kit to collect this sample directly to you. You simply follow the instructions and post it back.

### **Would there be any risks?**

We are not aware of any risks posed by taking a mouth swab.

### **Do you have to take part?**

No this additional part of the study is entirely voluntary. If you decide not to take part, you do not have to tell us why.

### **Who will be doing the research?**

Research using the samples may be done by approved researchers. The executive committee will control access to your samples but researchers involved in the genetic study will not have access to information that would identify you. It is possible that commercial organisations may carry out some of these analyses. Individual contributions do not have any commercial value and you will not receive financial gain from taking part.

### **What will happen to the samples after the study is finished?**

The samples will be stored for further research. Initial studies will focus on genetic tests to see if there are any genetic factors that predispose to side effects. Further research ideas will test other theories that arise either from the trial or subsequently. All samples will be handled in complete security and with the utmost respect. An independent research Ethics committee give their opinion on all future genetic research applications for these samples.

### **Who should you talk to if you have any questions or concerns?**

If you have any questions regarding this study, please use the 'Contact Us' button and email your questions.

**Thank you for your interest and for taking the time to consider this invitation.**