**A PRIORI CONSENT WITHIN PRAGMATIC RANDOMIZED CONTROLLED TRIALS:**

**A WEB BASED SURVEY**

**Online supplement: Example study background and scenarios presented to participants**

***Background***

There are many situations in which a GP does not know which is the better medication to prescribe, when more than one option is available. To help doctors to decide which of the commonly used medications is the most effective and safest, further research is needed in general practice.

The main problem with research in general practice is the difficulty in obtaining informed consent. This is because using the current system, patients are given a lot of information (often up to 20 pages), have unlimited time to decide, and are required to agree to up to 16 points in writing. This way of getting informed consent was designed to protect patients taking part in clinical trials testing new and experimental treatments. If the trial is comparing treatments that are already allowed to be prescribed by doctors and used by patients, this approach might be inappropriate and is also simply too difficult to undertake during a 10 minute GP appointment.

Some experts in ethics argue that written consent is not necessary if the trial is looking at two commonly used treatments to see which one is better. This is because a patient would end up being offered one of these two treatments by their doctor anyway and the treatments have been tested for safety by previous studies and licenced for use. The traditional approach might also be unethical because it prevents important research being undertaken in general practice.

This survey is to help us understand what patients feel might be the best way to achieve informed consent in a trial where two existing and often used medications are compared. We would like to run a range of these studies in General Practice to see if we can identify which commonly used drugs are better for New Zealand patients.

**Example of a clinical trial comparing the two most commonly used drugs to lower cholesterol in New Zealand**

The three scenarios below are all different ways of obtaining informed consent from a patient that is considering taking part in a trial.

This trial is looking at two drugs that are known to lower cholesterol levels in the blood and help prevent heart and blood vessel problems. Both of these drugs are very regularily given to patients by GPs across New Zealand.

Please imagine that you are the patient and that the trial has been fully approved by the New Zealand Ethics Committee. At the end you will be asked your opinion on each scenario.

***Scenario A:***

If you were not interested in the study you would not need to respond to the initial letter at all.

If, having initially agreed, you later decide that you do not want to take part, you can change your decision at any time.

***Scenario B:***

If you were not interested in the study you would not need to respond to the initial letter at all.

If, having initially agreed, you later decide that you do not want to take part, you can change your decision at any time.

***Scenario C:***