

## Appendix 6A: StatinWISE Patient Information Sheet – Optional Genetic Study

IRAS Project ID: 197990



Web-based Investigation of **STATIN** Side Effects

# INVITATION TO TAKE PART IN AN OPTIONAL GENETIC STUDY FOR StatinWISE

A randomised clinical trial to assess if atorvastatin treatment causes more muscle symptoms than placebo

Thank you for taking part in StatinWISE

Before you decide whether to take part in this optional genetic study, it is important for you to understand why the research is being done and what is involved. Please take time to read the information carefully and discuss it with friends or relatives if you wish. You are entirely free to decide whether or not to take part in this optional blood sample study. There are no extra visits to take part in this study. If you choose not to take part, the care you are given by your GP will not be affected.

If anything is unclear, or if you would like more information, please telephone the StatinWISE Research Nurse on [\[insert details\]](#)

*StatinWISE is coordinated by the London School of Hygiene & Tropical Medicine Clinical Trials Unit and funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme*

## Web-based Investigation of **STATIN** Side Effects

### 1. Why are we doing this optional genetic study

The link between taking statins and aches and pains is not fully understood, but may be linked to underlying genetic markers. This study aims to determine whether muscle pain considered to be due to statins is associated with genetic markers. Knowing this association may direct future medical management of using statins.

### 2. Why have I been asked to take part?

You have been asked to participate because you are taking part on StatinWISE. It is up to you to decide if you wish to participate or not. If you do not want to take part, your participation on StatinWISE will not change, neither will your future medical care be affected.

### 3. What will happen if I take part?

- Your GP practice research nurse will take one small (9mls, 2 teaspoons) blood sample
- Your sample will be labelled only with a trial identification number and sent to a laboratory at the University of Liverpool for analysis without any of your personal information.

### 4. What are the possible benefits of taking part in the study?

This optional study will allow scientists to understand if muscle symptoms experienced with statins are influenced by people's genes. The blood sample you give can be used also for other research studies. This may help direct future medical management of the use of statins.

### 5. What are the possible risks of taking part in the study?

It is very rare for a blood test to result in any serious complications. Risks associated with this test are no different to any regular blood test that you will have as part of routine clinical care. You may experience bruising as a result of taking the blood.

### 6. Will my participation in the study be kept private?

The only people who are allowed to look at your personal information will be the team responsible for the study at the London School of Hygiene & Tropical Medicine and regulatory authorities who check that the study is being carried out properly. The GP Practice will **not** share your personal information with the genetics laboratory. The results of the genetic analysis will not be shared with you, your GP or the StatinWISE team.

To contact the Clinical Trials Unit at London School of Hygiene & Tropical Medicine:

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