

*(To be printed on hospital/institution headed paper)*

## **ADDITIONAL PATIENT INFORMATION SHEET – DRUGS AFFECTING ABILITY TO DRIVE OR OPERATE MACHINES**

**Trial title: A randomized trial for adults with newly diagnosed acute lymphoblastic leukaemia**

**Short title: UKALL14**

Dear UKALL14 trial patient,

We would like to notify you of new information available for the trial you are currently taking part in. Please read the information below carefully and discuss any concerns you have with your study doctor.

Novartis Pharmaceuticals UK Ltd, the manufacturer of nelarabine, have recently identified that nelarabine has a major influence on the ability to drive and use machines. Patients treated with nelarabine are potentially at risk of suffering from drowsiness during and for several days after treatment. Since drowsiness can affect performance of skilled tasks such as driving, you are advised not to drive or operate machines if you experience drowsiness whilst receiving nelarabine.

We have also found that the previous patient information sheet you were given missed out the advice that pegylated asparaginase can cause drowsiness too. Baxalta, the manufacturer of pegylated asparaginase advise that you do not drive or operate machines if you experience drowsiness whilst receiving pegylated asparaginase.

In light of this new information, we are asking you to confirm that you are still happy to receive nelarabine and/or pegylated asparaginase treatment on the UKALL14 trial. If you do not wish to receive nelarabine and/or pegylated asparaginase, your trial treatment will be stopped, but you will continue to receive treatment for your ALL. Your doctor will discuss the available treatment options with you. If you decide to stop trial treatment, we would like your permission to continue to follow you up for the trial, collecting information about whether you are still in remission, and to check for any side effects of the trial drugs you have received. We would collect this information at the time of some of your routine hospital visits, so you would not need to have any extra visits. Remember that you are free to withdraw from trial treatment at any time, and this will not have any bearing on the medical attention that you will receive.

***Thank you for taking the time to read this patient information sheet. If you are happy to continue receiving trial treatment, please sign the consent form below.***

*(To be printed on hospital/institution headed paper)*

**UKALL14 RECONSENT FORM: DRUGS AFFECTING ABILITY TO DRIVE OR OPERATE MACHINES**

Site Name: \_\_\_\_\_

Patient Trial Number: \_\_\_\_\_

	Please initial box
<ul style="list-style-type: none"> <li>I confirm that I have read and understood the information provided above. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily</li> </ul>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>I am happy to continue on the UKALL14 study</li> </ul>	<input type="checkbox"/>

\_\_\_\_\_  
Name of Patient

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of person taking consent  
(if different from researcher)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date