*(Form to be on hospital/institution headed paper including CR-UK logo)*

UKALL14

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

**Additional Patient Information Sheet and Informed Consent Form:**

**Suspension of Palifermin randomisation, April 2016**

We would like to notify you of some new information about the trial you are currently taking part in. Please read the information below carefully and discuss any concerns you have with your study doctor. You will then be asked to sign at the bottom of the information sheet to show that you have read and understood this new information, and how it affects you.

When you first agreed to take part in UKALL14, you were informed that if you had a myeloablative transplant as part of the trial, you would be randomly allocated to having one of two different schedules of a drug called palifermin, which has been used to prevent mucositis (sore mouth) which may occur as a side effect of the drugs and radiotherapy given during the transplant.

At the beginning of April 2016, Swedish Orphan Biovitrum, who manufacture palifermin and supply the drug for the trial, stopped making and selling the drug in Europe due to poor sales. This means they have also stopped supplying the drug for UKALL14, so we cannot continue to test the different schedules of palifermin treatment.

***What does this mean for you?***

You will still have your myeloablative transplant as planned. However, you will not be randomised to one of the palifermin schedules, and will not be given this drug at is no longer available either within, or outside, the trial.

Your doctor will advise you on how best to prevent mucositis without taking palifermin. It is important that you follow your doctor’s advice about mouth care, as this will help to prevent or reduce the severity of mucositis.

Patient Consent Form:

Site Name: <<insert site name>>

Patient ID: <<insert patient ID>>

 **Please initial box**

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| 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 |  |
| I am happy to continue on the UKALL14 study |  |
|  |  |  |  |  |
| Name of Patient |  | Signature |  | Date |
|  |  |  |  |  |
| Name of person taking consent (if different from researcher) |  | Signature |  | Date |
|  |  |  |  |  |
| Name of Researcher |  | Signature |  | Date |