

## FAX MESSAGE

# NEW PATIENT REGISTRATION REQUEST 'REGISTRATION ONLY' SUB-STUDY

DATE (dd/mm/yyyy):

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ATTENTION:

**UKALL14** TRIAL TEAM

UKALL14 FAX No:

0207 679 9861

Number of pages (including cover sheet):

<b>RESEARCH CONTACT NAME:</b>	
<b>PHONE NO:</b>	
<b>EMAIL:</b>	
<b>FAX NO:</b>	

<b>PHARMACY CONTACT NAME:</b>	
<b>FAX NO./EMAIL:</b>	

Registering Centre	
Consultant	
Patient Initials	
Date of Birth	

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**UKALL14 'Registration only' Sub-study Entry Form (1/7)*****Patient Details***

Patient Initials

NHS Number

Date of Birth (*dd/mm/yyyy*)Sex (*1=Male, 2=Female*)Date of ALL Diagnosis  
(*dd/mm/yyyy*)

Centre

Consultant

## UKALL14 'Registration only' Sub-study Entry Form (2/7)

### Eligibility Checklist

ANSWERS TO THE FOLLOWING QUESTIONS MUST BE YES

	Inclusion Criteria for STUDY ENTRY	Yes	No
a	Aged $\geq 25$ and $\leq 65$ years at registration <b>OR</b> aged $\geq 19$ and $\leq 65$ years with Philadelphia Chromosome present	<input type="checkbox"/>	<input type="checkbox"/>
b	Newly diagnosed and previously untreated precursor B-cell ALL - Acute Lymphoblastic Leukaemia	<input type="checkbox"/>	<input type="checkbox"/>
c	Written informed consent	<input type="checkbox"/>	<input type="checkbox"/>

ANSWERS TO THE FOLLOWING QUESTIONS MUST BE NO

	Exclusion Criteria for STUDY ENTRY	Yes	No
a	Known HIV infection	<input type="checkbox"/>	<input type="checkbox"/>
b	Known history of hepatitis B infection	<input type="checkbox"/>	<input type="checkbox"/>
c	Known history of hepatitis C infection	<input type="checkbox"/>	<input type="checkbox"/>
d	Pregnant or lactating women	<input type="checkbox"/>	<input type="checkbox"/>
e	Blast transformation of CML	<input type="checkbox"/>	<input type="checkbox"/>
f	Mature B-cell leukaemia i.e. Burkitt's lymphoma t(8;14)(q24 ;q32) and variant c-myc translocations e.g. t(2;8)(p12 ;q24), t(8;22)(q24;q11)	<input type="checkbox"/>	<input type="checkbox"/>

### REMINDER

**Refer to Section 8.3 of the Sub-study Protocol (Protocol Appendix 1) for schedule of MRD and correlative science testing**

**UKALL14 'Registration only' Sub-study Entry Form (3/7)****Baseline Evaluation****Patient Assessments**Date of assessment  
(dd/mm/yyyy)

ECOG Performance Status

**Pregnancy Assessment**Is the patient a woman of child bearing  
potential? (1=Yes, 2=No)If yes, NEGATIVE pregnancy test date  
(dd/mm/yyyy)**CNS Involvement**Does the patient have suspected CNS involvement?  
(1=Yes, 2=No)*If Yes, please complete below:*Date of Lumbar Puncture  
(dd/mm/yyyy)Number of white cells/ $\mu$ LNumber of red cells/ $\mu$ L

**UKALL14 'Registration only' Sub-study Entry Form (4/7)****Baseline Evaluation****Extramedullary involvement**

Date of Assessment (dd/mm/yyyy)

Does the patient have extramedullary  
involvement? (1=Yes, 2=No)*If yes, please complete all boxes below**(1= Involved, 2=Not Involved, 3=Not Applicable)*

Liver

Is the liver enlarged?

(1= Yes, 2=No)

Spleen

Is the spleen enlarged?

(1= Yes, 2=No)

Mediastinum

Anterior mediastinal mass on chest X-ray?

(1= Yes, 2=No)

Lymph nodes

Any superficial lymph nodes enlarged?

(1= Yes, 2=No)

Testes

Other  
(specify)Other  
(specify)Other  
(specify)

## UKALL14 'Registration only' Sub-study Entry Form (5/7)

### Haematology Assessment

*Test should be from date of diagnosis. If these are not available, results prior to any steroid pre-phase (if given) should be used.*

Date of Haematology (dd/mm/yyyy)

White Blood Cell (WBC) Count x10<sup>9</sup>/L  ·

Haemoglobin g/dL OR g/L (circle units)  ·

Neutrophils x 10<sup>9</sup>/L  ·

Platelets x 10<sup>9</sup>/L

Is the % Bone Marrow Blasts result available at this time? Yes  Result   
No  Reason:   
1—Pending\*  
2—Unobtainable\*\*

*\* Please send in an anonymised diagnosis report confirming ALL. Once the diagnosis sample result is available, please update this page and fax to UCL-CTC.*

*\*\* Please send in an anonymised diagnosis report confirming ALL.*

**UKALL14 'Registration only' Sub-study Entry Form (6/7)*****Informed Consent***

*This section should be completed only if all criteria on the Eligibility Checklist have been satisfied*

**Section refers to the dates and version number of the Patient information sheet (PIS) for the 'Registration only' sub-study**

Date 'Registration only' PIS  
given to patient  
(dd/mm/yyyy)

Version number  
of PIS

***Part 1 of 'Registration only' Informed consent form is mandatory***

Date **Part 1** of the  
'Registration only' Consent  
Form signed  
(dd/mm/yyyy)

Version number  
of Consent Form

***Part 2 of 'Registration only' Informed consent form is optional***

Has the patient signed **Part 2**  
of the Consent Form?  
(1=Yes, 2=No)

Date **Part 2** of the  
Consent Form signed  
(dd/mm/yyyy)

On **Part 2** of the Consent Form, which boxes did the patient initial?  
1=Only box 1, 2=Only box 2, 3=Both boxes, 4=N/A

Has the patient initialled all the boxes on the consent form?  
(1=Yes, 2=No)

Has the patient personally signed and dated the consent form?  
(1=Yes, 2=No)

Has the person taking consent signed and dated form on the same date as the patient?  
(1=Yes, 2=No)

Has the person taking consent been delegated this role on the delegation log?  
(1=Yes, 2=No)

Name of person taking consent

**UKALL14 'Registration only' Sub-study Entry Form (7/7)***Informed Consent for Constitutional DNA***Genetic Testing: Buccal swab collection - Participation is optional**Date Patient Information  
Sheet given to patient  
(dd/mm/yyyy)Version number of  
Patient Information  
SheetHas the patient signed the Genetic  
Testing Consent Form? (1=Yes, 2=No)*If yes, please provide details below*Date patient signed Genetic  
Testing Buccal Swab Consent  
Form (dd/mm/yyyy)Version number  
Consent FormHas the patient initialled all the boxes on  
the consent form? (1=Yes, 2=No)Has the patient personally signed and  
dated the consent form? (1=Yes, 2=No)Has the person taking consent signed and dated  
the form on the same date as the patient?  
(1=Yes, 2=No)Has the person taking consent been  
delegated this role on the delegation log?  
(1=Yes, 2=No)

Name of person taking consent

Completed  
by:

Signature:

Date  
completed:

## SECTION TO BE COMPLETED BY UCL CTC

**Trial Registration Result**

Trial Number

**14 - 3 -**

This patient has been registered to the UKALL14 'Registration only' sub-study. Patient will receive standard treatment of their local clinician's choice

Registered by (UCL CTC)

Date of Registration  
(dd/mm/yyyy)