

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"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

ATTENTION:

UKALL14 TRIAL TEAM

UKALL14 FAX No:

0207 679 9861

Number of pages (including cover sheet):

RESEARCH CONTACT NAME:	
PHONE NO:	
EMAIL:	
FAX NO:	

PHARMACY CONTACT NAME:	
FAX NO./EMAIL:	

Registering Centre	
Consultant	
Patient Initials	
Date of Birth	

The Information contained in this fax is confidential and is intended only for the named recipient(s). If you are not the intended recipient you must not copy, distribute, or take any action or reliance on it. If you have received this fax in error, please notify the sender. Any unauthorised disclosure of the information contained in this fax is strictly prohibited.

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)

Disease Type:

1= Precursor-B cell Disease
2= T-cell disease

Centre

Consultant

Has the patient started a steroid pre-phase?

(1=Yes, 2=No)

If yes, steroid pre-phase start date
(dd/mm/yyyy)Proposed start date of ALL treatment
(dd/mm/yyyy)

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 ≥ 25 and ≤ 65 years at registration OR aged ≥ 19 and ≤ 65 years with Philadelphia Chromosome present	<input type="checkbox"/>	<input type="checkbox"/>
b	Newly diagnosed and previously untreated ALL - Acute Lymphoblastic Leukaemia. A steroid pre-phase of 5-7 days is required and can be started prior to registration.	<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 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 AssessmentIs 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/ μ LNumber of red cells/ μ 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 x10⁹/L .

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

Neutrophils x 10⁹/L .

Platelets x 10⁹/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 ResultTrial Number **14** - -

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)