

Site Name:					
Investigator Site File – document version checklist					
Complete 'yes' or 'no' to confirm the presence or absence of each document specified. Any missing documents will be provided to you for the ISF by UCL CTC following return of this checklist.					
Section	Document Name	Version	Date	Present?	Comments
01 CORRESPONDENCE & COMMUNICATION					
	Trial Newsletters:				
	- Easter 2011	-	Mar2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Christmas 2011	-	Dec2011	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Easter 2012	-	Mar2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Christmas 2012	-	Dec2012	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Easter 2013	-	27mar13	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Christmas 2013	-	Dec2013	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Christmas 2014	-	Dec2014	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- MRD lab move & Newsletter May 2015	-	15may15	Y <input type="checkbox"/> N <input type="checkbox"/>	
	- Newsletter Christmas 2015	-	02dec15	Y <input type="checkbox"/> N <input type="checkbox"/>	
	UKALL14 Monitoring Plan	4.0	18oct16	Y <input type="checkbox"/> N <input type="checkbox"/>	
	UKALL14 central monitoring checklists	-	-	Y <input type="checkbox"/> N <input type="checkbox"/>	Please file all previous versions of checklists here
	UKALL14 Incident Report form	2.0	25jun15	Y <input type="checkbox"/> N <input type="checkbox"/>	
02 CTC INFORMATION					
	CTC Contact List	6.0	08Feb17	Y <input type="checkbox"/> N <input type="checkbox"/>	
03	PROTOCOL & AMENDMENTS:	Tick to confirm previous versions have been superseded. <input type="checkbox"/>			
	Current approved protocol	9	17Feb17	Y <input type="checkbox"/> N <input type="checkbox"/>	
	Previously approved versions of protocol	8 7 (09.09.15 corrected 10.12.15)	12May16 10dec15	Y <input type="checkbox"/> N <input type="checkbox"/>	
		7	09sep15	Y <input type="checkbox"/> N <input type="checkbox"/>	
		6.1	27jan15	Y <input type="checkbox"/> N <input type="checkbox"/>	
		6	20jun14	Y <input type="checkbox"/> N <input type="checkbox"/>	
		5	20jul12	Y <input type="checkbox"/> N <input type="checkbox"/>	
		4	24apr12	Y <input type="checkbox"/> N <input type="checkbox"/>	
		3	18aug10	Y <input type="checkbox"/> N <input type="checkbox"/>	
		2	17may10	Y <input type="checkbox"/> N <input type="checkbox"/>	
		1	11nov09	Y <input type="checkbox"/> N <input type="checkbox"/>	
04	PATIENT INFORMATION	Tick to confirm previous versions have been superseded. <input type="checkbox"/>			
	Current approved PIS	7	17Feb17	Y <input type="checkbox"/> N <input type="checkbox"/>	
	UKALL14 Additional PIS - Suspension of palifermin	1	13apr16	Y <input type="checkbox"/> N <input type="checkbox"/>	
	Patient Information Sheet – Additional Genetic Testing – Buccal swab	1	09sep15	Y <input type="checkbox"/> N <input type="checkbox"/>	
	Patient Information sheet – Additional Genetic Testing v1.0 – Stored Bone Marrow	1	09sep15	Y <input type="checkbox"/> N <input type="checkbox"/>	
	Current approved Consent Form	1.2	29apr15	Y <input type="checkbox"/> N <input type="checkbox"/>	
	Consent Form - Genetic Testing - Buccal swab v1.0 09.09.2015	1	09sep15	Y <input type="checkbox"/> N <input type="checkbox"/>	

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	Consent Form - Genetic Testing - Stored Bone marrow	1	09sep15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Current approved GP Letter	1.0	11nov09	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Previously approved versions of PIS	6.0	12May16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		5.3	12May16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		5.2	29apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		5.1	16jun14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		5	13mar14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		4.1	16may13	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		4	01aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		3	18aug10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Previously approved versions of consent form	2.1	17may10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		2	24dec09	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Patient Card	1.0	11nov09	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Pregnancy Monitoring Information Sheet - patients	1.0	01aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Pregnancy Monitoring Information Sheet - partners	1.0	01aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Pregnancy Monitoring Consent Form - patients	1.0	01aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Pregnancy Monitoring Consent Form - partners	1.0	01aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Previously approved versions of Pregnant Partner Information Sheet & consent form	1.0	17may10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		1.1	18aug10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
05	ETHICS & REGULATORY APPROVALS *					
	*sites must have the initial approval letters, site approval letter and all relevant subsequent approvals					
	Ethics approval letter (Main REC)	-	13jan10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	MHRA approval letter	-	13jan10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Sponsorship letter	-	25mar09	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Letter of insurance from sponsor	-	15may09	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Letter of insurance from sponsor- previous years	-	Aug09-10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		-	Aug10-11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		-	Aug11-12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		-	Aug12-13	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		-	Aug13-14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		-	Aug14-15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		-	Aug15-16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Amendments– MHRA Approval Letters	PIS v2	23feb10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v2	21jun10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v3	17sep10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Labelling	03nov10	Y <input type="checkbox"/>	N <input type="checkbox"/>	

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Section	Document Name	Version	Date	Present?		Comments
		Protocol v4	09may12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v5	27sep12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6	15jul14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6.1	11mar15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v7	15nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v8	15Jun16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v9	13Mar17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Urgent Safety Measure Correspondence	USM email - Protocol v4	24apr12	Y <input type="checkbox"/>	N <input type="checkbox"/>	Email correspondence sent from CTC 24.04.12 regarding USM
	Amendments - MREC Approval Letters	Protocol v2	07jun10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v3	08sep10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Consent period	24aug11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v4	16may12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v5 PIS v4.0	23aug12	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		PIS 4.1	17may13	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		PIS 5.0	02apr14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6 PIS v5.1	09jul14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v6.1	23feb15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		PIS 5.2 ICF 1.2	21may15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v7	30sep15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v8	06Jun16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
		Protocol v9	09Mar17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
06 AGREEMENTS & CONTRACTS						
	Clinical trial site agreement	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Copy of site activation letter	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	First Amendment to CTSA	-		Y <input type="checkbox"/>	N <input type="checkbox"/>	As applicable
	Second Amendment to CTSA	-		Y <input type="checkbox"/>	N <input type="checkbox"/>	As applicable
07 SITE INFORMATION / SITE STAFF INFORMATION						
	Site staff delegation log	1.0	08aug11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Investigator Registration Forms	1.0	10aug11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Site Registration Form	1.0	04jul11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Site initiation report & documentation (e.g. slides)	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Other site visit reports (if applicable)	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
08 PATIENT SCREENING						
	Patient Screening Log	-	08dec10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Patient Screening Log Instructions	1.0	08dec10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Patient log	1.0	08dec10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Site informed consent log	1	08dec11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
09 LABORATORY						

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	Sample Request Form	3.0	09nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Price List – UCL Adult ALL Lab	-	08aug10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
10 SUMMARY OF PRODUCTS CHARACTERISTICS						
	Current versions of summary of products characteristics: - Mabthera - Kevivance - Oncaspar - Atriance	- - - -	Jun2016 May2013 Jan2016 Apr2015	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	Roche Six Monthly SUSAR reports	-	26may-25nov13 26nov13-25may14 26may-17nov14 18nov14-17may15 18may15-17nov15	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
11 STUDY DRUG SUPPLIES / PHARMACY AGREEMENTS <input type="checkbox"/> Tick if held in pharmacy file not ISF						
	Drug Supply Guidelines	2.1	25feb14	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Drug Accountability logs: - Phase 1 Oncaspar - Phase 1 Rituximab - Phase 2 Nelarabine - Consolidation Oncaspar - Intensification Oncaspar - Palifermin treatment	2.0 2.0 2.0 2.0 2.0 2.0	18may15 18may15 18may15 18may15 18may15 18may15	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	Stock Balance Logs: - Oncaspar - Rituximab - Nelarabine - Palifermin	1.0 1.0 1.0 1.0	18may15 18may15 18may15 18may15	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	Drug order forms: - Oncaspar - Rituximab - Nelarabine - Palifermin	3 1 1 4	11Feb13 22Oct10 22Oct10 09sep15	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	UKALL14 memorandum to Investigators and Pharmacists	-	26jan16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
12 DATA MANAGEMENT						
	CRF – Registration	6.0	27nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Cytogenetics	3.0	03may13	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Induction Treatment Phase 1	3.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Induction Treatment Phase 2	3.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	

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	CRF – Post Induction Treatment Allocation (PITA)	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Post Induction Registration - Maintenance	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Post Induction Registration- Transplant	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF - Intensification	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF - Consolidation	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Transplant – incorporating the following forms: <ul style="list-style-type: none"> - Conditioning (RIC/MAC) - Palifermin - ODMQ - Transplant - Day 100 - GvHD - Graft failure - Post-transplant assessment 	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Maintenance Treatment	1.0	08dec10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF - Relapse	2.0	19apr11	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Centre Transfer	3.0	10mar16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Treatment Summary	4.0	27nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF - Death	3.0	27nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF- Adverse Events (AEs) Forms <ul style="list-style-type: none"> - Induction Phase 1 - Induction Phase2 - Intensification - Consolidation - Transplant 	3.0 3.0 3.0 3.0 3.0	27nov15 27nov15 27nov15 27nov15 27nov15	Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/> Y <input type="checkbox"/>	N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/>	
	CRF - Adverse Event of Special Interest – Thromboembolic Event Urgent Event Form (v1.0 27Nov15)	1	27nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Annual Follow-up	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Late Effects	1.0	10mar16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Annual Follow-up (Not in CR after Phase 2)	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Annual Follow-up (Relapse/Second Cancer)	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Second Cancer	2.0	20apr15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF – Lost to Follow-up	3.0	27nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	CRF - Informed Consent – Constitutional DNA	1	27nov15	Y <input type="checkbox"/>	N <input type="checkbox"/>	

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	CRF Completion Guidelines	4.0	10mar16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	SAE Form Guidance	3.0	10feb17	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	SAE Report Fax Header	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	SAE Report	4.0	21jan16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	SAE Report Additional Pages	1.0	08dec10	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	File Note: SAE Report v3 not disseminated	-	22jan16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Pregnancy Report	2.0	21jan16	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Pregnancy Report Additional Pages	1.0	08dec10	Y <input type="checkbox"/>	N <input type="checkbox"/>	

13 PHARMACOVIGILANCE

	Safety updates/reports: - SUSAR Quarterly Line Listings	-	28aug12 10Jun-10Sep14 10Sep-10Dec14 11Dec-31Mar15 1Apr-30Jun15 01jul15-30sep15 01oct15-31dec15	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Common terminology criteria for adverse events (CTCAE)	4.03	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	

14 REGULATORY GUIDELINES

	Principles of ICH GCP	-	-	Y <input type="checkbox"/>	N <input type="checkbox"/>	
	Declaration of Helsinki	-	Oct2008	Y <input type="checkbox"/>	N <input type="checkbox"/>	

Previous versions of all documents listed above must be superseded. Please initial and date to confirm this action has been performed

Date Initials

Please provide the email address of the person to whom updated documents should be sent:

The completed form can be returned to ctc.ukall14@ucl.ac.uk or fax to 0207 679 9861

This is intended to support site's own internal systems for maintaining the ISF; therefore if the checklist is not returned to UCL CTC we will assume that documents contained within your ISF are up-to-date.

The following are general reminders regarding maintenance of the Investigator Site File:

The folder must be stored in a secure location with appropriate/restricted access.

The documents should be filed as per index.
 (CTC index or site's own index is acceptable)

Documents generated locally (e.g. local approvals, lab normal ranges, correspondence, etc.) must be filed in the applicable sections.

Where documents are held in an alternative location, file notes should be present to indicate this.

Up-to-date CVs must be present for all site staff.

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<i>(CVs should be signed & dated and updated regularly according to employing institution policy)</i>					
GCP certificates must be present (or details of course attended listed in the CV) for all site staff. <i>(All staff should have attended a course – frequency of repeat training may be dictated by the employing institution policy, or 2 yearly where the institution has no policy, and more frequently when there have been updates to the legal or regulatory requirements for conduct of clinical trials)</i>					