Site Name:

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Section	Document Name	Version	Date	Present?		Comments
01	**CORRESPONDENCE & COMMUNICATION**					
	Trial Newsletters:					
	- Easter 2011	-	Mar2011	Y ☐	N ☐	
	- Christmas 2011	-	Dec2011	Y ☐	N ☐	
	- Easter 2012	-	Mar2012	Y ☐	N ☐	
	- Christmas 2012	-	Dec2012	Y ☐	N ☐	
	- Easter 2013	-	27mar13	Y ☐	N ☐	
	- Christmas 2013	-	Dec2013	Y ☐	N ☐	
	- Christmas 2014	-	Dec2014	Y ☐	N ☐	
	- MRD lab move & Newsletter May 2015	-	15may15	Y ☐	N ☐	
	- Christmas 2015	-	02dec15	Y ☐	N ☐	
	- Spring 2017	-	Apr2017	Y ☐	N ☐	
	- Summer 2018	-	27Jun18	Y ☐	N ☐	
	UKALL14 Monitoring Plan	4.0	18Oct16	Y ☐	N ☐	
	UKALL14 central monitoring checklists	-	-	Y ☐	N ☐	Please file all previous versions of checklists here
	UKALL14 Incident Report form	2.0	25jun15	Y ☐	N ☐	
02	**CTC INFORMATION**					
	CTC Contact List	7.0	29Aug18	Y ☐	N ☐	
03	**PROTOCOL & AMENDMENTS:**		***Tick to confirm previous versions have been superseded.***			☐
	Current approved protocol	12	26Jun18	Y ☐	N ☐	
	Previously approved versions of protocol *[v10 was never approved, rejected by MHRA]*	11 9 8 7 (09.09.15 corrected 10.12.15) 7 6.1 6 5 4 3 2 1	11Sep17 17Feb17 12May16 10dec15 09sep15 27jan15 20jun14 20jul12 24apr12 18aug10 17may10 11nov09	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
04	**PATIENT INFORMATION**		***Tick to confirm previous versions have been superseded.***			☐
	Current approved PIS	10	28Jun18	Y ☐	N ☐	
	UKALL14 Additional PIS - Suspension of palifermin	1	13apr16	Y ☐	N ☐	
	UKALL14 Additional PIS – Drugs affecting ability to drive/operate machines	1.1	31Aug17	Y ☐	N ☐	
	Patient Information Sheet/Consent Form – 'Registration only' sub-study	3	28Jun18	Y ☐	N ☐	

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Section	Document Name	Version	Date	Present?		Comments
	Patient Information Sheet – Additional Genetic Testing – Buccal swab	1	09sep15	Y ☐	N ☐	
	Patient Information sheet – Additional Genetic Testing v1.0 – Stored Bone Marrow	1	09sep15	Y ☐	N ☐	
	GDPR Transparency Statement	1	11Jun18	Y ☐	N ☐	
	CTC GDPR Transparency Tracker	-	24May18	Y ☐	N ☐	
	Current approved Consent Form	1.2	29apr15	Y ☐	N ☐	
	Consent Form - Genetic Testing - Buccal swab v1.0 09.09.2015	1	09sep15	Y ☐	N ☐	
	Consent Form - Genetic Testing - Stored Bone marrow	1	09sep15	Y ☐	N ☐	
	Current approved GP Letter	1.0	11nov09	Y ☐	N ☐	
	Previously approved versions of PIS	9.0 8.0 7.0 6.0 5.3 5.2 5.1 5 4.1 4 3 2.1 2	11Sep17 09Aug17 17Feb17 12May16 12May16 29apr15 16jun14 13mar14 16may13 01aug12 18aug10 17may10 24dec09	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
	Previously approved versions of consent from	1 1.1	11nov09 03sep10	Y ☐ Y ☐	N ☐ N ☐	
	Previously approved versions of 'Registration only' PIS	2	11Sep17	Y ☐	N ☐	
	Patient Card	1.0	11nov09	Y ☐	N ☐	
	Pregnancy Monitoring Information Sheet - patients	1.0	01aug12	Y ☐	N ☐	
	Pregnancy Monitoring Information Sheet - partners	1.0	01aug12	Y ☐	N ☐	
	Pregnancy Monitoring Consent Form - patients	1.0	01aug12	Y ☐	N ☐	
	Pregnancy Monitoring Consent Form - partners	1.0	01aug12	Y ☐	N ☐	
	Previously approved versions of Pregnant Partner Information Sheet & consent form *(reformatted)*	1.0 1.1	17may10 18aug10	Y ☐ Y ☐	N ☐ N ☐	

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Section	Document Name	Version	Date	Present?		Comments
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 ☐	N ☐	
	MHRA approval letter	-	13jan10	Y ☐	N ☐	
	Sponsorship letter	-	25mar09	Y ☐	N ☐	
	Letter of insurance from sponsor - initial	-	15may09	Y ☐	N ☐	
	Letter of insurance from sponsor- subsequent years	-	Aug09-10 Aug10-11 Aug11-12 Aug12-13 Aug13-14 Aug14-15 Aug15-16 Aug16-17 Aug17-18 Aug18-19	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
	Amendments– MHRA Approval Letters	PIS v2 Protocol v2 Protocol v3 Labelling Protocol v4 Protocol v5 Protocol v6 Protocol v6.1 Protocol v7 Protocol v8 Protocol v9 Protocol v11 Protocol v12	23feb10 21jun10 17sep10 03nov10 09may12 27sep12 15jul14 11mar15 15nov15 15Jun16 13Mar17 21Nov17 31Aug18	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
	Urgent Safety Measure Correspondence	USM email - Protocol v4	24apr12	Y ☐	N ☐	Email correspondence sent from CTC 24.04.12 regarding USM
	Rejection of Protocol v10 amendment Correspondence	-	12Jul17	Y ☐	N ☐	
	Amendments - REC Approval Letters	Protocol v2 Protocol v3 Consent period Protocol v4 Protocol v5 PIS v4.0 PIS 4.1 PIS 5.0 Protocol v6 PIS v5.1 Protocol v6.1 PIS 5.2 ICF 1.2 Protocol v7 Protocol v8 Protocol v9	07jun10 08sep10 24aug11 16may12 23aug12 17may13 02apr14 09jul14 23feb15 21may15 30sep15 06Jun16 09Mar17	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	

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Section	Document Name	Version	Date	Present?		Comments
		PIS v8 Protocol v11 Protocol v12	05Sep17 30Oct17 27Jul18	Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐	
06	**AGREEMENTS & CONTRACTS**					
	Clinical trial site agreement	-	-	Y ☐	N ☐	
	Copy of site activation letter	-	-	Y ☐	N ☐	
	First Amendment to CTSA	-	-	Y ☐	N ☐	*As applicable*
	Second Amendment to CTSA	-	-	Y ☐	N ☐	*As applicable*
07	**SITE INFORMATION / SITE STAFF INFORMATION**					
	Site staff delegation log	1.0	08aug11	Y ☐	N ☐	
	Investigator Registration Forms	1.0	10aug11	Y ☐	N ☐	
	Site Registration Form	1.0	04jul11	Y ☐	N ☐	
	Site initiation report & documentation (e.g. slides)	-	-	Y ☐	N ☐	
	UKALL14 Training Manual	1.0	27Nov17	Y ☐	N ☐	
	UKALL14 'Registration only' Training Slides	1.0	15Nov17	Y ☐	N ☐	
	Other site visit reports (if applicable)	-	-	Y ☐	N ☐	
08	**PATIENT SCREENING**					
	Patient Screening Log	-	08dec10	Y ☐	N ☐	
	Patient Screening Log Instructions	1.0	08dec10	Y ☐	N ☐	
	Patient log	1.0	08dec10	Y ☐	N ☐	
	Site informed consent log	1	08dec11	Y ☐	N ☐	
09	**LABORATORY**					
	Sample Request Form	5.0	23Nov17	Y ☐	N ☐	*+ file note dated 23Nov17*
	Price List – UCL Adult ALL Lab	-	08aug10	Y ☐	N ☐	
10	**SUMMARY OF PRODUCTS CHARACTERISTICS**					
	Current versions of summary of products characteristics: - Mabthera 500mg &100mg - Kepivance - Oncaspar - Atriance	 - - - -	 26Apr2018 May2013 Dec2017 30Apr2018	 Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐	
11	**STUDY DRUG SUPPLIES / PHARMACY AGREEMENTS**			☐ Tick if held in pharmacy file not ISF		
	Drug Supply Guidelines	4.0	12Mar18	Y ☐	N ☐	
	Drug Accountability logs: - Phase 1 Oncaspar - Phase 1 Rituximab	 2.0 2.0	 18may15 18may15	 Y ☐ Y ☐	 N ☐ N ☐	

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Section	Document Name	Version	Date	Present?		Comments
	- Phase 2 Nelarabine - Consolidation Oncaspar - Intensification Oncaspar - Palifermin treatment	2.0 2.0 2.0 2.0	18may15 18may15 18may15 18may15	Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐	
	Stock Balance Logs: - Oncaspar - Rituximab - Nelarabine - Palifermin	 1.0 1.0 1.0 1.0	 18may15 18may15 18may15 18may15	 Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐	
	Drug order forms: - Oncaspar - Rituximab - Nelarabine - Palifermin	 4 1 1 4	 27Feb18 22Oct10 22Oct10 09sep15	 Y ☐ Y ☐ Y ☐ Y ☐	 N ☐ N ☐ N ☐ N ☐	
	UKALL14 memorandum to Investigators and Pharmacists	-	26jan16	Y ☐	N ☐	
12	**DATA MANAGEMENT**					
	CRF – Registration	6.0	27nov15	Y ☐	N ☐	
	CRF – Cytogenetics	3.0	03may13	Y ☐	N ☐	
	CRF – Induction Treatment Phase 1	3.0	20apr15	Y ☐	N ☐	
	CRF – Induction Treatment Phase 2	3.0	20apr15	Y ☐	N ☐	
	CRF – Post Induction Treatment Allocation (PITA)	2.0	20apr15	Y ☐	N ☐	
	CRF – Post Induction Registration - Maintenance	2.0	20apr15	Y ☐	N ☐	
	CRF – Post Induction Registration- Transplant	2.0	20apr15	Y ☐	N ☐	
	CRF - Intensification	2.0	20apr15	Y ☐	N ☐	
	CRF - Consolidation	2.0	20apr15	Y ☐	N ☐	
	CRF – Transplant – incorporating the following forms: - Conditioning (RIC/MAC) - Palifermin - ODMQ - Transplant - Day 100 - GvHD - Graft failure - Post-transplant assessment	2.0	20apr15	Y ☐	N ☐	
	CRF – Maintenance Treatment	1.0	08dec10	Y ☐	N ☐	

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	CRF - Relapse	2.0	19apr11	Y ☐	N ☐	
	CRF – Centre Transfer	3.0	10mar16	Y ☐	N ☐	
	CRF – Treatment Summary	4.0	27nov15	Y ☐	N ☐	
	CRF - Death	3.0	27nov15	Y ☐	N ☐	
	CRF- Adverse Events (AEs) Forms					
	- Induction Phase 1	3.0	27nov15	Y ☐	N ☐	
	- Induction Phase2	3.0	27nov15	Y ☐	N ☐	
	- Intensification	3.0	27nov15	Y ☐	N ☐	
	- Consolidation	3.0	27nov15	Y ☐	N ☐	
	- Transplant	3.0	27nov15	Y ☐	N ☐	
	CRF - Adverse Event of Special Interest – Thromboembolic Event Urgent Event Form	1	27nov15	Y ☐	N ☐	
	CRF – Annual Follow-up	2.0	20apr15	Y ☐	N ☐	
	CRF – Late Effects	1.0	10mar16	Y ☐	N ☐	
	CRF – Annual Follow-up (Not in CR after Phase 2)	2.0	20apr15	Y ☐	N ☐	
	CRF – Annual Follow-up (Relapse/Second Cancer)	2.0	20apr15	Y ☐	N ☐	
	CRF – Second Cancer	2.0	20apr15	Y ☐	N ☐	
	CRF – Lost to Follow-up	3.0	27nov15	Y ☐	N ☐	
	CRF - Informed Consent – Constitutional DNA	1	27nov15	Y ☐	N ☐	
	CRF Completion Guidelines	5.0	14Mar18	Y ☐	N ☐	
	CRF 'Registration only' Completion Guidelines	2.0	04Sep18	Y ☐	N ☐	
	CRF – 'Registration only' Sub-study Entry	2.0	20Aug18	Y ☐	N ☐	
	CRF – 'Registration only' Sub-study Induction Treatment	2.0	20Aug18	Y ☐	N ☐	
	CRF – 'Registration only' Sub-study Post-Induction Chemotherapy	2.0	20Aug18	Y ☐	N ☐	
	CRF – 'Registration only' Sub-study GvHD	2.0	20Aug18	Y ☐	N ☐	
	CRF – 'Registration only' Sub-study Transplant to D100	2.0	20Aug18	Y ☐	N ☐	
	CRF – 'Registration only' Sub-study Annual Follow -up	2.0	20Aug18	Y ☐	N ☐	
	SAE Form Guidance	4.0	23Nov17	Y ☐	N ☐	
	SAE Report Fax Header	-	-	Y ☐	N ☐	
	SAE Report	5.0	23Nov17	Y ☐	N ☐	

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	SAE Report Additional Pages	1.0	08dec10	Y ☐	N ☐	
	File Note: SAE Report v3 not disseminated	-	22jan16	Y ☐	N ☐	
	Pregnancy Report	3.0	23Nov17	Y ☐	N ☐	
	Pregnancy Report Additional Pages	1.0	08dec10	Y ☐	N ☐	
13	**PHARMACOVIGILANCE**					
	Safety updates/reports: - SUSAR Quarterly Line Listings	-	28aug12 10Jun-10Sep14 10Sep-10Dec14 11Dec-31Mar15 1Apr-30Jun15 01jul15-30sep15 01oct15-31dec15 01Jan16-31Mar16 01Apr16-30Jun16 01Jul16-30Sep16 01Oct16-31Dec16 01Jan17-31Mar17 01Apr17-30Jun17 01Jul17-30Sep17 01Oct17-31Dec17 01Jan18-31Mar18 01Apr18-30Jun18	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐ N ☐	
	Roche Six Monthly SUSAR reports	-	26may-25nov13 26nov13-25may14 26may-17nov14 18nov14-17may15 18may15-17nov15	Y ☐ Y ☐ Y ☐ Y ☐ Y ☐	N ☐ N ☐ N ☐ N ☐ N ☐	
	Common terminology criteria for adverse events (CTCAE)	4.03	-	Y ☐	N ☐	
14	**REGULATORY GUIDELINES**					
	Principles of ICH GCP	-	-	Y ☐	N ☐	
	Declaration of Helsinki	-	Oct2008	Y ☐	N ☐	

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.**

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Section	**Document Name**	**Version**	**Date**	**Present?**	**Comments**
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. *(CVs should be signed & dated and updated regularly according to employing institution policy)*					
GCP certificates must be present (or details of course attended listed in the CV) for all site staff. *(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)*					