Medical Assessment of patients for bone marrow harvest or therapeutic apheresis

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The Christie NHS
NHS Foundation Trust

Cellular Therapy and Transplant Programme

Medical Assessment of CAR-T Patients

Patient addressograph:	Height cms:	Weight kgs:
Name: Number: DOB: Address:	Date: PO number LYM number: NCCP: Date to panel:	

MEDICAL ASSESSMENT:

Review of Systems: Please tick Yes/No where appropriate

	Yes	**No**		**Yes**	**No**
Fever/sweats			Fits / Faints / Falls / Paresthesia		
Chest pain/palpitations			Back pain / joint pain		
SOB/Cough / Wheeze / Sputum / Haemoptysis			Hyperviscosity/ hyperleucostasis		
Adbo pain / N+V / Hematemesis			Bleeding / bruising		
Change in bowel habit / Malaena			Smoker ……/day		
Urinary symptoms?			Alcohol ……unit/week		
Headache/visual problems					

Pre Cart biopsy date: Pre CART PET scan date :

Details

Disease History:

Diagnosis, treatment and remission status:

Previous History: if yes provide details

	Yes	**No**		**Yes**	**No**
Cardiac or circulatory disease			General Anaesthetic		
Respiratory disease			Hepatitis, HIV, syphilis		
Diabetes Mellitus			Piercing / Tattoos last 3 months		
Acupuncture (past 3 months non-UK or by an unqualified practitioner)			Travel outside of Europe in the last year		
Any implantable medical devices			Malaria risk		
Jaundice					

Details:

Medication:				
				Allergies? :
				Previous G-CSF / cytokine?:
General Examination:				
Pulse:	Temp:	BP:	RR:	SaO_2:
CVS:	RS:	Abdo:		
CNS:	Musculoskeletal:	Liver/spleen:		

Washout criteria clinician to complete in clinic			
3 days	Has the patient received short acting cytotoxic therapy	☐ Yes	☐ No
5 days	Has patient received short acting growth	☐ Yes	☐ No
7 days	Has the patient received steroids?	☐ Yes	☐ No
7 days	Has the patient received IT Methotrexate	☐ Yes	☐ No
14 days	Has the patient received low dose maintenance chemotherapy? (6MP/MXT/vincristine) TKI therapy Blinatumomab GVHD treatment Lenolidamide Immune modulatory therapy including checkpoint inhibitors Radiotherapy	☐ Yes	☐ No
4 weeks	Has the patient received Peg asparaginase Donor Lympoctes Antibody therapy including CD20 specific treatments (rituximab, inotuzumab)	☐ Yes	☐ No
8 weeks	Has the patient received clofarabine T cell Lytic agents (Alemtuzumb)	☐ Yes	☐ No
12 weeks	Has the patient received Fludarabine Undergone an allogeneic transplant?	☐ Yes	☐ No
Other	Has the patient ever received Bendamustine treatment	☐ Yes	☐ No
Other	**Tecartus only:** Stop systemic therapies 2 weeks or 5 half-lives (whichever is shorter)	☐ Yes	☐ No

Clinician to tick to confirm results have been reviewed as stated above:

FBC	Yes ☐	
Urine dipstick analysis if indicated	Yes ☐	N/A ☐
Blood film (only if indicated)	Yes ☐	N/A ☐
Clotting screen	Yes ☐	
Christie Profile	Yes ☐	
Glucose	Yes ☐	
Blood group and antibody screen	Yes ☐	
Pre-harvest viral serology	Yes ☐	
Other serological testing as indicated	Yes ☐	N/A ☐
ECG	Yes ☐	
PA chest X-ray (if indicated)	Yes ☐	N/A ☐
MRSA screen and eradication (if for BM harvest or femoral line)	Yes ☐	N/A ☐

Other investigations (viscosity, cardiac, renal etc if indicated):

Peripheral Venous Access:			
LEFT	GOOD / POOR/femoral	RIGHT	GOOD / POOR/femoral

Medically fit to donate? : Yes No	Signature: _____ Name: _____ Date: _____ Time: _____
Written and verbal information given regarding the risks of HPC donation? : Yes No	

FINAL ASSESSMENT: (to be conducted by **collection facility medical director** or designee)

Passed final assessment?: Yes No	Signature: _____ Name: _____
Reason for Failure:	Date: _____ Time: _____

Cellular Therapy collection prescription and request for product processing – *to be completed by the clinician and sent with product*

Please arrange collection for _____

Patient likely to require central venous catheter?: ☐ Yes ☐ No

Product

☐ Kymriah (NOVARTIS) ☐ Tecartus (GILEAD)

☐ Yescarta (GILEAD) ☐ Other (please state): ……

☐ Trial (please specify) ……

Specific product requirements if stated

Number of collections allowed: ☐ 1 ☐ 2

TBV to be processed *if stated* ……..

Maximum or minimum collect volume *if stated* ……

Concurrent plasma to be collected: ☐ Standard ☐ Into product ☐ Not required

Cells to be transported: ☐ Fresh ☐ Cryopreserved

Target collection Dose *if stated*: CD3+____ TNC:_____ MNC:_____

FOR Kymriah/tisagenlecleucel collect requirements

Optimal collect range of 1.5 - 4 x10/9 CD3 cells but ideally greater than 2 and minimum for acceptance of 1

Greater than or equal to 2 x10/9 TNC

At least 3% of TNC being CD3+ cells

Any other Specific collection requirements: ……

Clinicians Signature: _____	Name: _____	Date: _____