Advanced Therapy Treatment Centres

Infusion of Cellular Products

Lead Organisation: iMATCH

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Infusion of Cellular Products

Author	
Revision	20
Changes from previous Version	Changes to product storage details. Products are no longer stored in a fridge, but in validated boxes

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1.0 Introduction & Scope

The procedures documented in this SOP are aimed to ensure all nursing and medical staff involved in the infusion of cellular products are aware of their responsibilities, the procedure and any action to be taken in the event of adverse reactions or incident.

The scope of this SOP covers all cellular infusions including both autologous and allogeneic from all donor sources. The source of cellular product for transplant can be either apheresed peripheral cells (HPC-A), bone marrow (HPC-M), Cord (HPC-C), Donor lymphocytes (TC –T),) of which are available in a cryopreserved or non-cryopreserved form.

The SOP also covers Immune Effector Cells (IEC) including the use of these products Advanced Therapy Medicinal Products (ATMPs) or Advanced Therapy investigational Medicinal Products (ATIMP). Immune effector cells (IECs) is an umbrella term for advanced cellular therapies which have been developed and/or modified with the specific aim of modulating an immune response for therapeutic intent against a target disease (FACT 2017). IECs can include CAR T, Cytotoxic T cells, Donor Lymphocytes (DLI), mesenchymal stem cells (MSCs), Tumour Infiltrating Lymphocytes (TILs). IECs may be administered within a clinical trial.

Cells which require cryopreservation are collected prior to transplant and then transferred to the stem cell laboratories at the Christie for further processing, cryopreservation and storage. IECs will be shipped offsite for manufacturing. The final product will be returned to the hospital stem cell lab in coordination with the stem cell lab/pharmacy, and transplant team/clinical trials team.

Reinfusion should always take place in JACIE designated areas (Please refer to QM-110 - Quality Manual for the list of designated areas). If reinfusion is required outside of these designated areas, this decision needs to be agreed at the cellular therapy operation meeting and a planned deviation form will be completed.

In exceptional circumstances for individual patients the transplant director (or deputy in their absence) must agree this decision, and complete an unplanned deviation.

Cells must only be infused by appropriately trained staff. For IECs staff must have undergone appropriate product training by pharmaceutical company or clinical trial sponsor or delegated trainer. When a delegated trainer is required the details of this are

Reinfusion should take place on day 0, as indicated on the individual patient's transplant/cellular therapy proforma.

Cellular products should NOT routinely be infused via an infusion pump or a PICC line due to the possibility of cell damage. In the rare situation a clinical trial protocol stipulates a pump is to be used this should be done in accordance with the trial protocol. Cells should be administered via a CVC or 18g (green) cannula (X1) only. NB. For DLI a Blue 22g cannula is satisfactory due to the small volume of DLI cells being re-infused.

The maximum DMSO a patient can have over 24 hours is 1mg/kg of their weight. This is calculated by total volume/10 = volume of DMSO to be added to the product. Therefore the patient may receive cells on consecutive days.

Where possible cellular products should be coordinated so they are administered within working hours (Monday – Friday 9am - 5pm) to allow for satisfactory medical and laboratory cover. If unable to administer within working hours a Datix deviation must be completed. NB. The “Type” of event on the Datix is “Monitoring/Information” and then “Category” is “Deviation: Stem cell transplant (planned/unplanned)”.

The product handling guides for clinical trials, and new commercial CAR-T products will be reviewed by Cellular Therapy Matron and Senior Clinical Educator to monitor if any deviances from infusion SOP.

For patients participating in clinical trials infusion procedures may be defined within the trial protocol. It is a regulatory requirement that clinical trials are approved by the national competent authority, MHRA and a research ethics committee. In addition clinical trial protocols must undergo a local capacity and capability review to ensure the research can be conducted in accordance with the protocol (Approving apheresis and high risk immune effector cell trials SOP (QM-11) and R&D001.000 Study Set Up - Capacity and Capability Process). The SOPs and trial protocol are used in conjunction where a patient is participating in a clinical trial.

2.0 Responsibilities

Medical Team including Advanced Nurse Practitioner:

- Prescribing of cellular products HPC-A, HPC-M, HPC-C, TC –T on the drug kardex.
- IECs will be prescribed on iQemo with pre-conditioning Chemotherapy.
- Prescribing of pre-medications of: Chlorphenamine, Paracetamol, Methylprednisolone **(Steroids should not be prescribed as premedication for T cell products)** and anti-emetics on the drug and infusion chart.
- Ensuring any adverse events are communicated to the responsible consultant, the HTA designated individual and transplant team/ or clinical trials team and documented in the medical notes. An IRF should be completed as a clinical event.

Laboratory staff:

- Issue of cells to the ward as guided by laboratory SOPs.
- Laboratory staff will ensure cells are signed for by the ward.
- Laboratory staff will collate documentation on procedural adverse reactions, deviations and non-conforming products.
- Issue of lab related documentation.

Nursing staff:

- Only nursing staff trained and competent for the infusion of cells are authorised to perform this procedure and two nurses should be present at all times.

- Preparation of the patient includes pre medication.
- Preparation of all materials required for infusion/thawing.
- Thawing if required and reinfusion of cellular products.
- Patient observation and monitoring.
- Completion of related documentation/checklists including FRM/SCL/CIFRIP (fresh) and FRM/SCL/THACH (frozen).
- The management and reporting of any infusion related reactions and events ensuring the medical team are aware.
- If an adverse reaction occurs ensure clear documentation and a datix form completed.

HTA designated individual (lab manager):

- To review all reported adverse events occurring during reinfusion and report to the Human Tissue Authority as appropriate.

Pharmacy:

- ATMPs are medicines as defined within Directive 2001/83/EC. The Chief Pharmacist is responsible for their use with the same responsibility as all other medicines used in the Trust. IECs on item will be screened by pharmacy.

Transplant Coordinator:

- Ensure request for issue of stored product form is complete and dispatched to the stem cell laboratory, this must be received within at least 2 working days prior to the date required. This identifies donor and/or recipient details, the date of harvest, date of transfusion and cell dose to be infused.
- Ensure that the transplant proforma has been circulated appropriately.

Clinical Trials Team:

- The clinical trials team have the responsibility that the trial protocol is followed. They will ensure that the IECs and any associated medications are prescribed. They will arrange the delivery and storage on the ward.
- Ensure any adverse events are managed and communicated to PI, Lead Research Nurse and documented on the 'Adverse Incident Report Form'. A trust Datix will also be completed as a clinical event.

The Quality Manager and Ward Nursing Leads are responsible for ensuring staff who are required to carry out activities described in this document receive a copy via the Q Pulse document distribution system.

All staff who are required to undertake activities described in this document must read and acknowledge receipt of this document, and where training is required shall not undertake described activities unsupervised until relevant training has been delivered.

3.0 Training and Competence

Prior to training on the infusion of cellular products staff should have attended the introduction to transplant and cellular therapy study day. Cellular product infusion competency is supported by completion of the workbook (doc TRN-24, TRN-17).

For IECs, key staff involved in product handling may receive training on risk minimisation material when set out by CAR-T company or clinical trial. All related company /clinical trial material will be located on Q pulse

Prior to implementation of any new or revised procedure there shall be a review and if considered appropriate training and competency shall be delivered prior to implementation of the procedure.

4.0 Procedure

4.1 Documentation and Equipment

- Patient case notes (electronic or paper)
- Original blue transplant/IEC proforma and consent form (including trial consent if applicable)
- Patient drug kardex with cells prescribed. IECs are prescribed on IQemo
- Product specific details can be accessed via the Haematology Q-Pulse system, please see section 4 for useful external documents to access.
- Observation chart/NEWs
- Checklist form (FRM/SCL/CIFRIP (fresh) or FRM/SCL/THACH (frozen))
- Product identifying Label/ Sticker
- Wristband
- Label 'Transplant Details' (attached to cells)
- Dry shipper (if frozen cells)
- Water bath (Grant Sub Aqua 5 or Grant Sub Aqua 18) with four or eight x1 Litre bottles of sterile water for irrigation
- Thermal insulated gloves
- Sterile scissors
- Sterile gloves (1 set per each bag of cells to be infused)
- A double spike wide bore 200µm blood transfusion set. (EMC9612), this is also for clinical trials unless otherwise specified by clinical trials team. If cord cells 2 administration sets are required, one for each cord.
- For Bone marrow it's advisable to use one set for each bag due to the volume and consistency.
- 3 way tap
- 0.9% normal saline 1 x 250mls and then a 100ml flush after each bag of cells
- Yellow waste bag x2 (**For CAR t/TCRs/TILs – use yellow clinical waste bags kept in CAR t box treatment room)**

- Research documentation to be completed on trial source documents as per the trust policy R&D 006.000 Handling Research Data
- **IEC's that are in vials:**
- **Needles (20 gauge or 2 gauge) x 8 (no filter), 1 ml, 3ml & 5ml luer lock, 2 x absorbant pads**

Emergency Equipment Box

The emergency equipment box should be stocked with the following:

Equipment	Drugs
Sterile Plastic Clamps x1	Pre filled Saline 0.9% flushes x4
Sterile Scissors x1	
2 ml syringe x2	
10 ml luer lock syringe x6	
20 ml luer lock syringe x2	
Filter safety needles x 5	
Non-filter safety needles (green) x5	
23G (Blue) needles x2	
50 ml luer lock syringe x6	
Sample site female coupler x2	
Sani-Cloths x10	
Flat head bungs x4	
Sterile gloves (mixture of sizes)	
IV 3000 Cannula dressing x4	
3 Way Tap x2	
Green Cannula x3	
Green needles x4	
Yellow bags x2	
Long bung x2	
Blood culture Bottles- Pink (0.5mls) and Purple (1ml)	
22G Monovette Needle X2	
Blood Culture adapter x1	
Gauze x1 pack	
Spare sterile outer bags	

4.2 Pre-Procedure

- The administering individual should contact the Stem Cell Laboratory (Ext 8096) by 12pm on the day of infusion to confirm the time of delivery of cells to the ward.

When administering cellular therapy products from more than one donor, each cellular Ward team to coordinate with stem cell lab timings to avoid infusions overlapping administration of subsequent cellular therapy products.

- Cryopreserved cells are transported in the dry shipper and non-cryopreserved cells will be transported in a cool box by a member of the laboratory stem cell team.
- On arrival to the ward all cells must be signed for by an appropriately trained nurse and stored correctly.
- Cryopreserved cells must be stored in the dry shipper in the clean clinical area until required.

Non cryopreserved cells remain in the credo box for 4 hours. These cells must be administered within 4 hours of arrival to the ward, or returned to the stem cell lab if there is a delay in infusion.

NB. For patients that have bone marrow administered and an ABO mismatch with their donor cells, ensure methylprednisolone 100mg is prescribed and administered prior to cells infusion as a premedication.
For Bone marrow infusions use one line per bag.

Preparation for procedure

- Ensure patient is wearing identity wrist band and verbally confirm their identity.
- Ensure cells are prescribed on drugs kardex/IQEMO (as issued on CWP) and the methylprednisolone 2mg/kg in-case of reaction (dose should be calculated and prescribed in advance of the transplant on once only administration of drugs kardex). **(Steroids should not be prescribed as premedication for T cell products)**
- Ensure all the correct equipment has been selected and transferred to the patient's room including the emergency equipment box.
- Administer 10 mgs IV Chlorphenamine and give 1g P.O Paracetamol prophylaxis 30 minutes prior to cells infusion. **NB: Methylprednisolone 100mg (prophylaxis) is only administered as a premedication if directed by consultant.**
- Due to the small amount of volume and DMSO in Donor Lymphocytes premedication is not required. IV Chlorphenamine and 1g P.O Paracetamol will be prescribed if required.
- **Commence the 2 x 250 mls 0.9% NaCl infusion on a slow free flow via the Y connector wide bore giving set (with 3 way tap attached) NB. 2 giving set lines required if a CORD transplant.**
- If the patient is on clinical trial and the giving set stipulated in the trials is different to the standard practice, the trial protocol is followed and the set will be provided by the trials team.
- Perform and record baseline observations: respiration rate, temperature, pulse, blood pressure and oxygen saturations. Report any abnormalities to medical staff before commencing infusion.
- Explain procedure to patient and ensure they are fully informed - highlight potential side effects and reactions.

4.3 Procedure

- Two nurses must be present to check the cellular products, and remain in the room until the bag is connected to the patient. Once the bag is infusing and the patient is well, the second nurse can leave the room. 2 x nurses having been appropriately trained and signed off as competent by the Clinical Educators.
- Where IEC's are administered with vials, two nurses must remain present throughout.
- In the event of a clinical trial, the appropriate trials team nurse must be present to ensure the trial protocol is followed.
- Positively confirm the patients identity once again and check all product documentation together with a second member of staff at the patient's bedside including:

1. Identity wrist band
2. Cells prescription on drug kardex,
3. Original blue proforma,/ trial proforma
4. Consent form for transplant,/clinical trial
5. Observation chart/ electronic NEWS
6. Product identifying sticker,
7. Checklist (FRM/SCL/CIFRIP ((fresh)) or FRM/SCL/THACH (Frozen))

NB: Also check timing of last SACT administration ensuring planned reinfusion of cells is 24 hours after chemotherapy or after the last dose of TBI (if applicable).

- Set up observation equipment to ensure regular monitoring during infusion.

Cryo-preserved Cells

The thawing of cells will be undertaken using the water bath technique; a water bath is available on PTW, TCPC, CRF and ambulatory care. If the clinical areas own water bath is unavailable (e.g. due to fault) the ward shall liaise with the other clinical area to use their equipment.

- Place water bath (Grant Sub Aqua 5 or Grant Sub Aqua 18) in the patient's room. For the five-litre water bath fill with the four x 1 litres of sterile water. For the eighteen-litre water bath fill with eight x 1 litres of sterile water. Then plug in, turn on and place lid on. The temperature should be preset to 37oC [LED display] – do not alter. If not set to 37oC, press '←' twice and then use '+' or '-'to select.
- If ERR is displayed contact the stem cell lab immediately
- Ensure dry shipper and trolley are in close proximity to minimizes the distance the cells are carried.
- Check cable tie tag number on dry shipping container against check list and is sealed before then removing using non-sterile scissors and both nurses countersign.
- Wearing thermal insulated gloves remove the first bag of cells from the shipper and immediately place into blue tray. Examine bags for any signs of damage remove. If problem observed place immediately back in shipper

and contact stem cell lab manager- DO NOT THAW. Report any problems to the Stem Cell Lab Manager (Ext 8096- if out of hours contact Biomedical scientist 07823536085) and seek medical advice in event of an incident.

- For IEC products depending on the company or clinical trial they may be issued in bags, vials or syringes. The ward will be provided with sterile outer bags for products which require thawing using the water bath. This is because some products aren't double bagged. These will be sent down from the lab with the IECs, and are ordered via the stem cell lab. Prior to thawing insert the cells into the sterile outer bag, and then seal. Follow the normal process to thaw.
- For IEC vials will be thawed as directed in the pharmaceutical company/clinical trial product handling guide. Where applicable product preparation worksheet will be sent with the product from the lab
- Check the product details against all patient documentation including:

  - Patient Name
  - Hospital Number
  - Date of Birth
  - DIN and BB Number (product unique identification number/ trial number)
  - Cell dose, including total dose if more than one bag is to be infused
  - Donor details should be checked against transplant proforma
  - Expiry date of cellular product.

- Once checked all details and identified patient is correct, immerse the first bag of cells into the water bath, recording the time that thawing commences on the infusion checklist (FRM/SCL/THACH).
- Remove thermal insulated gloves and put sterile gloves on.
- Gently manipulate the cells in the bag paying particular attention to administration ports, as this tends to be the most difficult area to thaw. Continually check the integrity of the bag and stop procedure – reporting immediately to the labs if any signs of damage.
- Remove the bag from the water bath and place into the blue tray as soon as the contents have become fluid. Observe and record the time of completion of thawing and temperature of the water bath, and record on the infusion checklist (FRM/SCL/CIFRIP and FRM/SCL/THACH).
- Review the integrity of the bag- if nil signs of damage; remove the outer bag from the cells bag using sterile scissors.
- Check the patient's details once again, and then administer cells STAT- recording the start time of the infusion on the FRM/SCL/THACH checklist.

NB: The administration set should be attached to the cell bag, accessed horizontally over the blue tray and administered as quickly as tolerated by the patient.

- Observe for any adverse reactions. Monitor and record the temperature, pulse, Blood pressure, respiratory rate and Oxygen saturations regularly throughout the infusion and compare to baseline observations- if a reaction noted please see section 3.4 Management in the event of a reaction.
- **Once the cells bag is empty, the 3-way tap is turned off to the patient and both giving sets opened. The empty cell bag will be lowered to allow the fluid from the other line to run some fluid into it. The saline**

bag is then turned off and the 3-way tap open to the patient to run the flush through. This process can be done up to 3 x times to ensure all of the product has cleared the bag. Flush the line with 0.9% NaCl 100mls post infusion until the line is clear. NB. document the end of infusion time on the FRM/SCL/THACH checklist once line is clear.

- Repeat the thawing procedure for any further bags of cells required (ensuring the water temperature is re-established at 37oC for each bag). Do not thaw a new bag of cells until previous cells have been completely infused, line flushed and observations recorded.

Discard used bags in a double purple bag according to Trust policy.
For IECs the empty bags and lines, will be disposed of in a double yellow bag, and black tag applied.
There is a designated bin for biological products in the waste room. The waste team needs to be notified that there is biological waste to be removed from the ward. See WRD-57 Palatine ward GMO waste management SOP or CRF 010.000 Management of GMM Waste Generated in the CRF and complete the waste traceability documentation located on the side of the bin.
If there is any spillage this must be cleaned up wearing PPE and use the Clinell red wipes. Inform stem cell lab and medical team.

- Ensure the FRM/SCL/THACH infusion checklist is fully complete and signed by both nurses (including the Adverse Reaction and Deviation box addressed and then place in the transfusion prescription box on the Ward.
- Both nurses countersign and attach the 'Details of Transplant' sticker to the back of the original blue transplant proforma and place in medical notes with transfusion report form.
- Both nurses countersign the cells prescription on drugs kardex/iQemo.
- Ensure water bath and trolley are cleaned following use with Clinell wipes. Return, water bath, and thermal insulated gloves to the store room.
- The dry shipper will be collected by the laboratory staff. NB. Ensure the lid is on correctly and the lid is fully aligned before returning to the labs.

CORD Cells:

- Treat as above**;** attach a fresh administration set for each cell bag/cassette. The infusion of cord products will be restricted to appropriately trained, senior ward nurses, experienced in the infusion of HPC under the supervision of the Clinical Practice Facilitator.
- Cord units may come in a variety of differing unit packs, depending on where and when they have been collected. These may fall outside of the standardized procedure outlined in the HPC infusion training. Therefore the infusion of cord products will be restricted to appropriately trained, senior ward nurses, experienced in the infusion of HPC under the supervision of the Clinical Educator .
- Laboratory representatives will be present to assist in thawing cord cells where possible. In dual unit cord transplants, the second unit must be administered via the second administration set and the additional unit not defrosted until the patient has tolerated the previous unit and does not display any symptoms of reaction.

- Reinfusions for CORD full intensity transplants are recommended to take place pre 10am the day after the final dose of TBI to ensure orderly provision of staff to oversee the process and allows for delays in TBI dosing.

Non-cryopreserved Cells

- Remove cells from Credo box, ensuring to record the temperature of the internal thermometer on FRM/SCL/CIFRIP infusion checklist and place into a blue tray to carry to the patient's bedside.
- With a second nurse present, check the product details against all patient documentation treat as above.
- If there are more than one bag, take bags out of the box one at a time.
- Reactions are managed and reported in the same way as cryo cells.
- Ensure all fresh cell checklist is completed and returned in the stem cell infusion box.
- **CART (a type of IEC)** The NHS England licensed products will be coordinated by the transplant team. For infusion follow the same process as cryoproserved cells any differences in the pathway are stipulated in the procedure section.
- **Non-licensed ATIMP** used in clinical trials will be administered by designated research nurses who have completed clinical trial training on the protocol, and cell infusion training. For infusions follow the same process as cryoproserved cells. In the situation a clinical trial products or method varies from the SOP, the clinical trial protocol will be followed.
- **Donor Lymphocyte infusion (DLI)** See DLI SOP (WRD-15) for indications and dosing. DLI doesn't require premedication to be administered due to the small amount of cells and DMSO. Paracetamol and Chlorphenamine should be prescribed if required.

4.4 Management in the Event of as Reaction

The patient should be monitored closely for any commonly occurring side effects. In the event that any related side-effect occurs during the infusion, pause the infusion, conduct A-E assessment, request immediate medical review, administer the methylprednisolone 2mg/kg, and recommence starting the cells at a slower rate (once medical review), closely monitoring patient throughout. Ensure that for IEC reactions the medical team approves any steroid use.

- DO NOT thaw or re-infuse further bags of cells until each bag is complete and you are sure the patient is not still suffering an infusion reaction.
- Note ensure adverse reaction is documented as YES on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and a Datix is completed. NB. The "Type" of event on the Datix is "Clinical event" and then "Category" is "Stem cell transplant".

Adverse reaction and Action required:

Adverse reaction	Action
Funny taste and smell	This requires no action but the patient should be warned that it might occur prior to infusion.

Flushing, headache	Slow the rate of infusion, continue to monitor closely.
Nausea and vomiting	Slow rate of infusion and administer stat dose of antiemetic.
Urticaria	Slow the rate of infusion, continue to monitor closely, if the rash is >30% Body Surface Area administer the methylprednisolone 2mg/kg. Inform medical staff and document as Adverse Reaction on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Respiratory complications including: Wheezing Shortness of Breath Desaturation oxygen saturations < 92% Chest tightness/ heaviness Sensation at back of throat	Pause the infusion, administer oxygen via face mask (ensure documented on the oxygen therapy administration record on kardex), call for help from senior nurses/ Clinical Practice Facilitator and request medical review, reassess patient- if clinically indicated administer the methylprednisolone 2mg/kg, and recommence at a slower rate closely monitoring patient throughout. Document as Adverse Reaction on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Hypotension	Slow the rate of infusion, continue to monitor closely, if drop 30 mm/hg below baseline request medical review and commence 0.9% sodium chloride intravenous infusion via second line as per PGD whilst transplant continues. Document as Adverse Reaction on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Anaphylaxis (Life threatening Problems)	Follow Anaphylaxis algorithm- Pause the infusion, call for help and immediate medical review- Full A-E assessment, administer oxygen via face mask, administer Adrenaline 1:1000 (Intra-Muscular) 0.5 mls. Transplant will continue as per the medical teams' guidance. Document as a Severe Adverse Reaction on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.

Trouble shooting

Problem	Action
Missing documentation including original transplant proforma, consent form, or Identification forms including shipper tag	Contact transplant coordinators and medical team. Do not administer cells without this. Contact Stem Cell Lab (ext 8096 - if out of hours contact Biomedical scientist 07823536085). Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Incorrect labelling	Do not thaw and contact Stem Cell Lab (ext 8096 if out of hours contact Biomedical scientist 07823536085). Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Leak identified on inspection of frozen cells	Place back into dry shipper and contact Stem Cell Lab (ext 8096 immediately- If out of hours contact Biomedical scientist 07823536085). Do not thaw! Inform transplant coordinators and medical team. Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Frozen cells bag dropped or suffers trauma	Do not thaw! Contact the Stem Cell Laboratory immediately (ext 8096- If out of hours contact Biomedical scientist 07823536085). The bags can then been thawed in a controlled environment and re-issued for infusion once re-bagged. Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Fresh cells bag dropped or sufferers trauma	Place cell bag immediately into blue tray. If damaged, invert bag if possible (to prevent further loss), use sterile clamps to clamp the area where damage has occurred. Call for help with senior nursing staff/ Clinical Practice Facilitator and ring Stem Cell Laboratory (Ext 8096- if out of hours contact Biomedical scientist 07823536085). Inform medical staff as patient may require I.V antibiotics. Insert sample site coupler into the receptor (if two receptors on the bag use the unopened receptor for the coupler), draw off the cells from the bag using a 50ml Luer lock syringe and infuse immediately via the 3 way tap as tolerated by the patient. Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Rapid expansion of the outer bag during thawing	Release pressure by making an incision in the outer bag and keep cut area above level of water, continue thawing. Contact the Stem Cell Laboratory immediately (ext 8096- If out of hours contact Biomedical scientist 07823536085). Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
What to do if the infusion isn't going fast enough or stops flowing	Seek senior nurse help. Flush line to ensure its patent. If the rate doesn't improve. Change the line and use the second port on the bag and continue.

Cells appear clotted on inspection	Do not administer, Contact stem cell labs immediately, (ext 8096- If out of hours contact Biomedical scientist 07823536085) and medical team, await further instruction. Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete datix.
Leak from bag of fresh or thawed cells including accidental spiking of the cell bag with giving set.	Place cell bag and/or giving set immediately into blue tray and invert bag if possible to prevent further loss. Using sterile clamps, clamp the area where leakage is occurring and call for help with senior nursing staff/ Clinical Practice Facilitator. Ring Stem Cell Laboratory (Ext 8096- if out of hours contact Biomedical scientist 07823536085). Inform medical staff. Insert sample site coupler into the receptor (if two receptors on the bag use the unopened receptor for the coupler), draw off the cells from the bag using 50ml Luer lock syringes and infuse immediately via the 3 way tap as tolerated by the patient. NB. Save 1.5 mls of the cells and as trust policy use luer slip syringe to transfer 0.5mls to the Pink Blood culture Bottle- and 1ml to the Purple Blood Culture Bottle. Patient may require I.V antibiotics- This culturing is not required if such incident occurs during DLI administration if volume <100mls. Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.
Infiltration of cells at cannula site	Pause the infusion, disconnect giving set from the 3 way tap and reattach the giving set to a second cannula/3 way tap. Call for help with senior nursing staff/ Clinical Practice Facilitator and inform medical team. Document as a deviation on FRM/SCL/CIFRIP or FRM/SCL/THACH checklist and complete Datix.

5.0 Monitoring Compliance

Compliance to this document will be monitored by a combination of audit where appliable, non-conformance monitoring and Datix incident reporting.

6.0 Dissemination/Distribution

This document will be distributed to staff members who need visibility of the document via Q Pulse.

7.0 References and Related Forms, Labels, Policies and Procedures

SCT/GEN/POL/BPTS “Blood Product Transfusion Support for ABO Mismatched PBPC and Marrow (HPC) Transplant Patients”

CLN-113 “Anaphylaxis Policy”

FRM/SCL/CIFRIP “Checklist for the Transport, Storage and Administering of Fresh Cells”

FRM/SCL/RISP “Request for Issue of Stored Product Form”

WRD-15 “DONOR LYMPHOCYTE INFUSION (TC-T)”
Trust SOP: R&D 006.000 Handling Research Data

Trust SOP: CRF 010.000 Management of GMM Waste Generated in the CRF

EXT-9 UK Combined Handling Guide
EXT-87 Kymriah CAR-T management guide
EXT-82 Yescarta CAR-T SOP Final product handling (Kite)
Ext-102 Lisocabtagene maraleucel Healthcare Professional Guide
Ext- 104 Lisocabtagene maraleucel Clinician Guide
Ext-106 Lisocabtagene maraleucel Product Handling and Administration Guide

All new procedures are approved by the Clinical Program Director or approved designate before implementation of the procedure.

Revisions to existing procedures will be approved by the Clinical Director or approved designate prior to implementation.

Procedures will be reviewed every 2 years as a minimum.

8.0 Appendices

8.1 Infusion of Stem Cell/Bone Marrow Checklist for Nurses

Infusion of Stem Cell/ Bone Marrow Checklist for Nurses	
Pre Administration:	
Contact the Stem Cell Laboratory (Ext 8096) by 12pm on the day of infusion to confirm the time of delivery of cells.	
Ensure cells are prescribed on drugs kardex (as issued on CWP) and the methylprednisolone 2mg/kg in-case of reaction. NB. For patients that have bone marrow administered and an ABO mismatch with their donor cells, ensure methylprednisolone 100mg is prescribed and administered prior to cells infusion as a premedication.	
Documentation: **Patient case notes for the original blue transplant proforma and consent form** **Patient drug kardex with cells prescribed** **Observation chart** **Transfusion product final report** **Checklist form (FRM/SCL/CIFRIP ((fresh)) or FRM/SCL/THACH ((frozen))** **Product identifying Label/ Sticker** **Wristband**	
Equipment: **If frozen cells:** **1. Dry shipper with Patients transport Label 'Transplant Details' & tag no.** **2. Water bath with four or eight x1 Litre bottles of sterile water for irrigation- set up in patient's room.** **3. Thermal insulated gloves** **4. Sterile scissors** **Sterile gloves (1 set per each bag of cells to be infused)** **Y connector Wide bore blood administration set x 1 - NB. If cord cells 2 administration sets are required, If BM one line per bag. For bone marrow one line per bag** **3 way tap (1 for the end of each wide bore administration set)** **0.9% normal saline 1 x 250mls and then a 100ml flush for after each bag of cells** **Yellow waste bag x2**	
Check Emergency Equipment Box- checklist in box and take to the patient's room.	
Administer 10 mgs IV Chlorphenamine and give 1g P.O Paracetamol prophylaxis 30 minutes prior to cells infusion.	
Commence the 1 x 250 mls 0.9% NaCl infusion on a slow free flow via the wide bore giving set.	
Post Administration:	
Ensure the FRM/SCL/CIFRIP infusion checklist is fully complete and signed by both nurses (including the Adverse Reaction and Deviation box) addressed and then place in the transfusion prescription box on the Ward.	
Both nurses countersign and attach the 'Details of Transplant' sticker to the back of the original blue transplant proforma and place in medical notes with transfusion report form.	
Both nurses countersign the cells prescription on drugs kardex.	

8.2 Infusion of Immune Effector Cells (CAR-T/TCR) Checklist for Nurses

Infusion of Immune Effector Cells (CAR T/TCR/) checklist for Nurses	
Pre Administration:	
Contact the Stem Cell Laboratory (Ext 8096) by 12pm on the day of infusion to confirm the time of delivery of cells.	
Ensure cells are prescribed on item.	
Documentation: **Patient case notes for the original blue transplant proforma and consent form** **IQEMO activated in patients room and cells prescribed and realised in IQEMO** **NEWS 2** **Transfusion product final report** **Checklist form, FRM/SCL/THACH ((frozen))** **Product identifying Label/ Sticker** **Wristband**	
Equipment: **Dry shipper with Patients transport Label 'Transplant Details' & tag no.** **Water bath with four or eight x1 Litre bottles of sterile water for irrigation- set up in patient's room.** **Thermal insulated gloves** **Sterile scissors** **Sterile Outer bag (provided by lab, spare in emergency box)** **Sterile gloves** **Y connector Wide bore blood administration** **1 x 3 way tap (both administration line connected to same 3 way tap)** **0.9% normal saline 1 x 250mls and then a 100ml flush for after each bag of cells** **Yellow waste bag x2 and black tag (located in bio waste disposal box in treatment room)**	
Check Emergency Equipment Box- checklist in box and take to the patient's room.	
Administer 10 mgs IV Chlorphenamine and give 1g P.O Paracetamol prophylaxis 30 minutes prior to cells infusion.	
Commence the 1 x 250 mls 0.9% NaCl infusion on a slow free flow via the wide bore giving set.	
Post Administration:	
Ensure the FRM/SCL/CIFRIP infusion checklist is fully complete and signed by both nurses (including the Adverse Reaction and Deviation box) addressed and then place in the transfusion prescription box on the Ward.	
Both nurses countersign and attach the 'Details of Transplant' sticker to the back of the original blue transplant proforma and place in medical notes with transfusion report form.	
Both nurses countersign the cells prescription on drugs item	
IEC empty bags and lines, disposed of in a double yellow bag, and black tag applied, and placed in bio hazard bin, located in waste area. Log sheet filled in and contact ex 7937.	