Non-Cytotoxic Intrathecal IMP Policy

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Controlled document

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Full History			
Version	**Date**	**Author**	**Reason**
1	19/10/2018	Dr T Harrower, Cassie Brady, Jane Hall, Anna Grice	New policy
2	06/01/2022		Scheduled review of policy Minor template updates

Associated Trust Policies/ Procedural documents:	Consent to Examination or Treatment Policy Control of Substances Hazardous to Health (COSHH)policy Health Records Policy Identification of Patients Policy Incident Reporting, Analysing, Investigating and Learning Policy Information Governance Policy Medicines Management Policy Intravenous Therapy Policy Waste Management Policy Infection Prevention and Control Policy Policy for Safe Practice with Intrathecal Cytotoxic Drugs
Key Words:	Intrathecal; IT; IMP

In consultation with:

Timothy Harrower – Consultant Neurologist/Principle Investigator	July 2018
Intrathecal Chemotherapy Lead	July 2018
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Policy Expert Panel	July 2018
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Contact for review:	Lead Nurse for Clinical Trials

Contents

1 INTRODUCTION

1.1 This policy governs the procedures for training in, prescribing, dispensing, supply, transport, storage, administration and disposal of **non-cytotoxic** Investigational Medicinal Products (IMP) to be administered via the Intrathecal (IT) route in clinical trials conducted at the Royal Devon and Exeter Hospital (RD&E).

1.2 This policy must be adhered to at all times, because the incorrect intrathecal (IT) administration of an IMP (e.g. incorrect route, incorrect dose or drug) may be life threatening.

1.3 Guidance is competency based i.e. the various tasks on the register can be carried out by members of staff who have been appropriately trained, deemed competent by the Trust Intrathecal Cytotoxic Lead or his/her designated representative designated lead and whose name appears on the register or designated personnel for that task.

1.4 It has been developed in conjunction with both national and RD&E guidelines and is intended to ensure all involved in the above are trained appropriately and are aware of their responsibilities, and to provide a framework for executing and documenting their actions. This document seeks to minimize the risk to patients, within a clinical trial setting, receiving intrathecal administration of a non-cytotoxic IMP by establishing standards of practice that must be adhered to.

1.5 This policy has been developed in conjunction with the Trust policies and University College Hospital policy re Intrathecal administration of Investigational Medicinal Product, Training, Prescribing, Dispensing, Supply, Administration and Disposal.

1.6 **Failure to comply with this policy could result in disciplinary action.**

2. PURPOSE

This policy describes and directs the local implementation of a study protocol at the RD&E relating to intrathecal administration of an IMP, outlining the standards for the training of research staff in prescribing, dispensing, transportation, storage, administration and disposal of an IT IMP as well as documentation of these activities

3. SCOPE

This policy applies to all staff undertaking any part in the processes relating to intrathecal administration of an IMP within the Trust.

4 DEFINITIONS

CRF	Clinical Research Facility
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GOG	Governance and Oversight Group
IMP	Investigational Medicinal Product
IT	Intrathecal
ITC	Intrathecal Chemotherapy
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research & Development
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TSU	Pharmacy Technical Services Unit

5. DUTIES AND RESPONSIBILITIES OF STAFF

5.1 It is the responsibility of all nurses, doctors and pharmacy staff involved in the prescribing, dispensing, supply transport, storage, administration and disposal of Clinical research IT IMP to undertake training and certification specific to their role in the study. All other staff involved in the study are required to familiarise themselves with this policy and comply with the instructions of trained personnel in relation to procedures described.

5.2 The R&D Governance and Oversight Group (GOG) is responsible for ratifying this policy

6. PROCEDURES

6.1 Intrathecal Investigational Medicinal Product Register

The Intrathecal Investigational Medicinal Product Register (IT IMP Register, Appendix 1) is a trial specific record of certified competent individuals who have undergone training in intrathecal IMP administration to the standards described in this document.

The IT IMP Register will be held in the Investigational / Trial Master File and maintained by the Principal Investigator for the study. Whenever the Register is updated for a pharmacist, a doctor or a nurse, an updated copy should be provided to the Pharmacy Clinical Trials team.

6.2 Certification Procedure

Because this policy is closely based on the Trust Intrathecal Cytotoxic Policy and Procedures, the training and certification process has two stages.

6.2.1 Training to a modified set of intrathecal cytotoxic medication standards, without certification

- Each staff member involved in Intrathecal administration will undertake the training required for their discipline as detailed in the Policy for Safe Practice with Intrathecal Cytotoxic Drugs
- The Trust Intrathecal Cytotoxic Lead or designated Lead Trainer for doctors, nurses, pharmacists or pharmacy staff will confirm satisfactory completion of training to the standards for intrathecal cytotoxic medication by signing the training certificate (see appendix1-3,) **but will not formally certify the staff member for administration of cytotoxic medication.**
- Evidence of completed training will be recorded in the study training log.

6.2.2 Certification by Principal Investigator for the administration of the IT IMP

- Once confirmed as having satisfactorily completed training in intrathecal cytotoxic administration, the staff member will complete and sign the IT IMP Register for the study.
- After reviewing the staff member's satisfactory completion of training in intrathecal cytotoxic administration, in addition to their curriculum vitae, training record and other documentation required for inclusion on the study delegation log, the Principal Investigator (PI) will countersign the IT IMP Register, indicating the staff member has completed the necessary training.

6.2.3 Maintaining registration on the IT IMP Register

- Staff will remain on the register for a period of one year, at which point staff who are carrying out any IT IMP assessments /IT cytotoxic administration regularly will sign the re-validation pro forma.

- It would be expected that those members of staff involved with intrathecal IMPs maintain a level of competency expected by the RD&E; that they attend yearly intrathecal training updates and are involved in a minimum of three (3) intrathecal administrations per year.
- Those staff not involved in any of the IT IMP assessments will be required to repeat the original training. Those staff who do not fulfil their role will be removed from the IT IMP register.
- If the status of the designated individual is not updated by the date of the annual review they cannot be involved in any procedure described here relating to intrathecal IMP for the study until the revalidation pro forma has been completed and signed off by the PI.

6.3 Areas approved for intrathecal IMP administration

Intrathecal drugs must be administered in a designated area. For the purpose of clinical trials this will be the either the side room on Bolham ward or 4 bedded areas in the Clinical Research Facility (CRF). If using the CRF, other beds in the 4 bedded areas will be unoccupied on these days.

6.4 Safety equipment

The following safety equipment is available in addition to standard clinical equipment:

- Immediate access to defibrillator and resuscitation trolley
- An emergency call bell
- Portable oxygen and suction
- ECG monitoring equipment
- A vital signs monitor to record pulse, blood pressure and oxygen saturations
- Anaphylaxis kit
- ‘No entry’ signage for use during intrathecal procedure

On days when the IT IMP is to be given, the room will be prepared and checked as described in IMP checklist.

6.5 Roles, Responsibilities and Training Curriculum of Staff

6.5.1 Doctors

Only the following designated RD&E medical staff may prescribe or administer the intrathecal IMP:

- hold substantive or honorary contract
- have sufficient lumbar puncture experience
- trained to a minimum of Specialist Registrar
- on the Intrathecal IMP Register for the study

Medical staff are **not** allowed to dispense or check IT IMP doses.

Before addition to the IT IMP register, medical staff must undertake the following core syllabus based on the Intrathecal Cytotoxic Training Programme:

- Read this policy, the Trust policy on Safe Practice with Intrathecal Cytotoxic Drugs and the latest relevant national guidance, and sign to say they have done so
- Attend a dedicated training session on safe practice with intrathecal cytotoxic drugs from the Trust Intrathecal Cytotoxic Lead or his/her designated representative

- Watch the DOH training video
- Attend at least one practical session of lumbar intrathecal drug administration, watch at least one IT drug administration and complete at least one IT drug administration independently. This training session could be in any relevant speciality e.g. Haematology or Anaesthetics.
- On completion of the core syllabus the doctor must complete the training record (Appendix 2)-and be signed by the Trust Intrathecal Cytotoxic Lead followed by verification and addition to the study IT IMP register (appendix 1). A hard copy must be retained by the Trainee and the study PI.
- All medical staff on the IT IMP register should have their training reviewed annually by the PI or delegate of the study, including written confirmation that they have re-read the latest relevant national guidance and local policy

6.5.2 Nurses

Only designated qualified nursing staff that are on the IT IMP Register for the study may carry out the nursing procedures described in this policy.

Nurses are **not** allowed to prescribe, dispense or administer IT IMP doses

Nurses must ensure that IT IMP doses are only administered in the designated area and that no other IT or IV drug procedures are carried out within the designated area.

Before addition to the IT IMP register nursing staff must undertake the following core syllabus:

- Read this policy the Trust policy on Safe Practice with Intrathecal Cytotoxic Drugs and the latest relevant national guidance, and sign to say they have done so.
- Attend a dedicated training session on intrathecal IMP administration arranged by the lead nurse trainer and watch the DOH training DVD.
- Affirm they have read and understood the policy.
- Observe and confirm they have understood the procedure for the safe checking of intrathecal administration. On completion of the core syllabus the nurse must complete the training record (Appendix 3) and the record be signed by the designated Lead Trainer.

On completion of the core syllabus the nurse must complete the training record. The record of clinical competence will be signed by the lead clinician or designated Lead Trainer responsible for RD&E IT training once s/ he has observed the research nurse follow the procedure for the safe checking of intrathecal administration. The research nurse will be added to the study IT IMP register by the study PI as holder of the IT IMP Register. An electronic copy will also be held with the Lead Nurse for Clinical Trials.

A hard copy of the record must be retained by the trainee and the study PI. All nursing staff on the IT IMP register should have their training reviewed annually by the Lead Research Nurse for Clinical Trials and PI of the study and sign the revalidation form which confirms they have re-read the latest relevant national guidance and local policy.

6.4.3 Pharmacy staff

An RD&E Clinical Trials Pharmacist (or suitably trained delegate Pharmacist) will clinically screen the trial IT IMP prescription in accordance with the trial specific IMP documentation. The screened prescription will go to the RD & E Pharmacy Technical Services Unit (TSU) where the IMP will be prepared and stored until collection by the doctor administering the IT IMP.

Only dedicated pharmacists who are on the IT IMP register for the study may clinically screen IT IMP prescriptions.

Even if on the IT IMP register, Pharmacy staff are **not** authorised, under any circumstance to prescribe, check (at the point of administration) or deliver IT IMP doses.

Before addition to the IT IMP Register, the pharmacy Clinical trials staff member must complete the background study training, observe procedures and complete the assessment as stipulated in the Trust Policy for Safe Practice with Intrathecal Cytotoxic Drugs.

On completion of the above, the Clinical Trials Pharmacy staff member must complete the local Trust training record (appendix 4). This will then be signed off by the principle Pharmacist Technical Services followed by verification and addition to the study IT IMP register by the holder of the register (study PI)

A hard copy of the IT IMP training register must be kept by the trainee and the study PI (An electronic IT IMP register will be kept with the Lead Nurse for Clinical Trials).

Pharmacy Production staff involved in the preparation of IT IMP doses will not be added onto the trial specific IT IMP registry. Pharmacy production staff and product approvers on the cytotoxic IT register are only allowed to prepare and approve intrathecal IMPs.

Only designated pharmacy staff that are on the Trust ITC register may prepare and final check IT IMP doses.

6.6 Procedures for Intrathecal IMP doses

This section describes the procedures to be carried out for each IT IMP dose within the study. The IT IMP check list (appendix 5) must be completed throughout the process then filed in the patient's notes. These procedures must be followed in conjunction with the latest approved version of the Study Protocol and Investigator Brochure.

6.6.1 IT IMP Room Preparation

On any day when the IT IMP is to be administered within the trial, the room will be designated for intrathecal use prior to the arrival of the study participant until their discharge. The following procedures will be carried out to ensure the room meets the requirements for safe IT IMP administration:

- All intravenous drugs removed from the room
- Ensure routine checks are complete as per the RD&E Policy
- Appropriate sharps bin present
- All non-essential equipment removed
- A sign reading: 'No Entry! Intrathecal Procedure in Progress' is placed on the door

The room must be checked by a doctor and nurse who are both on the IMP IT register and checks recorded in the check list (appendix - 5)

6.6.2 IT IMP Prescription

- The IT IMP prescription form template (including administration record) will be specifically designed for the trial using a local template approved for use by the RD & E Clinical Trials Pharmacist.

- The prescription must state the route of administration <u>**INTRATHECAL**</u> in full (no abbreviations)
- The prescription form must be signed by a doctor on the study IT IMP register and on the Trial Site Delegation Log
- Abbreviations are **not** acceptable
- Drug details may **not** be amended. If alterations are needed a new prescription form must be generated.
- If the date on the prescription needs changing the old prescription must be scored through and a new prescription provided.

There will be no negative statements on the prescription (e.g. "not for IV use" is not appropriate)

6.6.3 Pharmacy Preparation

6.6.3.1 <u>IT IMP screening</u>

- All clinical trial prescriptions including IT IMP will be clinically screened by a designated Pharmacist on the IT IMP register.
- The IT prescription will be sent to the RD&E Trials Pharmacy with a photocopy of the treatment plan (which includes dates of previous, current and future intrathecal IMP doses), relevant blood results (including platelets) and the original IT IMP Dose checklist (appendix 5).
- The Pharmacist will screen the prescription and verify this by signing and dating it. They will check patient bloods are within limits against the most recent safety blood test as specified in the protocol. They will double check patients concomitant medications to ensure safety, focusing on the excluded concomitant medications specified in the trial protocol.
- The Pharmacist will check the subject is not prescribed or expected to receive any intravenous medications on the day of dosing with the IT IMP, as confirmed by the prescriber on the prescription form.
- The Pharmacist will complete the checklist.
- The screened prescription will be provided to the RD&E TSU. A copy of the prescription will also be retained for filing in the pharmacy trial file held in the RD&E Clinical Trials Pharmacy. The original will be retained in this department until collection of the IT IMP dose.

6.6.3.2 <u>IT IMP Preparation and Labelling</u>

- RD&E Aseptic Services will prepare and dispense the IMP in accordance with the guidelines highlighted in the study protocol and the study drug manual.
- Preparation must be by designated Pharmacy Technicians and Pharmacists on the Trust ITC Register
- Drugs for intrathecal use will be clearly labelled. Additional information on the label must include: patient name, trial number, protocol identifier, PI, drug name or pseudonym, diluent (if appropriate), route, expiry date/time and batch number and comply with Annex 13 regulations for labelling of IMPs.
- All IT IMP doses will be prepared using the <u>surety</u> non-luer syringes and needles visually indicating that they are for IT administration.

6.6.3.3 IT IMP Delivery/ Collection

- Drugs for intrathecal administration will be packaged separately in a red/white intrathecal bag. For trial patients the drug is collected from Clinical Trials Pharmacy when the administering doctor is ready to perform the procedure. An intrathecal box should be used. No other drugs are to be transported with the intrathecal drugs
- The IT IMP can only be released by a Pharmacist who is on the IT IMP Register and release will occur only after checking that the collecting doctor is also on the IT IMP Register.
- The releasing Pharmacist and collecting doctor must both sign the prescription in the appropriate sections.

Intrathecal drugs must not be stored in the CRF. When ready to perform the procedure the designated doctor/nurse will collect the drug from Pharmacy Clinical Trials Unit.

6.6.4 IT IMP Administration

Intrathecal doses must only be administered within usual working hours: 08:00-17:00 Monday to Friday excluding public holidays and only when appropriate clinical cover can be provided. No exceptions apply to this guidance.

Intrathecal drugs must be administered in a designated area, separate from any area where other parenteral drugs are administered.

Equipment and procedures for lumbar puncture, withdrawal of CSF and IMP administration will be detailed in the Study Protocol and manuals.

Study personnel must comply with the Protocol, Investigator Brochure and this policy at all times.

Study-specific IMP administration guidelines may be written for each trial following Sponsor's protocol instructions.

In overview:

- No more than **4** people may be present in the room for IT IMP administration.
- IT drugs **must** be administered in a designated ward/ side room
- Two doctors will **never** carry out the checking of IT IMP doses in the absence of a nurse
- Before beginning the procedure, the doctor and nurse (both on the IT IMP Register) will carry out a pre- procedure check of the IT IMP documentation
- Lumbar Puncture and CSF collection is carried out according to Trust policy
- The final IT IMP check takes place between the administering doctor and designated nurse and identification should be checked with the patient
- Patient, doctor and nurse sign the trial script prior to the procedure commencing.
- The IT IMP syringe is attached and IMP is injected according to the study protocol.
- All doses administered must be recorded on the IT IMP prescription, the IT IMP checklist, and in the medical notes for each patient and in the study materials dictated by the sponsor.

The completed checklist and prescription form must be uploaded to the patient's clinical record after the IT administration and a copy placed in the Trial Master File.

6.6.5 Disposal of unused drugs

If the IT IMP procedure is cancelled or delayed (and the dose is still within its protective packaging) it must be returned to Clinical Trials Pharmacy or disposed of in the clinical area. This will be sponsor dependent.

6.6.5.1 Disposal within the clinical area

If a dose has already been removed from the protective packaging then it should be disposed of in the pharmaceutical waste bin in the clinical area or returned to Clinical Trials Pharmacy. As above this will depend on the Sponsor's instructions.

The disposal of any dose should be witnessed by the doctor and nurse and documented in the patient's notes. The Clinical Trials Pharmacy should be informed.

All disposed of doses must be recorded on the IT IMP prescription, on the checklist and as directed by the Sponsor.

6.6.5.2 Re issue

If administration is delayed by more than one hour after the IT IMP has been received the doctor authorised to administer the IT IMP should return it to Clinical Trials Pharmacy for safe storage.

The Pharmacy team will advise the PI if the IMP is suitable for re-issue.

If re-issue is not appropriate the PI and research team will be informed to organise rescheduling of the patient and re-prescribing of the dose.

7. Exceptions to the Policy

Any IT IMP procedure at variance with this policy must be reported to the study PI and the Sponsor in writing as soon as possible after the event and in accordance with the adverse events reporting requirements specified in the trial protocol.

The study PI will inform the R&D Director in writing of any exceptions to the policy. Issues will be escalated via R&D GOG and the R&D Group as appropriate.

Any breach in policy will act as a trigger for completion of an Incident report via Datix

8. DISSEMINATION AND TRAINING

8.1 This SOP and associated templates and forms will be uploaded to the Trust intranet and external website shortly after having been released.

8.2 All staff whose activities are subject to this policy should ensure that they take time to read and understand the content of this policy.

8.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this* policy*.*

9. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS POLICY

9.1 In order to monitor compliance with this Policy, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	The IT IMP Register will be held in the Investigational / Trial Master File and maintained by the Principal Investigator for the study. Whenever the Register is updated for a pharmacist, a doctor or a nurse, an updated copy should be provided to the Pharmacy Clinical Trials team. *check for 1 year revalidation.	TMF/ISF and Pharmacy File
2.	Evidence of completed training will be recorded in the study training log. *also check for annual revalidation	Study training log within TMF/ISF
3.	Only designated pharmacy staff that are on the Trust ITC register may prepare and final check IT IMP doses.	Prescriptions and Trust ITC Register
4.	The IT IMP check list (appendix 5) must be completed throughout the process then filed in the patient's notes and a copy filed in the TMF/ISF.	Patient notes/EPIC

9.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

9.3 Issues identified via the audit process which require escalation will be referred to GOG.

10. ARCHIVING ARRANGEMENTS

10.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Trust Intranet.

10.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

11. REFERENCES

- Department of Health (2009) Reference Guide to Consent for examination or treatment. Second edition, London: DoH publications.
- University College London Hospitals NHS Foundation Trust (2019) Intrathecal IMP Policy; version 2
- National Patient Safety Agency (2012) Central Alert NPSA/2-o11/PSA001: Safer spinal (intrathecal) epidural and regional devices, NPSA
- MHRA Phase I Accreditation Scheme. GOV.UK (4th Sept 2018)

12. ASSOCIATED TRUST POLICIES

- Consent to Examination or Treatment Policy
- Control of Substances Hazardous to Health (COSHH)policy
- Health Records Policy
- Identification of Patients Policy
- Incident Reporting, Analysing, Investigating and Learning Policy
- Information Governance Policy
- Medicines Management Policy
- Intravenous Therapy Policy
- Waste Management Policy
- Infection Prevention and Control Policy
- Policy for Safe Practice with Intrathecal Cytotoxic Drugs

Research and Development

Royal Devon and Exeter NHS
NHS Foundation Trust

STUDY ID ____________________ STUDY NAME ____ STUDY PI ________________

This register is an up-to-date record of designated doctors, nurses, pharmacists and technicians trained and approved in procedures relating to intrathecally-administered IMPs for this study. Signature by the staff member and study PI indicates training and approval to perform the study-specific tasks listed within the study at the RDE.

Name	Job Title	Initials	Signature	Date of completion of IT training	Name of IT cytotoxic lead signing off training*	Study-Specific Tasks (see codes below)	Start		End	
							Date	PI Signature	Date	PI Signature

PI Signature (at end of study only): ____________________________ Date: _______________

Study Task Codes

A: Write IT IMP Prescription	B: Carry out room and drug checks	C: Screen IT IMP Prescription
D: Prepare and dispense IMP	E: Collect IMP from pharmacy	F: Observe IT Administration
G: Administer IT IMP dose	H: Release IT IMP dose from pharmacy	

*Evidence of satisfactory completion of training must be provided. For Doctors, this sign off will be from the Site P.I. For product technicians, evidence of intrathecal training as standard is sufficient.

Research and Development

Royal Devon and Exeter NHS
NHS Foundation Trust

NAME: ____ (BLOCK CAPITALS)

Documentation	Signature	Date
I confirm that I have read and understood the study specific documentation on lumbar puncture.		
I confirm that I have read and understood the **Policy for safe practice with intrathecal cytotoxic drugs**		
I confirm that I have read and understood the Intrathecal IMP Policy		
I confirm that I have read and understood the DOH Updated national guidance on the safe administration of intrathecal chemotherapy (HSC 2008/001)		
I confirm that I have attended a training session and **watched the Department of Health DVD on Intrathecal Chemotherapy.**		
I have attended at least one of each of the following: – practical session of lumbar intrathecal drug administration – watching at least one IT drug administration – completing at least one IT drug administration independently. (This training session could be any relevant Speciality for example Haematology or Anaesthetics, under the supervision of an experienced SpR or Consultant)		
Independent IT competence should be demonstrated by a Direct Observation of Procedural Skills assessment filed electronically in the trainee's NHS e-portfolio		

I confirm that.. has been trained, authorised and accredited to participate in the Intrathecal IMP service in Royal Devon and Exeter NHS Foundation Trust.

In the case of re-certification please provide the number of Intrathecal IT IMP doses administered over the last 12 months and the date of the last administration:

Number of IT IMP administrations ________Date of last administration _______

ASSESSOR ____

SIGNATURE _________________________________DATE ________________

Research and Development

Royal Devon and Exeter NHS
NHS Foundation Trust

NAME: ____ (BLOCK CAPITALS)

Documentation	Signature	Date
I confirm that I have read and understood the **Policy for safe practice with intrathecal cytotoxic drugs**		
I confirm that I have read and understood the Intrathecal IMP Policy		
I confirm that I have read and understood the DOH Updated national guidance on the safe administration of intrathecal chemotherapy (HSC 2008/001)		
I confirm that I have attended a training session and **watched the Department of Health DVD on Intrathecal Chemotherapy.**		

I confirm that.. has been trained, authorised and accredited to participate in the Intrathecal IMP service in Royal Devon and Exeter NHS Foundation Trust.

ASSESSOR ____

SIGNATURE ________________________________DATE ________________

Research and Development

Royal Devon and Exeter NHS
NHS Foundation Trust

NAME: ______________________________________ (BLOCK CAPITALS)

Documentation	Signature	Date
I confirm that I have read and understood the **Policy for Safe Practice with Intrathecal Cytotoxic Drugs**		
I confirm that I have read and understood the Intrathecal IMP Policy		
I confirm that I have read and understood the DOH Updated national guidance on the safe administration of intrathecal chemotherapy (HSC 2008/001)		
I confirm that I have attended a dedicated training session on intrathecal cytotoxics by the Lead Trainer for Pharmacy Staff and **watched the Department of Health DVD on Intrathecal Chemotherapy.**		

I confirm that.. has been trained, authorised and accredited to participate in the Intrathecal IMP service in Royal Devon and Exeter NHS Foundation Trust.

ASSESSOR ____

SIGNATURE ________________________________**DATE** ________________

Intrathecal IMP Checklist

1 Patient Details		
Name	NHS Number	Date of birth
Visit Number	Date	Trial / Randomisation number

2 Room Check To be completed by doctor and nurse before patient is admitted		
	Dr	**Nurse**
Dr and Nurse on IMP register		
Rooms contain no other intravenous drugs		
Resuscitation and defibrillator accessible and up to date with checks		
Test emergency call bell		
Vital signs monitor working		
Non-essential equipment removed from the room		
Room configured to allow bed to be moved for emergency airway access if required.		
Do not disturb – room in use for intrathecal administration placed on the door		

3 Prescription screening check To be completed by the Clinical Trials Pharmacist	
	Pharmacist
Prescribing Dr and Pharmacist on the Intrathecal IMP register and delegation log	
Name, hospital number, dob, trial number correct on documentation.	
Script states for **intrathecal use only**	
Timing of dose according to study protocol treatment plan and previous doses	
Check date of administration is dated on the emailed prescription.	
Check dates of previous IT administration.	
Correct drug name or pseudonym, cohort/dose, volume, route	
Platelet within range(Y/N)	
No IV medications prescribed on day of IT drug administration	

4 Pre-procedure check To be completed by Doctor and Nurse before lumbar puncture begins		
	Dr	**Nurse**
Dr and Nurse on the intrathecal IMP register		
Patient name, hospital number, DOB, trial number correct on script.		
Signed informed consent in notes		
Dose in sealed package and stored correctly		
Date of administration is as dated on emailed prescription		
Check patient name band, prescription and syringe label		
Volume of fluid in syringe corresponds to the volume stated in the label and on the prescription		
Administration is within expiry time and date		
Route of administration on label is for Intrathecal use only		
Correct drug name or pseudonym and dose		

5 Final Check To be completed by Doctor and Nurse immediately before giving the IT IMP	**Dr**	**Nurse**
Patient, doctor and nurse to sign prescription chart before procedure commences		
Lignocaine and its syringe have been disposed of		
Maximum of 4 people in the room in addition to the patient		
Doctor reads out the syringe label immediately before attaching the syringe to the IT label		
Procedure documented in medical notes		

IT IMP checklist continued…..

IT IMP checklist continued….

6 After IT IMP Administration **To be completed by Doctor and Nurse after the IT IMP has been given**	**Dr**	**Nurse**
Extension tube and syringe disposed of in purple top bin and yellow sharps bin		
Procedure documented in medical notes		
7 Unused doses (Process may vary depending on Sponsor requirements)		
Dose returned to pharmacy		
OR dose disposed of in purple top bin		
Sponsor paperwork completed as required		

Once completed this checklist and the completed IT IMP prescription (original and emailed version) must be filed in the patients study folder and copy in the medical notes

Appendix 6: Door sign

NO ENTRY!

INTRATHECAL PROCEDURE IN PROGRESS

APPENDIX 7: EQUALITY IMPACT ASSESSMENT TOOL

Name of document	R&D Intrathecal IT Policy
Division/Directorate and service area	Research & Development
Name, job title and contact details of person completing the assessment	Samantha Smart Research Governance & Quality Manager samantha.smart1@nhs.net
Date completed:	08/12/2021

The purpose of this tool is to:

- **Identify** the equality issues related to a policy, procedure or strategy
- **Summarise the work done** during the development of the document to reduce negative impacts or to maximise benefit
- **Highlight unresolved issues** with the policy/procedure/strategy which cannot be removed but which will be monitored, and set out how this will be done.

1. **What is the main purpose of this document?**

   This policy governs the procedures for training in, prescribing, dispensing, supply, transport, storage, administration and disposal of non-cytotoxic Investigational Medicinal Products (IMP) to be administered via the Intrathecal route (IT) in clinical trials conducted at the Royal Devon and Exeter Hospital (RD&E)

2. **Who does it mainly affect?** *(Please insert an "x" as appropriate)*

   Carers ☐ Staff × Patients ☐ Other (please specify)

3. **Who might the policy have a 'differential' effect on, considering the "protected characteristics" below?** (By *differential* we mean, for example that a policy may have a noticeably more positive or negative impact on a particular group e.g. it may be more beneficial for women than for men)

***Please insert an "x" in the appropriate box** (x)*

Protected characteristic	Relevant	Not relevant
Age	☐	☒
Disability	☐	☒
Sex - *including: Transgender, and Pregnancy / Maternity*	☐	☒
Race	☐	☒
Religion / belief	☐	☒
Sexual orientation – *including: Marriage / Civil Partnership*	☐	☒

4. **Apart from those with protected characteristics, which other groups in society might this document be particularly relevant to…** (e.g. those affected by homelessness, bariatric patients, end of life patients, those with carers etc.)?

No additional groups identified

5. **Do you think the document meets our human rights obligations?** ✓

Feel free to expand on any human rights considerations in question 6 below.

A quick guide to human rights:
• ***Fairness –*** *how have you made sure it treats everyone justly?* • ***Respect –*** *how have you made sure it respects everyone as a person?* • ***Equality –*** *how does it give everyone an equal chance to get whatever it is offering?* • ***Dignity –*** *have you made sure it treats everyone with dignity?* • ***Autonomy –*** *Does it enable people to make decisions for themselves?*

6. Looking back at questions 3, 4 and 5, can you summarise what has been done during the production of this document and your consultation process to support our equality / human rights / inclusion commitments?

This document has been devised in line with and with reference to Trust policies to ensure staff are equipped to deliver IT IMP safely and within a clear competence framework

7. If you have noted any 'missed opportunities', or perhaps noted that there remains some concern about a potentially negative impact please note this below and how this will be monitored/addressed.

"Protected characteristic":	Not applicable.
Issue:	
How is this going to be monitored/ addressed in the future:	
Group that will be responsible for ensuring this carried out:	