WORK INSTRUCTION

WI 39 - VENEPUNCTURE IN INFANTS AND CHILDREN

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Controlled document

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It is the responsibility of all users of this Work Instruction to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Work Instruction (WI) must be followed unless a study specific SOP/WI exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
V1.1	31 December 2014	Caroline Harrill, Research Nurse	No significant changes. Minor change to format and content.
V2.0	01 July 2019	Su Wilkins, Senior Research Nurse	Minor changes to processes and transfer to new template.
3	21 September 2022	Lizzy Gordon, Lead Nurse Clinical Trials	Template update. No changes to process.

Associated Trust Policies/ Procedural documents:	S39 Venepuncture in Infants and Children Trust Inoculation Injury Policy Trust Decontamination Policy and Procedures
Key Words:	R&D Work Instruction Venepuncture
In consultation with: R&D Governance Oversight Group (GOG) – June 2022 Quality Assurance Working Group – May 2022	

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1 INTRODUCTION

Correct venepuncture technique is essential in order to protect patient safety and ensure data collected is credible. Venepuncture should only be undertaken for research purposes if specified in the study protocol, informed consent has been obtained by a parent or subject ≥ 16 years, and the child wherever possible has provided verbal assent.

2. PURPOSE

- To obtain blood samples via venepuncture safely.
- To ensure minimal distress to parent and child.
- To ensure safe transportation of samples to clinical area.

3. SCOPE

This working instruction applies to any health care professional who is undertaking venepuncture for research purposes.

4. DEFINITIONS & ABBREVIATIONS

CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
LRM	Local Research Meeting
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
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
TMF	Trial Master File
WI	Work Instruction

5. DUTIES AND RESPONSIBILITIES OF STAFF

This WI is applicable for all clinical trials sponsored and hosted by the Trust that involve minors. This WI relates to any child's participation in a clinical trial that requires a blood sample to be obtained.

6. PROCEDURES

6.1 Principal Equipment/Materials

- Appropriate size butterfly 23G or less, or appropriate trust/study sample collection system PDI swab
- Gauze
- Blood bottle
- Blood bottle label (if supplied)
- Tourniquet
- Disposable, powder free gloves/latex free
- Correct size syringe
- Sharps container
- Rubbish bag
- Clean paper towels
- Plaster
- Cool Box- if samples need to be stored refrigerated
- Topical anaesthetic cream
- Trust approved spillage kit

6.2 Obtaining the Blood Sample

6.2.1 Preparation Prior to procedure

In the context of clinical trials, informed written consent must be obtained routinely for all subjects, prior to the commencement of any clinical trial procedure.

Explain the procedure to the subject/parents/guardian. Obtain verbal consent for the procedure.

Where appropriate prepare the child for the procedure.

Check for any allergies to plasters or local anaesthetic cream.

Apply local anaesthetic cream (e.g. Ametop) to venepuncture site 30 minutes before planned venepuncture, or as per manufacturer's guidelines.

Where appropriate ask the parent/carer if they are happy to hold the baby/child during the procedure.

Ensure that the child is held securely. Very young children can be held securely but not too tightly. Wrapping the infant in a blanket and cuddling may be comforting as well as an effective holding technique.

6.2.2 Venepuncture Procedure

Clean tray and arrange all necessary equipment in the tray.

With clean hands, select an appropriate vein, preferably from the inner aspect of the elbow, or the back of the hand may also be used.

If possible, palpate vein to establish its position.

Clean hands and apply gloves.
Apply a tourniquet (in a younger child the tourniquet may be provided by a 2nd health care professional applying pressure) and ensure that the arm is being held securely.

Swab the skin over the chosen site with an alcohol swab and allow to dry for 30-60 seconds.

Select the appropriate size butterfly and syringe or trust approved blood collection system and select the vein to be used.

Hold the arm firmly ensuring the skin is stretched taut to fix the vein in position.

Insert the needle into the vein with the bevel side uppermost and observe for flashback (once the needle is in position, do not move that hand).

Pull back gently on the syringe until the required amount of blood has been obtained. If a blood collection system is being used attach blood bottles as per trust order of draw.

Once the required amount of blood has been obtained, release the tourniquet and apply the gauze with finger pressure to the puncture site, after the needle has been removed.

Continue applying pressure until bleeding ceases. Apply a plaster as required.

Discard the needle immediately into the sharps container.

Apply the blood bottle lid and label the blood tube with the appropriate labelling.

6.2.3 After the procedure

Insert the blood bottle into a sealed plastic bag and return to the relevant clinical department or area for processing as per study protocol instructions.

Return all waste to the department to be disposed of in an appropriate clinical waste bag.

6.3 Transporting samples from participants' homes

Ensure, if required, that the cool bag/box temperature is maintained at 2°c - 8°c.

Once sample obtained keep upright at room temperature for a minimum of 30-60 minutes.

Then place sample in either an ambient or cool bag/box and maintain study required temperature until sample has been returned to the lab for processing, or as per instructions specified in the study protocol.

6.4 Labelling of Samples

The sample bottle should be labelled or an identifiable mark placed on the bottle immediately after the sample has been obtained. If labels are provided by the sponsor for the study they should always be used.

The following information should be recorded:

- Identification of the study
- The study number
- Visit number
- Date and time sample obtained – this will always be recorded but not necessarily on the label if they are pre-printed.

6.5 Safety

Disposal of Needles

- Needles must not be re-sheathed prior to disposal.
- Always dispose of needles into approved sharps boxes.
- Never overfill sharps boxes.

6.6 Needlestick Injury

Immediately - Follow Inoculation Injury Policy:

- If there is bleeding from the site, encourage this.
- Wash affected area with soap and running water.
- Note the name and address of the person involved, date and time of incident and any other relevant details.
- Inform the Principal Investigator and Line Manager.
- Report the incident to Occupational Health Department (if closed and the injury is considered to be high risk attend the emergency department)
- Record the incident using the Incident report form on Datix

6.7 Spillages

- Spillage of blood must be dealt with immediately as per Trust Decontamination Policy and Procedures.
- Disposable gloves should be worn when dealing with spilt blood.
- Use the Trust spillage kit to deal with the spillage
- All waste will be disposed of in a clinical waste bag**.**

6.8 Maintaining competency to ensure safe practice

In the event of a break in the practice of venepuncture, of more than 6 months the research nurse / assistant will undertake a period of supervised practice, tailored to meet the individual needs identified by the practitioner. This could also take place at a shorter interval of time, if it was felt necessary by the practitioner or manager.

7. DISSEMINATION AND TRAINING

7.1 This WI and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

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

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

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

No	Minimum Requirements	Evidenced by
1.	**Informed Consent** - Venepuncture should only be undertaken when written informed consent has been obtained by a parent or subject ≥ 16 years, and wherever possible verbal assent from the child.	A copy of the consent form in the TMF/ISF and hospital notes/EPIC. Furthermore, a written note of the consent procedure should be recorded in the hospital notes/EPIC.
2.	**Sample labelling** - The sample bottle should be labelled with the study identification, the study number, visit number and the date and time the sample was obtained. The date and time this will always be recorded but not necessarily on the label if they are pre-printed.	Source document e.g. CRF, EPIC or study specific log.
3.	**Needlestick incidents** should be reported to a line manager and PI, Occupational Health notified and recorded on Datix.	Datix and Occupation Health Records
4.	**Maintaining competency -** In the event of a break in the practice of venepuncture, of more than 6 months the research nurse/assistant will undertake a period of supervised practice.	Staff training records. Or discussion with Senior Paediatric Research Nurse.

8.2 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.

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

9. ARCHIVING ARRANGEMENTS

9.1 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 RDE Research website.

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

10. REFERENCES

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