WORK INSTRUCTION

WI 39 - VENEPUNCTURE & HEEL PRICK SAMPLING IN INFANTS AND CHILDREN
Version 4

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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**
1.1	31 December 2014	Caroline Harrill, Research Nurse	No significant changes. Minor change to format and content.
2.0	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.
4	30 October 2025	Evanna Brook, Team Lead Research Nurse Peter Cummins, Senior Research Nurse	Addition of Heel Prick Sampling and minor changes following a recent audit. Transferred to a new template.

Associated Trust Policies/ Procedural documents:	S39 Venepuncture in Infants and Children Contamination (Inoculation) Incident Policy Trust Decontamination Policy and Procedures
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1 INTRODUCTION

Correct venepuncture & heel prick sampling (HPS) 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 obtain blood samples via heel prick sampling 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 or heel prick sampling 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
HPS	Heel Prick Sampling
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 Work Instruction (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

For venepuncture only

- Appropriate size butterfly 23G or less, or appropriate trust/study sample collection system PDI swab
- 2% chlorhexidine in 70% alcohol skin wipes
- Tourniquet
- Plaster
- Topical anaesthetic cream

For HPS only

- Age-appropriate automated incision device, designed to puncture ≤2mm deep
- Sterile Water or equivalent

Generic Equipment

- Gauze
- Blood bottle
- Blood bottle label (if supplied)
- Disposable, powder free gloves/latex free
- Correct size syringe
- Sharps container
- Rubbish bag
- Clinell Universal Wipes
- Clean paper towels
- Cool Box- if samples need to be stored refrigerated
- 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 equipment being used (i.e. plasters or local anaesthetic cream).

Venepuncture Only - Apply local anaesthetic cream (e.g. Ametop) to venepuncture site 30 minutes before planned venepuncture, or as per manufacturer's guidelines. Do not use when undertaking a HPS.

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 **Undertaking the Procedure**

6.2.2.1 **Venepuncture**

Clean tray with Clinell universal wipes 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 the alcohol wipe, (if site visibly unclean) and allow to dry for 30-60 seconds.

Select the appropriate size butterfly and syringe (or trust approved blood collection system).

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

Insert the needle into the chosen 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, (unless otherwise specified by study protocol).

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.

Discard the needle immediately into the sharp's container.

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

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

6.2.2.2 **HPS**

Clean tray with Clinell universal wipes and arrange all necessary equipment in the tray.

With clean hands, select an appropriate region of the heel (Figure 1 & 2), avoiding the posterior curvature of the heel.

Figure 1

Figure 2

Figure 1. For full-term and preterm infants. Skin puncture must be no deeper than 2mm.
Figure 2. For infants who have had repeated heel punctures. An automated incision device with a penetrative depth of no more than 1mm is recommended. These sites are also suitable for infants up to a year of age.

Clean hands and apply gloves.

Swab the skin over the chosen site with water (using cotton wool/gauze) and allow to dry.

Select the appropriate automated incision device.

Hold the foot firmly and apply the automated incision device to the selected site.

Activate the automated incision device and then remove from the child's skin, immediately disposing of the device in the sharp's container.

Once a blood droplet forms at the puncture site, touch the container edge to the child's foot and gently drag it across the site to collect the droplet.

Repeat process, as necessary, to obtain required sample volume. Ensure that the foot is not squeezed to increase blood flow; as this can cause pain and bruising; as well as potentially affect the results.

Apply pressure to puncture site until bleeding ceases.

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

6.2.3 Venepuncture and HPS limits

If first attempt is unsuccessful, the research nurse will discuss with subject/parent (as appropriate) whether to make a second attempt. This may be performed by the research nurse or other qualified person in the study team, if present. If the second attempt is also unsuccessful, no further attempt should be made in that visit.

Should it not be possible to obtain a blood sample after the above, the options should be discussed with the subject/parents i.e. to continue in the study without obtaining the blood sample, or to reschedule the visit for another attempt.

The staff member undertaking should inform Chief Investigator/Principal Investigator/Sub-Investigator if the sample is not obtained. Clearly record the reason for not obtaining the sample, the number of attempts, and the outcome in source document.

If the sample obtained is less than the amount required, in discussion and consent from parent(s) one further attempt may be made.

6.2.4 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 in the participants Case Report Forms (CRFs) and medical notes/EPIC:

- Identification of the study
- The study number or unique reference 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 Sharps

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

6.6 Needlestick Injury

Immediately - Follow Contamination (Inoculation) Incident 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, Lead Research Nurse 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.
- Datix report, Occupational Health report and outcomes relating to inoculation injury will be kept in staff members personal file.

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 or HPS, 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. The supervised practice/ renewed competency in Venepuncture and HPS will be recorded in the staff members 1 to 1 documentation.

7 DISSEMINATION AND TRAINING

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

7.2 All staff whose activities are subject to this WI must 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 and HPS should only be undertaken when informed consent (written or electronic) has been obtained by a parent or subject ≥ 16 years, and wherever possible verbal assent from the child.	A copy of the consent form (written or electronic) 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 following information should be recorded in the CRF and medical notes - study identification, the study number/unique reference, visit number and the date and time the sample was obtained.	Source document e.g. CRF, EPIC or study specific log.
3.	It should be clearly recorded in source documents any reason for not obtaining a sample, number of attempts, and outcomes.	Evidenced in study ISF/TMF file/patient hospital notes.
4.	**Needlestick incidents** should be reported to a Line Manager, Lead Research Nurse and PI. Report the incident to Occupational Health and recorded on Datix.	Discussion with Lead Research Nurse and PI.
5.	**Maintaining competency -** In the event of a break in the practice of venepuncture or HPS, of more than 6 months the research nurse/assistant will undertake a period of supervised practice.	Discussed and documented in staff members 1-to-1's and/or training records. Discussion with Senior Paediatric Research Nurse.
6.	Heel Prick Sampling Competency must be assessed by a Registered Professional.	Evidenced in staff training records on EDGE.

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 Royal Devon website.

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

10. REFERENCES

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