



# WORK INSTRUCTION

**WI 39 - VENEPUNCTURE IN INFANTS AND CHILDREN**

<b>Version</b>	2
<b>Effective Date</b>	01 July 2019
<b>Review Date</b>	30 June 2022
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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 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.

<b>Associated Trust Policies/ Procedural documents:</b>	<a href="#">S39 Venepuncture in Infants and Children Inoculation Injury Policy</a>
<b>Key Words:</b>	<i>R&amp;D Work Instruction Venepuncture</i>
<b>In consultation with:</b>	
Divisional Governance Group (DGG) Quality Assurance Working Group (June 2019)	

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## 1 INTRODUCTION

Correct venepuncture technique is essential in order to protect patient safety and ensure data collected is creditable. Venepuncture should only be undertaken for research purposes if specified in the study protocol, informed consent has been obtained by a parent or subject  $\geq 16$  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

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
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 SOP is applicable for all clinical trials sponsored and hosted by the Trust that involve minors. This SOP 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 2<sup>nd</sup> 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 place 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 injury considered to be high risk to 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 policies.
- 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 This WI will be audited in line with the relevant SOP and in agreement with the R&D audit process.
- 8.2 Outcomes from audit will be presented to the R&D Quality Assurance Group 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 the R&D Divisional Governance Group.

## 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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