STANDARD OPERATING PROCEDURE

S39 – VENEPUNCTURE IN INFANTS AND CHILDREN

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Controlled document

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It is the responsibility of all users of this SOP 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 Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1.1	20 March 2014		Minor formatting changes to SOP. Changes to the working document W39
2.0	01 July 2019	Su Wilkins, Senior Research Nurse	*Minor changes to processes and transferred to new template.*
3	21 September 2022	Lizzy Gordon, Lead Nurse Clinical Trials	Updated into new template and minor change to wording around training requirements.

Associated Trust Policies/ Procedural documents:	WI39 Venepuncture in Infants and Children Inoculation Injury Policy
Key Words:	*R&D* *Work Instruction* *SOP* *Venepuncture*
In consultation with: Divisional Governance Group (DGG) Quality Assurance Group (June 2019) Quality Assurance Group (June 2022)	

Contents

1 INTRODUCTION

This SOP covers the general aspects of administering venepuncture in infants and children.

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

It is the responsibility of staff undertaking venepuncture to read this SOP prior to participating in the trial.

4. DEFINITIONS & ABBREVIATIONS

GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
R&D	Research & Development
SOP	Standard Operating Procedure
WI	Work Instruction
TMF	Trial Master File

5. DUTIES AND RESPONSIBILITIES OF STAFF

It is the responsibility of staff undertaking venepuncture to have undertaken an educational programme recognised by the Trust and will be supervised by another research team member who is proficient in this task until they are able to perform this task independently.

It is the responsibility of the staff undertaking venepuncture to work according to the procedure outlined in this SOP.

If first attempt at venepuncture 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 at venepuncture 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 sample is not obtained. Clearly record reason for not obtaining sample, number of attempts, and 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. PROCEDURES

Please refer to relevant work instruction WI39 Venepuncture in Infants and Children.

7. DISSEMINATION AND TRAINING

7.1 This SOP 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 SOP should ensure that they take time to read and understand the content of this SOP.

7.3 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 SOP.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

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

No	Minimum Requirements	Evidenced by
1.	Staff undertaking venepuncture will have undertaken a recognised educational programme and been assessed as competent.	Evidenced in staff training record.
2.	It should be clearly recorded in source documents any reason for not obtaining a sample, number of attempts, and outcomes.	Evidenced in study TMF/site file/patient hospital notes.
3.	In the context of clinical trials, informed written consent must be obtained routinely from all subjects, prior to the commencement of any trial procedure.	Copy of consent form in TMF and patient hospital notes.

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

BROOKS N (2017) Venepuncture and cannulation: a practical guide. 2017 2nd Edition. M&K Publishing.

Caws L and Pfund R (1999) Venepuncture and cannulation in infants and children. Journal of Child Health Care 1999; 3 (2) 11-16.

Medical Research Council (2004) Medical Research involving children. MRC.