WORK INSTRUCTION

WI xx – Title

Version	
Effective Date	
Review Date	Maximum of 3 years after effective date
Author & Position	
Signature	
Date	
Approver & Position	
Signature	
Date	

Controlled document

This document has been created following the Royal Devon and Exeter NHS Foundation Trust Policy for the Development, Ratification & Management of Procedural Documents. It should not be altered in any way without the express permission of the author or their representative.

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 *Final version (use a whole number- 1; 2; 3 etc., rather than 1.1; 1.2; 1.3), from the first published SOP for which you have records. Draft versions of the current revision may be listed if helpful*	**Date**	**Author**	**Reason**
1.0			*e.g. New Policy, to meet … standards*
2.0			*e.g. Revision to reflect…*

Associated Trust Policies/ Procedural documents:	*List of all Trust procedural documents mentioned in the document and any associated Trust procedural documents not mentioned. Hyperlink to their location on the intranet.*
Key Words:	*List all key words relating to document (e.g. medicine; management; etc.). This ensures that the document will be searchable under these terms on the intranet.*
In consultation with: Reference key roles or groups who have been involved in drafting or reviewing the Work Instruction e.g. Divisional Governance Group, Team Leads, QA Team	

Contents

1 INTRODUCTION

This may include a statement of intent; may provide an overview and background or context.

2. PURPOSE

Will explain why the document has been written/what are its aims and objectives (for example: to guide/ensure compliance/ meet legislative requirements/ improve/ explain etc.).

3. SCOPE

Explain who this WI applies to e.g. all members of the Clinical Trials Pharmacy team.

4. DEFINITIONS *Include/add/remove as appropriate*

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
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 section will explain the duties and responsibilities of individual staff members and staff groups, broken down by job title, beginning at the highest (executive) level, where this is appropriate (e.g. for Trust policies and strategies). This is to ensure that each member of staff knows what is expected of him/ her, and that he/ she may be held to account. As in the Definitions section, the job title/ staff group should be in bold, followed, in standard text, by the description of the duties and responsibilities. Individual staff members should be listed first, followed by Groups/ Committees (again, with name in bold).

6. PROCEDURES

This section may be divided into as many sections as are suitable, and will generally-comprise a number of main sections and possibly subsections.

6.1 *Sub heading*

6.1.1

6.1.2

6.2 ***Sub heading***

6.2.1

6.3 ***Sub heading***

6.3.1

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 EFFECTIVESS 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.		
2.		
3.		
4.		

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

Hyperlink references to all external documents (legislation, journals etc.) where they are mentioned in the document. References throughout the document and in the References section list should be based on the principles of Harvard-style. Please contact the QA Manager for guidance if you have problems.

Please list all references that are mentioned in the body of the text in the

References Section.

Any further references not mentioned but which were consulted can be included in a second list titled "Bibliography" or "Works Consulted". The References section should take the form of a hyperlinked list, without bullets.