SOP 002 Good Clinical Practice (GCP) Training

For Use in:	Research & Development
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Good Clinical Practice (GCP) Training
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Date of approval:	*09 December 2019*
To be reviewed before: This document remains current after this date but will be under review	09 December 2022
Reference and / or Trust Docs ID No:	16908
Version No:	1.0
Description of changes:	This is a new SOP

SOP 002 Good Clinical Practice (GCP) Training

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
MHRA	Medicines and Healthcare Products Regulatory Agency
NIHR	National Institute of Health Research
R&D	Research and Development
SOP	Standard Operating Procedure

3. Scope

This SOP describes the process, the requirements and expectations for researchers and staff involved in different types of research. It covers the frequency of, scope and documentation for GCP training adopted at NNUH and UEA

4. Introduction

GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

The Joint Statement from the MHRA/HRA on the Application of GCP to Training for Researchers advocates a proportionate approach to the application of GCP training.

Different types of research may require different training, and some researchers are already well trained and competent in their area of expertise.

Researchers can sometimes be required, inappropriately and often disproportionately, to undertake GCP training when they do not conduct research in the field of clinical trials of investigational medicinal products (CTIMPs)/Devices or where their involvement in the trial is minimal and entirely within their professional expertise (see appendix 1 and 2).

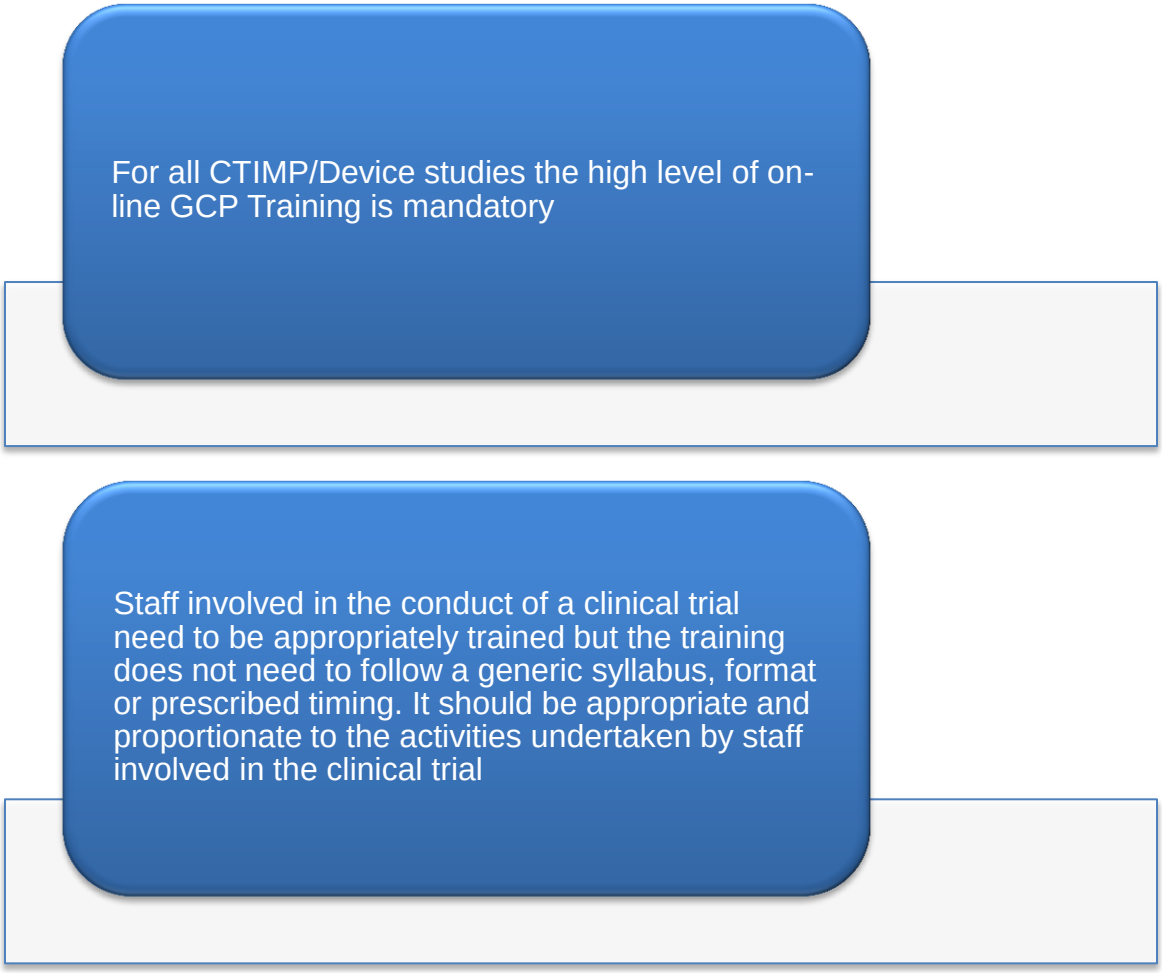
This SOP describes the approach for GCP training for research within the NNUH, for studies sponsored by NNUH and UEA Chief Investigators (CI)/Principal Investigators (PI) and UEA Research Staff

5. Rules

The frequency of GCP training is not defined in the regulations, however it is the responsibility of an organisation to demonstrate to inspectors that staff are trained appropriately to ensure the general principles of GCP are adhered to

- At NNUH initial training will be undertaken and will be repeated every 2 years (see Appendix 1 & 2) for further guidance
- It must be demonstrated that the GCP training covers the duration of the research being undertaken
- Two types of training will be adopted: on-line GCP and R&D Practical GCP
- This SOP is applicable for all research including NNUH Sponsored studies

6. CTIMP/Device Studies:



7. For other types of research:

There is no legal requirement for other types of research to be conducted in accordance with the conditions and principles of GCP.

It is still important that such research is always conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data is reliable. Members of the research team in such studies are expected to be qualified by education, training or experience and have an understanding in the principles GCP.

Training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards.

8. Process

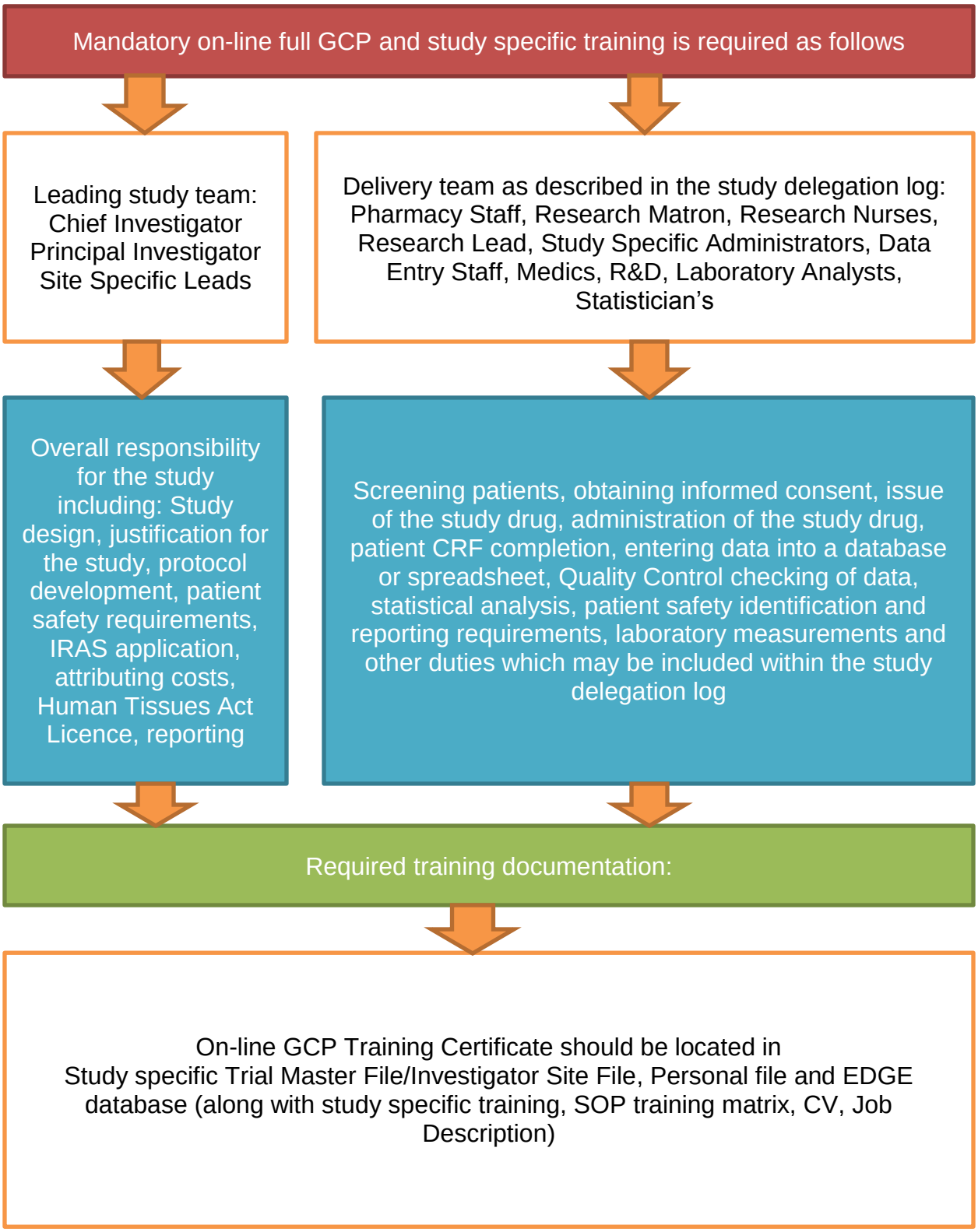
Staff involved in the conduct of research studies will be required to complete GCP training initially and every two years. The training certificate duration must cover all of the study duration.

Training will be required:

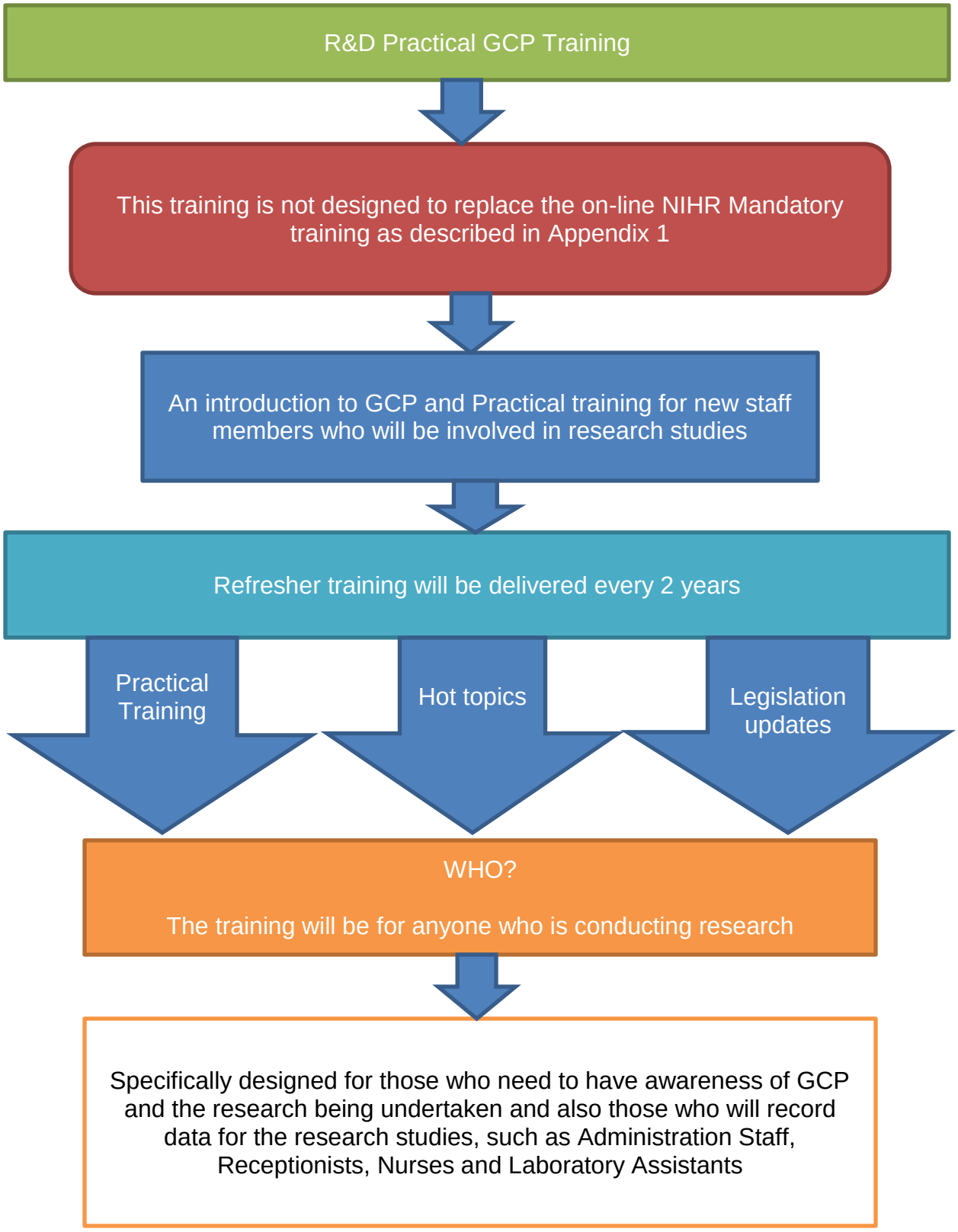
It is vital the staff members who are conducting research studies have a good knowledge of the protocol requirements for the specific work they are conducting.

Study specific training should be documented within the study site file; to demonstrate that they have a good understanding of the study requirements as well as GCP training.

9. Appendix 1 – Flow chart for On-line GCP Training



10. Appendix 2 – Flow chart for R&D Practical GCP Training



11. Approval

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12. Reason for Update and Training Implication

This is a new SOP

Update	Reason	Training Implication	Action
New SOP	Guidance GCP training at NNUH	Yes	Review SOP and update training matrix