Clinical Peer Review Monitoring

DLV-GEN-WI-009

Contents

1. Background/Introduction

Clinical peer review monitoring forms part of good clinical care for research participants. Clinical Teams within the Research Directorate are required to monitor other teams to ensure compliance with applicable legislation, quality of data input and correct participant oversight.

2. Purpose

The purpose of this SOP is to provide instruction and a process to support clinical personnel who are involved in recording and managing source data for research within the Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH), conduct peer review monitoring.

3. Scope of Document

The Scope of the SOP is to provide information on the procedure of Peer Review Monitoring, to ensure the quality of data entry into a participant's Electronic Health Record (EHR). Source data and Source documentation (known as the Source Record) is included in the scope.

4. Definitions

The following definitions have been adapted from the 'ICH GCP Integrated Addendum E6(R3) – Section: Glossary and the FDA's 'Guidance for Industry: Electronic Source Data in Clinical Investigations 2013':

Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities within a trial necessary for the reconstruction and evaluation of the trial events. Source data are contained in source documents (original records or certified copies) and can be in paper format, electronic format, or a combination of the two.

Source Documents: Original documents, data, and records. Examples include hospital records; clinical/office charts; laboratory notes; memoranda; subject diaries or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies or transcriptions certified after verification as being accurate and complete; microfiches; photographic negatives; microfilm or magnetic media; x-rays;

subject files and records kept at pharmacy, laboratories and/or medicotechnical departments involved in the trial.

5. Roles & Responsibilities

This SOP applies to clinical staff within each of the Delivery Teams.

6. Procedure

6.1 Team Leads are to nominate a clinical member of the team to conduct peer review monitoring. The workload should be spread across clinical team members to provide opportunity and shared workload. Each Clinical Team should conduct one peer review monitoring exercise on another team, each month

6.2 Nominated clinical member, will contact the Directorate Administrative Team to gain a team allocation for monitoring and be provided with four participant study identification numbers at random

6.3 Nominated clinical member to arrange a time to conduct the monitoring with the allocated team

6.4 The proforma “Peer Review Monitoring Checklist for Documentation Uploaded to eRecord and Entries into the Participant Medical Notes” (DLV-GEN-T-004) should be completed for each participant to document the monitoring

6.5 The proforma should be fully completed with additional comments to ensure review by others can be followed and the narrative is present

6.6 Upon completion of the peer review monitoring visit, the schedule should be completed and sent to the Team lead for review and comment. The Team Lead should sign the document to demonstrate their review.

6.7 The Team lead will send the signed report (and any additional correspondence) the NJRO Quality Assurance Team for review and RAG rating - nuth.njro.qa@nhs.net

6.8 Any further actions highlighted by the NJRO Quality Assurance Team will be sent back to the Delivery Team lead for completion in collaboration with the nominated monitor and the monitored team

6.9 Updated and final versions of the report should be sent to the NJRO QA Team and a copy retained by the reporting team