

Learning Contract - Safety Reporting in Clinical Research

Learning Contract: Work Based Clinical Research (SHE 3, 20 Credits) Subject Area: Safety Reporting in Clinical Research

Overarching Learning Outcome: Understand the theory and practice of safety reporting within the context of clinical research

Learning Outcomes	Specific Content	Learning Experiences	Evaluation Methods	Verified By
<p>1. Discuss the terminology specific to Safety Reporting in clinical research.</p> <p>2. Differentiate the responsibilities in Safety Reporting for clinical research.</p> <p>3. Review and analyse the local Safety Reporting protocol for clinical research.</p> <p>4. Identify the regulatory bodies with a responsibility for Safety Reporting.</p>	<p>Definitions used in Clinical Trials.</p> <p>Reporting mechanisms for Adverse Events</p> <p>Reporting mechanism for Serious Adverse Events.</p> <p>Reporting mechanisms for reporting SUSARs.</p> <p>Research personnel responsibilities.</p> <p>MHRA guidelines.</p> <p>NHS guidelines and local policy.</p> <p>UK Regulations and legislation.</p>	<p>Review of literature.</p> <p>Analysis of the literature.</p> <p>Discussions with Pharmacovigilance Officer.</p> <p>Review of regulatory documents.</p> <p>Discussions with research personnel.</p> <p>Discussions with clinical trial monitors.</p>	<p>Portfolio of learning activities.</p> <p>Essay (3000 words).</p>	

Learning Contract Approved- Date:

Student Signature:

Module Leader Signature.....