

# Learning Contract – Good Clinical Practice in Clinical Research

**Learning Contract: Work Based Clinical Research (SHE 3, 20 Credits)**  
**Subject Area: Good Clinical Practice in Clinical Research**

**Overarching Learning Outcome: Understand the implications of Good Clinical Practice in clinical research**

Learning Outcomes	Specific Content	Learning Experiences	Evaluation Methods	Verified By
<ol style="list-style-type: none"> <li>1. Outline the historical context within which Clinical Trial Research has developed.</li> <li>2. Analyse the impact of the EU Directive on Clinical Trials and UK Regulations.</li> <li>3. Describe the specific responsibilities incumbent upon trial investigators and sponsors.</li> <li>4. Utilise resources that support the application process for obtaining approvals before conducting a Clinical Trial.</li> <li>5. Appraise the issues involved in Pharmacovigilance and Safety Reporting.</li> </ol>	<p>European &amp; National impact of EU directive on clinical trials.</p> <p>Ethics application System</p> <p>NHS R&amp;D application system</p> <p>CTA application system</p> <p>Delegation logs in clinical trials</p> <p>Sponsor's responsibilities</p>	<p>Work based study day (1 Day)</p> <p>Review of the literature and web-sources</p> <p>Appraisal of the literature and web-sources</p> <p>Review of the regulatory process relating to clinical trials</p> <p>Discussions with research personnel in study teams</p> <p>Effective learning services (Glasgow Caledonian University)</p>	<p>Portfolio of learning activities</p> <p>Essay (3000 words)</p>	

**Learning Contract Approved- Date:** .....

**Student Signature:** .....

**Module Leader Signature**.....