

# Learning Contract – Informed Consent in Clinical Research

## Learning Contract: Work Based Clinical Research (SHE 3, 20 Credits) Subject Area: Informed Consent in Clinical Research

**Overarching Learning Outcome: Act within scope of professional practice to select and implement appropriate evidence based practices for obtaining informed consent from trial participants**

Learning Outcomes	Specific Content	Learning Experiences	Evaluation Methods	Verified By
<p>1. Discuss the abuses of consent that have lead to the present process.</p> <p>2. Analyse the ‘process’ of consent in clinical research.</p> <p>3. Utilise resources on the requirements for a Participant Information Sheet and Consent Form.</p> <p>4. Outline a Participant Information Sheet and Consent Form.</p> <p>5. Differentiate the requirements of consent for Adults with Incapacity.</p>	<p>Influences from history on consent process</p> <p>Participant Information Sheets</p> <p>Consent forms in clinical research</p> <p>Process of obtaining consent</p> <p>Responsibilities in consent process</p> <p>National Research Ethics Committees guidelines</p>	<p>Review of strategic documents and regulatory systems</p> <p>Review of the literature and web-sources</p> <p>Appraisal of the literature and web-sources</p> <p>Discussions with research personnel who take consent</p> <p>Discussions with research study team involved in any aspect of research.</p> <p>Informed consent study days</p> <p>Review and appraisal of Participant Information Sheets and Consent Forms</p>	<p>Portfolio of Learning Activities</p> <p>Essay (3000 words)</p>	

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

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

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