

**GLASGOW CALEDONIAN UNIVERSITY  
SCHOOL OF NURSING, MIDWIFERY AND COMMUNITY HEALTH**



**NURSING EDUCATION DEVELOPMENT UNIT**

**WORKING IN PARTNERSHIP WITH**



**October 2008**

## Work Based Learning

The Nursing Education Development Unit (NEDU) of Glasgow Caledonian University's (GCU) School of Nursing, Midwifery and Community Health in partnership with NHS Greater Glasgow & Clyde Clinical Research Facility is pleased to offer the opportunity to gain academic accreditation for those registered practitioners participating in the in-house clinical based "Clinical Research" education programme.

This academic accreditation can either be used as part of a BSc (Hons.) Professional Development (including top-up for Diplomates) or for existing graduates as part of an exit award entitled 'Graduate Certificate in Clinical Research.

Accreditation is through Work Based Learning which takes an organised and learner managed approach to utilising opportunities for learning and professional development in the work place. An essential feature of work based learning is the bringing together of self knowledge, expertise at work and university knowledge.

Work based learning has the following features:

- It focuses on tasks arising in the workplace,
- It is autonomously managed with the learner taking on the major, responsibility for ensuring that they seek out learning opportunities and learn from their work activities,
- It is concerned with enhancing performance and updating and upgrading experience.

Work based learning opportunities encourage students to identify significant learning experiences for reflection, and then relate theoretical knowledge to gain deeper understanding and meaning. The meaningful learning and behaviour change that results from the reflection will facilitate development of future practice. Thus, it places emphasis on a more integrated assessment of how knowledge, understanding and critical analysis are used to address particular clinical practice situations or problems.

Work based learning permits;

- Opportunities,
- Partnerships,
- Self direction,
- Relevance (individual and employer).

This will facilitate life long learning, continuing practice development and continuing professional development in a way that is responsive and receptive.

Work Based Learning opportunities emerge as a direct result of:

- Attending the in-house study day,
- Organising appropriate learning activities,
- Engaging in supervised practice.

Each unit is guided via a learning contract (Appendix 1.) and is offered as Continued Professional Development (CPD) or as 20 credit units at Scottish Higher Education Level 3 (Scottish Credit and Qualifications Framework 9) permitting students to consult with their line manager, their practice development facilitators and / or employers and then construct learning packages to meet personal and professional learning.

### CPD OPTION

CPD is defined as accessing the unit as part of the annual Personal Development Planning (PDP).

The CPD option comprises the following:

- Attendance at the study day,
- 500 word reflective account related to the learning that has occurred as a result of participating in the study day or specific directed activity associated with the study day.

Certificates of Continuing Professional Development will be issued if the registered practitioner submits to GCU's NMCH a reflective account (approximately 500 words) that outlines the learning arising from undertaking the educational element. Each student will receive written feedback from their clinical facilitator on the content, structure, strength and weakness of their reflective account. There will be charge of £30 for each CPD certificate being applied for. The cost is for the University processing and issuing a certificate.

### ACCREDITATION OPTION

The accreditation option requires the student to:

- Attend the study day,
- Complete the accompanying learning activities,
- Provide evidence to support attainment of the unit learning outcomes,
- Undertake the stipulated written assignments and attain a pass mark of 40% or more.

The accreditation option is designed as a 'stand alone' activity or can be combined with any other relevant units (e.g. Good Clinical Practice in Clinical Research, Informed Consent in Clinical Research, Safety Reporting in Clinical Research). The student fee will be on the premise that:

- Students will have the benefits of GCU registered students (library, IT, effective learning support)
- Academic support will be offered to **each student** by a member of the Clinical Research Facility education team,
- All marking, moderation (internal and external) will be conducted by GCU academic staff and the appropriate work based learning external examiner.

## OVERARCHING WORK BASED LEARNING OUTCOMES

By the end of the module:

- Appropriate Learning Outcomes will be communicated to the student via the Learning Contract

*Further Learning Outcomes to be achieved in addition to those identified in the learning contract:*

The student will be able to:

- Construct a relevant work based portfolio.
- Elicit and make use of a range of learning strategies.
- Adopt responsibility for their own learning within a work based environment.

## ASSESSMENT

Assessment at SHE 3/SCQF 9 requires to be formally structured and referenced. This applies to students who are either seeking CPD certificate or academic accreditation

All written work should be accompanied by a reference list. The reference list(s) should detail all the specific journal articles, books and publications you have read and used to compile your written pieces. Students are required to use a specific referencing system – the modified Harvard (See GCU's Referencing Guidelines).

APPENDIX 1.

# Learning Contract – Good Clinical Practice in Clinical Research

## Work Based Learning Contract (SHE 3, SCQF 9, 20 Credits)

Learning Outcomes	Specific Content	Learning Experiences	Evaluation Methods	Verified By
<p>1. Analyse the historical context within which Clinical Trial Research has developed.</p> <p>2. Explore the impact on contemporary practice of the; “EU Directive on Clinical Trials”</p> <p>“UK Regulations on good clinical practice in clinical research”.</p> <p>3. Explain the application process for obtaining approvals before conducting a Clinical Trial.</p> <p>4. Discuss the specific responsibilities incumbent upon trial investigators and sponsors conducting clinical research.</p>	<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**.....

# Learning Contract – Informed Consent in Clinical Research

## Work Based Learning Contract (SHE 3, SCQF 9, 20 Credits)

Learning Outcomes	Specific Content	Learning Experiences	Evaluation Methods	Verified By
<p>1. Discuss the ethical principles which underpin the concept of “Informed consent” in clinical research.</p> <p>2. Analyse the ‘processes’ of consent in clinical research which aim to overcome “abuses” and ensure “best practice”.</p> <p>3. Provide a rationale for the variation in the requirements of consent for specific groups/individuals.</p> <p>4. Evaluate a selection of Participant Information Sheets and Consent Forms taking cognisance of exemplary practice.</p>	<p>Historical influences on the 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**.....

# Learning Contract – Safety Reporting in Clinical Research

## Work Based Learning Contract (SHE 3, SCQF 9, 20 Credits)

Learning Outcomes	Specific Content	Learning Experiences	Evaluation Methods	Verified By
<p>1. Discuss the principles of Safety Reporting in clinical research.</p> <p>2. Appraise the responsibilities of regulatory bodies/ individuals involved in assessing &amp; monitoring for adverse events in clinical research.</p> <p>3. Evaluate the local Safety Reporting mechanism for clinical research.</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**.....

**For further information contact;**

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