Liverpool John Moores University

Title:	CLINICAL RESEARCH
Status:	Definitive
Code:	**6004SBACAP** (113419)
Version Start Date:	01-08-2011
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
Vicki Anderson	Y
Elsie Gaskell	

Academic Level:	FHEQ6	**Credit Value:**	12.00	**Total Delivered Hours:**	24.00
Total Learning Hours:	120	**Private Study:**	96		

Delivery Options
Course typically offered: Semester 2

Component	Contact Hours
Lecture	20.000
Workshop	2.000

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	AS1	Examination 50 % MCQ 50% SAQ	70.0	2.00
Essay	AS2	Coursework - written exercises	15.0	
Presentation	AS3		15.0	

Aims

To provide knowledge of the methodology required to plan, implement and manage clinical research to good clinical practice (GCP) standards. To provide knowledge of the clinical skills required to carry out and complete a clinical trial.

Learning Outcomes

After completing the module the student should be able to:

1	interpret protocols and case record forms for clinical research.
10	demonstrate the provision of adequate documentation for a clinical trial.
2	plan clinical research projects.
3	prepare for trial set-up and closedown visits and demonstrate a knowledge of data management.
4	demonstrate how standard operating procedures (SOPs) reflect good clinical practice.
5	demonstrate a knowledge of the role of the pharmaceutical company's legal department in a clinical trial.
6	demonstrate knowledge of advances in clinical trial management and technology.
7	construct a protocol.
8	demonstrate an understanding of the role of study personnel.
9	complete a CRF accurately.

Learning Outcomes of Assessments

The assessment item list is assessed via the learning outcomes listed:

EXAM	1	2	3	4	5	6	8	10
essay	7	9						
presentation	1							

Outline Syllabus

SOPs and GCP.
Protocols/protocol amendments.
Case rcord forms and their completion.
Project co-ordination and planning.
trial set-up.
Study documentation.
Patient recruitment.
Trial closedown.

Learning Activities

lectures and group workshops.

References

Course Material	Book
Author	Di Giovanni and Hayes G

Publishing Year	
Title	Principles of Clinical Research
Subtitle	
Edition	
Publisher	Wrightson Biomedical Publishing Ltd
ISBN	18718116459

Course Material	Book
Author	May P, Kolma J, Scott G
Publishing Year	
Title	Good Clinical Practice: Standard Operating Procedures for Clinical Researchers
Subtitle	
Edition	
Publisher	John Wiley and Sons Ltd
ISBN	

Notes

This module will provide students with knowledge of how clinical trials are designed by protocols and how to plan, implement and manage clinical research to GCP standards.