PROGRAMME SPECIFICATION		Newcastle University

1	**Awarding Institution**	Newcastle University
2	**Teaching Institution**	Newcastle University
3	**Final Award**	Postgraduate Certificate
4	**Programme Title**	Postgraduate Certificate in Clinical Research
5	**Programme Code**	3043
6	**Programme Accreditation**	
7	**QAA Subject Benchmark(s)**	
8	**FHEQ Level**	M
9	**Date written/revised**	11th February 2008

10	**Programme Aims**
To provide health care professionals within the NHS, ancillary services and Industry with a basic understanding of the processes involved in preparing for, planning, conducting, analysing and writing-up clinical research including; how to obtain legal and ethical approval for clinical research, how to design studies, collect and analyse data, and how to produce and evaluate written reports based on those studies.	

11	**Learning Outcomes**
The programme provides opportunities for students to develop and demonstrate knowledge and understanding, qualities, skills and other attributes in the following areas.	

Knowledge and Understanding
On completing the programme students should: A1. be able to describe current legislation relating to clinical research A2. have an understanding of the current issues relating to governance in clinical research A3. have an understanding and knowledge of local and national regulations and processes for obtaining permissions and approval for clinical research A4. understand the need for good practice in clinical research A5. be able to apply knowledge of ethical principles in clinical research projects and proposals A6. be able to differentiate qualitative and quantitative research methods A7. understand the application of different study designs in clinical research A8. understand the basics of data handling and management of clinical databases A9. understand the application of range of computer based packages for statistical analysis in clinical research and know how to use them to interpret basic research data A10. know how to source and assimilate information for appropriate background reading A11. understand the process of critical and peer-review as applied to published works A12. understand how to source guidelines for production of manuscripts for publication in peer-reviewed journals and grant applications A13. understand the issues of authorship, copyright ownership and plagiarism as they apply to their own work and that of others (including published works)
Teaching and Learning Methods
The programme comprises three 20 credit modules delivered in a series of one and two day blocks. The day blocks include a mixture of lectures, tutorials and workshop style seminars. Prior to the lectures the students will be able to access a series of on-line packages with information and exercises to complete. The lectures and self-directed study are designed to deliver the mixture of knowledge and understanding referred to above. The modules will employ structured feedback sessions using both formative and summative assessment to ensure the students engage in self-directed learning and achieve the learning outcomes.
Assessment Strategy
In the first module CMS8030: Research governance and ethics students will write a

number of research applications based on current ethical committee approval and R & D approval forms. These will be assessed in and formative feedback given in the tutorials The ability to correctly identify the prerequisites within the current forms will indicate a student's knowledge of regulations etc and understanding of the module as taught (A1 – A5). **In the second module CMS8031: Research study design and data interpretation** the students will be assessed by an MCQ test, a short oral presentation and a written study design (A6 – A10). The written study and MCQ in particular will test knowledge and understanding of different modes of clinical research and the different components of a research project as well as of differences between qualitative and quantitative research methodologies. **In the third module CMS8032: Medical writing in a research setting** the students will be assessed through production of three different written reports; a systematic review of the literature, a critical appraisal of a selected published paper and either an original research proposal or a research manuscript. This will allow the students to practice different forms of medical writing and will assess their knowledge and understanding (A8, A11– A13),

Intellectual Skills

On completing the programme students should be able to:
B1. understand the need for good practice in clinical research
B2. differentiate qualitative and quantitative research methods
B3. discuss the application of different study designs in clinical research
B4. select appropriate means of data handling, manage a clinical databases and select an appropriate statistical package for data analysis
B5. interpret data from clinical research projects in their own medical speciality
B6. discuss issues of peer-review, critical appraisal, authorship and copyright ownership in medical writing and the need to avoid and detect plagiarism in their own work and that of others

Teaching and Learning Methods

The programme comprises three 20 credit modules delivered in a series of one and two day blocks. The day blocks include a mixture of lectures, tutorials and workshop style seminars. Prior to the lectures the students will be able to access a series of on-line packages with information and these packages will also include exercises to complete. The lectures are designed to deliver a mixture of knowledge and understanding whilst the tutorials will and workshops will promote discussion and critical appraisal of the students work. Assessment will be both formative and summative. The key to achieving the learning outcomes under this heading is the use of feedback to promote discussion and appraisal of the students own work.

Assessment Strategy

In the first module CMS8030: Research governance and ethics students will write a number of research applications based on current ethical committee approval and R & D approval forms. These will assess intellectual skills B1 above. **In the second module CMS8031: Research study design and data interpretation** the students will be assessed by an MCQ test, a short oral presentation and a written study design (A6 – A10). The written study and MCQ will students ability to differentiate and discuss modes of clinical research and the different components of a research project as well as of differences between qualitative and quantitative research methodologies (B2 and B3). The short presentation will assess B4 and B5. The **third module CMS8032: Medical writing in a research setting** addresses B6 in particular – through production of three different written reports; a systematic review of the literature, a critical appraisal of a selected published paper and either an original research proposal or a research manuscript students will be able to different forms of medical writing and display their intellectual skills described in B6.

Practical Skills

On completing the programme students should be able to:
C1. prepare and evaluate relevant paperwork for: informed consent, ethical committee approval, MHRA, and NHS permission to conduct clinical research in line with local and national legislation and guidelines
C2. design a clinical research project
C3. collect, store and analyse data from clinical research projects using appropriate computer database(s) and appropriate statistical software
C4. source appropriate background reading
C5. peer-review manuscripts in their own area of speciality
C6. write appropriate grant applications and manuscripts for submission to either funding bodies (grants) or peer-reviewed journals as appropriate

Teaching and Learning Methods
The programme comprises three 20 credit modules delivered in a series of one and two day blocks. The day blocks include a mixture of lectures, tutorials and workshop style seminars to deliver the necessary mixture of knowledge and skills. The key to achieving the learning outcomes in this field is in the self-directed study and appraisal of the student's work which will take place in both group and one-to-one settings as appropriate. The knowledge base required to achieve these skills learning outcomes will be delivered in lectures and learning outcomes will be assessed formatively in the tutorials and workshops as well as summatively through submitted work.

Assessment Strategy
In the first module CMS8030: Research governance and ethics students will write a number of research applications based on current ethical committee approval and R & D approval forms (C1). T**he second module CMS8031: Research study design and data interpretation** addresses the practical skills of study design (C2) handling and analysing data appropriate to different research methodologies including identification of the correct statistical methods (C3). The students will be assessed by an MCQ test, a short oral presentation and a written study design. T**he third module CMS8032: Medical writing in a research setting** the students which will be assessed through production of three different written reports; enables the students to demonstrate (an the assessment of) a range of practical skills including sourcing information (C4), review (C5) and writing (C6).

Transferable/Key Skills
On completing the programme students should be able to: D1. critically appraise and evaluate: grant applications, research papers and applications for ethical approval related to clinical research (see C1 & C6) D2. source and evaluate appropriate background reading D3. present data from their own and published clinical research in an appropriate format either written (see C6) or oral as required D4. interpret and analyse their own and published data using appropriate resources (see C3)

Teaching and Learning Methods
Students will practice the skills above in tutorials and in self-directed learning using theon-line packages and exercises. These skills will be assessed in the tutorials and workshops and in submitted work.

Assessment Strategy
In the first module CMS8030: Research governance and ethics students will write a number of research applications based on current ethical committee approval and R & D approval forms these will be assessed in the tutorial. The ability to critical appraise (D1) these forms and source and evaluate appropriate information (D1 & D2) will be key within these assessments. T**he second module CMS8031: Research study design and data interpretation** will sue written and oral presentation to assess the students ability to source information (D2) and present information (D3) and to interpret and analyse information (D4). In the **third module CMS8032: Medical writing in a research setting** the students will be assessed through production of three different written reports; enables the students to demonstrate (an the assessment of) a range of practical skills including sourcing information (D2) and written presentation (D3) as wll as interpretation and analysis of information (D4).

12   Programme Curriculum, Structure and Features
Basic structure of the programme
The programme comprises three 20 credit modules: Research Study Design and Data Interpretation (CMS8031); Writing in a Medical Setting (CMS8032 The programme will run over a whole University year (3 semesters). All three modules will be run once a year. CMS8030 will run in semester 1, CMS8031 will span semesters 1 and 2 and CMS8032 will span semesters 2 and 3.
Key features of the programme (including what makes the programme distinctive)
Part-time delivery; in blocks to enable "day release" for student in full-time employment; developed specifically to enhance training options for post-graduate medical professionals; will suit students who wish to take one, two or three modules in a year.

| **Programme regulations (link to on-line version)** |
| http://www.ncl.ac.uk/regulations/programme |

| **13** | **Criteria for admission** |

Entry qualifications

A candidate may be entered for the certificate at the discretion of the Degree Programme Director and provided that such a candidate

(a) has sucessfully completed the final year of the Bachelor of Medicine and Bachelor of Surgery *or* Bachelor of Dental Surgery or equivalent; or

(b) has an appropriate degree or equivalent professional qualification in a profession allied to medicine with at least two years post-qualification experience; or

(c) has a minimum lower-second-class appropriate Honours degree

Admissions policy/selection tools

Applicants will apply directly via E2R for consideration of a place. Where appropriate, paramedical professionals will be invited to participate in a short informal interview process where eligibility for bursary support and the suitability of the course for their particular training needs will be considered by the DPD and the leader of the Research Governance and Ethics module (CMS8030; Dr Debbie Carrick – Sen).

Non-standard Entry Requirements: None

Additional Requirements: None

Level of English Language capability: overall IELTS score of 7.0, minimum 6.5 in each component.

| **14** | **Support for Student Learning** |

Induction
'As all of the students on this programme will be studying on a part-time basis with full-time professional responsibilities elsewhere, the usual University pattern of induction is not practical. Information is given in the Diploma Programme Handbook to introduce students to the sources of information/advice available. A brief induction talk will be held at the first session and students will also attend a library introduction session. Any students who need help or guidance with any aspect of becoming/being a postgraduate student are advised to contact the Programme Co-ordinator in the first instance.

Study skills support
Students will learn a range of Personal Transferable Skills, including Study Skills, as outlined in the Programme Specification. Some of this material, e.g. time management is covered in the appropriate Induction Programme. Students are explicitly tutored on their approach to both group and individual projects.

Academic support
The initial point of contact for a student is with a lecturer or module leader, or their tutor (see below) for more generic issues. Thereafter the Degree Programme Director or Head of School may be consulted. Issues relating to the programme may be raised at the Staff-Student Committee, and/or at the Board of Studies.

Pastoral support
All students are assigned a personal tutor whose responsibility is to monitor the academic performance and overall well-being of their tutees. In addition the University offers a range of support services, including the Student Advice Centre (http://www.unionsociety.co.uk/main/advice/studentadvicecentre , the Counselling and Wellbeing team (http://www.ncl.ac.uk/counselling-wellbeing/ , the Mature Student Support Officer, and a Childcare Support Officer, see http://www.ncl.ac.uk/support/welfare.phtml

Support for students with disabilities
The University's Disability Support Service provides help and advice for disabled students at the University - and those thinking of coming to Newcastle. It provides individuals with: advice about the University's facilities, services and the accessibility of campus; details about the technical support available; guidance in study skills and advice on financial support arrangements; a resources room with equipment and software to assist students in their studies. For further details see http://www.ncl.ac.uk/disability-support/

Learning resources
The University's main learning resources are provided by the Robinson and Walton Libraries (for books, journals, online resources), and Information Systems and Services, which supports campus-wide computing facilities, see http://www.ncl.ac.uk/undergraduate/support/acfacilities.phtml

The graduate school offers a student learning space with dedicated on-line computer facilities, a number of study rooms and social space for interaction with other postgraduate students.

All new students whose first language is not English are required to take an English Language Proficiency Test. This is administered by INTO Newcastle University Centre on behalf of Newcastle University. Where appropriate, in-sessional language training can be provided. The INTO Newcastle University Centre houses a range of resources which may be particularly appropriate for those interested in an Erasmus exchange. .

| 15 | Methods for evaluating and improving the quality and standards of teaching and learning |

Module reviews
All modules are subject to review by questionnaires which are considered by the Curriculum Committee and Board of Studies (Graduate School). Changes to, or the introduction of new, modules are considered at the Faculty Teaching and Learning Committee and at the Board of Studies. Student opinion is sought at the Staff-Student Committee and/or the Curriculum Committee. New modules and major changes to existing modules are subject to approval by the Faculty Teaching and Learning Committee.

Programme reviews
The Board of Studies (Graduate School) conducts an Annual Monitoring and Review of the degree programme and reports to Faculty Teaching and Learning Committee.

External Examiner reports
External Examiner reports are considered by the Curriculum Committee and Board of Studies (Graduate School). The Board responds to these reports through Faculty Teaching and Learning Committee. External Examiner reports are shared with institutional student representatives, through the Staff-Student Committee.

Student evaluations
All modules, and the degree programme, are subject to review by student questionnaires. Informal student evaluation is also obtained at the Staff-Student Committee and Curriculum Committee.

Mechanisms for gaining student feedback
Feedback is channelled via the Staff-Student Committee and the Board of Studies.

Faculty and University Review Mechanisms
The programme is subject to the University's Internal Subject Review process, see
http://www.ncl.ac.uk/aqss/qsh/internal_subject_review/index.php

Accreditation reports

Additional mechanisms

16	Regulation of assessment

Pass mark
The pass mark is 50%

Course requirements

Progression is subject to the University's Masters Degree Progress Regulations, Taught and Research (http://www.ncl.ac.uk/calendar/university.regs/tpmdepr.pdf) and Examination Conventions for Taught Masters Degrees
(http://www.ncl.ac.uk/calendar/university.regs/tpmdeprexamconv.pdf). Students who fail individual pieces of course work will be allowed to resubmit for a second assessmet on one occasion only. Alternatively students may opt to retake the whole module on one occasion only. Where students have failed modules or course work the maximum mark on reassessment is 50% (a pass). There is no restriction on progression to new modules whilst carrying failed modules however students will not be awarded the Certificate until they have successfully completed all three modules. Students will only be allowed two attempts at any module/piece of course work.

Common Marking Scheme

The University employs a common marking scheme, which is specified in the Taught Postgraduate Examination Conventions, namely:

Summary description applicable to postgraduate Masters programmes		Summary description applicable to postgraduate Certificate and Diploma programmes	
<50	Fail	<50	Fail
50-59	Pass	50 or above	Pass
60-69	Pass with Merit		
70 or above	Pass with Distinction		

Role of the External Examiner
An External Examiner, a distinguished member of the subject community, is appointed by Faculty Teaching and Learning Committee, after recommendation from the Board of Studies. The External Examiner is expected to:
    See and approve examination papers
    Moderate examination and coursework marking
    Attend the Board of Examiners

Report to the University on the standards of the programme

In addition, information relating to the programme is provided in:

The University Prospectus (see http://www.ncl.ac.uk/undergraduate/)

The School Brochure (contact enquiries@ncl.ac.uk)

The University Regulations (see http://www.ncl.ac.uk/calendar/university.regs/)

The Degree Programme Handbook

Please note. This specification provides a concise summary of the main features of the programme and of the learning outcomes that a typical student might reasonably be expected to achieve if she/he takes full advantage of the learning opportunities provided. The accuracy of the information contained is reviewed by the University and may be checked by the Quality Assurance Agency for Higher Education.

Mapping of Intended Learning Outcomes onto Curriculum/Modules

Either

Intended Learning Outcome	Module codes (Comp/Core in Bold)
A1	CMS8030
A2	CMS8030
A3	CMS8030
A4	CMS8030
A5	CMS8030
A6	CMS8031
A7	CMS8031
A8	CMS8031
A9	CMS8031
A10	CMS8031
A11	CMS8032
A12	CMS8032
A13	CMS8032
B1	CMS8030
B2	CMS8031
B3	CMS8031
B4	CMS8031
B5	CMS8032
B6	CMS8032
C1	CMS8030
C2	CMS8031
C3	CMS8031
C4	CMS8031
C5	CMS8031, CMS8032
C6	CMS8032
D1	CMS8030, CMS8032
D2	CMS8030, CMS8031, CMS8032
D3	CMS8031, CMS8032
D4	CMS8031

Or

Module	Type	Intended Learning Outcomes			
		A	B	C	D
CMS8030		1,2,3,4,5	1	1	1,2,
CMS8031		6,7,8,9,10	2,3,4,5	2,3,4	2,3,4
CMS8032		8,11,12,13,14	5,6	5,6	1,2,3