

<b>PROGRAMME SPECIFICATION</b>	 <b>Newcastle University</b>
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<b>1</b>	<b>Awarding Institution</b>	Newcastle University
<b>2</b>	<b>Teaching Institution</b>	Newcastle University
<b>3</b>	<b>Final Award</b>	Master of Clinical Research Postgraduate Diploma Postgraduate Certificate
<b>4</b>	<b>Programme Title</b>	See item 5
<b>5</b>	<b>Programme Code</b>	Master of Clinical Research 4853P Postgraduate Diploma in Clinical Research 3475P Postgraduate Certificate in Clinical Research 3107P CPD Clinical Research E-learning 6053P
<b>6</b>	<b>Programme Accreditation</b>	N/A
<b>7</b>	<b>QAA Subject Benchmark(s)</b>	N/A
<b>8</b>	<b>FHEQ Level</b>	7
<b>9</b>	<b>Last updated</b>	March 2024

<b>10</b>	<b>Programme Aims</b>
<p>The overarching aim of this suite of programmes is to develop and equip health care professionals with the skills, knowledge and attributes required to provide an understanding of clinical research.</p> <p>The suite of programmes will enable students to gain a strong theoretical as well as practical knowledge of clinical research that will help support their current or future professional as well as leadership roles. The programmes are UK based but globally aware, reflecting international collaborations and their requirements.</p>	

<b>11</b>	<b>Learning Outcomes</b>
<p>The number of learning outcomes achieved will depend on the programme taken (see annex 1)</p> <p>The programmes provide opportunities for students to develop and demonstrate knowledge and understanding, qualities, skills and other attributes in the following areas:</p>	
<b>Knowledge and Understanding</b>	
<p>On completing the programme students will be able to:</p> <p>A1. Appraise good practice principles in all aspects of clinical research;  A2. Recognise academic scholarship in their own work and when critiquing the work of others;  A3. Differentiate between different forms of clinical research in terms of fit-for-purpose design, appropriate methodological approaches, effective governance, sound ethical principles, effective time management and in the setting of priorities; and how these all contribute to effective clinical research delivery  A4. Evaluate their personal needs and identify opportunities in their chosen area of clinical research or chosen pathway (Postgraduate Diploma and Masters only)</p>	

**Teaching and Learning Methods**

The student has the opportunity to develop knowledge and understanding outcomes A1 to A4 through different forms of guided learning activities. All e-learning modules are delivered through the VLE.

A1 to A3 are addressed through a mixture of lectures, small group work with discussions, online or in-classroom exercises and augmented with independent study, directed by the provision of reading lists, resource materials, tutorials and mentor support. Knowledge and understanding are further developed through work-based assignments, such as those in MCR8010, MCR8013 and MCR8025.

A4 is addressed largely through independent, guided study and project work, including assignments that allow students to focus on areas of specific interest, particularly with the optional modules, the writing of a research proposal, and with the production of the dissertation. Students have an opportunity to select up to 40 credits of elective modules within their second year of study.

**Assessment Strategy**

A1-A3 are assessed formatively through various activities and tutorial discussions. Summative assessments are carried out via a variety of written and oral assignments, including essays, critical appraisal of published work, peer review of research proposals, reviewing regulations, procedures and ethical governance, production of documents and completion of forms required for study approval, the adoption of SOPs (standard operating procedures) as well as undertaking the procedures involved in gaining approval for the Masters project.

A4 is assessed formatively within module discussions and in personal reflective exercises. Summatively it is assessed through elements of assessments, including the dissertation module, where students contextualise topics to their own situations, specialities and needs.

**Intellectual Skills**

On completing the programme students will be able to:

B1. Critique and appraise all aspects of research designs, methodologies, methods and outcomes;

B2. Interpret and assimilate evidence to draw meaningful conclusions;

B3. Critically appraise their own and others' work in terms of academic standards and good practice;

B4. Critique research designs and study protocols to ensure the aims, design and management are fit for purpose & quality measures can be achieved.

**Teaching and Learning Methods**

All of these skills are developed through directed learning, formative assessment activities, and engagement with peers through discussion fora, reflections on practice and tutorial supported exercises. Students develop their intellectual skills by carrying out their work-based projects and gaining feedback from tutors.

B1-B4 The directed learning is designed to promote intellectual skills through discussion, critical appraisal and reflection of the student's own work/self and ideas as well as through drawing conclusions. Students are provided with preparatory activities and exercises to support the introduction of a topic and encouraged to develop their intellectual skills by incorporating feedback from formative and summative assessments to critically appraise their development and progress.

B4 is specifically addressed within MCR8013 – Designing a Research Proposal and in the dissertation module, both in the review of studies within existing literature but also of their own independent project. With each they receive formative feedback from supervisors and fellow students, and are expected to address the limitations of their work.

<b>Assessment Strategy</b>
<p>All skills are formatively assessed in teacher-led discussions and in tutorials. Summative assessments include a range of written assignments and oral presentations, including posters.</p> <p>B1-B4 are assessed via the outputs from completing established research procedures. The dissertation module is where all four intellectual skills, and in particular self-critique, are demonstrated within a body of work.</p>
<b>Practical Skills</b>
<p>On completing the programme students will be able to:</p> <p>C1. Peer-review specialty manuscripts and other research outputs such as grant applications, and study designs  C2. Design clinical research projects or trials that are underpinned by good research practices, effective governance and with justified ethical principles and theories;  C3. Obtain the necessary permissions and approvals for carrying out research (specific to Postgraduate Diploma and Masters);  C4. Collect, manage, analyse data using appropriate computer database(s) and statistical software and in compliance with relevant legislation;  C5. Translate research findings into clinical practice in the context of current research in their own fields (specific to the Postgraduate Diploma and Masters).</p>
<b>Teaching and Learning Methods</b>
<p>C1-C5 Practical skills are delivered throughout the programme but particularly in the Dissertation module where the student is able to develop and practise skills in a chosen area of clinical research.</p> <p>A number of practical skills may be enhanced within the workplace and supported by interactive online tutorials &amp; seminars, as well as feedback from assessments. The activities promote and enhance discussion, writing, critical appraisal, and presentation skills and occur in different formats at all stages of the programme.</p>
<b>Assessment Strategy</b>
<p>These skills are formatively assessed through tutor-set exercises and via group tutorials, many being integrated and becoming part of larger exercises (specifically, C1, C4 and C5).</p> <p>C1-C5 are summatively assessed within the dissertation module. However, all summative assessments have practical elements within them so each is being tested in some way within each module via written tasks and short oral presentations.</p> <p>All optional modules assess C1-C5 by asking students to produce written work and presentations that focus on elements of their specific area of interest.</p>
<b>Transferable/Key Skills</b>
<p>On completing the programme students will be able to:</p> <p>D1. Complete the various steps and documentation to gain access &amp; approval to data sources and to set up a research study.  D2. Present information or ideas in a variety of formats.  D3. Interpret and analyse data using appropriate resources.  D4. Make informed and defensible choices (Postgraduate Diploma and Masters only)  D5. Design, implement, adjust and manage projects in their own area of interest; (pg diploma and masters only)  D6: Set and manage timelines and identify priorities; (Postgraduate Diploma and Masters only)  D7. Critically evaluate and implement research findings. (Postgraduate Diploma and Masters only)</p>

**Teaching and Learning Methods**

The above skills are practised and developed across the modules by engaging in work-place and programme activities as well as working towards summative assessments and receiving feedback from formative assessments.

**Assessment Strategy**

D1-D7 These skills are formatively assessed in tutorials and online activities but also by formative assessments written specifically to aid the development of these skills. All skills should be evident in the dissertation module and, although these are not necessarily individually assessed, D5-D6 are specifically assessed in the dissertation. D1-4 and D7 are also indirectly assessed through the successful production of assessments.

**12 Programme Curriculum, Structure and Features****Basic structure of the programme**

Students wishing to study Clinical Research can gain an award at Masters, Postgraduate Diploma or Postgraduate Certificate level. The mode of delivery is by e-learning, except for one module offered as blended learning to students in the workplace. At the Postgraduate Certificate level awards there are two pathways, the *standard pathway* and the *research delivery pathway*. The standard pathway includes MCR8011 as a compulsory module and the Research delivery pathway includes MCR8032 as a compulsory module

**Masters**

The Clinical Research Masters programmes consist of a body of taught modules which comprise 80 credits of compulsory modules, 40 credits of optional modules, and a supervised project / dissertation worth 60 credits. To be awarded a Masters' degree, students must successfully complete 180 credits: taught modules account for 120 credits, while the dissertation accounts for 60 credits.

**Postgraduate Diploma**

The Clinical Research Postgraduate Diploma programmes consist of a body of taught modules which includes 80 credits of compulsory modules and 40 credits of optional modules. To be awarded a Postgraduate Diploma, students must successfully complete 120 credits of the taught programme of study.

**Postgraduate Certificate**

To be awarded a Postgraduate Certificate, students must successfully complete 60 credits of compulsory modules

**Programme regulations (link to on-line version)**

[R4853P, 3475P, 3107P, 6053P\\_2425\\_vFinal.pdf](#)

**13 Support for Student Learning**

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The Student Services portal provides links to key services and other information and is available at: <https://my.ncl.ac.uk/students/> as well as via the programme communities site of the Virtual Learning Environment (VLE)

*Induction*

As part of induction, students are introduced to the VLE. Important programme documents such as the programme handbook, contact details and general support information for students studying at a distance are also available on the communities' site on the VLE

New and continuing students are given detailed programme information and the online timetable of events.

### *Study skills support*

A range of study skills information, guidance and directed learning is offered by the University and students are signposted to these in the Programme Handbook and on the VLE.

Numeracy support is available through supervisory support and in-house online resources. Maths Aid and help with academic writing is available from the Writing Development Centre (further information is available from the University Library).

The library is available to support the needs of online students via email. Telephone support is also available and is signposted within each of the online modules.

### **Academic support**

The initial point of academic contact for a student is the Module Leader via the discussion forum on the programme's VLE, which is monitored closely by academic staff.

For dissertations, the student will have a University based advisor/supervisor who will support the student in the research processes, from project planning, through the research implementation to the conclusion of the project and production of the written dissertation documents. In addition, the student will be expected to identify a workplace supervisor. The student will maintain regular contact with a named supervisor in the workplace.

Most of the students will have a high level of workplace supervision. In this case the University based advisors/supervisor will in reality only need to ensure that the workplace supervision is timely and appropriate for a master's level of study, and also need to provide feedback on a draft of the written dissertation document.

In some cases, appropriate workplace supervision will not be available to the student. Here the University based advisors/supervisor will be required to take on a larger role to support the student in the research process, from project planning, through the research process to conclusion of the project and production of the written dissertation document

### **Pastoral support**

All students are assigned a personal tutor. Personal tutors provide guidance in relation to pastoral issues and would usually be the first point of contact for students for this form of support. Students are informed in the induction that they can contact Module Leaders, or the Degree Programme Director if preferred. The degree programme handbook provides further guidance for students, including what to do if they wish to discuss changing their personal tutor for any reason.

The University also offers a wide range of institutional services and support upon which students can call, such as the Writing Development Centre, Careers Service and Student Wellbeing Service. This includes one-to-one counselling and guidance or group sessions / workshops on a range of topics, such as emotional issues e.g. stress and anxiety, student finance and budgeting, disability matters etc. There is specialist support available for students with dyslexia and mental health issues. Furthermore, the Student Union operates a Student Advice Centre, which can provide advocacy and support to students on a range of topics including housing, debt, legal issues etc.

### *Support for students with disabilities*

The mode of delivery lends itself to supporting students with certain disabilities; all content is delivered online, and students never have to attend campus. The asynchronous activities allow students time to reflect and respond at their own pace.

The online delivery ensures a platform that does not contain barriers for users with disabilities.

In addition the University's Disability Support Service is able to provide advice for students with disabilities. It provides individuals with: advice about the University's facilities, services; details about the technical support available; guidance in study skills and advice on financial support arrangements. Access to the services of the University's Disability Support services, is signposted in the Programme Handbook. See <http://www.ncl.ac.uk/students/wellbeing/disability-support/>

### **Learning resources**

The main access to learning resources is via the programme's Learning Support Environment, which acts as a portal to all University online services including the library (online journals, e-books, online tutorials, help etc.).

Students will have electronic access to the Newcastle University Library and other Newcastle University services.

## **14 Methods for evaluating and improving the quality and standards of teaching and learning**

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### *Module reviews*

All modules are subject to review and considered by the Board of Studies. Changes to, or the introduction of new, modules are considered at the Board of Studies. Student opinion is sought at the Student-Staff Committee and/or the Board of Studies. The introduction of new modules and major changes to existing modules are subject to approval by the Faculty Education Committee (FEC).

### *Programme reviews*

The Board of Studies conducts an Annual Monitoring and Review of the degree programme and reports to FEC. The FEC takes an overview of all programmes within the Faculty and reports any Faculty or institutional issues to the Taught Programmes Sub-Committee.

### *External Examiner reports*

External Examiner reports are considered by the Board of Studies. External Examiner reports and the response to the External Examiner from the Board of Studies are shared with institutional student representatives, through the Student-Staff Committee.

### *Student evaluations*

All modules, and the degree programme, are subject to review. Informal student evaluation is also obtained at the Student-Staff Committee, and the Board of Studies. The Postgraduate Taught Experience Survey is sent out each year to eligible taught postgraduate students, and consists of a set of questions seeking students' views on the quality of the learning and teaching they have received. The results from all student surveys are considered as part of the Annual Monitoring and Review of the programme and any arising actions are captured at programme and School / institutional level and reported to the appropriate body.

### *Mechanisms for gaining student feedback*

Feedback is channelled via the Student-Staff Committee and discussed, via an online communication platform, at the Board of Studies.

### *Faculty and University Review Mechanisms*

Every six years degree programmes in each subject area undergo Learning and Teaching Review. This involves both the detailed consideration of a range of documentation, and a review visit by a review team (normally one day in duration) which includes an external subject specialist and a student representative. Following the review a report is produced, which forms the basis for a decision by University Education Committee on whether the programmes reviewed should be re-approved for a further six year period.

## 15 Regulation of assessment

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Please refer to the Postgraduate (Taught) Examination Conventions at <http://www.ncl.ac.uk/regulations/docs/>

### *Role of the External Examiner*

An External Examiner, a distinguished member of the subject community, is appointed by the University following recommendation from the Board of Studies. The External Examiner is required to:

- i. confirm whether the standards of the University's awards meet or exceed the academic standards specified in external reference points such as the Framework for Higher Education Qualifications, the UK Quality Code, subject benchmark statements, and, where appropriate, the requirements of professional, statutory and regulatory bodies;
- ii. confirm whether the academic standards of the University's awards are consistent with those of similar programmes in other UK higher education institutions;
- iii. report on whether the University's processes for assessment measure student achievement rigorously and fairly and are conducted in line with University policies and regulations; identify, where appropriate, examples of exemplary practice and innovation in learning, teaching and assessment; comment on opportunities to enhance the quality of the learning experience provided to students.

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

The University Prospectus: <http://www.ncl.ac.uk/postgraduate/courses/>

Degree Programme and University Regulations: <http://www.ncl.ac.uk/regulations/docs/>

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.

### Mapping of Intended Learning Outcomes onto Curriculum/Modules

#### PgCert (e-learning) *Standard pathway*

Module	Optional	Compulsory	Intended Learning Outcomes			
			A	B	C	D
MCR8009 – Research Integrity and Governance		√	1	1,3,4	2,3	1
MCR8010 – Doing Clinical Research Wellfor		√	1,3	1,2,4	12,4	2,3
MCR8011 – Writing in a Research Setting		√	1,2	3	1	1,2

#### PgCert (e-learning) *Research Delivery pathway*

Module	Optional	Compulsory	Intended Learning Outcomes			
			A	B	C	D
MCR8009 – Research Integrity and Governance		√	1	1,3,4	2,3	1
MCR8010 – Doing Clinical Research Well		√	1,3	1,2,4	12,4	2,3
MCR8032- Clinical Research Delivery in Practice		√	1,2,3	4	1,3,4	1,2,

#### PgDip (e-learning), in addition to modules from one of the above PgCert pathways:

Module	Optional	Compulsory	Intended Learning Outcomes			
			A	B	C	D
MCR8013 – Designing a Research Proposal		√	12,3,4	1-4	1,2,3	1,3,7
MCR8015 – Clinical Trials	√		1,3,4	1-4	2,3,5	1,2,4,5,6
MCR8019 – Clinical Research Statistics	√		1,3,4	1,3,4	1,2,4,5	1,3,5,6,7
MCR8033 Qualitative Research	√		1,2,3	1,2	1,4	1,2,3,4
MCR8036 – Clinical Research with older people	√		1,3	3,4	1,5	1,2,7

#### Masters (e-learning) In addition to modules from one of the PgCert pathways and relevant PgDiploma modules above:

Module	Optional	Compulsory	Intended Learning Outcomes			
			A	B	C	D
MCR8025 – Clinical Research Dissertation		√	1-4	1-4	1-5	1-7