PROGRAMME SPECIFICATION		

1	**Awarding Institution**	Newcastle University
2	**Teaching Institution**	Newcastle University
3	**Final Award**	Master of Clinical Research Postgraduate Diploma Postgraduate Certificate
4	**Programme Title**	See item 5
5	**Programme Code**	Master of Clinical Research 4853P Master of Clinical Research (1 yr Accelerated) 4855P* Master of Clinical Research (Ageing) 5844P* Master of Clinical Research (Ageing) (1 yr Accelerated) 5848P* Postgraduate Diploma in Clinical Research 3475P Postgraduate Diploma in Clinical Research (Ageing) 3446P* Postgraduate Diploma in Clinical Research (1 yr Accelerated) 3477P Postgraduate Diploma in Clinical Research (Ageing) (1 yr Accelerated) 3452P* Postgraduate Certificate in Clinical Research 3107P CPD Clinical Research E-learning 6053P *These programmes have been suspended for 2021/22 entry.
6	**Programme Accreditation**	N/A
7	**QAA Subject Benchmark(s)**	N/A
8	**FHEQ Level**	7
9	**Last updated**	July 2021

10	**Programme Aims**

To provide health care professionals within the healthcare provider setting, ancillary services and industry with an understanding of the processes involved in preparing for, planning, conducting, analysing and reporting 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. This programme enables students to gain a strong, practical knowledge of clinical research to support their current or future professional roles, giving the option of pursuing a pathway in Ageing.

11	**Learning Outcomes**

The programmes provide 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 will be able to:

A1. Demonstrate an advanced knowledge of current local, national and international (where appropriate) legal, governance and ethical issues relating to different forms of clinical research and the procedures for obtaining permissions and approval for clinical research.

A2. Demonstrate a systematic understanding of the need for good practice in clinical research and the basic principles of data handling and management of clinical databases.

A3. Source guidelines for production of manuscripts for publication in peer-reviewed journals and grant applications and understand the issues of authorship, copyright ownership and plagiarism as they apply to their own work and the work of others.

A4. Obtain the necessary approvals to develop and carry out their own research project in the context of effective governance, ethical principles and in line with good practice including time management and setting priorities within a project to ensure that the aims of a project are met (specific to Postgraduate Diploma and Masters).

A5. Be able to make an informed choice of research project based on their own career aspirations and be able to defend this choice (specific to Postgraduate Diploma and Masters).

A6. Have gained knowledge of how research programmes are designed, implemented, adjusted, managed; gained knowledge of the various outcomes from research programmes and the different methods by which they are prepared and presented to research community.

A7. Have a systematic understanding of the basic concepts, confounding factors, future direction and opportunity in their chosen area of clinical research or chosen pathway of Ageing.

Teaching and Learning Methods

Modules are delivered via e-learning.

All e-learning modules are delivered through the VLE. The student has the opportunity to develop knowledge and understanding outcomes A1 to A7 through guided learning activities.

All modules employ structured feedback from both formative and summative assessment and opportunities for discussion and debate to ensure that the student achieves all learning outcomes. For all modules, preparatory activities are provided to support the planned learning activities – these include reading material and exercises to complete. An online statistics package is included to support the statistical modules.

The Clinical Research dissertation allows further development of knowledge and understanding outcomes A1 to A7 and how these outcomes are applied to support a research project; this should be relevant, where appropriate, to the chosen pathway. The attainment of knowledge and understanding learning outcomes and their application within the dissertation is supported by self-directed learning and guidance from the dissertation mentor / module lead.

Assessment Strategy

Postgraduate Certificate

There is a combination of real-life research application processes based on current research ethics approval as a summative assessment. The ability to correctly identify the prerequisites within the current forms will demonstrate the student's knowledge and understanding of regulations, procedures and ethical governance. Further assessment includes a critical appraisal, a short oral presentation and development and submission of a questionnaire data-coding framework. Completing a SOP (standard operating procedure), a lay summary, a grant application, and a presentation (using Panopto software) on their own research idea, provides the students with the opportunity to practise different forms of medical writing and assesses their knowledge and understanding (A1, A2, A3, A6 and A7).

Postgraduate Diploma
Compulsory:

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The student practises the formulation of a research proposal and completes the necessary approvals paperwork for a Masters level project. A number of different application forms and information sheets are prepared (participant information sheet, integrated research application system forms, consent form and NHS permissions approval form). Students undertake a presentation and defence of the proposal using Panopto software. These assessments address learning outcomes A1, A2 and A4 – A7.

Optional:
Other examples (to meet the same learning outcomes), depending on module choices include:
-written work that focuses on the legal aspects of research and the scientific principles that underpin clinical research
-presenting their own research ideas
-producing a structured review of a funding proposal for a clinical trial
-written assessments that require self-reflection, self-development and critical incident review
-critique of research abstracts and a short MCQ
-a reflective blog

Masters
Students complete a research project. The project assesses the use of conventional scientific formats including: preparation of a lay summary, a poster, a short presentation and a 3,500 word dissertation. This tests a variety of key skills. The knowledge outcomes assessed include A1 – A7. If an Ageing pathway is chosen then the dissertation project should include some specific reference to the pathway topic.

Intellectual Skills

On completing the programme students will be able to:

B1. Discuss and identify good practice based on the application of appropriate ethical principles and theories in clinical research
B2. Differentiate between qualitative and quantitative research methods and outcome measures related to their own area of research or Ageing, should the pathway be chosen.
B3. Discuss the application of different study designs in clinical research
B4. Set priorities within a project to ensure that the aims of a project are met including the appropriate means of data handling, management of a clinical database and select an appropriate statistical package for data analysis
B5. Interpret data from clinical research projects in their own speciality
B6. Discuss issues of peer-review, critical appraisal, and the detection and avoidance of plagiarism in their own work and that of others
B7. Discuss and understand current issues relating to governance in different forms of clinical research, especially those relevant to their own chosen project and be able to prepare documents to meet the requirements of local, national and international (where appropriate) regulations and processes for obtaining permissions and approval for clinical research
B8. Discuss critically various outcomes from research programmes and the different methods by which they are prepared and presented to the research community within their chosen field including Ageing if appropriate to pathway

Teaching and Learning Methods

Modules are delivered by e-learning mode. A variety of different teaching and learning methods are used across these programmes.

Students undertaking e-learning modules are able to test and develop their intellectual skills by directed learning, formative assessment activities and engagement with peer students through discussion boards, email and Wikis. The directed learning is designed to deliver knowledge and understanding and promote intellectual skills through discussion, critical appraisal and reflection of the student's own work/self and ideas.

Students are provided with preparatory activities and exercises to support the introduction of each topic. This gives the students a chance to test their knowledge and relevant intellectual skills before delivery of the teaching materials.

Students are encouraged to develop their intellectual skills by incorporating feedback from formative and summative assessments to critically appraise their development and progress.

Masters students concentrate on an independent student research project and the production of a subsequent dissertation. This stage will largely consist of self-directed learning. Students are able to access online material with information and exercises to complete and have the opportunity to receive formative assessment from the Dissertation Supervisor and/or clinical academic supervisor.

Assessment Strategy

Postgraduate Certificate

Students will write a number of research applications based on current ethical committee approval and NHS permission approval forms. Further assessment includes development of a questionnaire coding framework, a short oral presentation and a critical appraisal. The written assessment tests the students' ability to differentiate and discuss modes of clinical research, the different components of a research project and the differences between qualitative and quantitative research methodologies. Completing a SOP (standard operating procedure), an abstract, a grant application and a presentation on their own research idea provides the students with the opportunity to complete the intellectual skills outcomes: B1-B5, B7-B8.

Postgraduate Diploma

Compulsory:
The student formulates a research proposal and completes the necessary approvals paperwork for the execution of an ethically and scientifically robust project within the scope of a Master's degree. A number of different application forms and information sheets will be prepared. The students also give a presentation, defending a proposal at a project review panel. This is undertaken by conference call for the e-learning module. These assessments will address intellectual outcomes B2, B4, B6 and B7.

Optional:
Students produce written work that focuses on the legal aspects of research and the scientific principles that underpin clinical research. Other examples, to meet the same learning outcomes, depending on module choices include:
-presenting their own research ideas;
-producing a structured review of a funding proposal for a clinical trial;
-written assessments that require self-reflection, self-development and critical incident review;
-critique of research abstracts and a short MCQ;
-a reflective blog.

This will meet the student's intellectual outcomes B1-B8.

Masters

The project will be assessed using a range of conventional scientific formats including: preparation of a lay summary, a poster, a short presentation and a short (3,500 word) dissertation. This will test a variety of key skills. If an Ageing pathway is chosen then the dissertation should reflect an interest in this area. The intellectual outcomes assessed include B1 – B8.

Practical Skills

On completing the programme students will 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,

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national and international (where appropriate) legislation and guidelines (including clinical trials)
C2. Design a clinical research project or trial in the context of good practice, effective governance and appropriate ethical principles and theories
C3. Collect, store and analyse data from clinical research projects using appropriate computer database(s) and appropriate statistical software
C4. Peer-review manuscripts in their own area of speciality or chosen pathway (Ageing).
C5. Write appropriate grant applications and manuscripts for submission to either funding bodies (grants) or peer-reviewed journals as appropriate.
C6. Obtain the necessary approvals for carrying out their own research project (specific to Postgraduate Diploma and Masters)
C7. Translate research findings into clinical practice in the context of current research in their own field, chosen pathway (Ageing) and within U.K. boundaries (specific to Postgraduate Diploma and Masters)

Teaching and Learning Methods

Practical skills are delivered throughout the programme but especially in the Dissertation modules where the student is able to develop and practise skills in a chosen area of clinical research or chosen pathway of Ageing (C1-C7).

A number of practical skills are also developed in the workplace and supported by interactive online tutorials & seminars, as well as feedback from assessments (C1-C7). The activities promote and enhance discussion, writing and presentation skills and occurs in different formats at all stages of the programme (C1-C7).

Assessment Strategy

Postgraduate Certificate
Students develop, write and submit a number of research applications based on current ethical committee approval requirements. This module addresses the practical skills C2 by undertaking tasks relating to study design, including handling and analysing of data appropriate to different research methodologies and the identification of the correct statistical methods. The students are assessed by written tasks and short oral presentations using Panopto. The practical outcomes assessed include C1-C5.

Postgraduate Diploma
Compulsory:
The students formulate a research proposal, completing the necessary approvals paperwork for the execution of a project at Masters level. Practical skills are assessed by the trialling of a number of different application forms and the production of a number of different information sheets, as well as the presentation of the project and the defence of the proposal to a project review panel C1, C2, C5 and C6.

Optional:
The practical skills assessed within the optional modules cover C1-C7. These include: -
producing written work that focus on the legal aspects of research and the scientific principles that underpin clinical research
-presenting their own research ideas
-producing a structured review of a funding proposal for a clinical trial
-identifying and reviewing different means of measuring clinical trials outcomes
-critically appraising a selection of research abstracts and a short MCQ
-submission of presentation slides
-completing a reflective blog

Masters
The project assesses the use of a range of conventional scientific formats including: preparation of a lay summary, a poster, a short presentation and a short dissertation. If an Ageing pathway is chosen then the dissertation should reflect an interest in this. This project tests a wide range of skills though the assessments focus on C1 to C7.

Transferable/Key Skills

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On completing the programme students will be able to:

D1. Critically appraise and evaluate: grant applications, research papers, and applications for ethical approval related to clinical research, and proposals for clinical trials
D2. Present information or ideas in a variety of formats including from their own and published clinical research. The formats include: a lay summary, poster or short thesis or as an oral presentation to an audience of their peer.
D3. Interpret and analyse published data using appropriate resource.
D4. Make an informed choice of research project based on their own career aspirations and be able to defend this choice (specific to Postgraduate Diploma and Masters)
D5. Design, implement, adjust and manage a research project in their own area of interest or chosen pathway of Ageing; manage their own time and set priorities within a project to ensure that the aims of a project are met (specific to Postgraduate Diploma and Masters)
D6.Critically evaluate and implement their own research findings and those of others (specific to Postgraduate Diploma and Masters)

Teaching and Learning Methods

The above skills are practised and developed across the modules.

Assessment Strategy

Postgraduate Certificate
The student writes a number of research applications based on current ethical committee approval. The ability to source and critically appraise these forms, and evaluate appropriate information, demonstrates the transferable skills. The student uses written assignments and oral presentation to demonstrate their ability to present information and to interpret and analyse information. This module enables the students to demonstrate a range of transferable skills including written presentation, interpretation and analysis of information-transferable skills outcomes D1-D3.

Postgraduate Diploma
Compulsory:
Students formulate a research proposal and obtaining the necessary approvals for the execution of an ethically and scientifically robust project at Masters level. By trialling a number of different application forms and producing a number of different information sheets, as well as presenting their project and defending the proposal to a project review panel. Transferable skills outcome D1, D3 and D6 are addressed.

Optional:
Assessment of transferable skills include:
-pieces of written work;
-presenting their own research;
-producing a structured review of a funding proposal for a clinical trial;
-requires the student to integrate their learning across this module and draw on learning from other modules;
-critical appraisal of a series of research abstracts;
-a reflective blog;
-identify and review different means of measuring clinical trials outcomes

The transferable skills developed and assessed in this module are D1-D5.

Masters
The project assesses a range of conventional scientific formats including: preparation of a lay summary, a poster, a short presentation and a short dissertation, addressing transferable skills D1- D6. If an Ageing pathway is chosen then the dissertation should reflect an interest in this.

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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 and Postgraduate Certificate level.

Students wishing to study Clinical Research (Ageing) can gain an award at Masters or Postgraduate Diploma level.

The Clinical Research Masters programmes consist of a body of taught modules which includes 80 credits of compulsory modules, 40 credits of optional modules, and a supervised project / dissertation worth 60 credits. The Clinical Research (Ageing) Masters programmes consist of a body of taught modules which includes 100 credits of compulsory modules, 20 credits of optional modules, and a supervised project and 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.

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. The Clinical Research (Ageing) Postgraduate Diploma programmes consist of a body of taught modules which includes 100 credits of compulsory modules and 20 credits of optional modules. To be awarded a Postgraduate Diploma, students must successfully complete 120 credits of the taught programme of study.

To be awarded a Postgraduate Certificate, students must successfully complete 60 credits of compulsory modules from the taught programme of study.

All programmes are available in part-time mode.

The normal period of study for the part-time Masters is 3 years. However, the period of study will vary depending on the selected route.

With permission of the Degree Programme Director, students can also choose to follow an accelerated programme and must successfully complete 120 credits over 1 year. Students are also able to study modules on a continuing professional development (CPD) basis.

Key features of the programme (including what makes the programme distinctive)

The key feature of this programme is it is delivered completely online. This means that the students can study at a time of their convenience and removes the need to visit the campus. This makes the programmes suitable for busy health professionals but also for a global market.

Programme regulations (link to on-line version)

https://teaching.ncl.ac.uk/docs/regsdocs2021/documents/-R4853P_3107P_vFinal.pdf

13	Support for Student Learning

*The link below contains information within Section 13 relating to Placements and is not relevant to this suite of programmes.

https://www.ncl.ac.uk/ltds/assets/documents/qsh_progspec_generic_info.pdf

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

https://www.ncl.ac.uk/ltds/assets/documents/qsh_progspec_generic_info.pdf

15   Regulation of assessment

*The link below contains information within Section 15 relating to Placements and is not relevant to this suite of programmes.

https://www.ncl.ac.uk/ltds/assets/documents/qsh_progspec_generic_info.pdf

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.

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