Programme Title: Clinical Research

Programme Specification

Awarding Body/Institution: Queen Mary, University of London
Teaching Institution: Queen Mary, University of London

Name of Final Award and Programme Title: PG Cert, PG Dip, MRes in Clinical Research
Duration of Study / Period of Registration: 1-2, 2, 2 yrs respectively

QM Programme Code / UCAS Code(s): A3U6/7/8 or A3V6/7/8

QAA Benchmark Group:

FHEQ Level of Award: Level 7

Programme Accredited by:

Date Programme Specification Approved: 2 Sep 2013

Responsible School / Institute: Barts and The London School of Medicine and Dentistry

Schools also involved in teaching part of the programme:

- William Harvey Research Institute
- Barts and The London School of Medicine and Dentistry

Programme Rationale

Clinically qualified individuals in medicine and dentistry who wish to pursue a career in academic research will generally apply for positions as Academic Clinical Fellows (ACFs). The NHS National Institute for Health Research (NIHR) provides funding for a number of such positions, awarded to institutions competitively, that permit the individuals employed to continue acquiring the clinical experience required to achieve Consultant status but with dedicated time allocated for academic research training over a three year period. The expectation is that during this period the ACFs will apply for a research training fellowship that will enable them to complete a higher degree (doctorate). NIHR funding to the University requires that a credit-bearing training programme be offered, allowing fellows to "obtain (or work towards) a higher qualification". Currently training is provided, but outside a credit-bearing framework.

It is a strategic and financial requirement for QMUL to offer a credit-bearing clinical research programme in order to continue receiving NIHR ACF funding.

The proposed programme includes a 60-credit section (4x 15-credit modules) leading to PG Certificate in Clinical Research, or forming Part 1 (compulsory) of a PG Diploma or MRes in Clinical Research. This section covers the key generic skills and knowledge to prepare students wishing to undertake clinical research. Students will be able to take modules covering topics such as ethics, epidemiology and statistics, and clinical study design from the existing MSc in Healthcare Research run at the William Harvey Institute and the programmes in international public health run at the Blizard Institute; acceptance on shared modules will be subject to approval by the module organiser. An additional option is a module in Communication and Public Engagement designed specifically for this course. It is envisaged that in the future a wider range of optional modules from existing Masters courses may be incorporated. Students may register initially for PG Certificate, with the option to transfer...
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registration to PG Diploma or MRes in year 2.

Part 2 of the programme comprises 3 optional 60-credit modules; successful completion of one or two further modules would lead to award of PG Diploma or MRes respectively. All three modules require students to critically review a research field and prepare dissertations requiring insight and novel interpretation of material, and are designed to provide preparation for a future career in research (or career requiring generic research skills). Training will be provided directly or indirectly by the ACF supervisor supported by the programme and module organisers.

Student numbers
Between 5 and 10 students per year are recruited as NIHR ACFs, and similar numbers undertake academic clinical fellowships with other sources of funding. All ACFs will be strongly encouraged to enrol for the PGCert. Completion of additional modules will assist students in the expected outcome of ACF training (to gain future funding for a doctoral programme), so it is judged that many of the students will enrol for the complete programme. NIHR and other Clinical Lecturers who have not previously had formal clinical research training may also find the PG Certificate useful and would be eligible to enrol (up to ca. 10 per year).

The ability to attract NIHR-funded ACFs is a major benefit to QMUL as a research-led university and to the joint role of SMD and Barts Health Trust in training future clinical academics. This programme utilises existing modules where possible and formalises training that was already in place, so that additional costs in providing a credit-bearing course are kept to a minimum.

Educational Aims of the Programme
This programme aims to
- prepare students for a career in academic clinical research
- provide formal training in the regulatory and ethical framework for clinical research
- provide key skills in research design, statistical analysis, critical review
- make students aware of the need to engage with public and patients, and communicate effectively with different audiences
- equip students to undertake independent research, including critical thinking and consideration of research impact
- meet the requirement of the NIHR and other funders to provide academic clinical fellows with relevant training in research methodology

Learning Outcomes
The programme provides opportunities for students to develop and demonstrate knowledge and understanding, skills and other attributes in the following areas. The programme outcomes are referenced to the relevant QAA benchmark statement(s) (see above) and the Framework for Higher Education Qualifications in England, Wales and Northern Ireland (2008), and relate to the typical student. Additionally, the SEEC Credit Level Descriptors for Further and Higher Education 2003 and Queen Mary Statement of Graduate Attributes have been used as a guiding framework for curriculum design.

<table>
<thead>
<tr>
<th>Knowledge and understanding of:</th>
<th>A1</th>
<th>A2</th>
<th>A3</th>
<th>A4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understand the regulatory and ethics framework for</td>
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<tr>
<td>clinical research</td>
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<tr>
<td>Understand the basis of clinical study design and</td>
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<tr>
<td>key concepts for statistical analysis</td>
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<tr>
<td>Understand the importance of effective communication</td>
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<tr>
<td>of research both orally and in writing</td>
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<tr>
<td>Develop a detailed knowledge of current research in</td>
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<tr>
<td>an area of clinical importance</td>
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</table>
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Intellectual skills - able to:

B1 Critically analyse research data and formulate a justified conclusion
B2 Critically analyse published work and assess its contribution to the field of study
B3 Apply knowledge of a research area, and available research techniques, to formulate novel research questions
B4 Engage effectively with people from different backgrounds to explain scientific and medical concepts in an appropriate way

Transferable skills - able to:

C1 Demonstrate the motivation and interest in continued independent learning
C2 Act autonomously in seeking out relevant information to complete a complex task
C3 Analyse complex information from a variety of sources, and justify the conclusions deduced
C4 Develop novel ideas based on a deep understanding of a problem

Practical skills - able to:

D1 Effectively utilise a wide variety of sources to gather information on a topic
D2 Select appropriate methodology for solving complex problems
D3 Prepare written documents and deliver oral presentations to a high standard of professionalism, complying with any specified requirements

Teaching, Learning and Assessment Strategies

Teaching for 15-credit “taught” modules is delivered mainly through lectures, workshops and problem-based learning. Modules are delivered jointly with existing masters programmes in Healthcare Research Methods and international public health. Students on these courses are from diverse backgrounds and form a peer group that should be advantageous for student development. One module is developed for this course, but is likely to be shared with future programmes; in this module there will be presentation workshops with video play-back. Some of the teaching material will be delivered on-line allowing students to complete tasks in their own time. The three optional research/dissertation modules will mainly require self-directed learning under supervision of the student’s personal supervisor and with oversight of the module organiser. Academic Clinical Fellows are placed in active research groups as part of their employment and should benefit from regular interaction within their groups. Assessment is based mainly on coursework through a range of written tasks and an oral presentation in one module. This is commensurate with the requirements for pursuing a career in clinical or scientific research.

Programme Structure(s) and Requirements, Levels and Modules

All students will be Academic Clinical Fellows or equivalent, employed in the School of Medicine and Dentistry or associated NHS Trusts for 3 calendar years. A proportion of their time (typically 25%) is assigned for academic study, but the organisation of
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Academic time varies widely and may be interspersed days or extended blocks. The programme structure is designed to maximise flexibility. To allow for different dates of employment, students may commence programmes in September or January. In all cases students must have adequate time remaining on their fellowship contract to complete the required modules at the time of entry into their final year of study.

PG Certificate
This requires completion of four 15-credit modules from a selection available within the School, principally shared with masters programmes offered by the William Harvey Institute and the Centre for Primary Care and Public Health in the Blizard Institute. All students are normally required to take one module covering statistical skills and one module covering ethics. Further modules will be selected based on previous experience and training requirements. Availability of individual modules will be confirmed in each academic year and acceptance of students on a module will be subject to approval of the module organiser.

PG Diploma
This requires completion of the four 15-credit modules required for PG Certificate, plus one 60-credit research module. Students may register directly for PG Diploma or register in year 1 for PG Certificate, then transfer to PG diploma after one year. Transfer is subject to having taken at least two of the modules required for PG Certificate (PG Certificate must not have been awarded).
Students registering directly for PG Diploma take either three 15-credit modules in year 1 and one 15-credit plus one 60-credit module in year 2 or four 15-credit modules in year 1 and one 60-credit module in year 2.
Students transferring from PG Certificate take all remaining modules in year 2.

MRes
This requires completion of four 15-credit modules as required for PG Certificate, plus two 60-credit research modules. Students may register directly for MRes or register in year 1 for PG Certificate or PG Diploma and transfer to MRes in year 2. Transfer is subject to having taken at least three of the modules required for PG Certificate (PG Certificate must not have been awarded).
Students registering directly for MRes take either three or four modules in year 1, including at least two 15-credit modules and no more than one 60-credit module. All remaining modules are completed in year 2.
Students transferring from PG Certificate or PG Diploma take all remaining modules in year 2.

[The structure is illustrated in excel file "Clinical Research Programme attachment on routes to qualification"]

<table>
<thead>
<tr>
<th>Module Title</th>
<th>Module Code</th>
<th>Credits</th>
<th>Level</th>
<th>Module Selection Status</th>
<th>Academic Year of Study</th>
<th>Semester</th>
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<tbody>
<tr>
<td>Clinical study design</td>
<td>WHRM903</td>
<td>15</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
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<tr>
<td>Ethics and regulation in clinical research</td>
<td>WHRM905</td>
<td>15</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
<td></td>
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<tr>
<td>Data management, statistics and pharmacokinetics</td>
<td>WHRM906</td>
<td>15</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
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<tr>
<td>Communication and public engagement</td>
<td>ICM7070</td>
<td>15</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semesters 1-3</td>
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<tr>
<td>Practical aspects of clinical research and early drug development</td>
<td>WHRM904</td>
<td>15</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semesters 1-2</td>
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<tr>
<td>Research from the literature</td>
<td>ICM7072</td>
<td>60</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semesters 1-3</td>
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<tr>
<td>Practical research project</td>
<td>ICM7071</td>
<td>60</td>
<td>7</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semesters 1-3</td>
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</table>
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<table>
<thead>
<tr>
<th>Course Title</th>
<th>Code</th>
<th>Credits</th>
<th>Elective</th>
<th>Duration</th>
<th>Semester(s)</th>
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<tbody>
<tr>
<td>The Grant Proposal</td>
<td>ICM7073</td>
<td>60</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semesters 1-3</td>
</tr>
<tr>
<td>Epidemiology and statistics</td>
<td>ICM7100</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 1</td>
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<tr>
<td>Health, illness and society</td>
<td>ICM7101</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 1</td>
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<tr>
<td>Health inequalities and social determinants of health</td>
<td>ICM7102</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 1</td>
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<tr>
<td>Health systems, economics and policy</td>
<td>ICM7103</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 1</td>
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<tr>
<td>Patients, quality and safety</td>
<td>ICM7107</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 2</td>
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<tr>
<td>Globalisation and contemporary medical ethics</td>
<td>ICM7108</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 2</td>
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<tr>
<td>Human rights and public health</td>
<td>ICM7111</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 2</td>
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<tr>
<td>Intellectual property, medicine and health</td>
<td>ICM7112</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 2</td>
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<tr>
<td>Primary health care - theory and practice</td>
<td>ICM7115</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 2</td>
</tr>
<tr>
<td>Public health, international law and governance</td>
<td>ICM7118</td>
<td>15</td>
<td>Elective</td>
<td>1 or 2</td>
<td>Semester 2</td>
</tr>
</tbody>
</table>

**Criteria for Admission to the Programme**

MBBS or BDS (or equivalent) plus employment as Academic Clinical Fellow or Clinical Lecturer at QMUL or associated NHS Trusts. Individuals with non-clinical qualifications and employment at QMUL or associated NHS Trusts will be considered on a case-by-case basis (for example senior clinical scientists).

**Quality Assurance Mechanism**

Include details of: SSLC meetings, student feedback mechanisms, personal tutor arrangements, programme induction, programme review and monitoring.

An MRes Studies Committee is being established to include Lucinda Hall (Programme Organiser), Joy Hinson (Head of Postgraduate Courses in SMD, Edel O’Toole (Academic Clinical Fellow Coordinator), and representatives of other programmes sharing modules.

The programme will be reviewed on an annual basis, to consider and comment on:
- the quality of the learning opportunities being provided
- the academics standards set and their achievement by students
- the extent to which learning outcomes are being attained by students
- the need to modify modules or programme approvals, including the effect of small changes over time
- progress on actions determined at the previous annual meeting
- the impact of changes in internal practice or strategies
- compliance with recommendations of external bodies, specifically NIHR
A student representative will be invited to annual review meetings.

Student feedback:
Informal feedback from students will be sought throughout the course, both in discussion, and via the message-board system or via the student representative. More detailed formal feedback about course structure will be sought at the end of the year.
• Feedback will be sought about a number of areas including:
  i. course content
  ii. course delivery
  iii. technical aspects of accessing the learning experiences
  iv. quality of associated materials
  v. The relevance to the career aspirations of students
• This feedback will be used to make alterations to the course for the following year.

Induction
• At the start of the course all students will receive a course handbook including information about the taught course, how to use the electronic classroom and advice on independent learning.
• Mechanisms for student support (academic, administrative and pastoral) will be detailed in the course handbook and online.

Personal Tutor arrangements
• each student will be assigned a personal tutor for academic support, separate from the student’s academic supervisor.

Programme-specific Assessment Regulations (if applicable)
In the case of programmes that deviate / do not comply with the Academic Regulations further information regarding the nature of any difference and/or deviation should be stipulated in detail.

Employers Links
Please provide details of any links with employers e.g.

• Details of advisory panels that include current or potential employers;
• Organisations that regularly employ graduates from this programme and the roles that graduates undertake.
• Student prizes donated by organisations that may offer employment to graduates from this programme.

If there are no links with employers consider the learning outcomes and transferable skills and explain how these might be used to inform employers about the qualities and skills a graduate from this programme might be expected to have.

Most students will be on Academic Clinical Fellowships funded by NIHR. Allocation of places and funding is routed through Postgraduate Deaneries (responsibly for NHS postgraduate clinical training).
The expectation is that ACFs will apply for substantive funding to support a PhD placement following their fellowship period. Ultimately the majority of ACFs will be employed by the NHS or Universities.
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<table>
<thead>
<tr>
<th><strong>Programme Specification Approval</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Person completing Programme Specification</strong></td>
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<tr>
<td><strong>Person responsible for management of programme</strong></td>
</tr>
<tr>
<td><strong>Date Programme Specification produced/amended by School or teaching and learning committee</strong></td>
</tr>
<tr>
<td><strong>Date Programme Specification approved by Programme and Module approval Board</strong></td>
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</tbody>
</table>