Imperial College
Academic Health
Science Centre
Improving Patient Care

Clinical Research Training Framework

2019

Approved by Imperial College Academic Health Science Centre

Aim of the Clinical Research Training Framework

To define the skills that a clinician of any professional background requires in order to support clinical research as an active participant (principal investigator, co-applicant, collaborator, recruiter)

Completion of this Framework will lead to an award of a Certificate of Completion of the Clinical Research Training Framework by Imperial College AHSC *(for AHSC employed staff only).*

Introduction

The Imperial College Academic Health Science Centre (AHSC) clinical research training framework has been developed to support clinical staff in the partner organisations develop a detailed understanding of research, and research skills, to allow them to become more directly involved in the mission of the AHSC: to accelerate the translation of research discoveries into improvements in human health. The framework will allow and facilitate staff to support NIHR and industry trials, or develop their own clinical-academic careers. It will tap into the extensive opportunities offered by the AHSC across Imperial College Healthcare NHS Trust, Royal Brompton and Harefield NHS Foundation Trust and The Royal Marsden NHS Foundation Trust and Imperial College London, and will offer certification of skills obtained when completing this framework.

This will increase clinical research knowledge and participation of staff in clinical research, foster core research skills and encourage NHS relevant practice, changing collaborative research. Research skills also enhance patient care more widely, and staff trained with research skills can better support patients, our NHS Trusts and their clinical departments.

It is intended that the framework can be completed by staff of any clinical professional background who have an interest in research training any time during their specialty training programme or postgraduate career. Completion will signify that the individual has extensive core skills and knowledge of clinical research, which would be of use both in supporting clinical research but also enhancing care provided within the NHS. It cannot count as credit towards a formal university course, however, completion of the Framework can be used by staff for appraisal, performance review and personal development.

Overall it is likely to take 1-2 years to complete all aspects of the framework, and it is expected that a certificate would only be awarded after 2 years since we would want evidence of progress through the framework over this period.

The ability to undertake and complete the modules should be agreed between the individual and their educational or clinical supervisor or line manager.

It is not mandated that original research ideas are implemented and executed during completion of the framework. Rather, that participants acquire professional skills, attitudes, and knowledge that enable them to participate in clinical research including developing protocols for research studies, obtaining relevant permissions, research governance, or being a local Investigator for a multi-centre research project.

Learning outcomes:

- Understanding of clinical research methods
- Competence to participate as an Investigator in research studies
- Good Clinical Practice research certification
- Competence to undertake critical review of research topics/ideas
- Understanding of statistics or qualitative methods for clinical research
- Knowledge of writing up research protocols, research data, and producing peer reviewed papers
- Understanding of how research training can be used in routine clinical practice to enhance patient care

Supporting documents for Doctors and Healthcare Professionals outside of medicine can be found on the Imperial College AHSC's Clinical Academic Training Office website CATO.

Completed documents (logbook, reflective summary and sign off pages) should be scanned and submitted by email to the CATO Office: cato@imperial.ac.uk.

We may also contact you if we require further information on the submitted documentation.

How to use this Framework

Completion of this framework demonstrates that you have undertaken learning and development in clinical research and research methods.

You should start by reading it completely. You may already have some knowledge and experience about some areas. Overall it might take you two or more years to finish all the activities and learning described.

Modules

The modules indicate the areas of knowledge that you need to gain. The column labelled **'evidence/ assessments'** indicates how you might show you understand each topic. We are not mandating specific training courses or learning methods, but the column labelled **'training to achieve this'** allows you to see the various ways we think you can learn about each topic, especially from the wide range of activities going on across all the sites of the Imperial AHSC. The column labelled **'professional skills and attitudes gained'** shows you and your line managers how research skills are important in routine patient care, and will make you a better health care professional in your day-to-day work.

Completing the Framework

- By completing the seven items in the log book and five training sessions listed on the **'sign off pages'**, you will have acquired all the knowledge and skills described in the modules. You need to complete this fully. It is the completed sign-off pages which will provide us with the evidence that you have undertaken the appropriate learning and allow us to award you the certificate of completion.
- For each item we are asking you to state what you did or attended, confirmed by your own signature. The five training courses or sessions need to be countersigned by the course organiser or session chair/leader.
- Finally, we need the signature of your line manager or clinical supervisor to confirm that you do work within an Imperial College AHSC organisation, and that to the best of their knowledge you have undertaken the activities you describe.

This Document has been adapted with kind permission from the Royal College of Obstetricians and Gynaecologists (RCOG).

Glossary of terms

AHSC	Academic Health Science Centre
BRC	Biomedical Research Centre
CATO	Clinical Academic Training Office
CLAHRC /ARC	Collaboration for Leadership in Applied Health Research and Care/Applied Research Collaboration
CPD	Continuing Professional Development
CRN	Clinical Research Network
GCP	Good Clinical Practice
GMC	General Medical Council
HRA	Health Research Authority
HPAG	Healthcare Professional Academic Group
ICHT	Imperial College Healthcare NHS Trust
ICL	Imperial College London
ICTU	Imperial Clinical Trials Unit
IRAS	Integrated Research Approval System
MHRA	Medicines and Healthcare Products Regulatory Agency
NMC	Nursing and Midwifery Council
PERC	Imperial Patient Experience Research Centre
PPE	Patient and Public Engagement
PPI	Patient and Public Involvement
QI	Quality Improvement
R&D	Research and Development
RBHT	Royal Brompton and Harefield NHS Foundation Trust
RMH	The Royal Marsden NHS Foundation Trust

Module 1 Research Methodology

Knowledge	Academic competency	Professional skills and attitudes gained	Training to achieve this	Evidence/Assessments
a) Developing a research idea **b) Researching the literature** **c) Involving patients in developing research ideas**	• Critical appraisal of papers or research proposals using a range of clinical research designs e.g. observations, trials, qualitative methods • Evaluation of the published literature • Awareness of hierarchy/ strength of evidence, and quality of evidence • Awareness of appropriateness of research design for the specific research question • Knowledge of methods to engage patients and public in research activity	• Attention to detail and accuracy • Sensitivity to ethical issues • Ability to obtain, receive, critique and incorporate advice	• Clinical colleagues/Peer support • University Departments • Online learning e.g. Coursera, FutureLearn, NHS Trust training eg ICHT Moodle critical appraisal, NW London CLAHRC QI Training • Access to electronic libraries and relevant Journals • Imperial College library training • Journal Clubs • Research Meetings • Taught Courses e.g. AHSC Starting Out in Research course or Imperial Researcher Development course	• Critiquing a Draft Protocol • Presentation of paper at a journal club/departmental clinical meeting • Documentary evidence of research appraisal e.g. Publication of letter/ abstract/internal report/ protocol • Evidence of participation in critical evaluation of articles as a peer reviewer for a journal
d) Writing a research protocol **e) Developing/reviewing a study/trial protocol**	• Explain justification for study • Awareness of potential risks and risk minimisation • Appreciation of appropriate research methodology • Develop database/data management strategy	• Appreciation of the need for high quality proposals • Knowledge of regulations governing research • Logical thinking and ability to develop clinical protocols	• Supervisors • Clinical Trials Unit • Statistician • Support from local R&D Offices • NIHR Research Design Service • Methodologist appropriate to research design	• Devise/critically appraise a research protocol • Presentation of research proposal at research meeting e.g. HPAG seminar

Module 1: Research Methodology

Knowledge	Academic competency	Professional skills and attitudes gained	Training to achieve this	Evidence/Assessments
f) Presenting research • Contributing to writing grant proposal or a peer reviewed paper • Preparing an oral or poster presentation • Correspondence/letters to journals	• Critical appraisal of the literature • Organisation and presentation of data • Academic writing skills • Clear communication of complex ideas, methods and results	• Attention to detail and accuracy • Ability to interpret data • Ability to define clinical relevance of data • Organisational skills • Confidence in presentation skills	• Supervisors • Training courses incl. AHSC Starting out in Research course, Imperial College Researcher Development and other skills courses • Journal CPD Resources • Taking up opportunities to present work at department meetings, HPAG seminars, etc.	• Draft or published manuscript, conference poster or conference presentation
g) Statistical techniques, Qualitative techniques, Data Analysis	• General statistical and scientific skills e.g: Descriptive statistics, Data distribution, Parametric and non-parametric tests, multivariate analysis, Sample sizes, Power calculations • Qualitative methods e.g: Data collection methods, (interviews, focus groups, observation), principles of qualitative analysis	• Attention to detail and accuracy • Ability to interpret data • Ability to define clinical relevance of data • Awareness of the value of qualitative methods in research	• Courses covering Basic Research methodology, qualitative research and Medical Statistics incl. AHSC Starting Out in Research or Imperial Researcher Development course, others • Online learning e.g: FutureLearn, Coursera, NW London CLAHRC QI training, others	• Record of attendance at an appropriate course • Completion of statistics exercises online or at an appropriate course

- *Some aspects of Quality Improvement/Innovation work would fit into this framework, when supported by training and learning about QI methodologies.*
- *This framework cannot however be used simply to certify QI work, but must include some research methods training and work on (clinical) research studies.*
- *Evidence must relate directly to the competency, ideally should demonstrate ongoing learning, and must reflect your own work or significant role in a collaboration. The evidence must be current and not just work undertaken in the past.*

Module 2 Clinical Studies

Knowledge	Academic competency	Professional skills and attitudes gained	Training to achieve this	Evidence/Assessments
a) Understanding Study design • Randomised control trials • Systematic reviews and meta-analysis/synthesis • Case control studies • Cohort and observational studies • Qualitative research studies • Interventional studies	• Critical appraisal • General research skills • Appreciation of different study designs • Advantages and disadvantages of different study design approaches	• Attention to detail • Assessing genuine data • Understanding high quality studies • Understanding different clinical research methodologies • Interpretation of evidence	• Courses e.g. AHSC Starting out in Research course • Online learning • Reading reviews, trials, papers • Journal clubs • ICTU Training • Participating in trial progress meetings	• Record of attendance • Evidence of other learning
b) Application for appropriate research project approvals e.g. Sponsorship, Research and Development, Clinical Trial Authority, Home Office, Caldicott Guardian, NIHR Portfolio Adoption	• Completion of IRAS and/or HRA submission (incorporating ethics) • R&D Submission • Data access application • Understanding Service user/patient and public involvement (PPI) in research • Understanding difference between research, audit and service evaluation	• Respect for patients rights • Awareness of cultural diversity • Ability to communicate the rationale of the research and ethical considerations • Patience	• R&D Offices • Academic colleagues • GCP training • Clinical Research networks • Online training for IRAS and HRA • BRC resources • PPI/E Training e.g. through PERC	• Acknowledgement of approval to carry out research from the ethics committee and R&D • GCP certification • Attendance at PPI meeting • Evidence of learning from online or face to face training

Module 2: Clinical Studies

Knowledge	Academic competency	Professional skills and attitudes gained	Training to achieve this	Evidence/Assessments
c) Developing Study documents • Ethical Committee regulations and requirements • Good Clinical Practice	• Development of appropriate study documentation (e.g. participant information leaflet, consent forms, case report forms, data collection) • Adverse events, Serious Adverse events and reporting	• Performing of ethical research • Organisational skills	• Ethics Committee • R&D Office • Experienced colleagues • Clinical Trials Unit	• Forms approved by Ethics Committee including: – Study consent form – Participant information leaflet – Data collection form • GCP certification
d) Understanding research legislation • Relevant legislation and ethics surrounding research • Storage of human tissue • Data protection and patient data legislation	• Maintain appropriate licences and approvals for research	• Awareness of the requirements of clinical governance especially probity	• Research methodology Course • Local Research Network Course • Online resources • Supervisor • MHRA	• Adherence to appropriate standards and legislation • Evidence of course attendance • GCP certification
e) Understanding Research infrastructure e.g. local and national NIHR Structure and function, clinical research networks	• Utilisation of research networks and support	• Communication and networking skills	• University Department/ Graduate School • Research Councils • NIHR, and NIHR Research Design Service • Clinical Research Network Training e.g. NIHR LEARN • BRC events	• Record of attendance at local research group or clinical study group • GCP certification

Module 2: Clinical Studies

Knowledge	Academic competency	Professional skills and attitudes gained	Training to achieve this	Evidence/Assessments
f) Research integrity • Issues surrounding fraud/scientific misconduct • Awareness of complex dilemmas in scientific research • Plagiarism	• Understanding of own role and responsibilites in the research process • Knowledge of issues around misuse of research • How to report concerns about research conduct • Following Good Clinical Practice	• Desire to develop ethical research practice • Awareness of dilemmas in clinical practice • Understanding of ability to raise concerns more broadly	• GMC, NMC, other regulators • Research methodology course • Local Research Network course • Online resources • Academic supervisor	• Record of attendance at an appropriate course • GCP certification
g) Patient and public involvement/engagement • How to involve patients in developing research ideas, and spreading outputs	• Knowledge of methods to engage patients and public in research activity • How to present information to a non-professional audience	• Awareness of working with patients and the public • Enhanced communication skills	• Imperial BRC PERC (Patient Experience Research Centre) • Online resources • Patient support groups	• Record of attendance at formal PERC or other training event • Record of PPI/PPE work undertaken e.g. workshops/events

Sign off pages

Completed documents (reflective summary, GCP certificate and sign off pages) should be scanned and submitted by email to the CATO Office cato@imperial.ac.uk. *We may also contact you if we require further information on the submitted documentation.*
*hand written signatures are required

Name: _____ **Email address:** _____

Specialty/ Profession: _____ **Job title:** _____ **Imperial AHSC NHS Trust or University:** _____

Name and email address of Line Manager: _____

Clinical Research Logbook	Date achieved	Your signature*
1. Written critical appraisal of a clinical research protocol or published paper *(give protocol or paper details here)*		
2. Present a research paper at a journal club/departmental clinical meeting *(state title of paper here)*		
3. Participate in an oral/poster submission and/or presentation at regional, national or international meeting *(give details of paper and meeting here)*		
4. Evidence of personal involvement in, and competence at, recruitment into a research study (if applicable) *(give details of study)*		
5. Participation in the local administration of a clinical trial or research study *(entry in a delegation log/site file)* **or involvement in discussion of trial or research study** *(where was this done)*		

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*hand written signatures are required

Clinical Research Logbook	Date achieved	Your signature*
6. Good Clinical Practice Training Certification must cover all the following objectives *(attach copy of GCP certificate)* • Demonstrate an understanding of the importance of the interwoven laws, frameworks and guidelines which govern the set up and conduct of clinical research • Demonstrate an understanding of the roles and responsibilities of different individuals and organisations in clinical research • Understand the regulatory applications required before clinical research can be started in the UK • Identify a range of essential study documents and their purpose e.g. trial master file • Understand the process of receiving informed consent and the roles and responsibilities of those involved • Demonstrate the ability to correctly and accurately complete case report forms and other relevant documentation and understand the process for data query resolution • Demonstrate an awareness of the correct safety reporting requirements that ensure patient safety • Know where to go for further advice and support and how to keep updated		
7. Reflective evidence-based summary of relevant research encounter during a Clinical Research Study 4,000 – 5,000 (maximum) words. Examples of potential themes to be covered could include: • Actual/Potential Adverse Event(s) • Ethical issues/challenges posed • Factors that affected optimal recruitment and how addressed • Potential clinical translation/benefits of study findings • Broader and translational learning *(please attach reflective summary to final submission)*		

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*hand written signatures are required

Training Courses or Sessions

Specific activity	Date achieved/undertaken	Signature of organiser*
1. Attendance at a Research Ethics Meeting *(give details)*		
2. Attendance at PPI/Research Service User meeting/forum *(give details)*		
3. Attendance of a Regional or other CRN or other research/trial meeting (face to face or online) *(give details)*		
4. Attendance at a course covering Research *(give details)*		
5. Research Methods/Statistical Methods in Medical Research/Qualitative methods training or course (face to face or online) *(give details)*		

Line Manager Signatures

(signatories are not confirming academic competency but to the best of their knowledge that the applicant has completed the activities as described above)

Name of clinical supervisor or line manager *(please print)*	Date	Signature