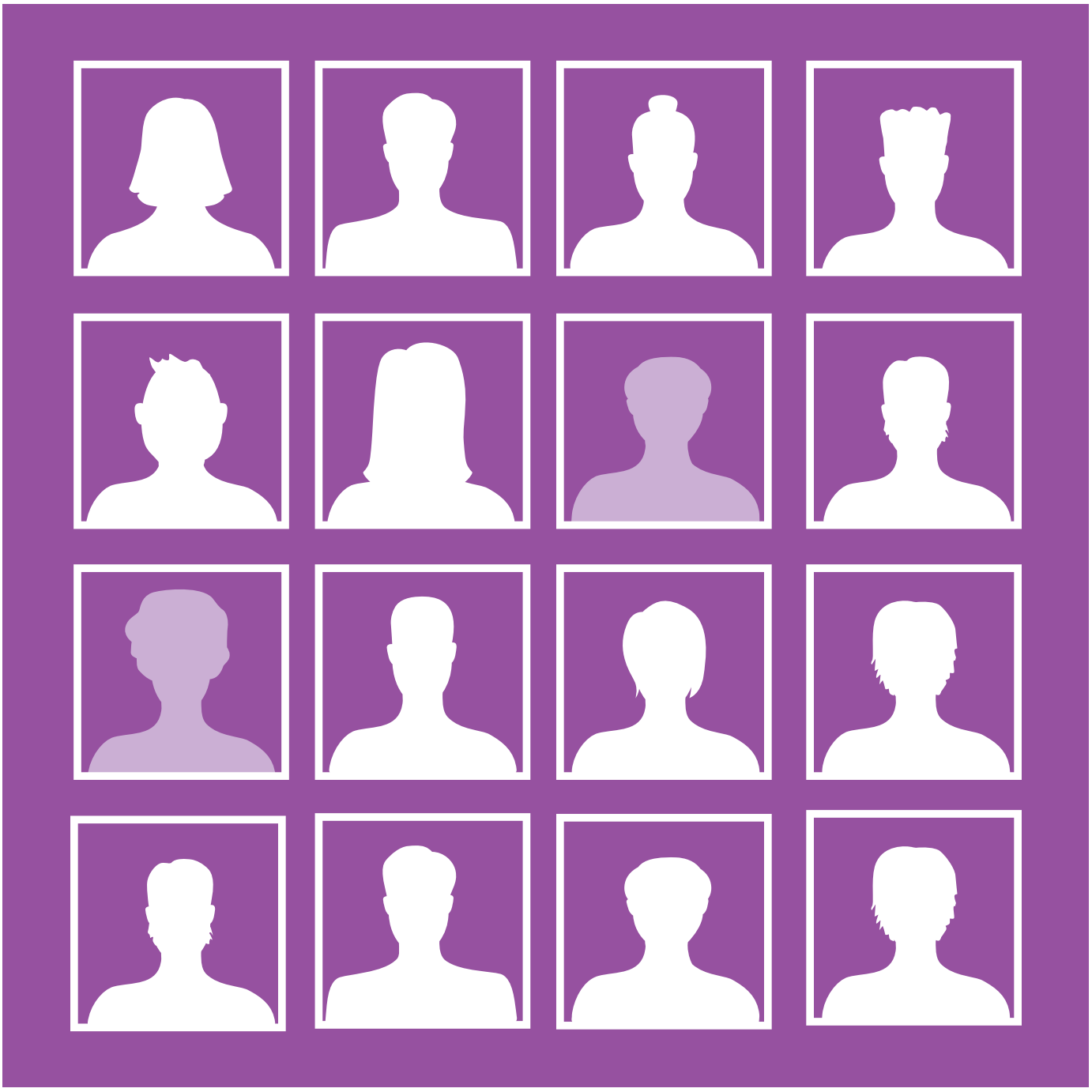
Advanced Professional Module

Royal College of Obstetricians & Gynaecologists

Advanced Professional Module
Clinical Research (2016)

Approved by GMC on 14 July 2016 and launched September 2016



Anchor Statement

To define the skills that a Consultant Obstetrician/ Gynaecologist requires, in order to support clinical research service as an active participant (Principal Investigator, co-applicant/ collaborator, recruiter) in a primary, secondary or tertiary care setting.

Introduction

The Clinical Research APM has been developed to increase the opportunities for trainees in non-academic posts to develop a specialised understanding of research governance and allow them to become directly involved in NIHR and industry portfolio trials.

This in turn will increase clinical research knowledge and participation of O&G trainees in clinical research. It is envisaged that the APM would foster core research skills and encourage NHS relevant, practice changing multicentre collaborative research.

- It is intended that the Clinical Research APM can be completed as an optional module for O&G trainees who have an interest in academic training anytime during their specialty training programme. Generally the most appropriate stage to consider undertaking this module will be from ST3 onwards.
- The module will also be available for NHS O&G consultants to develop their clinical research skills and knowledge.
- It is also intended that the Clinical Research APM will provide an alternative option for completing the research component for those O&G trainees who are undertaking subspecialty training and who are not research exempt.
- The ability to undertake and complete the module should be agreed between the trainee's educational and clinical supervisor

It is not mandated that original research ideas are implemented and executed during the course of the APM. Rather, that participants acquire skills that enable them to participate in clinical research including developing protocol for research studies, obtaining relevant permissions, research governance (management teams, steering groups and data monitoring committees) and being local Investigator for a multi-centre research project.

Learning outcomes:

- Understanding of clinical research methodology
- Competence to participate as an Investigator in Portfolio research studies
- Good Clinical Practice research certification
- Competence to undertake the critical review of a research topic/idea
- Understanding of medical statistics for clinical research
- Knowledge of participation in writing up research protocols and peer-reviewed papers

GMC Good Medical Practice (GMP) Domains:

Domain 1: Knowledge, skills and Performance
Domain 2: Safety and quality
Domain 3: Communication, Partnership and Teamwork
Domain 4: Maintaining Trust

Knowledge criteria	GMP	Academic competency	GMP	Professional skills and attitudes	GMP	Training support	Evidence /Assessment
Module 1 Research Methodology							
a) Developing a research idea b) Researching the literature – critical appraisal c) Writing a research protocol	1	Critical appraisal of papers or research proposals involving a prospective clinical study Evaluation of the published literature Awareness of hierarchy/strength of evidence	1	Attention to detail and accuracy Sensitivity to ethical issues Ability to obtain, receive and incorporate advice	1,2,3	University departments Clinical Colleagues RCOG Website www.rcog.org.uk Access to electronic libraries and relevant journals Online or face to face Journal Club e.g. BJOG Research meetings Taught courses	Developing/critiquing a Draft Protocol Presentation of paper at a journal club/ departmental clinical meeting (senior academic/ clinician) Presentation of research proposal at research meeting (clinician or senior academic) Documentary evidence of BJOG/TOG-based research appraisal e.g. Publication in BJOG/ Correspondence section. Evidence of participation in critical evaluation of BJOG articles –responses to CPD questions on BJOG articles in TOG (BJOG Scientific section)
d) Developing/Reviewing a study/trial protocol	1,2	Explain justification for study Awareness of potential risks and risk minimisation Develop database/data management strategy Develop operating procedures	1,2,3	Appreciation of the need for high quality proposals Knowledge of regulations governing research	1,2,3	Supervisors Clinical Trials Unit Statistician Health and Safety Support from local R&D office or equivalent	Devise/critically appraise a protocol for research through local/regional R and D Offices
e) Presenting research a. Contributing to writing grant proposal or a peer-reviewed paper b. Preparing an oral or a poster presentation. c. Correspondence/letters to Journals		Critical appraisal of the literature Organisation and presentation of data		Attention to detail and accuracy Ability to interpret data Ability to define clinical relevance of data Organisation	1,2,3	Supervisors Training courses TOG/BJOG clinical research/CPD Resources	Draft/published manuscript/poster/ presentation

Knowledge criteria	GMP	Academic competency	GMP	Professional skills and attitudes	GMP	Training support	Evidence /Assessment
Module 1 Research Methodology							
f) Statistical techniques and Data Analysis	1	General statistical and scientific skills • Descriptive statistics • Data distribution • Parametric and non-parametric tests • Generalized linear modelling • Survival data • Multivariate analysis	1, 2	Attention to detail and accuracy Ability to interpret data Ability to define clinical relevance of data organisation	1,2,3	Courses covering Basic Research methodology and Medical Statistics	Record of attendance at an appropriate course
g) Epidemiological Methods in Medical research • Design • Analyse • Report	1	• Strengths, limitations and weaknesses of different study designs and sources of epidemiological data e.g. prospective and retrospective studies. • Measures of health and disease incidence (risk, rate, odds) • Prevalence, measures of effect (e.g. relative and absolute risk) • Understanding standardisation, causality in non-randomised studies • Reporting results of an analysis of epidemiological data	1, 2	Attention to detail and accuracy Ability to interpret data Ability to define clinical relevance of data Organisation	1,2,3	Research methodology course Medical Statistics Course	Record of attendance at an appropriate course
h) Sampling techniques • Simple random sampling, stratification • Sample sizes, practical issues in sample surveys.	1						

Knowledge criteria	GMP	Academic competency	GMP	Professional skills and attitudes	GMP	Training support	Evidence /Assessment
Module 2 Clinical Studies							
a) Understanding Trial design • Controls • Protocols • Blind and double blind arrangements • Cross-over trials • Meta-analysis	1						
b) Application for appropriate research project approvals e.g. Sponsorship, Research and Development , Clinical Trial Authority, Home Office, Caldicott Guardian, NIHR Portfolio Adoption	1	Completion of IRAS submission (incorporating ethics) R&D Submission Home office personal or project licence-CTA application Data access application Understanding Service user/ patient involvement (PPI) in research.	2,4	Respect for patient's rights Awareness of cultural diversity Ability to communicate the rationale of the research and ethical considerations Patience	2,4	R&D Office Academic Colleagues	Acknowledgement of approval to carry out research from the ethics committee and R&D GCP certification Attendance at PPI meeting
c) Developing study documents • Ethical Committee regulations and requirements • Good Clinical Practice	1	Development of appropriate study documentation (e.g. patient information leaflet/ consent forms/case report form/ data collection) Adverse events, Serious Adverse events and SUSAR reporting Site files (SOPs)	2,3,4	Performing of ethical research	2,3,4	Ethics Committee R&D Office Experienced colleagues	Forms approved by Ethics Committee including: Study consent form Patient information leaflet Data collection form

Knowledge criteria	GMP	Academic competency	GMP	Professional skills and attitudes	GMP	Training support	Evidence /Assessment
Module 2 Clinical Studies							
d) Understanding research legislation • Relevant legislation and ethics surrounding research e.g. Home Office and Animal Licences • Storage of human tissue • Data protection and patient data legislation	1	Maintain appropriate licences and approvals for research	1,2,4	Awareness of the requirements of clinical governance especially probity	2,4	Research methodology course Local Research Network course MRC online resources Supervisor MHRA	Adherence to appropriate standards and legislation Evidence of course attendance GCP certification
e) Understanding Research infrastructure • NIHR structure and function - local - national - clinical study groups	1	Utilisation of research networks and support	3	Not applicable		University department/ graduate school Research Councils NIHR www.nihr.ac.uk	Record of attendance at local specialty group or clinical study group GCP certification
f) Research integrity • Issues surrounding fraud/scientific misconduct • Awareness of complex dilemmas in scientific research • Plagiarism	1,4	Knowledge of issues around misuse of research How to report concerns about research conduct Following Good Clinical Practice	4	Desire to develop ethical research practice		GMC Research methodology course Local Research Network course MRC online resources Academic Supervisor Home Office Inspector MHRA	Record of attendance at an appropriate course Ability to use appropriate plagiarism software GCP certification
g) Study closure • Responsibility for end of study procedures • Ethical, R&D, CTA requirements for end of study	1	Archiving of consent, data and tissues Reports and notifications Anonymisation of data and samples	1,2,4	Attention to detail		R&D Office Supervisors MRC Clinical Trials Toolkit	Documents demonstrating appropriate closure of study Archiving of data GCP certification

Clinical Research Logbook	Date competency achieved	Signature
Written critical appraisal of a clinical research protocol		
Present a research paper at a journal club/ departmental clinical meeting		
Participate in an oral/poster submission and/or presentation at regional, national or international forum		
Evidence of personal involvement in, and competence at, recruitment into a portfolio research study relevant to specialty/subspecialty*		
Participation in the local administration of a clinical trial/research study (entry in a delegation log/site file)		
Good Clinical Practice Training Certification must cover all the following objectives. • 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 documents and the purpose of maintaining a trial master file • Understand the process of receiving informed consent and the roles and responsibilities of those involved in this process. • 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.		

Clinical Research Logbook	Date competency achieved	Signature
Reflective evidence-based summary of relevant clinical research challenge encounter during a Clinical Research Study during the APM (about 5,000 words). Examples of potential themes to be covered could include: • Actual/Potential Adverse Event(s). • Ethical issues/challenges posed. • Potential modifications to trial design that could have been addressed differently. • Factors that militated against optimal recruitment at site and how addressed. • Potential clinical translation/benefits of study findings		

* Such evidence should include personal listing on the delegation log of a portfolio clinical trial AND evidence of personally recruiting reasonable and appropriate numbers of participants into such a trial (s).

Training Courses or sessions		
Title	**Signature of educational supervisor**	**Date**
Attendance at a Research Ethics (NRES) meeting		
Attendance at PPI/Research Service User meeting/forum		
Attendance of a Regional CLRN meeting		
Attendance at a course covering Research Methods/ Statistical Methods in Medical Research		
Attendance at Study Steering Committee meeting		

Authorisation of signatures (to be completed by the academic trainers)		
Name of Academic trainer (please print)	**Signature of Academic trainer**	**Date**

Key:

Common competency framework competencies

Medical leadership framework competencies

Health inequality framework competencies

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