SIPM: Clinical Research (CR)

SECTION 1: CAPABILITIES IN PRACTICE

CR CiP 1: The doctor will have an understanding of and be able to apply the principles of clinical research methodology	
Key Skills	**Descriptors**
Is able to develop a research idea and write a research protocol	• Critically appraises papers or research proposals involving a prospective clinical study • Evaluates published literature • Obtains, receives and incorporates advice • Pays attention to detail and accuracy • Is sensitive to ethical issues
Is able to develop and review a study or trial protocol	• Explains justification for study • Is aware of potential risks and risk minimisation • Develops database/data management strategy • Develops operating procedures
Is able to present research	• Contributes to writing grant proposal or a peer-reviewed paper • Prepares an oral or a poster presentation • Writes letters to journals • Organises and presents data • Critically appraises literature • Pays attention to detail and accuracy • Interprets and defines clinical relevance of data
Is able to use statistical techniques and carry out data analysis	• Familiar with general statistical and scientific skills • Pays attention to detail and accuracy • Interprets and defines clinical relevance of data
Is able to use epidemiological methods to carry out medical research	• Familiar with epidemiological methods • Can design, analyse and write reports using epidemiological data • Uses different sampling techniques • Pays attention to detail and accuracy • Interprets and defines clinical relevance of data

Evidence to inform decision	
• Online or face to face Journal Club • Presentation of research paper at a journal club/departmental clinical meeting x	• Evidence of participation in critical evaluation of BJOG articles, e.g. responses to CPD questions on BJOG articles in TOG

• Participation in an oral/poster submission and/or presentation at regional national or international forum
• Documentary evidence of BJOG/TOG-based research appraisal e.g. publication in BJOG/correspondence section
	• Written critical appraisal of a clinical research protocol
	• Draft/published manuscript/poster/presentation
	• Attendance at appropriate course
	  ○ basic research methodology
	  ○ medical statistics

Knowledge criteria

- Aware of hierarchy/strength of evidence
- Appreciates the need for high quality proposals
- Knowledge of regulations governing research
- Descriptive statistics
- Data distribution
- Parametric and non-parametric tests
- Generalised linear modelling
- Survival data
- Multivariate analysis
- Simple random sampling, stratification
- Sample sizes, practical issues in sample surveys
- 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

CR CiP 2: The doctor will be able to carry out clinical studies	
Key Skills	**Descriptors**
Is able to prepare research project submissions	• Completes appropriate documentation including: IRAS submission (incorporating ethics), R&D submission, Home Office personal or project licence – CTA application; data access application • Understands service user/patient involvement (PPI) in research • Respect for patient's rights • Awareness of cultural diversity • Communicates the rationale of the research and ethical considerations
Is able to develop study documentation and maintain appropriate licences and approvals for research	• Develops patient information leaflet, consent form, case report form, data collection • Performs ethical research • Reports on adverse events, Serious Adverse events and SUAS report • Works with site files (SOPs) • Awareness of the requirements of clinical governance especially probity • Adheres to appropriate standards and legislation

Is able to carry out research ethically and with integrity	• Awareness of issues surrounding fraud/scientific misconduct • Awareness of complex issues in scientific research • Awareness of plagiarism and can use plagiarism software • Reports concerns about research conduct • Develops ethical research practice
Is able to close a study	• Takes responsibility for end of study procedures • Applies ethical, R&D, CTA requirements for end of study • Archives consent, data and tissues • Completes reports and notifications • Ensures anonymization of data and samples • Pays attention to detail

Evidence to inform decision

• Evidence of personal involvement in, and competence at, recruitment into a portfolio research study relevant to specialty/subspecialty, to 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)
• Participation in the local administration of a clinical trial/research study (entry in a delegation log/site file)
• Acknowledgement of approval to carry out research from the ethics committee and R&D
• Good Clinical Practice certification to cover 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
	• 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 events
	  ○ 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
	• Attendance at PPI meeting
	• Forms approved by Ethics Committee including:
	  ○ Study consent form
	  ○ Patient information leaflet
	  ○ Data collection form
	• Attendance at appropriate course
	  ○ Research methodology
	  ○ Local research network
	  ○ MRC online resources
	  ○ Good Clinical Practice
	  ○ Local specialty group or clinical study group
	• Use of appropriate plagiarism software
	• Documents demonstrating appropriate closure of study
	• Archiving of data

○ 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	

Knowledge criteria

- Understands trial design
  - Controls
  - Protocols
  - Blind and double-blind arrangements
  - Cross-over trials
  - Meta-analysis
- Understands research project approval requirements
  - Sponsorship
  - Research and development
  - Clinical Trial Authority
  - Home Office
  - Caldicott Guardian
  - NIHR Portfolio adoption
- Ethical Committee regulations and requirements
- Good Clinical Practice
- Understands research infrastructure
  - NIHR structure and function – local, national, clinical study groups
  - Utilisation of research networks and support
- Understands issues around misuse of research
- Knows how to report concerns about research conduct
- Understands plagiarism
- Understands ethical, R&D, CTA requirements for end of study

SECTION 2: PROCEDURES

There are no procedures in this SIPM.

SECTION 3: GMC GENERIC PROFESSIONAL CAPABILITIES

This SIPM maps to all 9 GMC domains

Mapping to GPCs
Domain 1: Professional values and behaviours Domain 2: Professional skills

- Practical skills
- Communication and interpersonal skills
- Dealing with complexity and uncertainty

Domain 3: Professional knowledge

- Professional requirements
- National legislative structure
- The health service and healthcare system in the four countries

Domain 5: Capabilities in leadership and team working
Domain 6: Capabilities in patient safety and quality improvement
Domain 9: Capabilities in research and scholarship

SECTION 4 MAPPING OF ASSESSMENTS TO CR CiPs – Not applicable

SECTION 5 RESOURCES (OPTIONAL)

SIPM Clinical Research – Suggested learning resources

- MRC online researches
- R&D Office
- MHRA
- Research Councils
- NIHR
- GMC
- MRC Clinical Trials Toolkit