SIPM: Clinical Research (CR)

SECTION 1: CAPABILITIES IN PRACTICE (CiP)

CR CiP 1: The doctor will have an understanding of and be able to apply the principles of clinical research methodology.	
Key skills	**Descriptors**
Can 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 from research into their practice. • Pays attention to detail and accuracy. • Is sensitive to ethical issues.
Can develop and review a study or trial protocol	• Explains justification for study to all audiences. • Is aware of potential risks and how to manage these. • Develops a database and data management strategy. • Develops operating procedures.
Can present research	• Contributes to writing a 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 the clinical relevance of data.
Can use statistical techniques and carry out data analysis	• Familiar with general statistical and scientific skills. • Pays attention to detail and accuracy. • Interprets and defines the clinical relevance of data.
Can 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 the clinical relevance of data.
Evidence to inform decision	

• Attendance at an online or face-to-face journal club
• Presentation of a research paper at a journal club or departmental clinical meeting
• Participation in an oral presentation or poster submission at a regional, national or international forum
• Documentary evidence of a British Journal of Obstetrics and Gynaecology (BJOG) or The Obstetrician and Gynaecologist (TOG)-based research appraisal (e.g. publication in BJOG/correspondence section)
	• Evidence of participation in critical evaluation of BJOG articles (eg responses to Continuing Professional Development (CPD) questions on BJOG articles in TOG)
	• Written critical appraisal of a clinical research protocol
	• Draft or published manuscript, poster or 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**

Can prepare research project submissions	• Completes appropriate documentation, including:
	  ○ Integrated Research Application System (IRAS) submission (incorporating ethics).
	  ○ research and development (R&D) submission.
	  ○ Home Office personal or project licence (e.g. clinical trial authorisation (CTA) application, data access application).

	• Understands patient and public involvement (PPI) in research. • Respects patients' rights. • Awareness of cultural diversity. • Communicates the rationale of the research and ethical considerations.
Can develop study documentation and maintain appropriate licences and approvals for research	• Develops a patient information leaflet, consent and case report form, and carries out data collection. • Performs ethical research. • Reports on adverse events, serious adverse events (SAEs) and SUAS report. • Works with standard operating procedures (SOPs). • Awareness of the requirements of clinical governance, especially probity. • Adheres to appropriate standards and legislation.
Can carry out research ethically and with integrity	• Awareness of issues surrounding fraud and 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.
Can close a study	• Takes responsibility for end of study procedures. • Applies ethical, R&D and CTA requirements for the end of a study. • Archives consent, data and tissues. • Completes reports and notifications. • Ensures that data and samples are anonymised. • 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 or subspecialty. This will include a 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 or research study (entry in a delegation log / site file) • Acknowledgement of approval to carry out research from the ethics committee and Research &Development.	• Reflective evidence-based summary of relevant clinical research challenges encountered during the Clinical Research SIPM (about 5,000 words). Examples of potential themes to be covered could include: o actual/potential adverse events o ethical issues/challenges posed o potential modifications to trial design that could have been addressed differently o factors that militated against optimal recruitment of trial participants and how this was addressed.

• 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
  ○ demonstrate the ability to correctly and accurately complete case report forms and other relevant documentation and understand the process for resolving data queries
  ○ demonstrate an awareness of the correct safety reporting requirements that keep patients safe
  ○ know where to go for further advice and support and how to keep updated
	○ 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
	  ○ Medical Research Council (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

Knowledge criteria

- Understands trial design:
  - controls
  - protocols
  - blind and double-blind arrangements
  - cross-over trials
  - meta-analysis
- Understands research project approval requirements:
  - sponsorship
  - R&D
  - Clinical Trial Authority
  - Home Office

- Caldicott Guardian
- National Institute for Health and Care (NIHC) portfolio adoption

- Ethical Committee regulations and requirements
- Good clinical practice
- Understands research infrastructure:
  - National Institute for Health and Care (NIHR) structure and function – local, national, clinical study groups
  - Use of research networks and support
- Understands issues around misusing research
- Knows how to report concerns about research conduct
- Understands plagiarism
- Understands ethical, R&D, CTA requirements for the end of a study

SECTION 2: PROCEDURES

There are no procedures in this SIPM.

SECTION 3: GMC GENERIC PROFESSIONAL CAPABILITIES (GPCs)

This Special Interest Professional Module (SIPM) maps to all nine General Medical Council (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

1. General Medical Council
2. Medical Research Council (MRC) online researches
3. Medicines and Healthcare products Regulation Agency (MHRA)
4. Research Councils
5. Research and Development Office
6. NIHR Clinical Trials Toolkit
7. National Institute for Health and Care Research (NIHR)