Royal College of Obstetricians & Gynaecologists

Curriculum 2024 Guide for Special Interest Professional Module (SIPM): Clinical Research (CR)

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1. The Clinical Research SIPM

This SIPM is aimed at learners with an interest in clinical research. Clinical research skills are essential in obstetrics and gynaecology, and they are a requirement of the Core Curriculum. Learners who undertake this SIPM will develop the knowledge and skills beyond the 'core' expectation, and will be able to competently support clinical research as an active participant (Principal Investigator, Co-applicant/Collaborator, Recruiter) in a primary, secondary or tertiary care setting. The SIPM aims to increase the opportunities for clinicians 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. It is expected that the SIPM would foster research skills and encourage NHS-relevant, practice-changing, multi-centre collaborative research.

As a learner progresses through the SIPM, they will be exposed to and participate in a wide variety of research scenarios. Learners will also participate in educational events to further develop their training.

Throughout training, learners will need to reflect on whether a project has gone well, learn from positive and negative experiences, and use this to improve their own skills.

Before signing off on this SIPM, the Educational Supervisor will decide whether the learner is meeting expectations for completion of each Clinical Research Capability in Practice (CiP). More detail is provided in Section 5 of the Special Interest Training Definitive Document.

2. Design of the SIPM

The 2024 Clinical Research SIPM is made up of two Clinical Research CiPs. If undertaking the module full time, it is expected to take 18–24 months. However, this timeframe is indicative as training is entirely competency based.

This SIPM is not required for certificate of completion of training (CCT), but will develop the learner's professional skills in the field of clinical research.

Here is the GMC-approved Clinical Research SIPM:

3. Capabilities in Practice (CiPs)

Clinical Research CiP 1: The doctor will have an understanding of and be able to apply the principles of clinical research methodology.	
Key skills	**Descriptors**

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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 – examples of evidence (not mandatory requirements)	
• 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	• Evidence of participation in critical evaluation of BJOG articles (e.g. responses to Continuing Professional Development (CPD) questions on BJOG articles in TOG) • Written critical appraisal of a clinical research protocol

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• 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)	• Draft or published manuscript, poster or presentation
	• Attendance at appropriate course
	  ○ basic research methodology
	  ○ medical statistics

Mandatory requirements	
No mandatory evidence	
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	

Clinical Research 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 – examples of evidence (not mandatory requirements)	
• 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: ○ 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 of trial participants and how this was addressed

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• 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

No mandatory requirements	
No mandatory evidence	
Knowledge criteria	

• Understands trial design:
  ◦ controls
  ◦ protocols
  ◦ blind and double-blind arrangements
  ◦ cross-over trials
  ◦ meta-analysis	

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- 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

4. GMC Generic Professional Capabilities (GMCs)

The key skills in the Clinical Research CiPs also map to a variety of generic professional capabilities (GPCs). When providing evidence of their progress in this SIPM, learners should make sure that it also displays progress/capability in the GMC GPCs, such as dealing with complexity, teamwork and leadership, and knowledge of patient safety issues.

Mapping to the GPCs
Domain 1: Professional values and behaviours
Domain 2: Professional skills
Domain 3: Professional knowledge
Domain 4: Capabilities in health promotion and illness prevention
Domain 5: Capabilities in leadership and team-working
Domain 6: Capabilities in patient safety and quality improvement
Domain 7: Capabilities in safeguarding vulnerable groups
Domain 8: Capabilities in education and training

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Domain 9: Capabilities in research and scholarship

Learners can expect to be assessed on their wider skills as a medical professional, their skills in leadership and teamwork and those relating to knowledge and processes of clinical research. Evidence showing progress in these areas will result in the learner progressing through the SIPM.

To help learners and Educational Supervisors determine what acceptable progress looks like, there is a Statement of Expectations for each Clinical Research CiP.

	Statement of Expectations for the Clinical Research SIPM
Meeting expectations for the Clinical Research CiP1	Learners meeting expectations are able to understand, review and critique a research idea, study or trial protocol. They can develop a study or trial protocol, and employ epidemiological methods to carry out medical research. They have the ability to use statistical techniques to analyse study data. The learner can present a research idea or study within different settings, employing a range of presentational formats.
Meeting expectations for the Clinical Research CiP2	Learners meeting expectations are able to understand the ethical framework and good practice of clinical research within the NHS. They can apply for and receive approvals for research studies, and maintain the associated research documentation safely and securely. Learners can independently provide leadership or collaboration in clinical research studies of various types, enabling recruitment of patient participants into portfolio clinical studies. Learners are able to complete and conclude clinical studies, and recognise and manage clinical research events.

The CiP knowledge criteria show the processes/frameworks a learner should understand and the professional knowledge they must have if they want support clinical research as an active participant. This is more in-depth than the knowledge base expected for the MRCOG. The key skills and descriptors outline the expected learning outcomes for the SIPM. However, learners will not experience the entire range of possible scenarios during their training for this SIPM; therefore, after completing the module they should continue their learning and skill development through their independent practice in this field.

5. Evidence required

As learners progress through SIPM training, they are expected to collect evidence that demonstrates development and acquisition of the key skills and knowledge. This evidence will be reviewed by the SIPM Educational Supervisor when they are making their assessment for each CiP. Examples of types of evidence a learner may use to show progress in the SIPM are given below. **Please note that this list shows possible, not mandatory, types of evidence** (see Section 5 in the Special Interest Training Definitive Document for more detail).

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If workplace-based assessments are listed, then at least one must be presented as evidence. The emphasis should be firmly on the **quality** of evidence, not the quantity.

• Case-based discussions	• Attendance at relevant conferences and courses
• Reflective log of study conduct	• Quality improvement activity
• Local, deanery and national teaching	• Observation of or participation in meetings
• Delegation log	• RCOG Learning, BJOG or other eLearning
• Recruitment log	• Peer-reviewed journal publications
• Case report forms	• GPC certificate

6. Career guidance

Learners can undertake any of the three SIPMs. There is no 'protected' training time allocated to undertake SIPMs, and they are not required for CCT. The Clinical Research SIPM can be undertaken at any stage during the training programme. The most appropriate stage to consider undertaking this SIPM will be from ST3 onward, so that learners can focus on the clinical research skills in the Core Curriculum before embarking on the SIPM, where they will develop those skills and knowledge to a higher level. Learners aspiring to take on clinical research roles in their consultant career should undertake this SIPM.

For further careers advice, learners should have a discussion with their SIPM Director.

7. Further resources

The further resources listed below can be found on the RCOG Curriculum 2024 webpages:

- Essential Curriculum Guide
- Special Interest Training Definitive Document

Find out more at

rcog.org.uk/curriculum2024

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