Hong Kong College of Emergency Medicine

Research Requirement
Education Committee (EC), HKCEM

Version	Effective date
1	01 April 2019
2	01 July 2021
3	1 July 2023

Document number	EC-TG-RR-001-V3
Author	Dr Chun-tat Lui Chairman of Training & Exam Subcommittee
Custodian	Secretariat Office
Approved by	Education Committee
Approver	Dr Matthew TSUI Censor-in-Chief
Endorsed by	College Council
Approved date	17 April 2023
Distribution List	Training Supervisors, Trainers and Trainees

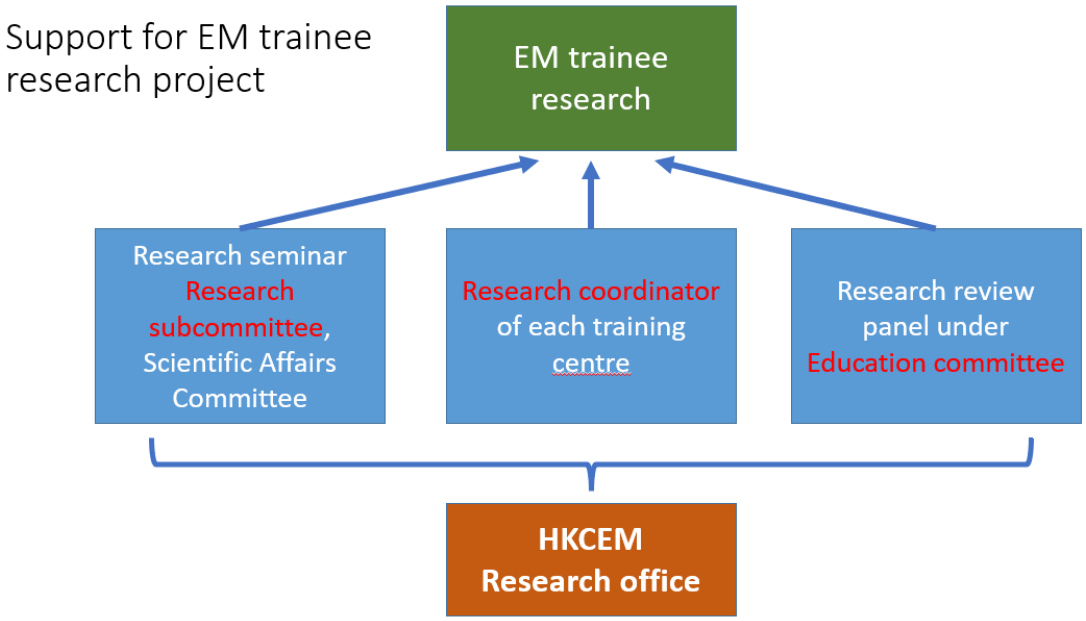
Fulfillment of Research Requirement
Education Committee (EC), HKCEM

Objectives

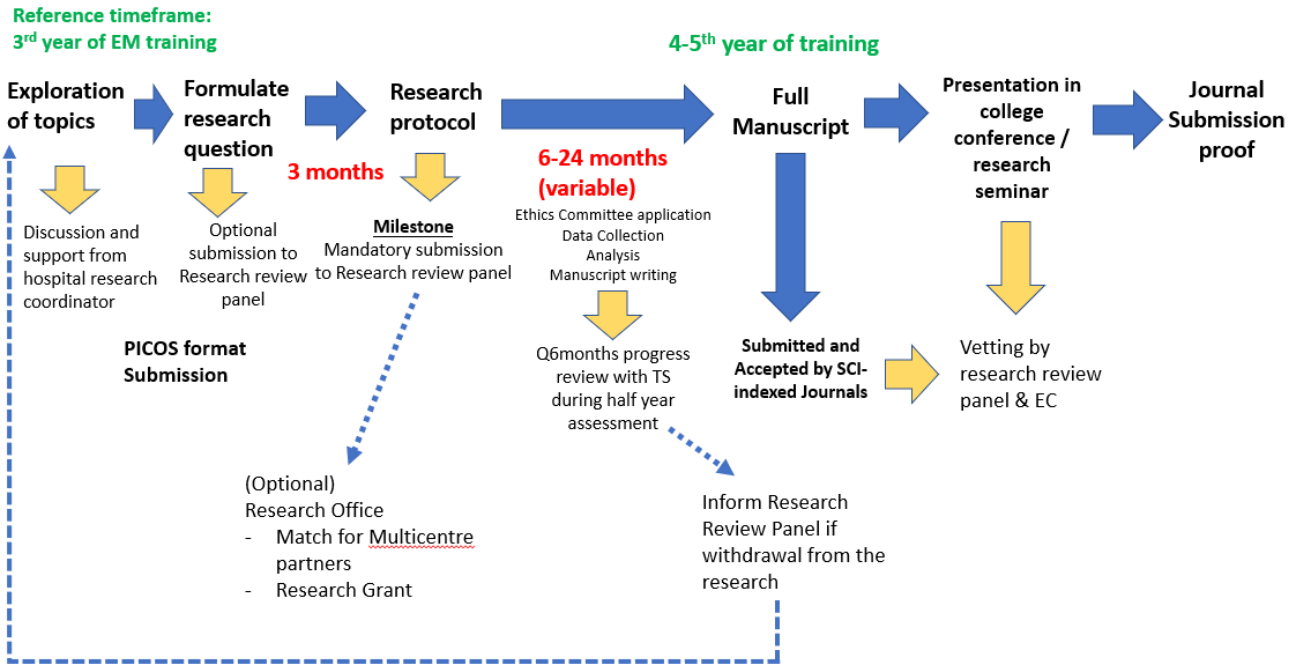
- The primary objective of research requirement within training in emergency medicine under HKCEM (the college) is to equip the future EM fellows with background skills and competencies in clinical research. The secondary objective is to learn and expose to clinical research in context of emergency medicine, which would allow unearthing EM researchers in the professional development.
- Throughout the process of research project, trainees are expected to learn through the process of a clinical research, from formulating research question, literature search, writing up a research protocol, undergoing review by institutional review board, to publications including presentation, journal submission and the process of peer-review.

Background

- The college had set up the ***research office***, chaired by the vice-president of the college, for centralizing the coordination and development of research in emergency medicine. For each training centre, on top of the overseeing training supervisor, there will be a designated ***research coordinator*** to support research activities for both trainees and fellows. The updated framework for research requirement for EM training aligns the direction of the college and intends to ***provide better support and guidance to EM trainees***.
- The college provides various support modalities and training provision to EM trainees, including research seminars to provide basic training on research skills, designation of research coordinators in each training centre, a new pathway to support trainees' research project from initiation instead of sole assessment of final product.

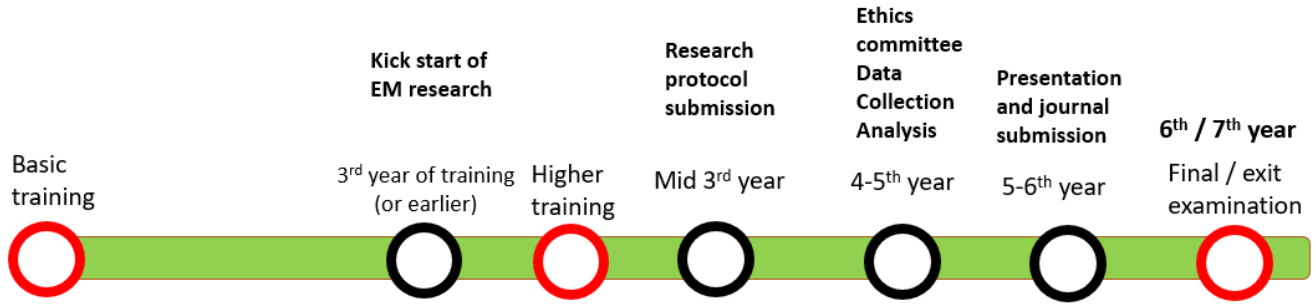


The EM trainee research pathway



- Throughout the research journey, trainees would be coached by the training supervisor and research coordinator of the parent training centre. Trainees may opt to attend the research seminar series organized by the research subcommittee of college, or other clinical research training courses. The research seminar provides formal standardized training of core knowledge on clinical research, together with supervised coaching by experienced fellows and researchers on their research topic.
- The submission of ***research question*** to research review panel is optional. Trainees may consider submission to the panel if they had query on the topic could fulfill the research requirement.
- The submission of ***research protocol*** to research review panel is mandatory. The research protocol may be submitted to ethics committee for approval at the same time or afterwards. In general, the affirmative reply from the research review panel would be within 30 days after submission. The trainees should continue the process of ethics committee application, data collection and analysis after approval from the research review panel.
- After completion of the data collection, analysis and writing up the manuscript. The trainee should be presenting the result and manuscript in occasions approved by the Education Committee. The presentation and full manuscript will be vetted by representatives nominated by the Education Committee. Alternatively, trainees may submit the manuscript to journals under Scientific Citation Index Expanded (SCI-E) [https://www.scijournal.org].
- Published papers in journal alone, without following the EM trainee research pathway, is **NOT** accepted as fulfillment of research requirement.
- The research progress should be reviewed between the training supervisor and the trainee, in the half-year assessment exercise for progress review and timeline consolidation.

Steps and plans on timeline in research project of EM trainee



- It is strongly advisable to trainees to work out a timeline with the training supervisor and research coordinator for their research project planning. A reference timeline is to kick start by the 3rd year of training, no matter the trainee is in basic of higher training. Trainees are welcomed to kick off the research planning and protocol submission at any timeline during EM training, for both basic and higher trainees.

Requirement in the research topic and study design

- Original research with well-defined research question, research method and statistical analysis are expected.
- Case reports, case series and review articles are not accepted. Well-conducted meta-analysis is accepted.
- Whether the study design fulfills the research requirement, would be subjected to the final decision of the **research review panel**.
- The research topic should be relevant to science and practice of emergency medicine.
- Research performed during undergraduate medical training is generally not accepted.
- Research completed before EM training enrollment or outside EM training period are generally not accepted, unless under special circumstance where the research is of outstanding quality and EM-related. Individual application would be required and up to the adjudication of the research review panel.
- In general, the EM trainee should be the single first author. The trainee must demonstrate proof of major role in the authorship if not listed a first author and the decision remained by adjudication in the research review panel under Education Committee. Co-first authorship or shared first authorship were not accepted unless prior approval by research review panel. In principle, each research project should be led by one trainee only.
- Whether the study design fulfills the research requirement, would be subjected to the final decision of the research review panel under HKCEM Education Committee.

Formulation of a well-defined research question [Appendix A]

- Formulation of the research question should generally align the standard framework of PICOS or PEOS format.
  - PICOS framework
    - Patient or population – including the inclusion and exclusion criteria
    - Interventions / Exposure – could be a particular treatment in therapeutic studies, or diagnostic test / prediction rules in diagnostic studies
    - Control or comparator – the control group of subjects for comparison
    - Outcome – objective outcome parameters with definitions
    - Study design – e.g. case control study, cross-sectional study, prospective cohort study, retrospective cohort study, randomized controlled trial, etc.
  - In some study designs lacking active interventions, PEOS framework, where E stands for exposure, may be more appropriate.
- Trainees may discuss with research coordinators, training supervisor and coaches in research seminar for a novel, impactful, practical and feasible research topic. It is advisable for trainees to read up local and international EM journals to understand on various topics and recent trends in emergency medicine research.

Research protocol

- It is highly advisable to follow the framework of reporting guidelines under the Equator Network (https://www.equator-network.org). Though the documents and guidelines are intended to standardize the reporting style in manuscript writing for various study designs, the structure and layout are highly relevant in research planning and protocol writing for clinical research.
- A series of reference template for common study designs were set up for trainees' reference [see appendix B]
- Trainees should discuss with the research coordinator and training supervisor before submission to the research review panel.
- Submission of research protocol to research@hkcem.org.hk. There is no rigid timing for submission of research question / protocols and trainees could submit throughout the year. In general, the panel would get back the reply to trainee within 30 days.
- Trainee can change topic at any time of the pathway but the pathway needs to be started again.

The Research Review Panel

- The governance of the Research Review Panel is under the Education Committee of the college
- The chairperson(s) of the research review panel is/are the Vice-chairperson(s) of the Training and Examination Subcommittee
- There are two pools of reviewers
  - Pool of members from the Education Committee / Research subcommittee / EBM subcommittee / Academia
  - Pool of members from the research coordinators of training centres

- Each research protocol submitted by the trainee would be reviewed by two reviewers in the panel, one from each of the pools above. The chairperson of the panel would avoid review of trainees' submissions by reviewers in the same training centre, co-authorship involved or other situation of potential conflict of interest.
- The role and responsibility of the research review panel, is to
  - To assess on the appropriateness of methodology and if research context fulfills the college research requirement, rather than comment on feasibility and potential clinical impact of the study.
  - There will be free narration by the reviewers on comments and ***constructive advice to the trainee***, intending to give support and hint to the trainee to carry out the research smoothly.
- The review framework is attached in appendix C for reference
- In case of discrepant opinions from the vetting reviewers, adjudication would be carried out by the review chairperson and deliberated in the Education Committee.

Journal submission

- The manuscript should be submitted for publication by a peer-review journal indexed in Science Citation Index Expanded (SCI-E)
- Trainee are expected to go through and learn from the peer-review process.
- The journal submission proof should be submitted to the ePortfolio.

Run-in period of the new research pathway for EM trainees

- Trainees who started higher training **before 1 January 2024**
  - Can follow the old research requirement [appendix D], OR
  - Opt-in to follow new research pathway if not yet kick-started research planning, to get additional support from research review panel
  - Research protocol submission will not be included as eligibility criteria to sit in exit examination or assessment

- Trainees enrolled higher training **on or after 1 January 2024**
  - Mandatory to follow new research support pathway and updated research requirement
  - Exception:
    - Trainees had started research during EM basic training and demonstrated evidence of progress, or completed research requirement. Application is required within 1/7/2023 – 31/12/2023
  - The application would be reviewed and final decision would be adjudicated by EC

Appendix A

Guidance to HKCEM trainees for trainee research project – Defining research question

Defining research question

Common study designs for EM research includes (not exhaustive):

1. Observational studies
    - Prospective and retrospective cohort studies, including derivation and validation for clinical prediction rules
    - Cross-sectional studies
    - Case control studies
    - Diagnostic studies
2. Experimental/interventional studies
    - Randomized controlled trial
    - Mannikin studies
    - Quality improvement studies and Before-and-after comparative studies
3. Others
    - Surveys and questionnaire studies

Method to define research questions for experimental/interventional studies/validation studies for clinical prediction rules – PICOS

- Patient or population – including the inclusion and exclusion criteria
- Interventions / Exposure – could be a particular treatment in therapeutic studies, or diagnostic test / prediction rules in diagnostic studies
- Control or comparator – the control group of subjects for comparison
- Outcome – objective outcome parameters with definitions
- Study design – e.g. case control study, cross-sectional study, prospective cohort study, retrospective cohort study, randomized controlled trial, etc.

Method to define research questions for observational studies – PEOS

- P = Patient – Inclusion and exclusion criteria, study settings
- E = Exposure – objective definition of primary exposure factor to be evaluated
- O = Outcome – objective definition of outcome parameters to measure, including primary and secondary outcome
- S = Study design

Appendix A

Guidance to HKCEM trainees for trainee research project – Research protocols

Guidance on Research Protocol

Trainees could take reference to the standard reporting frameworks and guideline on the Equator Network (https://www.equator-network.org/) based on the study design

Types of studies	Reference Reporting guideline in Equator Network
Observational studies - **Prospective cohort studies** - **Retrospective cohort studies** - **Cross-sectional studies** - **Case control studies**	STROBE
Diagnostic studies	STARD
Randomized controlled trial	CONSORT
Quality improvement studies and Before-and-after comparative studies	SQUIRE

3 common research protocol frameworks would be available for trainees to take reference and serve as backbone: randomized controlled trials, observational studies, and diagnostic studies.

HKCEM trainee research – Research Protocol
Guidance Framework for Randomized controlled trial and other interventional studies
(modified from CONSORT 2010)

Protocol Version: [ ] Date: [ ]

Authorship
Principle investigator: [ ]
Co-investigators:

Take reference to ICMJE authorship definition:
https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Title
[ ]

Introduction
- Background
- Citation of existing scientific evidence
- Define objective of the study

Methods
1. Study design
   - e.g. Parallel, factorial, cross-over
   - allocation ratio
   - Important changes to methods after trial commencement (such as eligibility criteria), with reasons
2. Participants
   - Inclusion criteria
   - Exclusion criteria
   - Settings and locations where the data were collected
3. Interventions
   - The interventions for each group with sufficient details, including how and when they were actually administered
4. Outcomes
   - Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed

- If adopt composite outcome, should be clearly defined

5. Sample size
   - How sample size was determined
   - When applicable, explanation of any interim analyses and stopping guidelines
6. Randomization
   - Sequence generation
     - Method used to generate the random allocation sequence
     - Type of randomization; details of any restriction (such as blocking and block size)
   - Allocation concealment mechanism
     - Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
   - Implementation
     - Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
7. Blinding
   - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
8. Statistical methods
   - Statistical methods used to compare groups for primary and secondary outcomes
   - Methods for additional analyses, such as subgroup analyses and adjusted analyses
   - Tentative statistical software or package to adopt

Other Information

1. Funding
2. Trial registration
3. Institutional review board submission
4. Anticipated limitation of current study design

References

(Citation in Vancouver style: https://libguides.lib.cuhk.edu.hk/Citation_Styles/Vancouver with 6 authors before et al.)

HKCEM trainee research – Research Protocol
Guidance Framework for Observational studies
(modified from STROBE)

Protocol Version: [ ] Date: [ ]

Authorship
Principle investigator: [ ]
Co-investigators:

Take reference to ICMJE authorship definition:
https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Title
[ ]

Introduction
- Background
- Citation of existing scientific evidence
- Define objective and hypothesis of the study

Methods
1. Study design and setting
   - Define study design
   - Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
2. Participants
   - Inclusion criteria
   - Exclusion criteria
   - Sources and methods of selection of participants
   - *Specific for Cohort study — Describe methods of follow-up. For matched studies, give matching criteria and number of exposed and unexposed*
   - *Specific for Case-control study — methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. For matched studies, give matching criteria and number of exposed and unexposed*

3. Variables
    - All outcomes, exposures, predictors, potential confounders and effect modifiers, diagnostic criteria (for studies on clinical prediction rules)

Variable	Definition	Type	Data sources
		Continuous / categorical / count	Electronic database / manual chart review

4. Outcomes
    - Define clearly the primary outcome and secondary outcome
5. Sample size
    - How sample size was determined
6. Statistical methods
    - Describe all statistical methods, including those used to control for confounding
    - If adopt multivariate statistical model, the detail setup of the model
    - Describe any methods used to examine subgroups and interactions
    - Explain how missing data were addressed
    - *Specific for cohort study — If applicable, explain how loss to follow-up was addressed*
    - *Specific for Case-control study — If applicable, explain how matching of cases and controls was addressed*
    - *Specific for Cross-sectional study — If applicable, describe analytical methods taking account of sampling strategy*
    - Tentative statistical software or package to adopt

Other Information

1. Funding
2. Institutional review board submission
3. Anticipated limitation of current study design

References

(Citation in Vancouver style: https://libguides.lib.cuhk.edu.hk/Citation_Styles/Vancouver with 6 authors before et al.)

HKCEM trainee research – Research Protocol
Guidance Framework for Diagnostic studies
(also applicable to validation studies on clinical prediction rules)
(modified from STARD)

Protocol Version: [ ] Date: [ ]

Authorship
Principle investigator: [ ]
Co-investigators:

Take reference to ICMJE authorship definition:
https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Title
[ ]

Introduction
- Scientific and clinical background, including the intended use and clinical role of the index test / rule
- Citation of existing scientific evidence
- Define objective and hypothesis of the study

Methods
1. Study design and setting
   - Define study design: Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)
   - Describe the setting, locations, and relevant dates, including periods of recruitment, exposure on diagnostic test/rule, follow-up, and data collection
2. Participants
   - Inclusion criteria
   - Exclusion criteria
   - Sources and methods of selection of participants - On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)
   - Where and when potentially eligible participants were identified (setting, location and dates)
   - Whether participants formed a consecutive, random or convenience series

3. Test methods / prediction rules and the Reference standard
    - Index test/rule, in sufficient detail to allow replication
    - Other comparative diagnostic tests and the detail, if any
    - Reference standard / gold standard in clear definition. Rationale for choosing the reference standard (if alternatives exist)
    - Definition of and rationale for test positivity cut-offs or result categories of the index test and reference standard, distinguishing pre-specified from exploratory
    - Blinding
        - Whether clinical information and reference standard results were available to the performers/readers of the index test
        - Whether clinical information and index test results were available to the assessors of the reference standard
4. Variables
    - All outcomes, exposures, diagnostic test value, predictors, components of diagnostic criteria (for studies on clinical prediction rules)

Variable	Definition	Type	Data sources
		Continuous / categorical / count	Electronic database / manual chart review

5. Sample size
    - How sample size was determined
6. Statistical methods
    - Methods for estimating or comparing measures of diagnostic accuracy
    - How indeterminate index test or reference standard results were handled
    - How missing data on the index test and reference standard were handled (verification bias for missing reference standard)
    - Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory

Other Information

1. Funding
2. Institutional review board submission
3. Anticipated limitation of current study design - including sources of potential bias, statistical uncertainty, and generalisability

References

(Citation in Vancouver style: https://libguides.lib.cuhk.edu.hk/Citation_Styles/Vancouver with 6 authors before et al.)

Appendix C. Assessment Framework of HKCEM trainee Research protocol submissions

EM trainee Research protocol submission

↓

Study Design fulfilling requirement
(NOT accept case reports, case series, review articles)

☐ No → **Reject**
Reason:
_____
_____
_____
_____
_____
_____
_____

☐ Yes ↓

Research context and topic relevant to science and practice of emergency medicine

☐ No → **Reject** (see above)

☐ Yes ↓

Trainee being sole first author

☐ No → **Reject** (see above)

☐ Yes ↓

Comments/constructive advice:

Title/Research question/PICOS: _____
_____

Novelty: _____
_____

Scientific background / literature search: _____
_____

Study Setting (Participants, variables and outcome definition): _____
_____

Statistical methods and sample size: _____
_____

Practical feasibility: _____
_____

Protocol writing and other comments: _____
_____
_____
_____
_____
_____
_____
_____

↓

Decision: ☐ Support / ☐ Return for amendment

Appendix D

Old Research requirement criteria

(applicable to trainees enrolled higher training before 1 January 2024)

- Trainees should complete at least ONE original research project and pass the vetting, preferably before attempting the Exit Examination. EC takes note that sometimes more time is needed to complete a complex project and to get the paper published. Starting from 2021, trainees may sit the Exit Exam before the Fulfillment of College Research Requirement.

1. A trainee is not eligible to apply for the Fellowship of HKCEM before Fulfillment of College Research Requirement.
2. After passing the Exit Examination, a 'pre-fellow', who should be a member of the College, has to fulfill the College Research Requirement within 2 years, counting from the day of passing the Exit Exam.
    - A pre-fellow has to maintain his continuous professional development by attending College CME activities to acquire the required training points during this window period.
    - The training points required are 30 per year (Cat A or Cat B), courting from 1 Jan of each year.
3. EC will closely monitor the research project progress and training point acquisition of a pre- fellow through his training supervisor or delegate as mentor.
4. Fulfillment of the College Research Requirement after 2 years post Exit Examination is not entertained. Cases with exceptional justifications will be subjected to review and approval by EC. EC may impose remedial actions on the applicants. An applicant may be required to re-sit the Exit Examination as the most serious consequence. The decision of the College shall be final.

- Case report, case series or review articles are NOT accepted

- The project should be written up. The paper must satisfy the following criteria:
    - Trainee as the first author, AND
    - Related to medical science, AND
    - Any one of the followings

A. Accepted for publication, OR

B. Accepted for oral presentation in a HKCEM-organized education activity (e.g. SSEM, Research Seminar Presentation) and judged by College appointed adjudicators as of satisfactory standard. Followed by submission of paper for publication.

A. Accepted for publication

- The paper should be accepted for publication by a peer-review journal that is indexed in EM Base. Medline, Web of Science or Scopus (e.g. HKJEM, HKMJ)".
- After the research paper has been accepted for publication, a trainee or pre-fellow can apply for vetting through HKCEM ePortfolio. (https://e-portfolio.hkcem.com)
- The paper will be vetted by two EC members to make sure it satisfies the above requirements.
- After vetting, the trainee or pre-fellow who has fulfilled the College research requirement will be notified by an email generated by HKCEM ePortfolio. The fulfillment will be documented in ePortfolio as one criteria of eligibility to apply for Fellowship of the College

B. Accepted for oral presentation

Arrangement for oral presentation in a designated HKCEM-organized education activity:

- Separate application has to be made to the Education Committee, through HKCEM ePortfolio; in addition to the organizer of the Event/Activity
- At least 1 month before the date of the oral presentation
- The full paper should be submitted to the EC through ePortfolio
- Upon receiving the application, EC will arrange a panel of adjudicators to review the paper before the event and then attend the presentation to ensure they are of satisfactory standard. The result will be notified by an email generated by ePortfolio
- After the presentation, the paper should be sent to a peer-review journal indexed in EM Base. Medline, Web of Science or Scopus for publication. The acknowledgement of submission should be sent to EC as the final step for vetting
- After vetting, the trainee or pre-fellow who has fulfilled the College research requirement will be notified by an email generated by HKCEM ePortfolio. The fulfillment will be documented in ePortfolio as one criteria of eligibility to apply for Fellowship of the College