Operational Guideline for Chinese Medicine Research

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Content

Appendices

1. Purpose

This operational guideline provides the application procedure and monitoring mechanism for the application of Chinese medicine (CM) research projects in Hospital Authority Chinese Medicine Department (HACMD) and the Chinese Medicine Centres for Training and Research (CMCTRs).

2. Background

In accordance with Government's direction set out in 2000 Policy Address to provide out-patient CM services in the public sector, the Hospital Authority (HA) Board has endorsed the development of an evidence-based CM (EBCM) service model. The HA was subsequently tasked to set up 18 CMCTRs operated on a tripartite collaboration model involving the HA, a non-governmental organization ("NGO") and a local university, with the NGOs as the operators of CMCTRs, to deliver the EBCM service model. The CMCTRs not only provide CM services, but also a platform for training and research to the Chinese medicine practitioners (CMPs).

To better steer and govern the EBCM development, HACMD has established the (a) Central Research Working Group (CRWG) for setting thematic priorities; and (b) Expert Panel for providing opinion in the research planning.

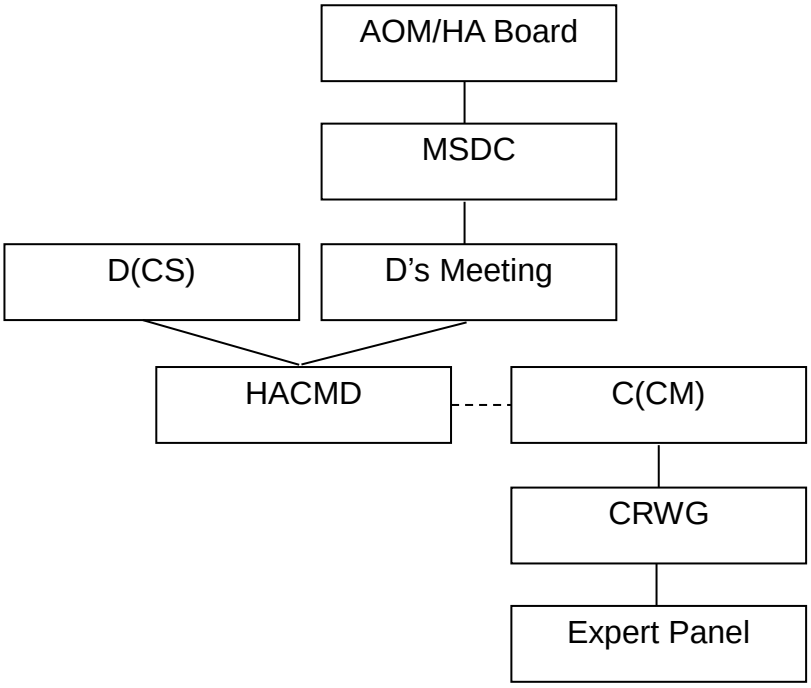
3. Objective

To provide guidance on the application procedure and monitoring mechanism for the CM research projects administered by HACMD.

4. Governance Structure

HACMD has established CRWG under the Committee on Chinese Medicine Services (C(CM)) and the Expert Panel under CRWG. Issues regarding CM research and training will be discussed in CRWG and the resolutions will be reviewed and endorsed in C(CM). HACMD provides administration support for C(CM) and reports to higher management of HA, e.g. Director of Cluster Services (D(CS)), Directors' Meeting (D's Meeting), Medical Services Development Committee (MSDC) and Administrative and Operational Meeting (AOM) or HA Board, if necessary.

Diagram of the governance structure



4.1 Central Research Working Group

4.1.1 Objective

To facilitate CM research according to the development directions of CMCTRs, and to advise on the development of CM research monitoring and training by HACMD.

4.1.2 Composition of Membership

Chairman: Chief (Chinese Medicine Department)

Secretary: 1 Representative from HACMD

Members: 1 Representative from HA Head Office (HAHO)
3 Representatives from local universities
3 Representatives from NGOs
2 Chinese medicine practitioners from the private sector

4.1.3 Terms of Reference

a. To determine the strategic direction and thematic priorities in CM research and training.
b. To advise in setting up appropriate monitoring mechanism, collaborative platform and training modules in research.

4.1.4 Frequency of Meeting

Yearly

4.1.5 Tenure

2 years

4.2 Expert Panel

4.2.1 Composition of Membership

Experts(1) in specific research areas.

4.2.2 Terms of Reference

a. To review scientific merit, feasibility and desirability.
b. To make recommendations on research proposals.

4.2.3 Frequency of Meeting

Ad-hoc

4.2.4 Tenure

2 years

(1) Invite by CRWG and endorse by C(CM)

5. Application and Vetting Procedures, and Research Monitoring Mechanism

According to the funding source, there are three types of research projects:
Type I: Research projects funded by HACMD
Type II: Research projects funded by CMCTR(s), including provision of manpower support by CMCTR(s)
Type III: Research projects in CMCTR(s) without additional funding request (funded from other sources)

The respective application and vetting procedures, and research monitoring mechanism established according to the type of research project are as follows:-

5.1 Type I: Research Projects Funded by HACMD

5.1.1 Application Procedures

a. HACMD announces the endorsed thematic priorities and prepares the specifications accordingly. HACMD may seek professional input from the Expert Panel where necessary.
b. HA Business Support Services (BSS) issues tender/ quotation invitation with the specifications.
c. Principal Investigator (PI) submits application to BSS according to the specifications.
    i) If the research is to be collaborated with CMCTR(s), PI should liaise with the CMCTR(s) to complete the HA Tripartite Clinic Indication of Interests for Research Form (Appendix I).
    ii) Application documents should include the followings:
        - Research proposal (please refer to *Guidelines for Good Clinical Practice in Clinical Research on Chinese Medicine* (Lo & Ko, 2001) for the content of a research protocol);
        - Curriculum vitae of PI;
        - HA Tripartite Clinic Indication of Interests for Research Form signed by CMCTR(s) (if the project is to be collaborated with CMCTR(s));
        - Approval letter of REC when available, if necessary.

5.1.2 Vetting Procedures

a. Member(s) of Expert Panel will be invited to be part of the Assessment Panel (AP) for the review of applications according to assessment criteria.

b. After the review of applications by AP, HACMD submits the results to BSS for further approval in accordance with HA tendering procedure.
c. BSS informs successful applicant(s) for the accepted application(s). Applicants who do not receive any notification after the validity period as stated in the invitation may assume their applications unsuccessful.
d. PI attends preparatory meeting convened by HACMD and finalizes the proposal.
e. PI seeks Research Ethics Committee (REC) approval in parallel, if necessary.
f. HACMD arranges 1st payment.
g. PI submits REC approval letter, if necessary, to HACMD.
h. PI commences the research project. If the project is collaborated with CMCTR(s), PI shall seek endorsement from the corresponding Centre Management Committee(s) (CMC) of the CMCTR(s).
i. HACMD informs members of CRWG and C(CM) of the award results.

5.1.3 Research Monitoring Mechanism

a. PI commences the research project.
b. HACMD convenes quarterly monitoring meetings. PI shall attend the meetings and submit quarterly progress reports.
   i) The quarterly report should be submitted 1 week before the quarterly research monitoring meeting.
   ii) The quarterly report should include the progress of the project, incidents if any, encountered difficulties and identified areas where the PI may need support or advice from HACMD.

5.1.4 Project Completion

a. PI submits final report and complete all deliverables stated in the contract.
   i) The final report should be submitted within 30 days of the project end date. It must be concise and provide HACMD with sufficient information to evaluate the project completeness. It should comprise of the following:
      - An abstract written in a style similar to a journal article
      - Main body of the report; it should be written in a style similar to that of a journal article. Submitted reports should be on par with those submitted to refereed journals
      - Copy of manuscript(s) and/ or abstract submitted to particular journal(s) and/ or conference(s)
      - All raw data of the project
      - Official financial statement of the project

ii) The content of report should contain sufficient information for HACMD to assess whether the work has been carried out in accordance with the approved proposal and evaluate the quality of the research output. PI is obliged to revise the report according to the feedback of HACMD, if any, and submit their response in compliance with the deadlines specified by HACMD.

iii) PI is encouraged to submit the manuscript to an international journal for publication.

b. HACMD arranges final payment to the PI after all the deliverables have been completed in accordance with the terms and conditions of the contract and to the satisfaction of the HA.

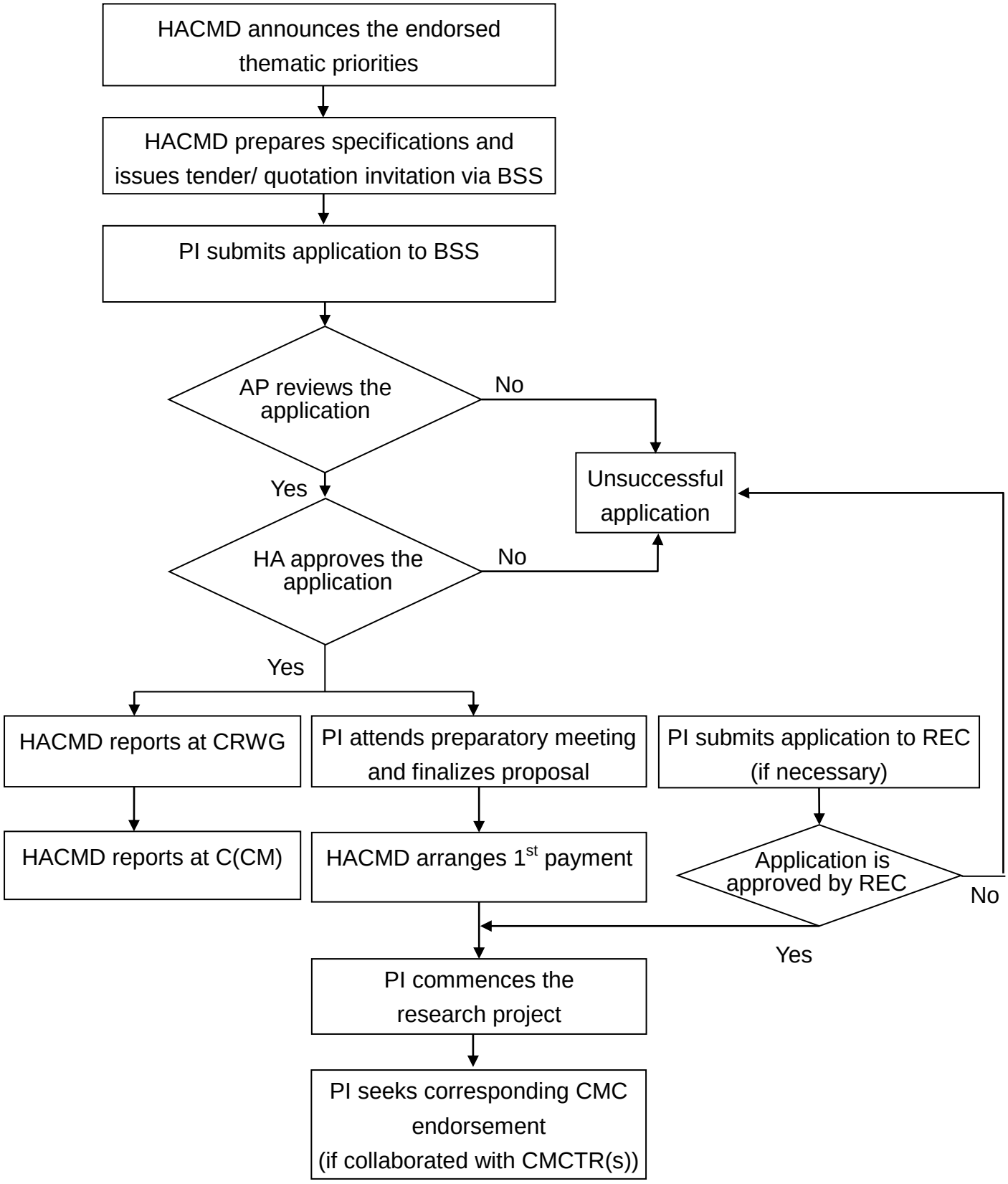
5.1.5 Actions for Non-Compliance

If the PI cannot fulfil the requirements and complete the deliverables stated in the contract, attend the monitoring meetings, submit/ revise the quarterly and final reports as required, HA shall request PI to provide explanations as well as remedial actions through quarterly meetings or via email. Should non-compliance continues, HACMD shall issue written letter and reserve the right to:

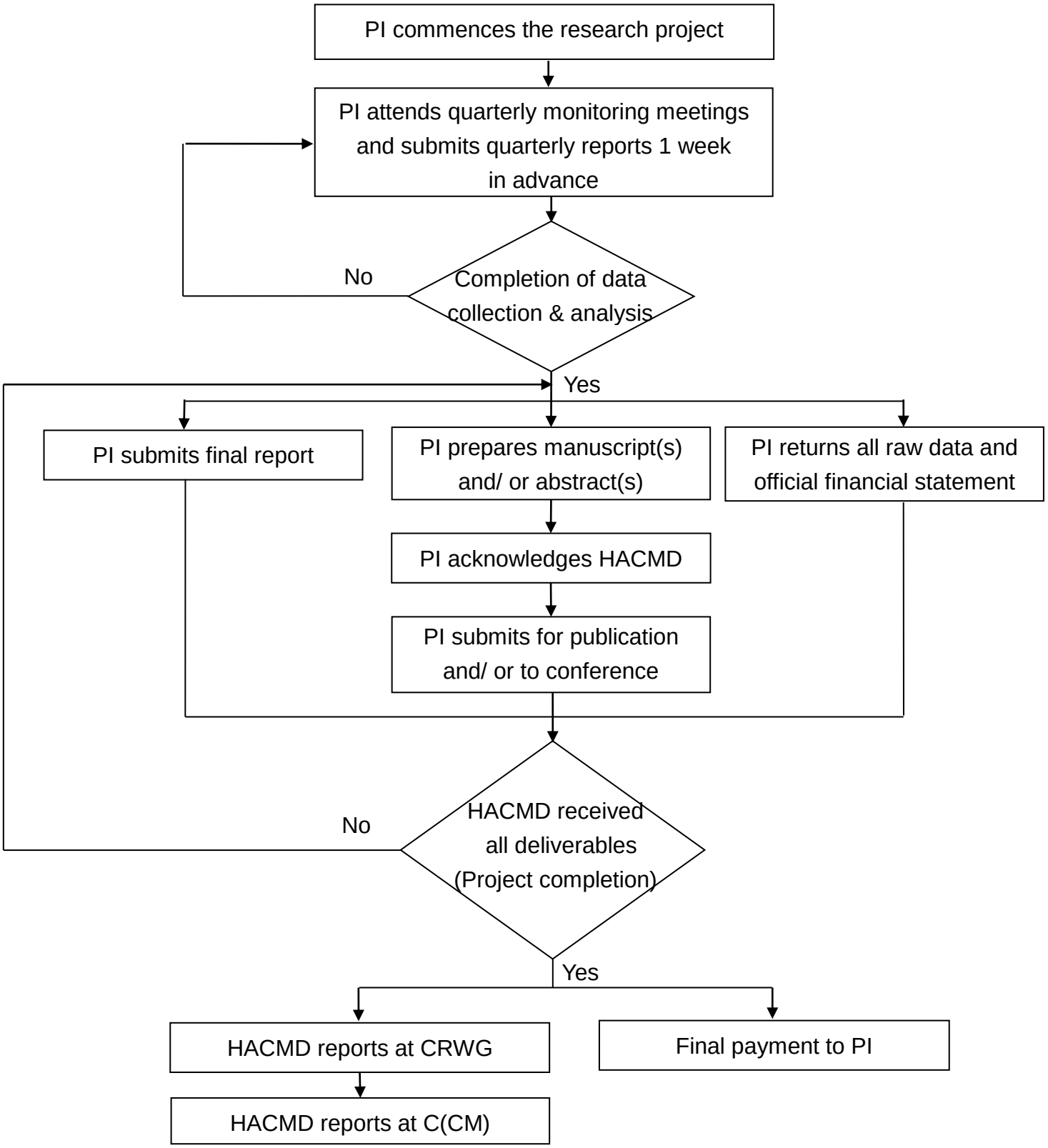
a. withhold the final payment;
b. terminate the project; and
c. arrange refund from the PI for the payment made, if necessary.

5.1.6 Flowcharts for Type I Projects

a. Flowchart of Application and Vetting Procedures



b. Flowchart of Research Monitoring Mechanism



5.2 Type II: Research Projects Funded by CMCTR(s)

Type II projects refer to research projects funded by CMCTR(s), including projects utilizing manpower support provided by CMCTR(s).

5.2.1 Application Procedures

a. HACMD announces the endorsed thematic priorities.
b. PI initiates and drafts research proposal according to the thematic priorities.
c. PI liaises with the CMCTR(s) for collaboration and completes the HA Tripartite Clinic Indication of Interests for Research Form (Appendix I).
d. PI submits application to HACMD.
   i) PI should seek REC approval in parallel, if necessary.
   ii) Application documents should include the followings:
      - Application form (Appendix II(a) for clinical research; Appendix II(b) for systematic review);
      - Research proposal (please refer to *Guidelines for Good Clinical Practice in Clinical Research on Chinese Medicine* (Lo & Ko, 2001) for the content of a research protocol);
      - Curriculum vitae of PI;
      - HA Tripartite Clinic Indication of Interests for Research Form signed by CMCTR(s);
      - Approval letter of REC when available, if necessary.

5.2.2 Vetting Procedures

a. HACMD collects the applications and verifies CMCTR's reason to support the research project which is relevant to the development direction of the CMCTR. CMCTRs shall seek CRWG approval via HACMD for collaborating projects outside thematic priorities.
b. HACMD sends the applications to the Expert Panel.
c. Expert Panel reviews the applications
d. HACMD informs PI and CMCTR(s) of the recommendations of Expert Panel.
e. PI submits REC approval letter to HACMD, if necessary.
f. PI submits the research proposal to the relevant Operation & Risk Management Sub-committee (O&RM) and CMC of the CMCTR(s) for discussion and endorsement. PI attends and presents the proposal at the meetings.
g. After obtaining CMC endorsement, PI attends preparatory meeting convened by HACMD and finalizes the proposal.

h. For projects where funding will be released from CMCTR(s) to the collaborating institution, e.g. university, a research collaboration agreement (including but not limited to funding sources, research indemnity, intellectual property, confidentiality, etc) shall be signed between the supporting CMCTR(s) and the collaborating institution. The study results shall be jointly owned by the collaborating institution, supporting CMCTR(s) and HA.
i. CMCTR(s) arrange 1st payment and PI commences the research project.
j. HACMD informs members of CRWG and C(CM) of the award results.

5.2.3 Research Monitoring Mechanism

a. PI commences the research project.
b. HACMD convenes quarterly monitoring meetings. PI shall attend the meetings and submit quarterly progress reports. For the requirement of the reports, please refer to Section 5.1.3b.
c. PI shall also report the progress at ORM and/or CMC meetings if required.

5.2.4 Project Completion

a. PI submits final report and completes all deliverables stated in the proposal and agreement. For the requirement of the final report, please refer to Section 5.1.4a.
b. HACMD confirms completion of all deliverables and informs CMCTR(s).
c. PI reports the research findings at O&RM and CMC of the CMCTR(s).
d. CMC approves project completion and CMCTR(s) arrange final payment after all the deliverables have been completed in accordance with the agreement.

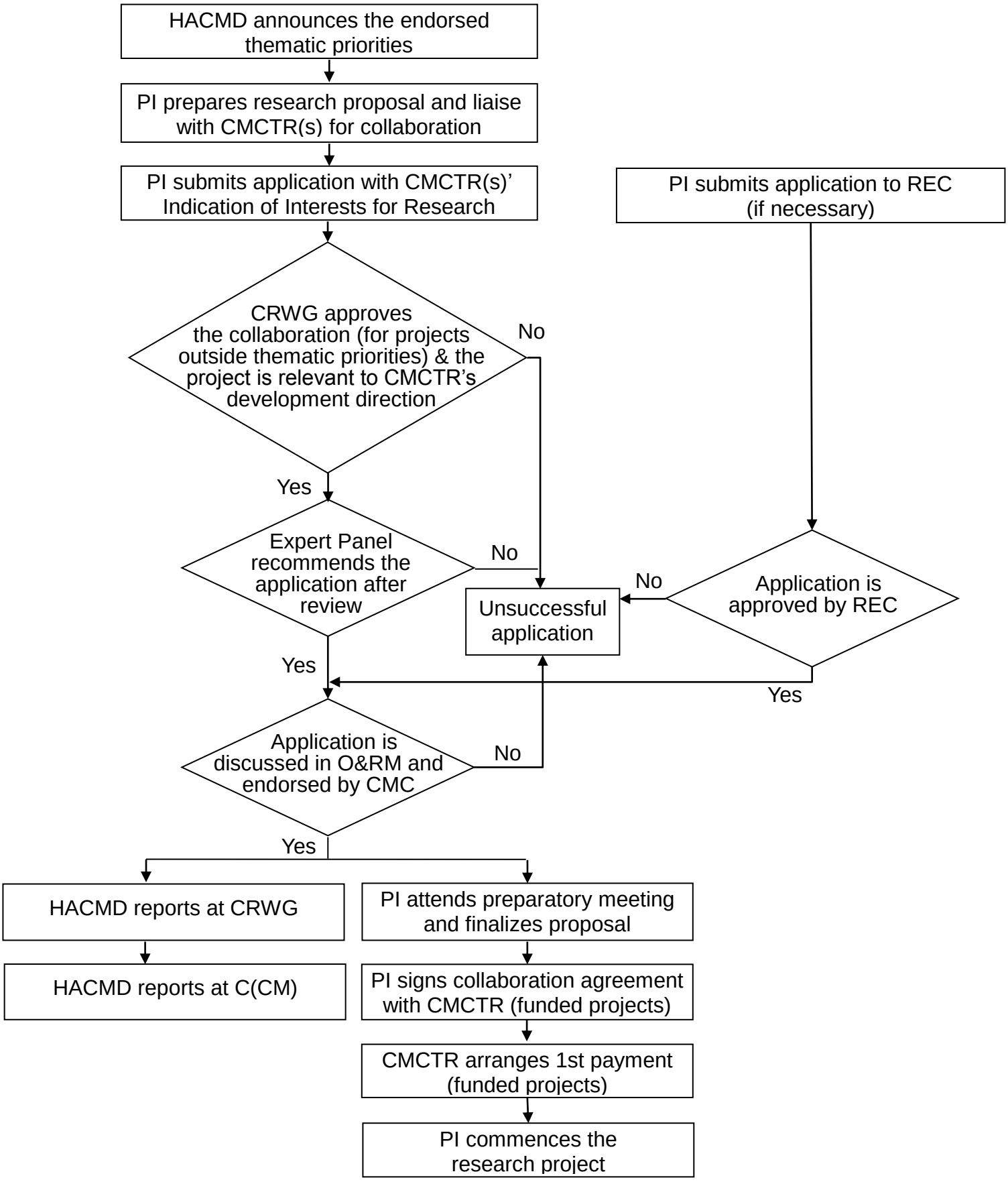
5.2.5 Actions for Non-Compliance

If the PI cannot fulfil the requirements and complete the deliverables stated in the proposal and agreement, attend the monitoring meetings, submit/ revise the quarterly and final reports as required, HA shall request PI to provide explanations as well as remedial actions through quarterly meetings or via email. Should non-compliance continues, HACMD/ CMCTR(s) shall issue written letter and reserve the right to:

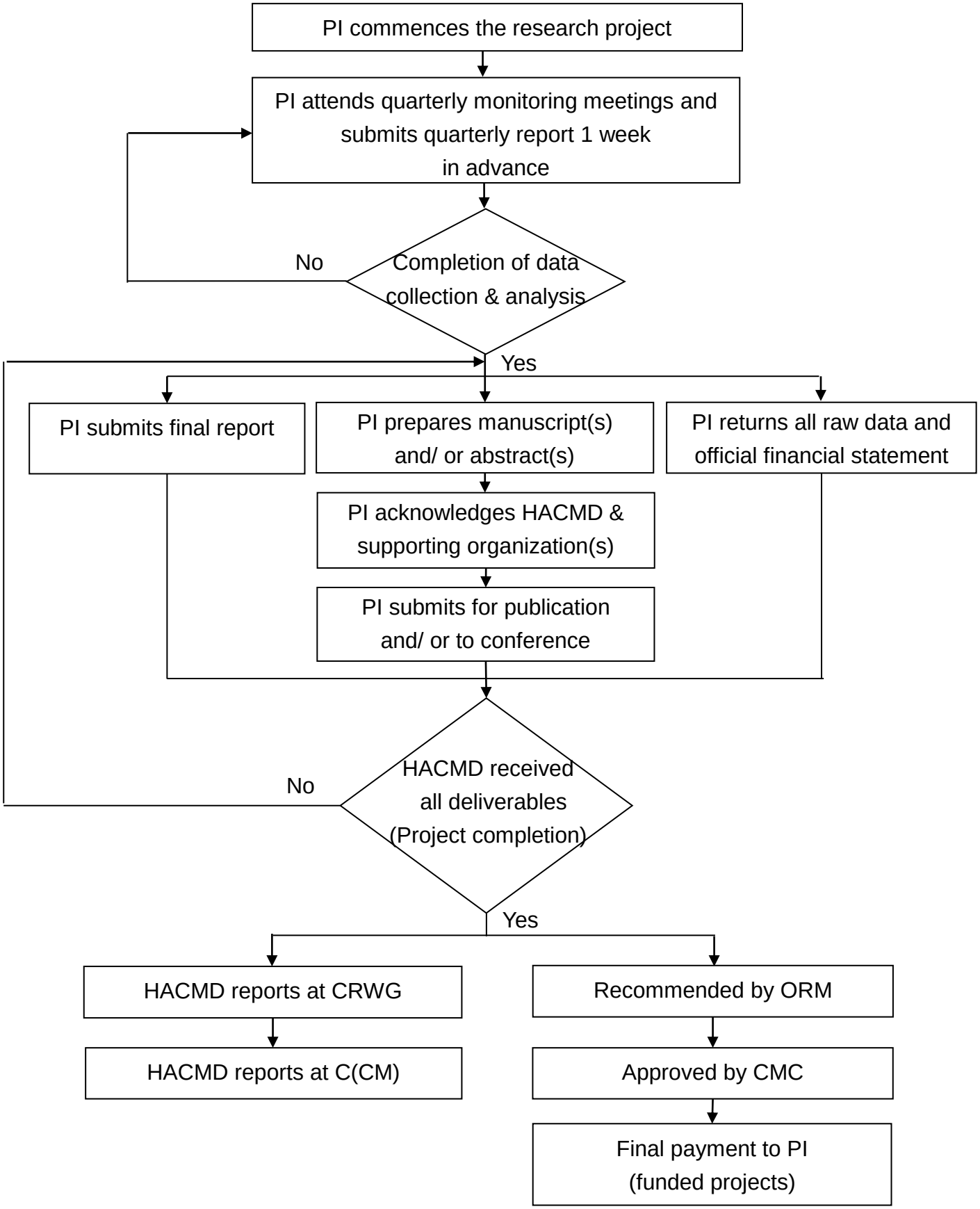
a. withhold the final payment;
b. terminate the project; and
c. arrange refund from the PI for the payment made, if necessary.

5.2.6 Flowcharts for Type II Projects

a. Flowchart of Application and Vetting Procedures



b. Flowchart of Research Monitoring Mechanism



5.3 Type III: Research Projects in CMCTRs without Additional Funding Request (Funded from Other Sources)

Type III projects refer to research projects with no research funding and manpower support from HACMD/ CMCTR(s).

5.3.1 Application Procedures

a. PI seeks collaboration for an endorsed/ funded research proposal with REC approval, if necessary.
b. PI liaises with the CMCTR(s) for collaboration and completes the HA Tripartite Clinic Indication of Interests for Research Form (Appendix I). CMCTRs should consider the collaboration under the circumstance that the collaboration should have minimal influence on the daily operation of the CMCTR.
c. PI submits application to HACMD with the REC approval, if necessary.
   i) Application documents should include the followings:
      - Application form (Appendix II(a) for clinical research; Appendix II(b) for systematic review);
      - Research proposal (please refer to *Guidelines for Good Clinical Practice in Clinical Research on Chinese Medicine* (Lo & Ko, 2001) for the content of a research protocol);
      - Curriculum vitae of PI;
      - HA Tripartite Clinic Indication of Interests for Research Form signed by CMCTR(s);
      - Approval letter of REC, if necessary.

5.3.2 Vetting Procedures

a. HACMD collects the application and verifies CMCTR's reason to support the research project. The collaboration should have minimal influence on the daily operation of the CMCTR.
b. HACMD sends the application to the Expert Panel.
c. Expert Panel reviews the application.
d. HACMD informs PI and CMCTR(s) of the recommendations of Expert Panel.
e. PI submits the research proposal to the relevant O&RM and CMC of the CMCTR(s) for discussion and endorsement. PI attends and presents the proposal at the meetings.
f. After obtaining CMC endorsement, PI commences the research project.
g. HACMD informs members of CRWG and C(CM) of the endorsement.

5.3.3 Research Monitoring Mechanism

a. PI commences the research project.

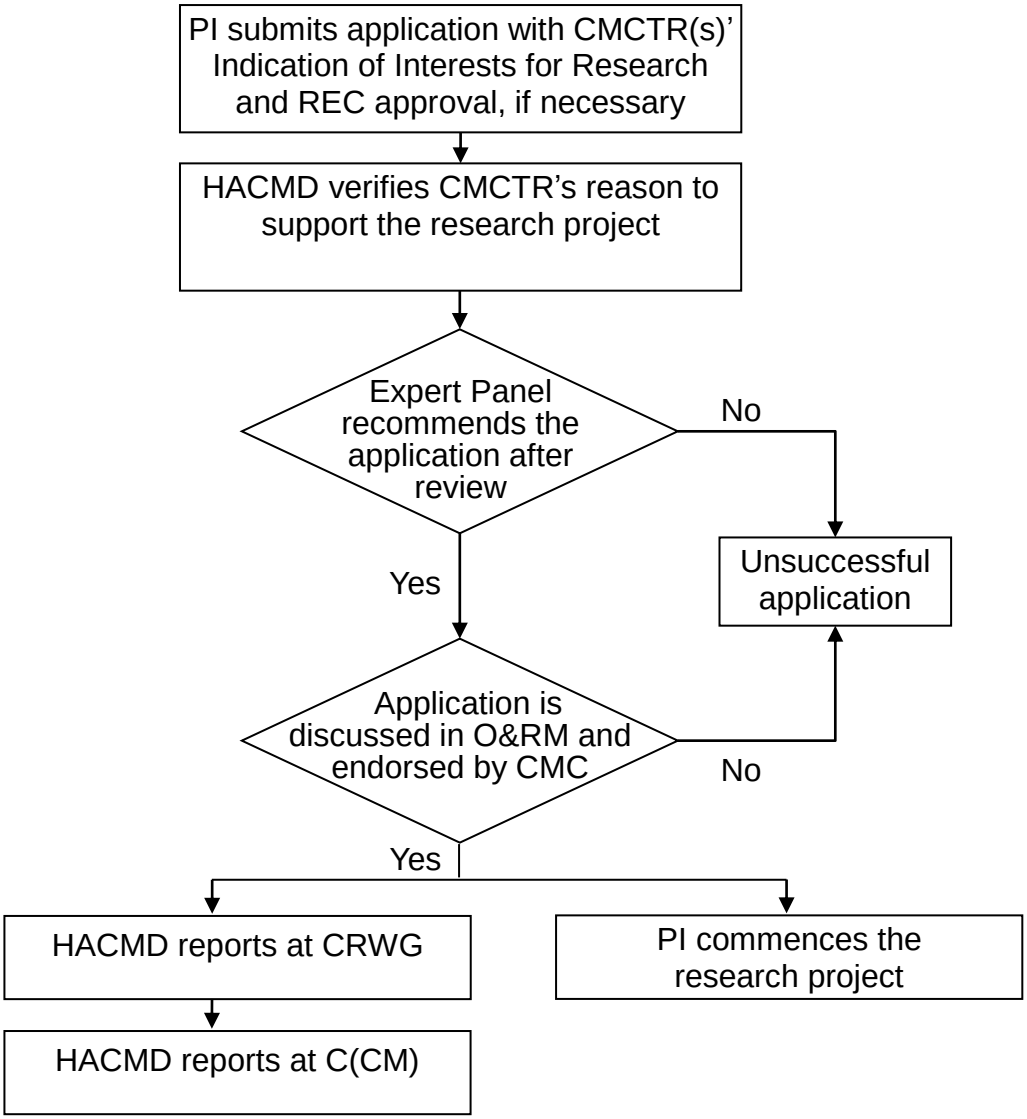
b. On behalf of the CMCTR, Chinese Medicine Chief of Service (CMCOS) is responsible to monitor the progress of the research. PI should report regularly to CMCOS as required. PI should also report to O&RM and/ or CMC if required.

5.3.4 Project Completion

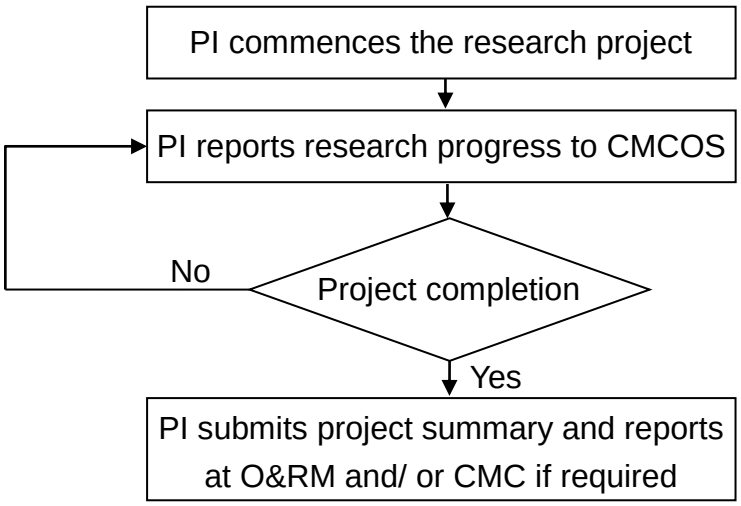
PI should prepare project summary within 2 months upon project completion and submit to O&RM and CMC via CMCOS. PI should also report to O&RM and/ or CMC if required.

5.3.5 Flowcharts for Type III Projects

a. Flowchart of Application and Vetting Procedures



b. Flowchart of Research Monitoring Mechanism



6. Other Relevant Guidelines

6.1 Hospital Authority. (2010). *Clinical Research Management and Compliance at Study Sites.* Retrieved from http://qsdportal/cetm/Website/Research_ethics/ha_handbook.pdf

6.2 Lo, S. V., & Ko, W. M. (2001). *Guidelines for Good Clinical Practice in Clinical Research on Chinese Medicine*. Retrieved from Hospital Authority, e-Knowledge Gateway (eKG) website (intranet): http://www.ekg.org.hk/html/gateway/clinical/guidelines/tcmguidelines.pdf

Enquiries

Please contact HACMD (research@hacmk.org.hk) for any enquiries concerning the content of this operational guideline.

Please refer to http://cmk.ha.org.hk/ for the most updated version

Appendix I

HA Tripartite Clinic Indication of Interests for Research

To: Secretariat
Hospital Authority Chinese Medicine Central Research Working Group
Email: research@hacmk.org.hk
Fax: 2338 5189

We ***are / are not** interested to support ***with / without** financial and/or manpower indications to the following project :

Project Title	
Principal Investigator	
Institution	
Reason to Support *(Example: relevant to the development direction of the CMCTR, ie. cancer)*	

* Please delete where inapplicable

Name : _____

Post Title : _____

For and On Behalf of HA Tripartite Clinic : _____

Signature : _____

Date : _____

Central Research Working Group
Chinese Medicine Research
Application Form (For Clinical Research)

PART I: OUTLINE OF APPLICATION

1. Name of Study

1.1 Scientific Title (should include study design, name of intervention, condition being studied and study outcomes):

1.2 Short Title (for easy quote):

1.3 Is this application for continuation of a project already started?
☐ Yes (Please specify: _____) ; ☐ No

1.4 Have you applied to other bodies for financial support towards this project?
☐ Yes (Please specify: _____) ; ☐ No

1.5 Have you applied to research ethics committee for approval?
☐ Yes (Please specify: _____) ; ☐ No

2. Applicant (Principal Investigator)

2.1 Title: Surname: First Name:

Name in Chinese:

University Staff ☐ Position:

Department/ University:

HA Staff ☐ Position:

Department/ Hospital:

NGO Staff ☐ Position:

NGO:

2.2 Qualifications and relevant experience (<500 words)

2.3 Phone number:

2.4 Fax number:

2.5 E-mail:

2.6 Mailing address:

3. Co-investigators

Title	Surname	First Name	Post	Relevant Qualifications	Department	Institution

4. Study Site(s)

4.1 Is this a multi-centered trial? ☐ Yes ☐ No

4.2 Please indicate your study site(s) in HA cluster and/ or CMCTR.

5. Milestones

5.1 Proposed study start date: (mm/yyyy)

5.2 Proposed study end date: (mm/yyyy)

6. Brief Summary of Study (<1000 words)

7. Major Ethical Issues (<500 words)

PART II: STUDY DETAILS

8. Scientific basis

8.1 Disease group (choose from the thematic priorities):

8.2 Background, current evidence and key references:

8.3 Aim of study:

8.4 Hypothesis (for quantitative studies only):

8.5 Intervention, if applicable:

8.6 Study design:

8.7 Methodology:

8.8 Methods of analysis:

	Outcome measure(s)	Time-point
8.9 Primary outcome, if applicable		
8.10 Secondary outcome(s), if applicable		

9. Study subjects

9.1 Inclusion criteria:

9.2 Exclusion criteria:

9.3 Sample-size and rationale for calculation:

Sample size = based on the following rationale:

9.4 How will subjects be identified and recruited?

10. Anticipated Benefits to Study Subjects

PART III: BUDGET AND USE OF RESOURCES

11. Source of Funding

11.1 NGO: ☐ Yes (Please specify: _____) ; ☐ No

11.2 University: ☐ Yes (Please specify: _____) ; ☐ No

11.3 Government: ☐ Yes (Please specify: _____) ; ☐ No

11.4 Others: ☐ Yes (Please specify: _____) ; ☐ No

11.5 Amount requested: HKD_____

Staff Cost	
Equipment	
Others (Please Specify)	
Admin Overhead	
Total	

12. Resources Implication and Conflict of Interest

12.1 Will this study use HA / CMCTR resources? ☐ Yes ☐ No

12.1.1 If yes, provide details:

12.2 Will study site receive reimbursement for the study? ☐ Yes ☐ No

12.2.1 If yes, provide details:

12.3 Is there a non-monetary (drug, consumable or equipment) sponsorship? ☐ Yes ☐ No

12.3.1 If yes, provide details:

13. Financial Costs and Payment to Subjects

13.1 Will the subjects be charged for the study? ☐ Yes (Please specify: _____) ; ☐ No

13.2 Will subjects receive payment? ☐ Yes (Please specify: _____) ; ☐ No

14. Research Indemnity and Clinical Trial Certificate

14.1 Will a clinical trial certificate be applied? ☐ Yes (Please specify: _____) ;
☐ No

14.2 Will research indemnity be covered? ☐ Yes (Please specify: _____) ;
☐ No

15. Recommended Reviewers

15.1 Title: ☐ Prof ☐ Dr ☐ Mr ☐ Mdm ☐ Ms

Name:

Institution:

Email:

15.2 Title: ☐ Prof ☐ Dr ☐ Mr ☐ Mdm ☐ Ms

Name:

Institution:

Email:

16. Date of Submission

Central Research Working Group
Chinese Medicine Research
Application Form (For Systematic Review)

PART I: OUTLINE OF APPLICATION

1. Name of Study

1.1 Scientific Title (should include study design, name of intervention, condition being studied and study outcomes):

1.2 Short Title (for easy quote):

1.3 Is this application for continuation of a project already started?
☐ Yes (Please specify: _____) ; ☐ No

1.4 Have you applied to other bodies for financial support towards this project?
☐ Yes (Please specify: _____) ; ☐ No

2. Applicant (Principal Investigator)

2.1 Title: Surname: First Name:

Name in Chinese:

University Staff ☐ Position:

Department/ University:

HA Staff ☐ Position:

Department/ Hospital:

NGO Staff ☐ Position:

NGO:

2.2 Qualifications and relevant experience (<500 words)

2.3 Phone number:

2.4 Fax number:

2.5 E-mail:

2.6 Mailing address:

3. Co-investigators

Title	Surname	First Name	Post	Relevant Qualifications	Department	Institution

4. Milestones

4.1 Proposed study start date: (mm/yyyy)

4.2 Proposed study end date: (mm/yyyy)

5. Brief Summary of Study (<1000 words)

PART II: STUDY DETAILS

6. Scientific basis

6.1 Disease group (choose from the thematic priorities):

6.2 Background, current evidence and key references:

6.3 Aim of study:

6.4 Data Source:

6.5 Intervention:

6.6 Data Extraction:

7. Anticipated Potential to Research Studies

PART III: BUDGET AND USE OF RESOURCES

8. Source of Funding

8.1 NGO: ☐ Yes (Please specify: _____) ; ☐ No

8.2 University: ☐ Yes (Please specify: _____) ; ☐ No

8.3 Government: ☐ Yes (Please specify: _____) ; ☐ No

8.4 Others: ☐ Yes (Please specify: _____) ; ☐ No

8.5 Amount requested: HKD_____

Staff Cost	
Equipment	
Others (Please Specify)	
Admin Overhead	
Total	

9. Resources Implication and Conflict of Interest

9.1 Will this study use HA / CMCTR resources? ☐ Yes ☐ No

9.1.1 If yes, provide details:

9.2 Will study site receive reimbursement for the study? ☐ Yes ☐ No

9.2.1 If yes, provide details:

9.3 Is there a non-monetary (drug, consumable or equipment) sponsorship? ☐ Yes ☐ No

9.3.1 If yes, provide details:

10. Recommended Reviewers

10.1 Title: ☐ Prof ☐ Dr ☐ Mr ☐ Mdm ☐ Ms

Name:

Institution:

Email:

10.2 Title: ☐ Prof ☐ Dr ☐ Mr ☐ Mdm ☐ Ms

Name:

Institution:

Email:

11. Date of Submission

醫院管理局
HOSPITAL AUTHORITY

Chinese Medicine Research Monitoring Report

Important: Please complete ALL sections with sufficient detail to allow review of the progress of the research project. Incomplete or insufficiently detailed reports will be returned for revision and resubmission. The Principal Investigator and all Co-Investigators are required to sign the Monitoring Report.

Monitoring Period: 1Q / 2Q / 3Q / 4Q (*Please delete as appropriate)

1. Project Title:_____
2. Grant Period: Commencement Date: _____ End Date: _____
3. Principal Investigator:

4. Co-Investigators:

5. Administering Institution:

6. Aims/ Objectives of the Research:

List the main objectives as stated in the approved proposal. Approval must be sought for any change to the study objectives.

7. Timetable of Work:

Document the study progress according to the proposed timetable.

Chinese Medicine Research Monitoring Report

8. Achievements/ Major Findings of the Project in this Quarter:

9. Investigators' Comments:

Describe the potential of further investigations or exploitation of results. May include reflection/ feedback of investigators and/ or any difficulties encountered during the course of project. Comment of the potential for/ current dissemination of research findings

10. Incident Report, if applicable:

Report all incident(s) happened in this quarter, if any

Chinese Medicine Research Monitoring Report

11. Signatures of Project Team:

The Principal Investigator and all Co-Investigators are required to sign the Monitoring Report. By signing this Monitoring Report, the Principal Investigator and all Co-Investigators (if any) acknowledge that they have contributed to the Project and agree with the information contained herein.

	Signature of Investigators	Name	Date
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			