Health and Medical Research Fund

- Investigator-initiated Projects

Guidelines for Accounting, Reporting, Project Monitoring and Change Requests

These guidelines serve to remind the Principal Applicants (PAs) and the Administering Institutions (AIs) about the key issues relating to accounting, reporting and monitoring requirements of investigator-initiated research and health promotion projects funded by the Health and Medical Research Fund (HMRF) administered by the Food and Health Bureau.

PAs and AIs shall comply with these guidelines in conjunction with the signed Agreements. PAs are advised to contact the research offices of their respective AIs for accounting and research administrative support. For further queries, please contact the Research Fund Secretariat (the Secretariat) (Email: rfs@fhb.gov.hk).

The reports, change requests and claims for reimbursement shall be submitted via the electronic Grant Management System (eGMS) (https://rfs.fhb.gov.hk/eGMS/).

1. Accounting arrangements

Expenditures incurred in the claims for reimbursement or payment instalments shall only cover the period between the project commencement date and end date (both dates inclusive) as set out in the Agreement. Cost of work incurred before the commencement of the project date is **not** allowed. Additional funding is **not** allowed.

- (a) Claims for reimbursement shall only cover the period between the project commencement and end date as set out in the Agreement.
- (b) Claims for reimbursement should be duly submitted to the Secretariat when expenditures are incurred. Claims shall be made no more frequently than bimonthly.
- (c) Prior approval from the Secretariat is required for budget virement between any two categories (e.g. "Staff" and "Other Expenses"), or addition of new budget items, or change of staff composition.
- (d) Revised monthly salary for budgeted staff due to cost-of-living adjustment under AI's policy is automatically approved **provided** that the total of the staff budget remains unchanged.

Key updates are highlighted in yellow.

- (e) With effect from 1 October 2014, the HK\$4,000 limit of overspending has been further relaxed: overspending of any individual item within any category is automatically approved **provided** that the accumulated overspending of any individual item does not exceed 10% of the item's budget **and** does not exceed the ceiling for that item as set out in the grant policy (e.g. a maximum of HK\$20,000 for publication costs) **and** the budget total of the category concerned is unchanged.
- (f) Payment will be made within **six weeks** to AI after satisfactory progress of the project, verification and acceptance by the Government of each reimbursement claim form submitted by the AI. The Secretariat will put the claim on hold under the following circumstances
 - i. When the project account is frozen due to unsatisfactory progress and overdue deliverables such as report and financial statement.
 - ii. After the reminder has been issued to the PA/AI for submission of Interim Report (IR) or Final Report (FR) and before the acceptance of the relevant report.
 - iii. The accumulated claim amount has been over 80% or 90% of the total approved budget or the ceiling for payment/instalment as specified in the Agreement.
- (g) Research offices and finance offices should make proper arrangements **in advance** with related department(s) and audited firm(s) and submit the certified financial statement (FS) / Audited Account (AA) on time. IR/FR **cannot be accepted** without submission of certified FS / AA, which will affect the payment to the AI.

2. Submission and assessment of reports

- (a) Progress Reports (PRs), IRs, FRs and Dissemination Reports (DRs), certified FSs and AAs shall be submitted according to the specific due dates and formats.
- (b) Reminders will be issued to PA and AI before the due date of submission and deliverables will be assessed by the respective parties set out below –

Deliverables	Reminder issued before due date of submission		Reviewing parties for PR, IR, FR and DR*
	To PA	To AI	TK, IK, TK and DK
Progress Report (PR)	Two weeks	-	Secretariat**
Interim Report (IR) and certified financial statement (FS)	One month	One month	First Speaker***
Final Report (FR), Dissemination Report (DR), certified FS and Audited Account (AA)	One month	One month	First-tier External Reviewer(s) (ERs) Second-tier First Speaker who recommends the overall rating and action(s) required by PA. Please refer to Annex A for details of the workflow.

^{*} First Speaker and Second Speaker are Grant Review Board (GRB) Members, and ERs are normally overseas experts who reviewed the proposal of the approved project concerned at the application stage. Normally, two ERs and two Speakers are invited to review one proposal. For proposal requesting \$100,000 or below, one Speaker and one ER are invited to review the proposal. FS and AA are reviewed by the Secretariat.

(c) Warning letter will be issued to PA and AI if overdue deliverable(s) is not submitted after issuance of two overdue reminders with extended deadline. The following actions will be carried out if PA fails to submit the deliverable(s) by the final deadline given in the warning letter: termination of project, recovery of the grant, marking track record and debarment from applying HMRF grants.

^{**} The Secretariat may seek views from Speaker(s) where appropriate.

^{***} If adverse/critical comments are given by First Speaker, comments from Second Speaker will be sought where appropriate. The GRB Executive will make decision where two Speakers have discrepant comments.

- (d) The account of on-going project with unsatisfactory progress or overdue report(s) will be frozen (i.e. all claims and payment will be put on hold) until the outstanding issues have been resolved. PA and AI will be informed of the decision once the project account is frozen.
- (e) In the PR and IR, PA should report the progress according to the expected target(s) during the reporting period set out in the Timetable of the approved proposal / special condition(s) stipulated in the Agreement or specified by the Secretariat. In particular, if the study involves subject recruitment, please state the number of subjects recruited up to a date and the difference from the expected target(s) during the report period and the total target(s) of the study.
- (f) PA should adhere to the approved study design of their ongoing programmes. If the progress is behind schedule, PAs should submit practical and feasible contingency plans together with the PR or IR whichever earlier to address the possible pitfall(s) so as to complete the project. In order to ensure the approved projects can come up with satisfactory outcomes, recruiting the same group of subjects to multiple studies (especially COVID-19 studies) with direct conflict to each other should be avoided.
- (g) According to the Agreement, PA and AI shall render their advice or recommendation on an impartial basis without giving favour to any particular product or service in the project. PA and AI shall seek the Government's permission to all or any facts which **may reasonably be considered to give rise** to a situation where the financial, professional, commercial, personal or other interests of the PA or AI or any of their respective associates and associated persons, or any member of the Project Team (i.e. Co-applicant(s)), conflict or compete, or may conflict or compete, with the PA's or the AI's duties under the approved project.
- (h) The Government's contribution shall be properly acknowledged in all research outputs, academic conference presentations and press conference materials, specifically "Health and Medical Research Fund, the Food and Health Bureau, The Government of the Hong Kong Special Administrative Region". Please include the project reference number for easy reference.
- (i) PA should strictly adhere to the format of FR and DR, in particular a maximum of 2,000 words for DR (including main text, references, key messages) with not more than 3 tables and/or figures and 5 references. DR should be brief and written in non-technical language to facilitate wider dissemination. According to the guidelines of the International Committee of Medical Journal Editors, DR is

considered as "acceptable secondary publications" with proper citation of the primary reference and is not a duplicate publication.

- (j) A list of publications (including in press), patents and other Intellectual Property Rights that have resulted directly from the research/project shall be provided. PA/AI should seek written consent from the Government before filing a patent application. Please provide information on the patent to be filed or obtained where applicable. If there is no patent related items, please state "None".
- (k) During the submission of FRs, please provide an equipment list, if any, containing (i) serial number or unique stock code; (ii) date of purchase; (iii) location; and (iv) actual value of each item of equipment purchased under the grant.
- (l) Subject to First Speaker's advice, PA will be invited to revise FR ONCE if it is rated "2 Unacceptable", "3 Accepted" or "4 Satisfactory". Failure by the PA to satisfactorily address the comments raised by the reviewers may lead to FR being downgraded. Penalties for FR rated "1 Unredeemable" or "2 Unacceptable" include holding of 10% or 20% of the approved budget (subject to the Agreement), partial/full recovery of grants and marking track record of PA.

3. Dissemination of results

- (a) FR eligible for dissemination of results (i.e. rating of "Accepted" or above) will be uploaded to the Secretariat's website within one month after closure of project. The relevant DR may be published in the Hong Kong Medical Journal Supplement where appropriate. PA should provide valid justifications for the Government's consideration if deferral for dissemination of FR or DR is required. Please note according to the Agreement, the Government or PA/AI shall have the right to use the Materials for non-commercial academic purpose without the consent from each party.
- (b) The impact of projects with Final Reports rated "3 Accepted" or above are evaluated on a regular basis using a "payback framework" an internationally recognised measure of health research activities, **two years** after project completion. It is also a **contractual requirement** that PA and AI shall provide information relating to projects under the HMRF for the purpose of evaluation after project completion.

4. Project monitoring

- (a) PAs shall comply with the Clearance Requirements as stipulated in the Agreements. The study protocol/scope approved by the AI's Institutional Review Board (IRB) / Ethics Committee (EC) must be the same as that approved by the HMRF.
- (b) For projects requiring the use of data from the Hospital Authority (HA), please submit the relevant approval(s) from the Central Panel on Administrative Assessment of External Data Requests of HA to the Secretariat in a timely manner. Please visit http://www3.ha.org.hk/data/Provision/Index/ for details.
- (c) PAs and/or AIs shall notify the Secretariat effectively and as early as possible of any event which is likely to prejudice the project outcome, whether in a qualitative, quantitative or financial aspect, or the timely completion of the project.
- (d) If the PA/AI fails to comply with any terms and conditions stipulated in the Agreement, the project will be subject to termination and recovery of grants.
- (e) Any improprieties such as misconduct, early termination, incomplete project without valid justification, and non-disclosure of research work done before commencement date will lead to penalty actions. Please refer to the *Management of Track Records of Applicants* (Annex B), which can be downloaded from the Secretariat's website (http://rfs.fhb.gov.hk).

5. Change requests

- (a) **Prior approval from the Secretariat** is required for all change requests. Each request will be considered on a case-by-case basis.
- (b) To change the PA: The existing PA and/or AI shall seek prior approval to replace the PA by nominating a suitably qualified candidate and submitting relevant supporting documents (i.e. support letter from the Department Head of the existing PA, Curriculum Vitae (CV) of the nominated PA, signature of both existing and nominated PAs) via the Research Office of the existing AI.

For projects approved in the 2015 Open Call and thereafter, each PA cannot hold more than one approved project in the same application round. Please ensure the nominated new PA does not hold another approved grant in the same application round.

- (c) <u>To change the AI</u>: The existing PA and/or AI shall seek prior approval to change the AI by submitting support letters from the Department Heads and Research Offices of both existing and proposed new AIs.
- (d) To change a Co-Applicant (Co-A): The PA and/or AI shall seek prior approval to replace a Co-A by nominating a suitably qualified candidate and submitting the CV of the nominee. Prior approval is also required to remove a Co-A without replacement. The PA and/or AI shall submit a written request with rationale justifying removal and no replacement is necessary. The PA should provide written consent from the Co-A concerned for removing the Co-A from the Project Team.
- (e) To extend the project end date: The PA and/or AI shall seek prior approval to extend the end date by submitting a written request with full justifications and the revised work plan. The PA and/or AI shall make internal arrangements to absorb the expenditure incurred during the extended project period. Normally, request for project extension submitted after the project completion date will not be considered.

With effect from 1 October 2017, the cumulative period of project extension has been capped at 18 months. Requests for project extension over 18 cumulative months will only be considered on a discretionary basis.

- (f) To change the study protocol: The PA and/or AI shall seek prior approval to change the study protocol (including the number of subjects and inclusion and exclusion criteria) by providing full justifications with a discussion of the anticipated impact on the study objectives and timeline. PA should indicate the amount of reduced budget in the request for reduction of study scope. The amount of approved budget shall be reduced proportionally to the reduction of the scope of study. The Government shall not be liable to make any payment to the PAs, AIs or any other persons as a result of termination or reduction in scope of the study or extension of study period. PA shall obtain the relevant approvals from the IRB/EC and regulatory bodies after a change of study protocol is granted.
- (g) Decision on change request will be normally issued to PA and/or AI within 10 working days. Longer processing time is needed if approval from Speakers or Grant Review Board Executive (GRBE) is required. The approving authorities for change requests are set out below –

Change requests		Approving authorities		
Change	of PA			
i.	New PA is not Co-A of the Project Team	Speaker(s)		
ii.	New PA is Co-A of the Project Team	Secretariat		
Change of AI		Secretariat		
Change of Co-A				
i.	Without replacement	Speaker(s)		
ii.	With replacement	Secretariat		
Project extension				
i.	12 months or below cumulatively	Secretariat		
ii.	Over 12 months up to 18 months	Speaker(s)		
	cumulatively			
iii.	Over 18 months cumulatively	$GRBE^*$		
Protocol change		GRBE*		
Budget virement		Secretariat		

^{*} Members of GRBE are Chairpersons of GRB. Change request will be considered by three to four Members with expertise in the corresponding area of project and without conflict of interest with the Project Team members. The decision will come up by taking majority vote.

6. Improprieties of Applicants

Improprieties may arise at any point in the funding cycle (e.g. grant application submission, peer review, ongoing project or post-completion evaluation) including:

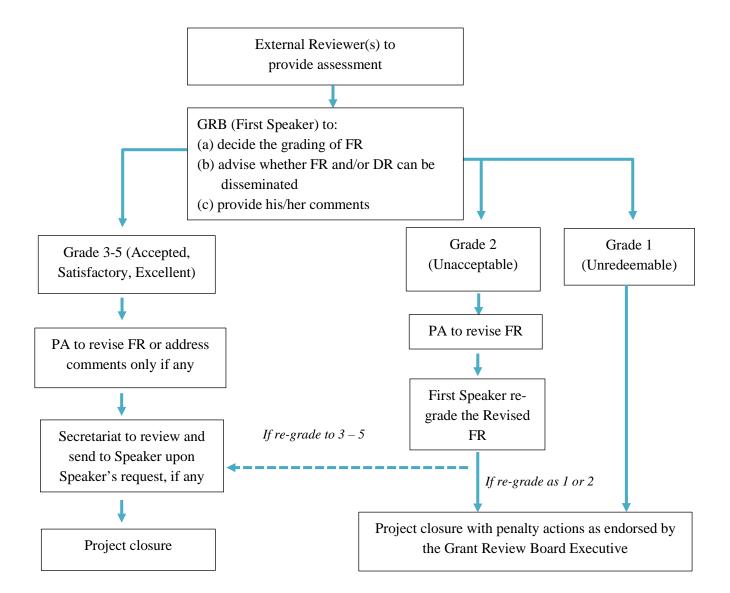
- i. Scientific misconduct;
- ii. Non-disclosure of important information (e.g. conflict of interest (COI), double dipping and research work done before project commencement); and
- iii. Non-compliance to funding regulations without valid justifications (e.g. failure to submit final report and outcome evaluation, early termination, incomplete, etc.).
- (a) Als should have in place adequate systems to ensure the quality of research conducted by PAs and their compliance to the terms and conditions under the HMRF, in particular effective mechanisms for identifying and handling allegations of scientific misconduct.
- (b) In the event of improprieties, PA and/or Co-A concerned will be requested to provide clarification. Where violation of research ethics is suspected (including plagiarism, fraudulence, non-disclosure of important information), the respective AI will be requested to conduct investigation and report the findings to the

Secretariat within three months. The GRBE will examine the case and advise the next course of actions according to the *Management of Track Records of Applicants* (Annex B). Research Council's decision on penalty actions is final.

(c) Normally, PA and/or Co-A and AI concerned will be informed of the decision and consequence of improprieties within 6 months. Longer processing time is needed where complex issues or multiple parties are involved.

Research Fund Secretariat Research Office Food and Health Bureau December 2021

Review of Final Reports of Investigator-initiated Research Projects



Remarks:

- 1. Only one revision of FR is allowed.
- 2. Penalty actions for FR graded "1 Unredeemable" or "2 Unacceptable" include (a) withholding 10% or 20% of the final payment subject to the terms and conditions in the Agreement; and (b) the track record of the PA shall be marked and taken into account when considering of future grant applications for up to 5 years.

<u>Key</u>

DR: Dissemination Report

FR: Final Report

GRB: Grant Review Board

GRBE: Grant Review Board Executive

PA: Principal Applicant

Management of Track Records of Applicants¹ (Effective from 1 November 2018)

Improprieties	Description	Gravity	Actions ^{2,3}
Scientific Misconduct ⁴	Plagiarism, fraudulence, etc.	Serious	i. Disqualification in the related funding exercise; and ii. Debar ⁵ for 5 years
Double dipping not declared	Receiving grant from HMRF or any of its preceding funding schemes, or other funding agencies (local or overseas)	Heavy	i. Disqualification in the related funding exercise; and ii. Debar for 1 year
	Submission of grant applications or similar proposals to HMRF or any of its preceding funding schemes, or other funding agencies (local or overseas)	Light	Warning letter
Conflict of Interest not declared	The nominated reviewer(s) as a direct relative or a close personal contact with Principal Applicant (PA) or Co-applicant (Co-A)	Medium	Disqualification in the related funding exercise
	The PA has the following relationship(s) with the nominated reviewer in the past 3 years at the time of grant application – - research collaborator - mentor/student - work colleagues in the same department - employer/ employee/ business partner	Medium	Disqualification in the related funding exercise

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¹ Unless otherwise determined, the principal applicant shall be held primarily responsible for the conduct of the project and any penalties imposed as a consequence of any misconduct or non-compliance.

² The track record of the principal applicant who has committed any of the improprieties mentioned in this Annex shall be marked for and taken into account when considering of future grant applications for up to 5 years.

³ If the misconduct is reported after commencement of the study, assessment will be made to determine whether any of the approved amount should be returned to the Government.

⁴ Scientific misconduct means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgements of data.

⁵ Debarment covers applying and receiving grants from the Health and Medical Research Fund in the capacity of principal applicant.

Improprieties	Description	Gravity	Actions ^{2,3}
Conflict of Interest not declared	The Co-A has the following relationship(s) with the nominated reviewer in the past 3 years at the time of grant application – - research collaborator - mentor/student - work colleagues in the same department - employer/ employee/ business partner	Light	Warning letter
Non-compliance	No submission of final report by deadline without valid justification	Heavy	 i. Withhold funding of the project or recovery of the grant ii. Debar for 2 years and until the final report is submitted, whichever is later
	Any of the following without valid justification – - Early termination - Incomplete project - Research work done before project commencement not declared	Heavy	i. Partial payment or recovery of grant ii. Debar for 2 years
	Final report graded "Unredeemable" or "Unacceptable"	Medium	Withhold 10% or 20% of the grant subject to the terms and conditions in the agreement