Health and Medical Research Fund Investigator-initiated Projects

Guidance Notes on Grant Application

February 2024

Preamble

This document is designed to provide background information and advice on the funding opportunities for investigator-initiated projects of the Health and Medical Research Fund (HMRF) administered by the Health Bureau.

Applicants should read this document carefully in conjunction with the <u>Policy Statement</u> and the <u>Explanatory Notes on Grant Application</u> before preparing grant applications which are available on the <u>Research Fund Secretariat's website</u>.

Queries should be addressed to the Research Fund Secretariat by email: rfs@healthbureau.gov.hk.

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PART 1 BACKGROUND

1.1 Fund Administration

- 1.1.1 The Research Council (RC) chaired by the Secretary for Health is responsible for providing strategic steer for funding health and medical research and health promotion projects and overseeing the administration of the Health and Medical Research Fund (HMRF). The RC is supported by the Referee Panel, Grant Review Board (GRB) and Grant Review Board Executive (GRBE) as the technical arm. The Research Fund Secretariat (the Secretariat) provides administrative and logistic support to the RC and their constituent boards and panels.
- 1.1.2 Details of the organisational structure of the HMRF, the roles and responsibilities, composition and terms of reference of its constituent council, boards and panels are stipulated in the *Policy Statement*.

1.2 Project Scope

- 1.2.1 As HMRF emphasises the importance of translational potential of research findings, only clinical research and research on infectious diseases with public health implications will be supported. Making reference to the definition of clinical research by the National Institutes of Health of the United States¹, clinical research refers to "research with human subjects that is:
 - (a) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. It includes: (i) mechanisms of human disease, (ii), therapeutic interventions, (iii) clinical trials, or (iv) development of new technologies. Excluded from this definition are in vitro studies that utilise human tissues that cannot be linked to a living individual;
 - (b) Epidemiological and behavioural studies; and
 - (c) Outcomes research and health services research."
- 1.2.2 The HMRF considers funding investigator-initiated health and medical research as well as health promotion projects in the following broad areas -
 - (a) public health, human health and health services (e.g., primary healthcare, non-communicable diseases, Chinese medicine, etc.);
 - (b) prevention, treatment and control of infectious diseases with public health implications;
 - (c) advanced medical research which applies advanced technologies to facilitate the translation of knowledge generated from health and health services or infectious diseases studies into clinical practice and to inform health policy; and
 - (d) health promotion that facilitates mobilisation of local resources to promote good health and prevention of illness in the community.

<u>Public health, human health and health services research</u> examine the cause, prevention and treatment of the full range of diseases and conditions that affect

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¹ National Institutes of Health of the United States https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm

human health; and the impact of the organisation, financing and management of healthcare services on the delivery, quality, cost, access to, and outcomes of such services. Research proposals under this theme should focus on one of the three broad areas of public health, health services and Chinese medicine.

- Public health research addresses issues such as prevalence, epidemiology and surveillance of specific diseases with the aim of identifying modifiable risk factors and behaviours that can be targeted to enhance prevention and treatment and so improve population health.
- Health services research is essential to determine which interventions and services are effective and cost-effective in the local healthcare setting.
- Chinese medicine research must be clinical research which is based on Chinese medicine theory or clinical research on Chinese medicine theory and methodology.

Research proposals on <u>infectious diseases</u> should focus on those diseases which are prevalent in or pose threat to Hong Kong and neighbouring regions or areas in which the Hong Kong academic community has a competitive edge. Research proposals on infectious diseases with **public health implications** from bench to bedside and at community level, and with **translational value** are supported.

<u>Advanced medical research</u> shall be **clinical studies** which apply advanced technologies to facilitate the translation of knowledge generated from health and health services or infectious diseases studies into clinical practice and to inform health policy.

Examples of clinical studies include clinical trials on effectiveness of disease treatment using genome editing technologies (such as CRISPR/Cas9) and their derivative reagents as gene editing tools; clinical applications of sequencing technology for disease prognosis, diagnosis and treatment strategies; development of machine learning and artificial intelligence approaches for drug treatments, surgical procedures, systemic therapy and radiotherapy with evaluation in clinical practices.

Other examples which apply advanced technologies to evaluate treatments and therapeutic interventions in clinical, community or applied settings include **clinical application and evaluation of** pharmaceuticals; cellular, tissue and gene therapies; medical devices; surgical, obstetric and dental interventions; radiotherapy and other non-invasive therapies; psychological and behavioural approaches, etc.

<u>Health promotion projects</u> should be based on scientific evidence and evaluated in a systematic way. They should include a coordinated set of activities that help people adopt healthier lifestyles by enhancing awareness, changing adverse health behaviours and creating a conducive environment that supports good health practices.

1.2.3 Examples of research within or outside the funding scope mentioned in paragraph 1.2.1 are provided at **Appendix A**.

- 1.2.4 Routine public health or clinical services that are provided by the Government or government funded agencies will not normally be considered for support.
- 1.2.5 The project scope described in 1.2.2 may be subject to change and refinement by the RC.

PART 2 APPLYING FOR A GRANT

2.1 Grants

- 2.1.1 The HMRF supports quality health and medical related research, in particular those applied research that would have impact in changing health policies, clinical practices, or behaviour of people with ultimate aim in improving the health of the population. The HMRF also supports evidence-based health promotion projects in the community. The normal grant ceiling for an investigator-initiated project is HK\$1,500,000. Higher grants may be awarded where justified.
- 2.1.2 Seed grant with grant ceiling of HK\$500,000 per project supports larger-scale pilot studies such as those evaluating trialability and scalability for future implementation and small-scale research with achievable objectives. Examples include small clinical trials, feasibility studies for future clinical trials, validation of screening tools/diagnostic frameworks, epidemiological modelling of infectious or non-communicable diseases, cost-effectiveness studies, and analysis of prospective/retrospective clinical data, etc. Studies may be conducted in clinical or community settings with a small sample size for preparation of a large-scale research with full sample size in future. For example, clinical validation of a diagnostic tool with tests for acceptability and feasibility; evaluation of clinical surveillance method for pathogens in a small community region; investigation of the prevalence of disease risk factors within a specific subject group; comparison of clinical outcomes retrospectively or prospectively, etc.
- 2.1.3 Grants are intended to cover direct costs attributable to the project **excluding** costs of premises, established academic or service staff, and sub-contracting project work without the RC's approval. In general, indirect costs of projects will not be supported. A list of allowable and unallowable items is shown in **Appendix B**.
- 2.1.4 Having regard to the general aim of funding a wide spectrum of projects with maximum possible coverage of contemporary health care issues, the RC may give higher priority to lower cost projects in the event that scientific merits of proposals under consideration are similar.

2.2 Eligibility

2.2.1 In general, members of any discipline or profession in the health or health-related field can apply for funding. Grants may be awarded to locally based tertiary institutions, hospitals, medical schools, non-governmental organisations or other appropriate centres, units and services. Members of other disciplines, such as social welfare and education may also apply if the proposed project is within the ambit of the HMRF.

- 2.2.2 The principal applicant shall be based in a Hong Kong organisation throughout the project period and be employed by the administering institution at the time of submitting the application.
- 2.2.3 Individuals not employed by any administering institution and staff of Government Bureaux/Departments are not eligible to apply as principal applicants but their participation as co-applicants is acceptable.
- 2.2.4 Administering institutions should make sure that all applicants meet the eligibility requirements before submission of grant applications.

2.3 Availability of Advice

- 2.3.1 Detailed information about the HMRF can be found on the Secretariat's website (https://rfs.healthbureau.gov.hk). For general enquiries about completing the electronic Application Form (e-Form), please contact the Secretariat (email: egmsenquiry@healthbureau.gov.hk).
- 2.3.2 Applicants are strongly recommended to consult the field experts to improve the feasibility of proposals, in particular clinical studies and those involving human subjects.
- 2.3.3 Applicants from UGC-funded institutions should direct their inquiries to the Research Offices of the respective institutions in the first instance.
- 2.3.4 All clinical trials should be conducted according to Good Clinical Practice (GCP) guidelines covering the responsibilities and expectations of investigators, monitors, sponsors and Institutional Review Boards (IRBs). For details, please refer to the *Efficacy Guidelines* (E6 Good Clinical Practice) published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use at https://www.ich.org/page/efficacy-guidelines.
- 2.3.5 Reporting of randomised controlled trials should conform to the Consolidated Standards of Reporting Trials (CONSORT) statement (https://www.equator-network.org/reporting-guidelines/consort/).
- 2.3.6 Reporting of clinical trials involving herbal medicinal interventions, Chinese herbal medicine formulas, or acupuncture should conform to the relevant extensions of the CONSORT statement (https://www.equator-network.org/reporting-guidelines/consort/).
- 2.3.7 Reporting of studies involving animals should conform to *The ARRIVE Guidelines* (https://arriveguidelines.org).

2.4 Grant Applications

- 2.4.1 Applications under the project scope as described in 1.2 can be submitted. Applications addressing the thematic priorities announced in the current HMRF Open Call will be given higher priority for funding. The priorities areas include
 - (a) Infectious Diseases;
 - (b) Non-communicable Diseases;

- (c) Primary Healthcare;
- (d) Preventive Medicine:
- (e) Telehealth and Advanced Technology; and
- (f) Clinical Trials and Implementation Science.

The full list of thematic priorities can be found on the **Secretariat's website**.

2.4.2 Principal applicants and co-applicants are jointly responsible for the scientific oversight and implementation of the project. Before making a grant submission, applicants are required to read the *Explanatory Notes on Grant Application* which can be found on the Secretariat's website.

Resubmission

- 2.4.3 Applications rated "2" or above in a previous HMRF Open Call can be submitted under the category of "Resubmission". Structured point-by-point response to address all comments stated in the GRB Assessment Report (where applicable) should be submitted. Please note
 - (a) Application rated "3"/"4" the proposal should be revised to address all GRB and/or reviewers' comments (where applicable) in a structured and consistent manner in the resubmission.
 - (b) Application rated "2" the proposal should be **substantially** revised to address all GRB and/or reviewers' comments in a structured and consistent manner in the resubmission.
 - (c) The continued relevance of the application with respect to knowledge gaps, policy needs, translational value and prevailing thematic priorities at the time of resubmission will be considered. **Having satisfactorily addressed comments of GRB/reviewers is not a guarantee of funding**.

Applications declined by the HMRF or other funding agencies

- 2.4.4 Applications declined on the ground of misconduct by the HMRF (including Open Call and Research Fellowship Scheme) or any of its preceding funding schemes, or other funding agencies (local or overseas) will not be considered.
- 2.4.5 **Resubmission of rejected application is not accepted.** Applications rejected in a previous HMRF Open Call (i.e. no rating, rated "1", incomplete or outside of the funding scope) or Research Fellowship Scheme, or by other funding agencies (local or overseas) must be submitted **as a new application with extensive changes or improvements** made to the rejected application and with full justifications. Principal applicant should provide (a) all comments raised by the funding agency; (b) the principal applicant's point-by-point responses to address these comments; (c) the revised proposal with highlights of changes made; and (d) detailed explanation and justifications if no change is made in the proposal.

Similar studies and other funding

- 2.4.6 **Applicants should declare any duplicate funding in the e-Form**. At any time before the announcement of the funding decision of the HMRF Open Call, applicants are required to notify the Secretariat immediately about
 - (a) any other similar or related application submitted to other funding agencies in addition to those listed in the e-Form; and

(b) the funding decision of any similar or related application once available.

Supplementary sponsorship

- 2.4.7 Supplementary sponsorship must be fully justified. Applicants shall state clearly whether any supplementary support has been/will be received from other sources, including but not limited to monetary, investigational new drugs/devices, reagents, and consumables and rental of equipment.
- 2.4.8 Administering institution or any of the applicants listed in Section 7 of the e-Form, or any of the proposed personnel and sub-contractors/agencies to be engaged in the project, shall declare any actual or perceived conflict of interest, such as receiving any funding or assistance directly or indirectly from industries (including but not limited to tobacco related businesses, infant formula companies, or organisations funded by such businesses). The declaration shall include any use of the grant monies to purchase products or services from businesses owned wholly or partly by the administering institution or any of the applicants, or any of the proposed personnel and sub-contractors/agencies to be engaged in the project.

Plagiarism

- 2.4.9 The Principal Applicant is responsible for ensuring that the submitted grant application and all supplementary materials (where applicable) comprise **original work** and are not plagiarised (or self-plagiarised) from other sources according to the definitions in paragraphs 2.4.10 and 2.4.11. Plagiarism, including self-plagiarism, is not tolerated and is considered as a type of serious misconduct.
- 2.4.10 Plagiarism is the appropriation or use of the work of others for example, copying sentences, paragraphs, sections or whole articles from other publications without acknowledgement or credit. Apart from words, figures, tables, images and software, etc., can also be considered plagiarism if the source is not acknowledged.
- 2.4.11 Self-plagiarism occurs when researchers reuse their own data or previously published work without appropriate acknowledgement that the material had previously been published.
- 2.4.12 Common examples of plagiarism and self-plagiarism found in the preparation of grant applications are illustrated below
 - (a) **Example 1 (plagiarism):** The applicant copies verbatim the sentence(s) from another source in the proposal without citing the reference or giving any indication that it had been previously published by others. This is unacceptable the source of the original text must be acknowledged; the passage should be enclosed by quotation marks to indicate that it has been cited in its entirety.
 - (b) **Example 2 (plagiarism):** The applicant copies a sentence or text from another source and makes minor editorial adjustments such as adding or removing abbreviations, changing tenses, etc. but acknowledges the original source. This is unacceptable the acknowledgement of the original source merely indicates the text was consulted; it does not indicate that a portion has been quoted almost verbatim with only minor editorial changes. For the avoidance of doubt, the edited passage should have been enclosed in quotation marks.

- (c) **Example 3 (plagiarism):** The applicant replicates the plan of investigation, research aims, objectives and hypotheses of another research group without acknowledgement. This is unacceptable the research study should be original and studies conducted by others should be acknowledged clearly.
- (d) **Example 4 (plagiarism):** One or more of the figures used in the grant application was found to have been used in a previous publication or public presentation such as a symposium or conference without acknowledgement. This is unacceptable plagiarism can involve non-textual items such as figures, images, tables, software, etc. and prior usage should be acknowledged clearly.
- (e) **Example 5 (self-plagiarism):** The applicant reproduces text and/or figures from his/her own previously published work in the proposal without acknowledgement. This is unacceptable all previously published work by the applicants should be acknowledged.

Work done before project commencement

- 2.4.13 Costs of work (e.g. the purchase of equipment or the first working day of a project staff) incurred before the commencement date or the writing-up of such work are **not** allowed.
- 2.4.14 Research work (e.g. subject recruitment) conducted before the commencement of the project which includes the period before and after application submission is not allowed. If such case is declared upfront before the Agreement is signed for fundable application, the principal applicant has to adjust the funding scope and the funding amount for the GRB's consideration and approval.

Management of track records

2.4.15 The RC has delegated its authority to the GRBE to exercise its discretion on cases of management of track records. Plagiarism or double dipping not declared or research work done before project commencement without declaration, if substantiated, will lead to severe consequences including but not limited to disqualification from the current HMRF Open Call, debarment from applying and receiving grants from the HMRF in the capacity of principal applicant/fellowship applicant, marking of the track record of the applicants and recovery of grants. The track record of the affected applicant shall be taken into account when considering future applications to any funds administered by the Secretariat. *The Management of Track Records of Applicants* is available on the Secretariat's website.

2.5 Submission of Applications

- 2.5.1 Each principal applicant is allowed to **submit one application only** (either a new or a resubmission of an application).
- 2.5.2 All applications must be submitted via the electronic Grant Management System (eGMS) (https://rfs.healthbureau.gov.hk/eGMS) by completing the e-Form on or before the deadline of submission specified by the Secretariat. Principal applicants, especially those who are new to the eGMS, are strongly advised to prepare their applications well before the deadline of submission to avoid unexpected situations.

- 2.5.3 Applications that are incomplete, inconsistent with the submission requirements, out-of-scope or insufficiently detailed to allow peer review will not be processed and may result in administrative withdrawal. Applications which do not use the standard proposal template for Research and Health Promotion Project respectively (Section 10 of e-Form) will be treated as incomplete. The proposal templates can be downloaded from the Secretariat's website.
- 2.5.4 The following must be stated clearly in the proposal (Section 10 of the e-Form) or the application will be treated as incomplete
 - (a) Advanced medical research projects the application of advanced technologies to facilitate the translation of knowledge generated from health and health services or infectious diseases studies into clinical practice and to inform health policies.
 - (b) Research projects addressing the thematic priorities of Implementation Science the proposed framework(s)/model(s) to analyse barriers and facilitators of implementation outcomes.
 - (c) Health promotion projects pre-set criteria for process and outcome evaluation based on the RE-AIM framework. Please refer to https://www.fic.nih.gov/About/center-global-health-studies/neuroscience-implementation-toolkit/Pages/methodologies-frameworks.aspx">https://www.fic.nih.gov/About/center-global-health-studies/neuroscience-implementation-toolkit/Pages/methodologies-frameworks.aspx for reference.
 - (d) Seed grant proposals the pre-defined outcome indicators that would enable scale-up to a larger project and/or enhance the efficacy/effectiveness of existing practice.
 - (e) All proposals potential pitfalls and contingency plans
- 2.5.5 As the HMRF emphasises the importance of the translational potential of research findings, the principal applicant is required to provide a clear explanation in simple language on how the research findings will benefit patients and/or the healthcare system such as improving patient care, population health, influencing clinical practice and/or health services management, or informing health policy in Hong Kong and elsewhere (Section 6 of e-Form).
- 2.5.6 The principal applicant should **select the most relevant reference code of thematic priority** in the application (Section 3 of e-Form). If the application is outside the thematic priorities, please select "N/A" (i.e. Not Applicable).
- 2.5.7 Collaborative project, including collaboration with non-local organisations is encouraged. A principal applicant and **up to nine co-applicants** may work together in a project team.
- 2.5.8 Interested parties from non-academic institutions are highly recommended to collaborate with partners from academic institutions to prepare implementation science proposals.
- 2.5.9 The principal applicant should make sure that all co-applicants endorse the application as the track record for the whole project team might be adversely

- affected if misconduct/fraud is found. All project team members should be well aware of their participation and roles and responsibilities in the project.
- 2.5.10 Application without the signatures of principal applicant, co-applicant(s), Head of Department (or Head of Agency in non-governmental organisation (NGO)), and authorised persons on behalf of the administering institution and finance office will be treated as incomplete application and will not be considered.
- 2.5.11 Provision of the regulatory/ethics approval(s)/consent for accessing third-party data is not required at the time of submission of grant application. The status of seeking such approval(s)/consent should be documented under Section 15 of the e-Form at the time of submission. Principal applicants should submit such approvals/consent within 12 weeks (or as specified by the Secretariat) from the date of decision letter of the application, and failure to do so may result in withdrawal of grants. Letters of exemption for non-applicable regulatory committees are not required. Please refer to paragraph 2.10 for further details.

2.6 Assessment Criteria

2.6.1 Applications will undergo peer review process and be assessed according to the following criteria –

Health and medical research projects

- (a) Originality of the research topic
- (b) Relevance to the scope of funding and thematic priorities
- (c) Significance of the research question
- (d) Quality of scientific content
- (e) Credibility for study design and method
- (f) Feasibility of the intended project
- (g) Research ethics
- (h) Translational potential/value
- (i) Past performance and track records of applicants
- (j) Research capacity of the administering institution
- (k) Justification of requested budget
- (l) Value for money

Health promotion projects

- (a) Relevance to the scope of funding and thematic priorities
- (b) Innovation and potential impact in response to the health needs of the target local community
- (c) Scientific evidence of effectiveness of the proposed health promotion activities
- (d) Feasibility of the proposal
- (e) Evaluation plan of programme effectiveness
- (f) Tack records of applicants and the administering institution
- (g) Cross-sector collaboration, in particular collaboration between NGOs and tertiary institutions
- (h) Justification of requested budget
- (i) Sustainability of the programme
- (j) Potential to build community capacity in health promotion
- (k) Value for money

2.7 Funding Decisions

- 2.7.1 Applicants will normally be informed within six months of the deadline of submission the results of their applications by email to applicants' email addresses entered in the e-Form via the eGMS. Information about the approved applications will be posted on the Secretariat's website at https://rfs.healthbureau.gov.hk for public inspection.
- 2.7.2 The funding decision of the RC is final.
- 2.7.3 Principal applicant shall inform the Secretariat immediately if he/she plans to leave his/her administering institution after submission of application. Failure to do so will result in disqualification of the application.
- 2.7.4 Principal applicant's track record of overdue or unacceptable report(s) of project(s) supported by the HMRF or any of its preceding funding schemes is taken into consideration when assessing a grant application. Approval for new funding will not be granted if the principal applicant has not submitted outstanding/overdue report(s)/certified financial statement(s) and audited account(s)/evaluation questionnaires for his/her other grants supported by the HMRF.

2.8 Project Duration and Expenditure Estimates

- 2.8.1 Funded projects must start **within six months** from the grant approval date and should be completed within three years. Longer duration may be awarded where justified.
- 2.8.2 Expenditures incurred in the claims for reimbursement shall only cover the period between the project commencement date and end date (both dates inclusive) as set out in the Agreement.
- 2.8.3 Claims for reimbursement of expenditure are compared against the relevant estimation in the approved budget. The principal applicant and the administering institution should submit change request to the Secretariat for prior approval if a claim varies from the estimate.

2.9 Reimbursement of Expenditure

2.9.1 **Financial arrangements:** Details of financial arrangements are detailed in paragraph 3.4 of Part 3 and **Appendix C**.

2.10 Research Ethics/Safety Approval/Consent for Accessing Third-party Data

- 2.10.1 The primary responsibility for seeking relevant approvals rests with the principal applicant. Written clearance from recognised ethics committee/IRB and safety approval from a designated Safety Officer, or equivalent, must be obtained prior to the commencement of the project.
- 2.10.2 The ethics committee/IRB determines whether or not ethics approval is required for the intended proposal. Principal applicants should ensure that the regulatory/ethics approval(s)/evidence for accessing third-party data **bear(s)** the same project title as that in his/her approved application. The protocol/scope

- included in such approval(s) / evidence for accessing third-party data must be the same as that in the application.
- 2.10.3 Applicants shall comply with *Animals (Control of Experiments) Ordinance (Cap. 340)*, where applicable.
- 2.10.4 For research proposals on clinical trials, under **Regulation 36B** of the *Pharmacy* and Poisons Regulations (Cap. 138A), for the purpose of conducting a clinical trial on human beings or medicinal tests on animals using pharmaceutical products, a Certificate for Clinical Trial/Medicinal Test issued by the Pharmacy and Poisons Board must be obtained prior to the commencement of the research project. According to Section 129 of the Chinese Medicine Ordinance (Cap. 549), for the purpose of facilitating the conduct of a clinical trial or medicinal test of any proprietary Chinese medicine, a Certificate for Clinical Trial and Medicinal test issued by the Chinese Medicines Board must be obtained prior to the commencement of the research project. Principal applicants are strongly advised to confirm the need for the relevant certificate as early as practical (preferably before/during the submission of applications to the HMRF) to avoid delay in project commencement. If a relevant certificate is required, failure to present a valid certificate by a specified deadline, may result in the application being rejected. For further details, please refer to the relevant guidance notes available in the websites of the Department of Health's Drug Office and the Chinese Medicine Regulatory Office.
- 2.10.5 Consent for accessing third-party data, e.g., a letter of support, must be obtained from the data owner (or their authorised representative) when access to third-party data is required by the applicants. Any fee or payment required for accessing third-party data should be clearly documented under "Other Expenses".
- 2.10.6 **Hospital Authority (HA)'s Data Access**: Approval from the Central Panel on Administrative Assessment of External Data Requests of HA is required for using HA data where applicable. Please visit http://www3.ha.org.hk/data/Provision/Index/ for details. Use of Clinical Data Analysis & Reporting System (CDARS) for research purpose must only be conducted with written approval by appropriate Research Ethics Committee.

PART 3 STANDARD CONDITIONS OF GRANT

This section sets out the general conditions under which the RC may offer to support investigator-initiated projects. Non-compliance with these terms and conditions may result in the suspension of the grant and/or the principal applicant's future grant applications. The specific conditions under which a grant is provided are set out in the contractual agreement.

Grants will be awarded to applications in the name of the principal applicant with the approved grant allocated to the administering institution. Both the principal applicant **and** the representative of the administering institution are required to sign a contractual agreement covering the terms and conditions of the project. A template of the agreement is available from the <u>Secretariat's website</u> for reference.

3.1 General Terms and Conditions

- 3.1.1 The project shall be carried out by or under the general direction of the person named in the e-Form as the principal applicant who shall be responsible for the scientific oversight and management of the project.
- 3.1.2 The RC will withdraw the grant if the project does not commence within six months from grant approval date.
- 3.1.3 The principal applicant and the administering institution are responsible for ensuring that the project is completed within the financial limits of the grant and must advise the RC immediately of any occurrence which may prejudice the completion of the project.
- 3.1.4 The administering institution shall be responsible for the provision of the basic facilities required to support the project including employment service of the required project staff, procurement of services and equipment, accounting services, etc.
- 3.1.5 The principal applicant and the administering institution shall submit interim, progress, final and dissemination reports, certified financial statements and/or audited accounts, and evaluation questionnaires as required by the RC.
- 3.1.6 The principal applicant and the administering institution are jointly and severally responsible for ensuring compliance with all conditions contained in this section.

3.2 Staff

- 3.2.1 All employment under projects funded by the HMRF should observe the Laws of Hong Kong.
- 3.2.2 It is the responsibility of the administering institution to enter into contracts of employment with all persons whose salaries are reimbursed from the grant. Such contracts should provide the rate of pay normally applicable to the appropriate grades of the persons employed by that institution.
- 3.2.3 The administering institution shall comply with the relevant Ordinances such as the *Employment Ordinance (Cap. 57)*, the *Employees' Compensation Ordinance (Cap. 282)*, the *Mandatory Provident Fund Schemes Ordinance (Cap. 485)* and the *Minimum Wage Ordinance (Cap. 608)*.

3.3 Equipment

3.3.1 Applicants should refer to the contractual agreement (Clauses 14 and 15) for details of the requirements related to equipment purchased under the grant. The administering institution should pay attention to the transparency and fairness in the procurement process and follow its disposal procedures properly. Where the relevant guidelines are not in place, the administering institution should adopt the *Notes on Acquisition and Disposal of Equipment Items for Institutions without Established Guidelines* which can be obtained from the Secretariat by email.

Risk in and Title to the Equipment

- 3.3.2 Any equipment paid by the HMRF shall be and remain the property of the administering institution and shall be in the care of, and maintained in good condition, by the administering institution.
- 3.3.3 The risk in and the legal and beneficial title to the equipment shall vest in and remain with the administering institution as and when it passes upon procurement of the equipment by the administering institution.
- 3.3.4 The administering institution (a) shall retain the legal and beneficial title to the equipment from the date of procurement of the equipment until at least two years after the closure of the project; and (b) shall not sell, lease, mortgage, charge, create any encumbrance or otherwise part with possession of the equipment or any part thereof during the period from the date of procurement of the equipment until at least two years after the closure of the project.
- 3.3.5 For any piece of equipment with unit price more than HK\$200,000, notwithstanding that the risk in and legal and beneficial title to the equipment have passed to the administering institution, the Government may at any time within two years after the closure of the project, or at any time upon the termination of the project, direct the administering institution to deliver and hand over any or all of such equipment to the Government or Government's nominee at the administering institution's sole cost and expense. Upon service of a notice on the administering institution, the legal and beneficial title and ownership to and in that piece of equipment specified in the notice shall vest in the Government absolutely and the administering institution shall forthwith at its own cost and expense arrange physical delivery of the equipment to the Government.

Equipment List

3.3.6 Unless otherwise directed by the Government, the administering institution shall submit to the Government a list of equipment (i.e. inventory register) which has been procured for the purposes of the project. The inventory register should contain (a) serial number or unique stock code; (b) date of purchase; (c) location; and (d) actual value of each item of equipment purchased under the grant.

3.4 Finance

3.4.1 The principal applicant and the administering institution shall exercise financial control of the grant. All expenditures on the project shall be met in the first instance by the administering institution, which shall submit bimonthly claims for reimbursement to the RC. Such claims shall indicate the category of the expenditure under which they fall, which shall be consistent with Section 14 of the e-Form.

- 3.4.2 The RC shall not be bound to reimburse claims for expenditure in any category in excess of the maximum stated in the approved budget or in excess of any amended maximum which has been agreed in accordance with paragraph 3.13.
- 3.4.3 The RC shall pay claims only in respect of expenditure properly incurred during the currency of the grant (as stated in the e-Form), or as has been agreed in accordance with paragraph 3.13. The administering institution is required to provide such additional financial information as may reasonably be requested by the RC.
- 3.4.4 For grant amount exceeding HK\$100,000, authorised expenditure up to 80% of the grant limit is reimbursed bimonthly in arrears. Actual expenditure is compared with the relevant estimate in the approved budget. The remaining 20% is payable subject to the acceptance of a final report, a dissemination report and an audited account to the satisfaction of the RC.
- 3.4.5 For grant amount of HK\$100,000 or below, authorised expenditure up to 90% of the grant limit is reimbursed bimonthly in arrears. The remaining 10% is payable subject to the acceptance of a final report, a dissemination report and a certified financial statement for the grant to the satisfaction of the RC.
- 3.4.6 Costs of Audited Account allowable are: (a) HK\$5,000 per project for grant amount between HK\$100,001 and HK\$1,000,000 and (b) HK\$10,000 per project for grant amount over HK\$1,000,000.

3.5 Sub-Contracting

3.5.1 The principal applicant and the administering institution shall not sub-contract any part of the project without the prior written consent of the RC. In giving consent for the engagement of sub-contractors, the sub-contractor concerned will be required to enter into a direct covenant with the Government to indemnify the Government against any loss or damage caused. The principal applicant and the administering institution shall remain liable for the full remuneration and liability of the contractor.

3.6 Privacy, Confidentiality and Data Protection

- 3.6.1 The principal applicant and the administering institution are responsible for ensuring that the requirements of any data protection are fully observed. In particular, the principal applicant shall ensure at all times that any personal data collected in the course of the project shall be securely held and handled and that the anonymity of persons to whom the data refer shall be preserved in any report or publication.
- 3.6.2 The principal applicant and the administering institution shall adhere to the *Personal Data (Privacy) Ordinance (Cap. 486)*.
- 3.6.3 The information and personal data provided in the e-Form will be used by the RC, External Reviewers, the GRB, the Secretariat and the relevant government department(s) or its authorised users for the purposes of assessing applications to the HMRF or checking of plagiarism/duplicate funding. For successful applications, such information and personal data will also be used for project

monitoring, research and statistical analysis, promotion, publicity and dissemination purposes as appropriate. Contents of the submitted application set out in Sections 1 to 9 and 13 of the e-Form with the status of project will be made available for public access once funding approval is offered.

- 3.6.4 Applicants have the right to access and correct the personal data provided in accordance with sections 18 and 22 and Principle 6 of Schedule 1 of the *Personal Data (Privacy) Ordinance (Cap. 486)*. Their right of access includes the right to obtain a copy of their personal data provided in the e-Form.
- 3.6.5 Enquiries concerning the personal data collected in the e-Form, including access and corrections, should be addressed to –

Research Fund Secretariat Research and Data Analytics Office Health Bureau 9/F, Rumsey Street Multi-storey Carpark Building 2 Rumsey Street, Sheung Wan Hong Kong

Email address: rfs@healthbureau.gov.hk Website: https://rfs.healthbureau.gov.hk

3.7 Ethics

- 3.7.1 Written documentation of approval from a recognised ethics committee/IRB with the same project title as that in the HMRF application **must** be provided prior to commencement of any approved application. The RC reserves the right to refuse an award on ethical grounds, even if the approval of an ethics committee/IRB has been obtained. If the project involves multiple centres (e.g., Hospital Authority hospital clusters), the written approval of all relevant ethics committees/IRBs must be obtained.
- 3.7.2 For other details, please refer to paragraph 2.10.

3.8 Monitoring and Evaluation

- 3.8.1 After a reasonable notice is provided by the RC to the principal applicant, an authorised member of the RC or a group appointed on its behalf must be allowed to discuss any aspect of the project with the principal applicant or the staff involved, and to inspect any equipment or other materials provided under the grant.
- 3.8.2 The principal applicant and the administering institution shall provide an interim report on a yearly basis or as may be required by the RC. Such reports must conform to guidelines which are issued from time to time by the RC. The timing and frequency of such reports, which shall depend on the nature of the project, shall be notified to the principal applicant and the administering institution by the RC.

- 3.8.3 If after due assessment, the project is not considered to be making satisfactory progress, the RC reserves the right to discontinue the provision of financial support under the terms of the grant and may seek the return of any funds provided to date.
- 3.8.4 Within six months, or three months if the grant amount is \$100,000 or below, after the end date or within 60 days after the termination of the project, the principal applicant and the administering institution shall provide a final report and a dissemination report to the RC. The reports must conform to the guidelines which are issued from time to time by the RC.
- 3.8.5 Unless specified, the administering institution shall submit an annual certified financial statement within 2 months following the first anniversary of the commencement date of the project, and shall submit the audited account within 6 months after the end date, or within 60 days after the expiry or termination of the project, whichever is earlier.
- 3.8.6 The principal applicant shall complete at least two evaluation surveys to assess the outcomes and impacts of the completed project two and four years after completion of the project or at other timeline specified by the Secretariat.
- 3.8.7 If any false, fictitious, under declaration, or fraudulent statements or claims are detected and subsequently substantiated after the project is approved, the principal applicant and the administering institution shall refund all grants received, and are liable for damages and losses incurred. Track records of the principal applicant may be affected. Please refer to paragraph 2.4.15.

3.9 Publicity of Financial Support and Objectives

3.9.1 The RC, principal applicant and administering institution may publish details of the financial support and objectives of the project.

3.10 Acknowledgement, Publication or Disclosure of Results

- 3.10.1 The RC attaches great importance to the publication of the results of the project undertaken with the assistance of the grant. The principal applicant and administering institution shall properly acknowledge the contribution of the Government, specifically "Health and Medical Research Fund, the Health Bureau, The Government of the Hong Kong Special Administrative Region" to the project in any relevant correspondence, public announcement, advertising material, report or other material produced by, on behalf of or through the principal applicant or the administering institution in any manner relating to the project.
- 3.10.2 In addition to the presentation of interim, final and dissemination reports the principal applicant must inform the RC of any publications containing results, information or technical knowledge connected with the project and shall forward a royalty-free copy of the work to the RC. The RC will maintain a database of all published work attributed to projects funded by the HMRF (as well as its preceding funding schemes).
- 3.10.3 The RC may approach former and/or current principal applicants at intervals in order to ensure that all relevant publications and other relevant outcomes attributable to the grant have been reported.

3.11 Intellectual Property Rights

3.11.1 All rights in the results of the project shall jointly belong to the Government and the administering institution as their absolute property. This does not preclude in any way normal academic and professional use of data and documents, subject to the requirements in 3.10. Applicants should refer to the contractual agreement (Clauses 10 and 11) relating to intellectual property rights and invention.

3.12 Commercial Application of Results

- 3.12.1 The principal applicant and the administering institution shall inform the RC in writing of any discovery, development, application or technical knowledge arising in the course of the project which could have commercial value.
- 3.12.2 Commercial use of the project results may not be made without the prior written consent of the Government. The principal applicant and the administering institution must obtain the Government's approval in advance of any proposed discussion or negotiation with any person, company or firm with a view to commercial use or other application of such results.
- 3.12.3 The Government reserves the right to be represented in any negotiations held with a view to commercial use or application of any discovery arising from the project.

3.13 Variation of Conditions

- 3.13.1 No alteration, deletion or addition may be made to any of these conditions or any part of the e-Form without the **prior** agreement in writing of the RC if the change is proposed by the principal applicant and the administering institution. In particular
 - any change of substance in the objectives and methodology of the project;
 - any change of the principal applicant, co-applicants and the administering institution:
 - any change of the approved budget total for each category (Staff, Equipment,
 Other Expenses) of the grant given in the e-Form or the accumulated
 spending of any individual item within a category exceeds (a) 10% of the
 budget of that item or (b) the ceiling for that item as set out in the grant policy;
 - any change of the type of project staff under approved Staff budget given in the e-Form;
 - any change of the duration/commencement date/end date of the project

must be so approved. If the RC does not approve a change proposed by the principal applicant and the administering institution, the RC may cancel or renegotiate the arrangements for support of the project and may seek the return of any funds provided to date, if necessary.

3.14 Liability

- 3.14.1 Notwithstanding the provision of the grant by the Government, or the compliance by the principal applicant and the administering institution with the conditions of such grant the principal applicant and administering institution shall remain solely liable for all costs, liability or damages relating to the project and the publication of such work.
- 3.14.2 Without limiting 3.14.1, the principal applicant and the administering institution shall be solely responsible for claims that the project or any part thereof infringes the intellectual property or other rights of a third party.

3.15 Conflict of Interest

3.15.1 The principal applicant and the administering institution shall render their advice or recommendation on an impartial basis without giving favour to any particular product or service in the project. The principal applicant and the administering institution 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 principal applicant or the administering institution 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 principal applicant's or the administering institution's duties under the approved project.

EXAMPLES OF RESEARCH THAT WOULD BE WITHIN AND OUTSIDE THE FUNDING SCOPE OF HEALTH AND MEDICAL RESEARCH FUND (Research Fellowship Scheme and Investigator-initiated Projects)

Within funding scope

i. Clinical research: mechanisms of human disease, therapeutic interventions, clinical trials, development of new technologies

No.	Research Area	Examples
1.	Clinical virology	A combination of pre-clinical and clinical research to investigate the immune responses and the associated cellular pathways among vaccinees and SARS-CoV-2 infected subjects. The pre-clinical part is to conduct animal experiments to study the functional role of a selected type of immune cell and evaluate potential drug treatment. Research conducted with human subjects involving primary data collection to identify correlation with results generated from animal experiments.
2.	Treatment	Clinical research: therapeutic interventions/clinical trials A prospective cohort study aiming to determine the safety and efficacy of novel drug therapy regimen among patients with a particular medical condition.
3	Clinical study of Chinese Medicine formula	Clinical research: therapeutic interventions/clinical trials A study aiming to investigate the clinical efficacy and safety of an empirical formula consisting of multiple Chinese herbal medicines on patients with a particular medical condition using a randomised placebo-controlled clinical trial. The effects of this formula on the modulation of the oral and fecal microbiota of these patients will be determined by metagenomics.
4.	Integration of Chinese medicine and Western medicine	Clinical research: therapeutic interventions/clinical trials A clinical trial aiming to investigate the clinical efficacy and drug interaction of the combination of Chinese and Western medicines in certain cancer patients. Blood samples will be collected from each patient at pre- and post-treatment for assessing the changes in molecular markers and treatment responses.
5.	Treatment	Clinical research: therapeutic interventions A combination of pre-clinical and clinical research involving biopsy samples obtained from prospectively recruited cancer patients and used for drug sensitivity profiling. Ex vivo cultured biopsy tissues will be tested against a panel of anti-cancer chemo- and immunotherapies. The treatment response in ex vivo culture will be correlated with treatment response among those patients assigned to chemotherapy or immunotherapy.

Within funding scope

i. Clinical research: mechanisms of human disease, therapeutic interventions, clinical trials, development of new technologies

No.	Research Area	Examples
6.	Diagnosis/ Disease	Clinical research: development of new technologies
	monitoring	A study conducted with human subjects involving primary data collection aiming to develop and validate an AI-based system for automated image-based diagnosis of specific health conditions and disease progression risk. Scanned images of the relevant organ will be obtained from retrospective archives of clinical data and from prospectively recruited patients and healthy controls to train and validate the AI-based algorithm.

ii. Epidemiological study/Behavioural study

No.	Research Area	Remarks
7.	Longitudinal study	Epidemiological study/Behavioural study A longitudinal study conducted over several years to examine trajectories of chronic diseases and associated morbidities in the local population, and to identify modifiable risks and protective factors for different chronic disease outcomes for future preventative intervention work.
8.	Infectious disease epidemiology	A study which aims to characterise the pre-existing risk factors and severity of reinfection of a particular pathogen by using machine learning approach to identify patients' subphenotypes associated with the reinfection. It involves the use of data from electronic medical records to identify the study subjects with the relevant clinical information (e.g. pre-existing risk factors like comorbidities, medication history and severity of infection) and make associations with mild or severe re-infection for comparison.

iii. Outcome research and health services research

No.	Research Area	Remarks
9.	Health economics	Outcome research and health services research
		A study which aims to evaluate the cost-effectiveness of telehealth versus conventional face-to-face care for managing chronic diseases in Hong Kong.

iv. Research on infectious diseases with public health implications

No.	Research Area	Remarks
10.	Risk assessment and surveillance	A study which aims to determine the microbiome and antimicrobial resistome shared by environmental samples collected at different sites and time periods using metagenomics sequencing, followed by associating them with the clinical multi-drug resistant organisms (MRDO) strains reported in different community regions to review whether there is any epidemiological lineage.
11.	Antimicrobial agent	A study which aims to develop a novel nanomaterial that is effective in bioaerosol disinfection. The disinfection efficacy of the proposed nanomaterial will be evaluated in a laboratory under various environmental conditions against designated microorganisms, followed by further open field testing for natural airborne microbial communities.

Outside funding scope

i. Basic / preclinical research on Chinese medicine

No.	Research Area	Remarks
1.	Biochemical study of medicinal plant extracts	Non-clinical research A pre-clinical study which aims to determine the treatment effect of a traditional Chinese medicine/herbal formula for a particular disease using mouse models.

ii. Research on infectious diseases with low public health implication

No.	Research Area	Remarks
2.	Phylogenetic analysis	A study which aims to identify novel virus species by next-generation sequencing of samples collected from various animal sources, followed by bioinformatics analysis to investigate the virus evolution and the susceptibility of transmission to potential new hosts. This study is a viral evolutionary biology project, and is unlikely to identify new viruses that can infect human and cause public health threats.

ITEMS ALLOWABLE AND UNALLOWABLE FOR REIMBURSEMENT

1. Items Allowable

1.1 Staff costs

Funds may be requested for the salaries of project staff and other supporting staff. Staff cost (full or part-time) includes salary and mandatory provident fund of staff employed. For part-time staff, the effort on the project must be at least 20%.

For instance, the RC is prepared to reimburse 20% of staff salary for a project or support staff provided that it is used for 20% of time on the project. When applying for reimbursement, the principal applicant should specify the particular staff to which the costs relate and the percentage of time the staff spent on the project.

The administering institution shall enter into **contracts of employment with** all **persons** whose salaries are to be reimbursed from the Grant and the administering institution. Each of such contracts should provide for the rate of pay normally applicable to the appropriate grade of the person employed by the administering institution. The Government has no obligation to reimburse any salary of a person unless and until the administering institution has entered into a contract of employment with that person. Notwithstanding the reimbursement of any salary in respect of a person by the Government, should the Government subsequently form the view that the administering institution did not enter into a contract of employment with that person as required, the administering institution shall repay some or all of the reimbursed amount as and when the Government requests.

1.2 Facilities

1.2.1 Computer equipment, software and computing consumables

The principal applicant should provide valid justifications for purchase of software and computing equipment/facilities. Local departmental computing charges which can be assigned to the project will be considered as an allowable cost, including stationery supplies and software licences. Expenses for computing equipment specific for the project, such as notebook computers, software, etc., will be covered. Central computing facilities remain the responsibility of the administering institution.

1.2.2 Equipment

Maintenance costs, service contracts and spare parts for equipment not purchased specifically for the project but used for a significant portion of the project will be paid on a pro rata basis.

For example, a piece of equipment that is used 50% of the time for an approved project and 50% of the time for other purposes will be covered for half of the maintenance costs. When applying for maintenance costs, the principal applicant should specify the piece of equipment to which the costs relate and the percentage of time the equipment will be in use on the project.

Equipment costing less than HK\$10,000 should be charged under "Other Expenses".

1.3 Administrative services

1.3.1 Cost of Audited Account

HK\$5,000 per project for grant amount between HK\$100,001 and HK\$1,000,000.

HK\$10,000 per project for grant amount over HK\$1,000,000.

1.3.2 Administrative expenses

Costs such as printing, telephone, fax, postage, etc., are allowed where they are separately metered and can be attributed to a specific project.

1.4 Others

1.4.1 Travel and subsistence

All reasonable costs associated with conference attendance are supported up to a maximum of HK\$10,000 (e.g., registration, travel, accommodation, subsistence and preparation of materials).

The cost of local travel for project staff to attend clinics, training sites, patients' homes, etc., for purposes directly related to the project are allowed.

1.4.2 Publication costs

The cost of publishing the results of project grant up to a maximum of HK\$20,000 is allowed.

1.4.3 Reference materials

Purchase of essential reference materials, e.g., textbooks downloads of articles, is an allowable cost up to a maximum of HK\$5,000.

1.4.4 Incentives

The purchase of gifts, coupons, etc., as incentives/tokens of appreciation for study participants is allowed if well justified with valid reason(s). A governance system shall be in place to adequately monitor the disbursement of incentives to ensure accountability and traceability.

2. Items Unallowable

- 2.1 Employment of all applicants listed in Section 7 of the Electronic Application Form
- 2.2 Employment of established academic and service staff (e.g., Assistant Professor and Post-doctoral Fellow) supported by other funds (e.g., University Grants Committee/Research Grants Council).

- 2.3 General premises costs including
 - construction and maintenance of buildings
 - land purchase/lease
 - refurbishment/renovation/adaptation
 - basic services and utilities (including heating, lighting and communications)
 - lease/rent/rates
 - insurance
 - cleaning/pottering/security/safety
- 2.4 Cost of unspecified research/project work.
- 2.5 Cost of work incurred before the commencement of the project date, or the writing-up of such work.
- 2.6 Cost of literature surveys.
- 2.7 Remuneration of undergraduates (other than payment for vacation work under the existing award if such earnings are allowed by the administering institution).
- 2.8 Studentship for a research student. Letter of admission/acceptance letter to a research programme is not accepted as proof of employment contract.
- 2.9 Cost of the facilities of the administering institution to which the applicants and hired staff normally has free access.
- 2.10 Staff benefits such as gratuity, bonus, severance payment and untaken leave of staff employed.
- 2.11 All kinds of insurance costs, such as medical insurance, labour insurance, clinical trial insurance.
- 2.12 Costs for clearance/approvals/certificates from relevant ethics committees/IRBs and regulatory bodies.
- 2.13 Entertainment and overseas visits not directly related to the research/project.
- 2.14 Advertising costs for recruitment of staff.

FINANCIAL ARRANGEMENTS

1. Approval of Grant

1.1 Approved projects are funded on actual basis with a pre-approved cash ceiling.

2. Payment of Grant

2.1 For grant amount of HK\$100,000 or below

The principal applicant and the administering institution must ensure that the expenditure incurred is within the ambit and the scope of the approved budget. A duly completed reimbursement claim form signed by principal applicant and the administering institution and the supporting documents thereof (including, for the latter, the original of all relevant invoices and receipts or, where invoices and receipts are not available for reasons reasonably accepted by the Government, all declaration of expenditure duly signed by the principal applicant and the administering institution) to request payment by the Government no more frequently than every two months from the commencement date.

The administering institution shall submit the certified financial statement **within three months** after the end date or **within 60 days** after the termination of the project, whichever is earlier.

2.2 For grant amount of HK\$100,001 or above

An annual certified financial statement must be submitted covering the 12-month period from the project commencement date. The administering institution shall submit an annual certified financial statement within two months following the first anniversary of the commencement date, and shall submit the audited account within six months after the end date or within 60 days after the termination of the project, whichever is earlier.

2.3 Final claim for reimbursement of expenditures

Claims for reimbursement of expenditures may only cover **the period between the commencement date and end date** of the project. A final reimbursement claim form shall be submitted together with the audited account and the final report.