

The Chinese University of Hong Kong

Policy on Research

(With effect from: 17 January 2024)

N.B. Please refer to the “Policy on Intellectual Property” at https://www.orkts.cuhk.edu.hk/images/Policy/Policy_on_IP_2020.pdf for policies on intellectual property and knowledge transfer matters

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PREAMBLE

1. Background

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| <i>University mission</i> | 1.1 | The Chinese University of Hong Kong is committed to the preservation, creation, application and dissemination of knowledge by teaching, research and public service in a comprehensive range of disciplines, thereby serving the needs and enhancing the well-being of the citizens of Hong Kong, China as a whole, and the wider world community. |
| <i>Mission Statement with regard to entrepreneurship and knowledge transfer activities</i> | 1.2 | As an international centre of research excellence, the University strives to nurture innovation, entrepreneurship and knowledge transfer for the advancement of humanity. |
| <i>Role of research</i> | 1.3 | <p>In pursuance of this mission, the University regards research as an integral and essential part of its academic activities, and it is intended that research should serve the following functions:</p> <ul style="list-style-type: none"> (a) to attract, retain and enhance the most enquiring minds, and therefore to ensure the highest standards in teaching, and the best graduates that society needs; (b) to train postgraduate students, in particular through research activities, for the increasingly sophisticated needs of society; (c) to contribute to the advancement of human knowledge; (d) to contribute to the elucidation and analysis of issues of local and regional concern, especially in an era of rapid development and transformation; and (e) to develop products and processes that are of practical utility through applied research, to benefit humankind, and to contribute to the industry and economy of Hong Kong and the region. |
| <i>Research policy</i> | 1.4 | The University has an established policy on research addressing also professional ethics and research misconduct and is summarised hereunder. |
| <i>Policy on Intellectual Property</i> | 1.5 | The University has an established policy on intellectual property and knowledge transfer, which is summarized under the Policy on Intellectual Property (with effect from: 1 August 2020) at https://www.orkts.cuhk.edu.hk/images/content/about/policy-documents/Policy_on_IP_2020.pdf . This Policy and the Policy on Intellectual Property jointly replaced the “Policy on Research, Intellectual Property and Knowledge Transfer” as of 1 August 2020. |

2. Organization and implementation of the document

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| <i>Part A:</i> | 2.1 | <i>Part A</i> of this document contains the policy and principles, and |
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| <i>Policy and principles</i> | | comes into effect upon approval by the University's Administrative and Planning Committee ("AAPC"), Senate and the Council. The relevant approval(s) from one or more of these bodies is/are required for any significant changes in the future. |
| <i>Part B: Procedures and implementation guidelines</i> | 2.2 | <i>Part B</i> of this document contains the detailed procedures and implementation guidelines that give substance to the policy and principles, and comes into effect upon endorsement by AAPC. These procedures and implementation guidelines may be amended from time to time by the relevant administration units after consultation with the Research Committee, and where necessary AAPC. |
| <i>Replacement of certain regulations</i> | 2.3 | In cases where the policy, principles and procedures in this document conflict with such existing regulations as are within the powers of AAPC, Senate or the Council to vary, the existing regulations are deemed to be revoked and replaced upon the adoption of the relevant parts of this document by AAPC, Senate or the Council, as the case may be. |
| <i>Continuation of other regulations and contracts</i> | 2.4 | In cases where the policy, principles and procedures in this document conflict with such existing regulations or contractual terms as are not within the powers of AAPC, Senate or the Council to vary unilaterally, the existing regulations and terms shall stay in force unless and until they are varied, or superseded. |
| <i>Exceptions</i> | 2.5 | Exceptions to these policies, principles and procedures may be approved by the AAPC, Senate or the Council, as the case may be, on a case-by-case basis. |

3. Distribution and feedback

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| <i>Distribution</i> | 3.1 | This document should be made available to all academic and research staff, as well as to administrative and professional staff, support staff and students who have a role in the research activities of the University. |
| <i>Acceptance of policy</i> | 3.2 | All new staff shall be required, as part of their obligation under contract, to sign an undertaking that they accept the policy, principles and procedures in this document. All existing staff should do the same as a condition before the University endorses research proposals or releases grant monies. |
| <i>Intention to simplify procedure</i> | 3.3 | This document, though lengthy, is intended to simplify procedures and administrative workload. It is hoped that some of the good practices here mandated by detailed guidelines would eventually become part of the tradition and ethos of the University, and need no longer be spelt out or monitored. |
| <i>Review and feedback</i> | 3.4 | This document, and in particular the procedures, need to be reviewed from time to time to ensure consonance with changing circumstances and to achieve maximum efficiency. Feedback and suggestions are welcome, and should be addressed to the Pro-Vice-Chancellor for Research. |

Part A: Policy and Principles

4. Philosophy

Retention of control of research programmes

- 4.1 The scope and quality of the University's research has been facilitated by the extensive external grants and contracts awarded by the University Grants Committee ("UGC"), Research Grants Council ("RGC"), foundations and industry. Nevertheless the University must retain control of its research programmes and only undertake research activities that contribute to its educational and scholarly objectives.

5. Conditions for research and funding

Principal investigators

- 5.1 Academic staff at Assistant Professor rank or Research Assistant Professor rank or above may serve as Principal Investigators of externally supported research awards. Other staff members, with the approval of the immediate supervisor and the Chairperson of the Research Committee may serve as Principal Investigators under special circumstances, provided that a named full-time academic staff member at Associate Professor rank or Research Associate Professor rank or above assumes responsibility for ensuring that the administration of the award conforms with the sponsor's requirements.

Conditions for accepting grants

- 5.2 The University will only accept a research award, in the form of a grant or other type of legal agreement, from an external sponsor for the support of a research project if the terms and conditions are consistent with the following criteria:

Scope

- (a) The work is consonant with the University educational and research objectives, and the University would itself have supported the research if its own funds were adequate.

Exclusion of funding

- (b) The University reserves the right to refuse acceptance of any research grants offered by or entering into contracts with any companies as it considers appropriate. As a rule, the University does not accept any research grants offered by or in the name of tobacco companies.

Freedom to publish

- (c) The agreement, except for the protection of the sponsor's confidential and proprietary information, does not restrict the freedom to publish and otherwise disseminate the results of research.

Access to technical data

- (d) The Principal Investigator and other members of the research team will be permitted to retain copies of such data and information for their own academic (but not commercial) use, and that other *bona fide* researchers should be given access to the data under suitable conditions. Subject to contractual arrangement that the University may have with the sponsor university or organization or the prior agreement of the Research Committee, the University will own the data and other products generated from or purchased for a sponsored project.

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| <i>Not for publicity</i> | (e) | The results of sponsored research with the name and/or logo of the University shall not be used for advertising, commercial publicity or other commercial purposes. The name and/or logo of the University shall not be used in any way, whether in the form of written or oral statements, that could constitute or imply an endorsement by the University of any commercial product or its packaging or service, without the prior written approval of the University. |
| <i>Exceptions</i> | 5.3 | In recognition of the possibility of special circumstances, the Research Committee is empowered to grant exceptions to the stipulations in Paragraph 5.2. |
| <i>Research ethics</i> | 5.4 | The University takes research ethics seriously. All staff members who apply for research grants are mandatorily required to go through research ethics training, and are expected to adhere to the best research practices in the conduct of research. |
| <i>Safety</i> | 5.5 | In accepting an award in support of a research project to be conducted at the University, the University will need to satisfy itself that the facilities and procedures meet approved standards of chemical, biological and radiation safety (see Paragraph 16). |
| <i>Ethics on human and animal subjects</i> | 5.6 | In any research project involving human and animal subjects, or involving tissues directly obtained from human and animal subjects, it is incumbent upon the Principal Investigator to obtain the approval of the relevant Ethics Committee, unless the project satisfies all the requirements for exemption set by that committee. The committee will be particularly concerned that (a) the rights and welfare of subjects are adequately protected; (b) the risks to subjects are outweighed by potential benefits; and (c) appropriate informed consent of subjects is obtained. Similar considerations for (a) and (b) apply to research projects involving warm-blooded animals (see Paragraph 17). |
| <i>Publication ethics</i> | 5.7 | The Publication Ethics Committee is in place to provide advice to researchers on all aspects related to publication ethics. Researchers are expected to follow the best practices in publication and are held accountable for publishing research findings in the research community and the general public (See paragraph 8). |
| <i>Confidentiality</i> | 5.8 | The Principal Investigator and other members of the research team are responsible for protecting the privacy of research participants and maintaining the confidentiality of research information such as health data, personal information, and proprietary data/information. The Principal Investigator and other members should implement appropriate measures to ensure the privacy and confidentiality of the aforementioned research information throughout all stages of the research. |
| <i>Compliance</i> | 5.9 | The Principal Investigator and other members of the research team must comply with University guidelines and policies, any relevant local and national laws and regulations, regulatory constraints, and contractual obligations. |

6. Outside practice

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| <i>Authoritative regulations</i> | 6.1 | It is recognized that members of staff may undertake outside practice related to research or knowledge transfer subject to the |
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relevant University regulations. Outside practice is governed by relevant clauses in the Terms of Service and by the Council regulations adopted from time to time. The regulations defining and governing outside practice are set out in Chapter B7 of the Staff Handbook (<http://www.hro.cuhk.edu.hk>) which may be amended from time to time.

7. Sponsored future research

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| <i>Sponsorship in return for future results</i> | 7.1 | The University permits staff members to seek research support from companies wishing to have the right to commercialize the possible results of their research activities. |
| <i>No substantial holdings or management control</i> | 7.2 | A staff member must not have substantial holdings in or have management control of a company that supports his/her research activities, by any means other than an unrestricted grant. |
| <i>Integrity of results</i> | 7.3 | Neither the direction of the University's research activities nor the interpretation of research results should be altered or appear to be altered by the commercial interests of any company. |
| <i>Clear delineation</i> | 7.4 | Any contract granting to a company rights to license future patents arising from research activities sponsored by the company must clearly delineate the scope of that work in order to distinguish it from research activities supported by other funds, especially public funds for which the University has a special responsibility. |
| <i>No outside control of dissemination</i> | 7.5 | The University is willing to keep sponsors fully informed of the research activities they support, but the University does not automatically grant to outside organizations the right to delay submission or to refuse publication of research papers. |

8. Professional ethics

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| <i>Quality of employees</i> | 8.1 | The quality of instruction and research at the University depends first and foremost on the quality of its employees. To maintain its stature, the University must give highest priority to recruiting, retaining and promoting employees of exceptional qualifications at all levels. |
| <i>Respect right of others</i> | 8.2 | All members of the community, whether staff or students, are expected to respect the rights of every other member, his or her academic freedom to pursue knowledge and to disseminate his or her ideas and research results, and to share the use of University equipment, facilities or other resources to achieve these goals subject to relevant policies and procedures. |
| <i>Recognition of contribution of others</i> | 8.3 | University staff members should recognize the contributions of other staff members and students (particularly those under their direct supervision) to their own research and scholarly undertakings. Acknowledgment may take various forms, including co-authorship in publications where appropriate. Co-authorship is appropriate when a staff member or student has made an intellectual contribution, or has been responsible for the experimental observations and/or interpretation of the data leading to the research publication, in other words, when their idea or work is critical to the outcome of the research. Similar considerations should apply to the handling of research ideas and inventions that |

result in the filing of patents.

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| <i>Principle of fairness</i> | 8.4 | The University recognizes the principle of fairness: credit is assigned where credit is due. Under no circumstances should an individual take unfair advantage of another member of the community. All members of the community are expected to respect the intellectual property of others. It is considered unprofessional conduct to misappropriate the ideas of others, or to misrepresent them. |
| <i>Plagiarism</i> | 8.5 | In particular, the use of the work of others or one's own previous work (whether word-for-word or rephrased) without proper attribution of the source amounts to plagiarism or unacknowledged duplicate publication and constitutes grounds for disciplinary actions. |
| <i>Co-authorship</i> | 8.6 | Co-authorship should reflect the nature and degree of the participation, taking into consideration the conceptualization, execution, as well as the solicitation of sponsorship for the project. The order of co-authorship should conform to acceptable professional practice. An individual should not expect co-authorship for peripheral participation that does not carry a degree of intellectual input. Supervisors of staff members should be especially sensitive to this issue in order to ensure fairness in the distribution of professional credit and to maintain an atmosphere of openness and collegiality. |
| <i>Computer ethics</i> | 8.7 | <p>The University provides computer resources for education and research activities. These resources are intended for the legitimate business of the University. As in the use of other University property, staff and students who use campus computing resources should be guided by the principles of respect for public property and respect for members of the community. Some examples of inappropriate use are: harassment of other users; destruction or damage to equipment, software or data belonging to others; disruption or unauthorized monitoring of electronic communications; violations of computer security systems; unauthorized use of accounts, access codes, or identification numbers; use of facilities in ways that intentionally impede the computing activities of others; violation of copyrights and software license agreements; violations of another's privacy; and academic dishonesty.</p> <p>Inappropriate uses of University resources may result in administrative discipline up to and including dismissal from the University. In addition, illegal acts involving University computing resources may result in criminal prosecution.</p> |

9. Research misconduct

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| <i>General considerations</i> | 9.1 | As a respected research-intensive university, the Chinese University of Hong Kong has always sought to uphold the highest standards of research integrity. The University will not tolerate any research misconduct on the part of its staff or students, either in its main campus in Hong Kong or in its Shenzhen Research Institute, and will vigorously pursue any allegation of research misconduct. At the same time, the University recognizes its responsibility to investigate such allegations evenhandedly, respecting the rights of both the complainant and the respondent. |
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The policy set out in the following paragraphs aims to ensure that allegations of research misconduct are resolved both fairly and expeditiously.

Definition

- 9.2 Research misconduct is a form of academic misconduct. Academic activities normally involve either teaching or research, and research misconduct refers to improper behaviour in research and related activities. The standards of professional ethics expected of researchers at the University are set out in Paragraph 8, and research misconduct can be broadly defined as a failure to meet these standards.
- 9.3 The term 'research misconduct' is broader than research fraud, and includes conduct such as non-compliance with ethical or safety protocols. For the purposes of this policy, the term 'research misconduct' includes:
- (a) fabrication or falsification of research results;
 - (b) plagiarism;
 - (c) unacknowledged duplicate publication;
 - (d) misleading ascription of authorship;
 - (e) misuse of research funds and related resources;
 - (f) sabotage;
 - (g) non-compliance with research safety protocols;
 - (h) non-compliance with ethical protocols;
 - (i) breach of confidentiality; and
 - (j) research-related breaches of the law.

These types of research misconduct are further defined in *Schedule 1*.

- 9.4 Misconduct related to the University's policies on knowledge transfer, such as conflict of interest or infringement of the rules on outside practice, does not fall within the ambit of research misconduct, and is covered under other sections of the University's policies.

Responsibilities

- 9.5 The Chinese University of Hong Kong enjoys a proud reputation for the excellence of its teaching and research and for the integrity of its staff and students. This hard-earned reputation is an important asset for the University. If its members fail to uphold the highest standards of research integrity, they risk tarnishing the collective reputation of the academic community and bringing the University into disrepute. It is therefore in the interest of all staff and students to support the University's efforts to investigate suspected cases of research misconduct.
- 9.6 To ensure that the University's policies on research misconduct are widely disseminated and understood, it is the responsibility of the Dean of each Faculty and the Director of each research unit to properly inform their staff and students of these policies.
- 9.7 To ensure that all cases of research misconduct are fully

investigated, it is the responsibility of all staff and students of the University to report any suspected violations or attempted violations that come to their attention. The University appreciates that it is not always easy to come forward in such cases, and will handle all reports in the strictest confidence, particularly as regards the identity of the complainant where appropriate.

Governing principles

9.8 The University will rigorously pursue all allegations of research misconduct that are brought to its attention, regardless of when or where the alleged misconduct occurred, and will take appropriate disciplinary action if research misconduct is confirmed through established university policies and procedures. At the same time, it recognizes its responsibility to treat all parties fairly and impartially, having regard to the sensitivity of such allegations. The University's procedures for investigating allegations of research misconduct have therefore been developed with the following principles/considerations in mind:

- (a) Allegations or complaints must be submitted in writing to the University via the Office of the Pro-Vice-Chancellor for Research.
- (b) The Pro-Vice-Chancellor for Research, with the concurrence of the Provost, may also initiate an inquiry or investigation into any significant incident of possible research misconduct, even in the absence of a written complaint.
- (c) Confidentiality should be maintained as far as possible, particularly as regards the identities of the parties concerned.
- (d) All conflicts of interest must be formally declared, and avoided where practicable.
- (e) Frivolous or malicious complaints should be identified and dismissed or referred to the University for further consideration.
- (f) All victimization cases will be referred to the university for possible investigation and disciplinary action. Victimization occurs when a person treats another person (hereafter 'the victim') less favourably than they would treat other persons, and does so because the victim or a third person:
 - (i) has made, or intends to make, a complaint; or
 - (ii) has furnished, or intends to furnish, information or documents in relation to a complaint; or
 - (iii) has appeared, or intends to appear as a witness in an investigation; or
 - (iv) has reasonably asserted their own or another person's rights in matters related to this policy.
- (g) In all stages of the inquiry, the investigation and resolution process should be conducted expeditiously and be properly documented.

Preliminary inquiry, investigation, resolution and

9.9 If an allegation of research misconduct is made against a staff member of the University (hereafter 'the respondent'), the Pro-Vice-Chancellor for Research will determine whether the

disciplinary action

allegation merits further consideration. If the allegation is brought by an individual, this will normally be by means of a preliminary inquiry. If the allegation is found to merit further consideration, the Pro-Vice-Chancellor for Research may set up an investigation committee. Upon receipt of the investigation committee's report, the Pro-Vice-Chancellor for Research may decide (or recommend in cases involving termination of employment) on the disciplinary action to be taken. The respondent will be given the opportunity to present his or her case during the investigation, and if necessary to appeal the decision to the Vice-Chancellor, whose decision shall be final. In cases where the Pro-Vice-Chancellor for Research recommends termination of employment, the relevant University Procedure for Staff Discipline will be followed.

- 9.10 Cases involving research misconduct on the part of students will normally be dealt with under relevant academic honesty policies and procedures applicable to students.
- 9.11 If, during these procedures applicable to students in 9.10, it is found that university staff members are involved, or that the case involves university employment, sponsored research or grant supported research, the case should immediately be referred to the Pro-Vice-Chancellor for Research for determination of the appropriate process and procedures to be followed. Normally, the preliminary inquiry and investigation procedures will then follow those outlined in this document, before reverting back to relevant bodies for disciplinary consideration where applicable.
- 9.12 If, during the above process, it is believed that the case may involve any breach of the law, the University has the right to refer the case to the relevant law enforcement agencies. In the event that the case is under criminal investigation by a law enforcement agency, or is the subject of criminal or civil proceedings in court, the University may suspend its processes. The University may resume its processes if the criminal investigation is abandoned, not proceeded with, discontinued or completed, or following the dropping or completion of criminal or civil proceedings.
- 9.13 Authority on procedural matters is delegated to the Convenor or Chairperson of the relevant panel/committee under this policy, except where procedures are to be varied from that being established in writing here, in which case, the endorsement of the Pro-Vice-Chancellor for Research is required. While the maintenance of procedural fairness is paramount, broad discretion is entrusted to the Convenor or Chairperson to tailor the procedures to suit the particulars of the case.
- 9.14 The Inquiry panel and the investigation committee may receive any material and attach such weight to the material as it deems appropriate.
- 9.15 In cases where any party fails to provide submissions (in writing or orally) as requested, the University is entitled to draw an adverse inference against that party in its consideration of the case.
- 9.16 The standard of proof to be used in all proceedings is the balance of probabilities, appropriately adjusted to correspond to the gravity of the charge.
- 9.17 Cases (directly) involving members of the university at the level of Pro-Vice-Chancellor or above will be referred to the Vice Chancellor for the determination of process and procedures.

Cases that directly involve the Vice Chancellor will be referred to the Chairperson of the University Council for the determination of process and procedures.

- 9.18 Detailed procedures on preliminary inquiry, investigation, resolution, and disciplinary action are described in Paragraph 19.

10. Relationship between the University and staff — personnel policy

Patent/Copyright agreement

- 10.1 The above policies will be reflected in employment contracts for all new teaching and research staff joining the University after said policies have been approved for adoption. Existing University personnel will be required to sign an agreement assigning ownership of all intellectual property produced as part of University duty to the University as outlined above each time they submit a research grant to the University or solicit research funding from any source, unless an updated patent/copyright agreement is on file with the Human Resources Office.

Conflict of interest and commitment

- 10.2 Scholarly research and knowledge transfer are central to the mission of the University. The University also wishes to serve society by encouraging business to transform results of research into products, processes, and services that will become available in the marketplace. Moreover, in many areas of research, contact with industry and entrepreneurship are essential for success, and need to be encouraged and rewarded. These legitimate interests can sometimes come into conflict. For example, experience shows that research and teaching are best carried out in an environment that encourages the free exchange of ideas between participants, both staff members and students. On the other hand, private sponsors of research activities may have good reasons for wanting to keep certain research results secret, at least temporarily. However, activities of this kind may pose real or apparent conflicts with the integrity and objectivity of research at the University, and with the staff members' primary professional commitment, which is to the University. To help the staff members understand their duties and responsibilities in resolving these potential conflicts, the following principles and rules have been adopted by the University.

General principles

- 10.3 Acceptance of employment at the University involves a commitment that is full time in the most inclusive sense. Each member of staff is expected to accord complete professional loyalty to the University, and to arrange outside obligations, financial interests, and activities in such a way that they do not interfere with this primary, overriding commitment. In addition, the University charges its staff with a particularly heavy burden of responsibilities to safeguard the basic principles of research integrity, academic freedom, and public interest. When performing research sponsored by private interests, or negotiating with companies or entrepreneurs, or forming a company for commercial purposes, or engaging in any other activity in which a conflict of interest may arise, it is the responsibility of the staff member to protect:
- (a) the integrity of all research activities done at the University;
 - (b) the reputation and goodwill of the University;
 - (c) the academic freedom and economic rights of fellow staff

members, students, and postdoctoral associates; and

(d) the public interest.

Outside commitment

10.4 Principles and rules concerning outside commitment:

- (a) a staff member may not hold a position in an outside enterprise for pay or profit;
- (b) staff members shall not engage in outside business activity to the detriment of his University duties or to the detriment of the reputation and goodwill of the University;
- (c) outside practice is subject to the University's regulations, and if approved, is limited to the time restriction set out in the University's prevailing regulation and the approval for the particular activity if applicable; and
- (d) staff members are required to inform the Chairperson of the Research Committee and the Chairperson of the Committee on University Subsidiaries and Spin-off Companies, promptly and in writing, of any consulting for, or substantial holdings in, a firm with which their research at the University becomes involved.

Part B: Procedures and Implementation Guidelines

11. General considerations

Purpose

- 11.1 The purpose of setting down detailed guidelines is to avoid ambiguity, and to reduce many necessary steps to routine.
- 11.2 The Administration Team and Grants Team of the Office of Research and Knowledge Transfer Services is the central contact point for all documentation and monitoring related to researches under research grants from various sources, and is guided in policy matters by the Research Committee.

Revisions

- 11.3 These procedures and implementation guidelines may be revised from time to time, and staff members should ensure that they are acquainted with any changes.

12. Types of external funding

Types

- 12.1 The University (and in the case of (e) below, individual members of staff) may, subject to these Guidelines, accept external funding under a variety of circumstances, including, but not limited to:
 - (a) donations or gifts;
 - (b) research grants;
 - (c) outside practice of individual staff members;
 - (d) research grants awarded to individuals; and
 - (e) consultancy or other services performed by individuals.

For each of these categories, different rules apply for approval, overhead and additional charges, division of income and intellectual property rights.

*Other types
not covered*

12.2 Other types of activity may involve income or funding. These are not dealt with separately in these Guidelines, and current University policy concerning these activities is summarized here for convenience:

- (a) Outside employment is prohibited.
- (b) Non-executive directorship with fees for the provision of professional service shall be regarded as a form of outside practice.
- (c) Remunerative public service is governed by separate regulations (Chapter B10 of Staff Handbook at <http://www.hro.cuhk.edu.hk>).
- (d) Organization of courses, conferences, exhibitions etc. for a fee paid to member(s) of staff shall be regarded as outside engagement (Chapter B9 of Staff Handbook at <http://www.hro.cuhk.edu.hk>).
- (e) Prizes and awards for professional attainments are not subject to any controls, but should be reported to the University for record.
- (f) Outside business activities are governed by the Regulations Governing Outside Business Activity (Chapter B17 of Staff Handbook at <http://www.hro.cuhk.edu.hk>). In general, dividends and proceeds from investments or donated shares are not subject to any controls, and need not be reported.
- (g) Royalty from patents and copyrights already acquired by staff before joining the University is not subject to any control. However, members of staff should be aware that the acquisition of such rights arising out of work done at the University is subject to University policy and guidelines in the Policy on Intellectual Property.
- (h) Grants awarded by an outside body to an individual to attend a conference, workshop or seminar need not be reported to the University unless the individual member of staff also applies for and/or receives travel or conference support from the University for the same activity.
- (i) Grants awarded by an outside body to an individual to purchase equipment or gifts of such equipment (for teaching and research) for personal use shall be regarded as a personal gift, and permission in writing from AAPC is required if this constitutes an advantage which the staff member would not have been offered were he/she not employed by the University, for a service which is directly concerned with and arises directly out of his/her University duties (see Guidelines on Acceptance of Advantages). Similar grants awarded to a unit of the University shall be treated under donations or gifts.

Donation

12.3 A donation or gift to the University may be made with restriction as

to use (e.g., a donation to support research in a particular subject, or a donation to purchase an item of equipment), but there must be no condition on the outcome or deliverables in return, apart from the recognition of the donation or gift.

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| <i>Research grant</i> | 12.4 | A research grant is awarded to the University to support research activities that the University (and its staff) would of its own accord wish to engage in. The project would usually be initiated by a principal investigator (rather than the sponsoring agency) via a proposal, and no specific deliverables are expected apart from the usual forms of scholarly output (e.g., publications, conference presentations), development of impact, as well as progress and final reports. |
| <i>Outside practice</i> | 12.5 | <p>Outside practice refers to the use for reward (which shall include fees, honoraria, retainers and any other remuneration whatsoever) by a staff member, who assumes personal liability, of his professional knowledge or specialised skill outside of or in addition to the application of this knowledge or skill to his University duties. The University is not a party to the agreement, and has an interest only in ensuring that:</p> <ul style="list-style-type: none"> (a) the outside practice is not detrimental to the University and/or its reputation and goodwill and does not pose any actual or potential conflict with the interests of the University; (b) the outside practice does not interfere with normal duties of the staff member concerned; and (c) approval is given and appropriate charges are levied in cases where University facilities or equipment is used (see Paragraph 15). |
| <i>Research grants awarded to individuals</i> | 12.6 | <p>If a sponsoring body awards a research grant to an individual member of staff, the member of staff may choose one of the following arrangements:</p> <ul style="list-style-type: none"> (a) regard the project as outside practice, and seek approval under the relevant regulations; and (b) seek approval from the Research Committee to regard the project as a University research project. If such approval is given, the entire sum of the grant shall be paid to the University, and the regulations pertaining to research grants shall apply. |
| <i>Consultancy or service by individuals</i> | 12.7 | If a sponsoring body awards a contract for consultancy or other services to an individual member of staff, the contract should be regarded as outside practice, and permission should be sought under the relevant regulations. Such contract should be signed by the staff member in his/her personal capacity and NOT as a University employee. |
| <i>Exceptions and sanctions</i> | 12.8 | <p>If research grants or contracts awarded to individuals are not handled according to Paragraphs 12.6 and 12.7, the member of staff must ensure that the activities are consistent with the law and with staff regulations, e.g.:</p> <ul style="list-style-type: none"> (a) the entire sum is disbursed for project expenses, with none |

accruing to the income of the member of staff concerned (so that the donation does not constitute an “advantage” for the purpose of the Prevention of Bribery Ordinance), and there is no additional use of the University facilities and services as a result of the grant; or

- (b) the project falls outside the range of normal duties and does not involve the use of professional knowledge (so that the activity is not regarded as outside practice).

However, in such cases, the onus of proof falls on the staff concerned; so the arrangements in Paragraphs 12.6 and 12.7 are strongly recommended in cases where there may be any element of doubt. Staff members are in particular reminded of the Guidelines on Acceptance of Advantages in relation to the Prevention of Bribery Ordinance.

Examples

12.9 Examples are given in *Schedule 2* to illustrate the principles that differentiate between these types of external funding. In case of doubt, enquiries should be addressed to the Office of Research and Knowledge Transfer Services as appropriate. Ambiguities in the application of these guidelines will be resolved jointly by a panel consisting of:

- (a) the University Secretary;
- (b) the Director of Human Resources; and
- (c) the Chairperson of the Research Committee.

13. Application and approval

Donation

13.1 Donations and gifts to the University should be reported to the University Secretary, who will seek AAPC and Council approval for acceptance. The approval for acceptance will also specify the unit and/or activity (including any research activity) to which the donation is to be applied.

Research grants

13.2 All applications for research grants should be approved by the University at the application stage. The University would need to satisfy itself that:

- (a) the proposal is consonant with the general principles governing research (Paragraph 5);
- (b) the proposed research has the requisite safety approval (Paragraph 16) and ethics approval (Paragraph 17);
- (c) a suitable level of overhead is levied where appropriate (Paragraph 14); and
- (d) the intellectual property rights of the University are protected.

The application should be channelled through the Office of Research and Knowledge Transfer Services, and approval will be given by the Chairperson of the Research Committee upon the advice of the Research Committee and its subject Panels. In cases where prior approval is not sought, the investigator will run the risk that when the grant is awarded, the University may decline

to accept it, or to accept it under conditions that may not be agreeable to the granting agency.

Contracts

13.3 The University enters into a variety of contracts with outside bodies, of which contracts involving research, knowledge transfer, consultancies and the delivery of related services are only examples. In general, each type of contract has its particular:

- (a) approving procedure (e.g. approval by a designated committee or officer);
- (b) authorized signature on behalf of the University (normally acting upon the advice rendered in the approving procedure);
- (c) archival arrangements; and
- (d) administering unit (to ensure the contract is adhered to and follow-up action is initiated).

The arrangements in respect of contracts concerning research, knowledge transfer, consultancy and the delivery of related services, as well as some other types of contracts, are specified in *Schedule 3*.

Not to enter contract unless authorized

13.4 Members of the University as well as units in the University may not enter into any contract on behalf of the University unless authorized to do so, and should also ensure that no verbal commitments are given before formal contracts are signed. All documents produced for negotiation should be labelled as "subject to contract". Contracts and agreements made without authority will be null and void. In the event that any member of the University without proper authorization imposes an obligation on the University, the University may recover any costs and damage incurred by deduction from the contract income, or, where appropriate, from the salary of the individual concerned. The University will not accept any liability arising from such unauthorized contracts. The University will reserve its right to take necessary action against the member concerned.

Outside practice

13.5 Application for outside practice should be made to the relevant approving authorities. In cases where University facilities or equipment is used, the Human Resources Office will seek advice from suitable parties and recommend a scale of charges (Paragraph 15).

14. Overhead charges

Principles

14.1 Overhead charges may be levied on externally funded activities in order to meet the indirect costs associated with administration (personnel, contract administration, safety), increased use of facilities (libraries, computers), maintenance of premises, utility charges, increased depreciation of furniture and equipment etc. The intention is not to make any profit, but to ensure that resources are not drained from educational activities for which public funding is provided. All overhead charges will accrue to the University and not to individual units. An additional charge may be made for the use of special facilities and equipment (see Paragraph 15).

Donation

14.2 There shall be no overhead on donations or gifts.

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| <i>Research grant</i> | 14.3 | In principle, there should be an overhead charge on research grants, to reflect the indirect cost of the project; the scale of overhead is given in <i>Schedule 4</i> . However, there shall be the following exceptions: <ul style="list-style-type: none"> (a) For projects funded by UGC or RGC, there shall be no overhead charge, since on-costs are already provided by UGC or RGC to the University to cover indirect costs; and (b) For other projects, the Chairperson of the Research Committee is authorized to approve reduction of the indirect cost, in recognition of fact that such research activities would be new/innovative which is worth exploring, in line with core research excellence and strengthen the development of the University, contributory to accomplishment of the academic and societal missions of the University, or would promote knowledge transfer to local community. However, such reduction is unlikely to be granted where the project represents a major departure from existing activities. |
| <i>Contracts</i> | 14.4 | The scale of overhead charges for contracts to provide research, knowledge transfer, consultancy or other services is listed in <i>Schedule 4</i> . Reduction in the scale of charges can only be approved by AAPC. |
| <i>Outside practice</i> | 14.5 | For outside practice, there will be no general overhead. However, there may be additional charges for the use of specific facilities or equipment (Paragraph 15). |

15. Additional charges

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| <i>Principles</i> | 15.1 | Additional charges may be levied on outside practice to cover the cost related to the use of special facilities and equipment. Such additional charges will not be levied on donations or on research grants. |
| <i>Determination of charges</i> | 15.2 | The level of these charges and the division of the income between the unit concerned and the University shall be determined according to the University's prevailing policies and guidelines at the time when approval is given for engaging in outside practice. |
| <i>Separate from contract and outside practice</i> | 15.3 | The approval and additional charges for the use of facilities or equipment are in principle separate from outside practice income. The member of staff concerned is responsible for these charges when the facilities or equipment are used for purposes other than those encountered in the course of normal University duties. If there is no provision for such charges in the outside practice, or if such provision is inadequate, or if there is failure to collect from the client, the member of staff concerned may incur a net loss personally in carrying out the project. Members of staff are particularly alerted to this possibility, especially in cases where approval is sought retroactively. |
| <i>Use of income from such charges</i> | 15.4 | Income from such additional charges shall accrue to the unit(s) concerned in the case of equipment use. In case where University space or central facilities is used, the income shall accrue to the University central account. |

16. Safety approval

Responsible units

- 16.1 The Committee on Safety is the policy body for safety in laboratory-related research, teaching and other activities, and the University Safety Office is responsible for the implementation of that policy, and also acts as the secretariat for the Committee on Safety.

Authorization to stop

- 16.2 The Director of University Safety and any of the Safety Officers are authorized to immediately stop any experiment or activity that is deemed to pose an actual or potential safety hazard. The experiment or activity shall cease until any safety problem is rectified to the satisfaction of the Director of University Safety or the Safety Officer concerned, unless the decision is overturned by the Committee on Safety upon appeal by the investigators concerned.

Prior application

- 16.3 All research proposals, contracts for knowledge transfer, consultancy and services, or application for Outside Practice that involves laboratory work at the University should either:

- (a) recommend that safety approval is not required; or
- (b) seek safety approval.

Approval not required

- 16.4 In cases where the Principal Investigator recommends that safety approval is not required, the Research Committee (or the relevant subject Panel by delegation) will scrutinize the project proposal and may disagree with that recommendation, in which case the Research Committee will direct that safety approval be sought.

Approval required

- 16.5 In cases where safety approval is sought, information will have to be provided to the Director of University Safety, who may decide to:

- (a) grant approval;
- (b) grant approval subject to certain conditions being met;
- (c) grant interim approval pending further information to be provided before the research project is approved for funding; or
- (d) deny safety approval.

Appeals may be made to the Committee on Safety.

General approval

- 16.6 To simplify safety approval procedures, a laboratory, an individual or a group of individuals may seek general approval for a class of activities. Such approval may be granted in writing by the Director of University Safety, and shall always carry the following conditions, together with any others that may be deemed necessary:

- (a) the Director of University Safety or his staff may inspect the relevant facilities or require reports at any time; and
- (b) the general safety approval may be revoked at any time.

17. Ethics approval

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| <i>When required</i> | 17.1 | <p>Ethics approval is required in the following areas:</p> <ul style="list-style-type: none"> (a) experiment and/or clinical treatment of human subjects; (b) experiments and/or clinical treatment of animals; and (c) survey, observation or collection of data on human subjects, in which the condition of the subject is not altered by any external agent. |
| <i>Prior application</i> | 17.2 | <p>All research proposals, contracts for knowledge transfer, consultancy and services or application for outside practice that involves any of the activities list in Paragraph 17.1 should either:</p> <ul style="list-style-type: none"> (a) recommend that ethics approval is not required; or (b) seek ethics approval. |
| <i>Approval not required</i> | 17.3 | <p>In cases where the Principal Investigator recommends that ethics approval is not required, the Research Committee (or the relevant subject Panel by delegation) will scrutinize the project proposal and may disagree with that recommendation, in which case the Research Committee will direct that ethics approval be sought.</p> |
| <i>Approval authorities</i> | 17.4 | <p>In cases where ethics approval is sought, application should be made to the units listed in <i>Schedule 5</i>.</p> |
| <i>Ethics guidelines</i> | 17.5 | <p>The guidelines adopted by these units in considering ethics approval are given in <i>Schedules 6, 7, 8, 9 and 10</i>.</p> |
| <i>General approval</i> | 17.6 | <p>To simplify ethics approval procedures, an individual investigator or group of investigators may seek general approval for a class of activities. Such approval may be granted in writing by the relevant authorities specified in <i>Schedule 5</i>, and shall always carry the following conditions, together with any others that may be deemed necessary:</p> <ul style="list-style-type: none"> (a) the activities may be inspected at any time and the investigator(s) may be required to submit reports at any time; and (b) the ethics approval may be revoked at any time. |

18. Related entrepreneurial activities

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| <i>General principles</i> | 18.1 | <p>The University encourages staff to develop and commercialize research output and other intellectual property. The motivation is both for the benefits to mankind and also for income to support and enhance the University's educational, research and knowledge transfer activities.</p> |
| <i>Use of a company</i> | 18.2 | <p>It is often necessary for such development and commercial activities to be handled by a company, in order that sound commercial principles are followed and that there is no hidden subsidy from public funds. When such a company is formed, the Regulations Governing Outside Business Activity (Chapter B17 of Staff Handbook at http://www.hro.cuhk.edu.hk) will apply, and in brief as follows:</p> |

- (a) a member of staff who is an owner or a director or a member of the management of a company which business concerns the profession for which the staff member is employed must report such to the respective Dean of Faculty (for academic and research staff) or unit head, who will determine whether the company's operations or the staff member's participation is in relation to the work or expertise for which the staff member has been engaged by the University, and whether the University's consent is required for such participation;
- (b) all intellectual property rights generated in the course of employment at the University would normally belong to the University (for details see Paragraph 5 of the Policy on Intellectual Property) and cannot be transferred to any company without permission from the University, and usually also with compensation to the University, e.g. in the form of licensing fees;
- (c) a member of staff working for a company shall be subject to outside practice/outside business activities regulations in the usual manner;
- (d) in dealings and negotiations with the University, ownership and any beneficial interest in any such company must be declared and conflicts of interest avoided.

Companies owned by the University

- 18.3 Subsidiaries and spin-off companies from The Chinese University of Hong Kong are regulated according to the Governance Framework for Subsidiaries and Spin-off Companies (http://www.orkts.cuhk.edu.hk/images/CUSSOC_gov_frame.pdf). The Office of Research and Knowledge Transfer Services is the contact point for pursuing such possibilities.

19. Investigation into research misconduct

Introduction

- 19.1 The University's principles and general approach in dealing with cases of research misconduct is described in Paragraph 9. This paragraph describes the procedures to be adopted in investigations into research misconduct.

Allegations of research misconduct

- 19.2 All allegations of research misconduct shall include:
- (a) any allegation of research misconduct brought against a member of the University either by an individual, or by an external funding agency, or by the University Safety Office or the university's Ethics Committees;
 - (b) any official enquiry by the University (official enquiry) in respect of a grant or sponsored research application, or a research paper submitted by a member of the University;
 - (c) cases of possible significant research misconduct, initiated by the Pro-Vice-Chancellor (for Research), with concurrence of the Provost;
 - (d) any suspected research-related breach of the law by a member of the University; and

19.3 Any allegation of research misconduct, either against a staff member or a student involved with sponsored or grant research, should be directed in the first instance to the office of the Pro-Vice-Chancellor for Research. In order to deter frivolous or malicious accusations, complainants should supply their full name and provide a sufficiently detailed written statement of the case. Anonymous allegations will not normally be considered.

19.4 Where an allegation is made by an individual, a preliminary inquiry will be initiated by the Pro-Vice-Chancellor for Research in accordance with the procedures described below in paragraphs 19.5 to 19.10. In the case of an official enquiry, cases initiated by the Pro-Vice-Chancellor for Research with the concurrence of the Provost, or an allegation of research misconduct originating from an external funding agency or from the University Safety Office or the university's Ethics Committees, an investigation will be conducted in accordance with the procedures described in paragraphs 19.11 to 19.18.

Preliminary inquiry

19.5 Upon receiving an allegation of research misconduct from an individual, the Pro-Vice-Chancellor for Research will conduct a preliminary inquiry to determine whether the allegation merits further consideration.

19.6 The Pro-Vice-Chancellor for Research will normally delegate this inquiry to the Dean of the most relevant Faculty, or to the Director of the most relevant Research Institute. If the Dean or Director are themselves the subject of the allegation, or deemed to have conflict of interest in the case, the Pro-Vice-Chancellor for Research will appoint an appropriate alternate.

19.7 The preliminary inquiry will be conducted by an ad hoc panel, normally consisting of four members. The panel convenor should normally be the Dean of the most relevant Faculty, the Director of the most relevant Research Institute, or an alternate appointed by the Pro-Vice-Chancellor for Research. Two other panel members should be nominated by the panel convenor and appointed by the Pro-Vice-Chancellor for Research. The fourth member of the panel should have no connection to the Faculty or the Research Institute concerned, and will be appointed by the Pro-Vice-Chancellor for Research. The panel's deliberations will be made in confidence, and the identity of the complainant will not be disclosed at any stage to the respondent. Depending on the nature of the evidence presented by the complainant, the panel may decide to seek clarification from the respondent. If so, the respondent should be given at least seven calendar days' notice to respond. Proper notes should be taken of the panel's deliberations.

19.8 The objective of the preliminary inquiry is to establish whether there is a *prima facie* case which warrants further action.

19.9 The ad hoc panel should conduct the preliminary inquiry expeditiously, and its convenor should submit a written record of the panel's findings to the Pro-Vice-Chancellor for Research within 30 calendar days of the appointment of the inquiry panel. If this deadline cannot be met, the panel convenor should file a report within the 30 calendar day limit citing progress to date and the reasons for the delay, and other involved individuals should be informed.

19.10 Based on the preliminary inquiry findings, the

Pro-Vice-Chancellor for Research shall decide on whether further action is warranted, including the setting up of an investigation committee (paragraphs 19.11 – 19.18). The relevant parties will be notified of this decision.

Investigation

- 19.11 Upon receiving an official enquiry or an allegation of research misconduct from an external funding agency or from the University Safety Office or the university's Ethics Committees, or if the findings of the preliminary inquiry so warrant, the Pro-Vice-Chancellor for Research may appoint an investigation committee to: (a) determine whether the respondent has engaged in research misconduct; and if so, (b) assess its nature and severity; and (c) recommend disciplinary action to be taken against the respondent where appropriate.
- 19.12 For cases reported by external funding agencies, the Pro-Vice-Chancellor for Research may appoint an investigation committee to receive and review the allegations. The committee may conduct its own investigation before recommending whether further disciplinary action should be taken.
- 19.13 For cases previously investigated by the University Safety Office or the university's Ethics Committees, the Pro-Vice-Chancellor for Research will receive the recommendation and dispose of the case. Normally, the Pro-Vice-Chancellor for Research will not initiate another investigation, and the University Safety Office or the university's Ethics Committees will be entrusted with the conduct of the investigation and a recommendation on appropriate penalties. The recommendation will be submitted to the Pro-Vice-Chancellor for Research for endorsement. If the decision is not endorsed, the case may be returned to the originating Committee for re-consideration. Alternatively, an investigation committee will be set up by the Pro-Vice-Chancellor for Research to conduct its own investigation and to make its recommendation to the Pro-Vice-Chancellor for Research.
- 19.14 Where an investigation committee is established, it should normally consist of a Chairperson and at least two other members, appointed by the Pro-Vice-Chancellor for Research. Members of the committee should include at least (a) one person familiar with the respondent's field of research, and (b) one person who has no connection to the respondent's Faculty or Research Institute.
- 19.15 The investigation committee shall inform the respondent in writing of:
- (a) the specific allegations;
 - (b) the appointment of a committee to investigate the matter; and
 - (c) their right to make a representation, with at least seven days' notice, to the investigation committee.
 - (d) If the respondents are to make a representation personally, they may be accompanied by another person, who shall however not be a legal representative, subject to the approval of the Committee Chairperson. The request for an accompanying person must be submitted in writing to the Committee Chairperson, in advance, and must set out the reasons for the request, the name,

occupation, and other relevant particulars for the Chairperson's consideration. The decision of the Chairperson shall be final. Accompanying person will not be entitled to address the investigation committee.

19.16 The investigation committee may decline to reveal the identity of the complainant or of any persons who have provided evidence in support of the allegation of research misconduct, and may refuse any demand by the respondent to question these persons.

19.17 The investigation should be completed, and a report filed, within 120 calendar days of its formation. If this deadline cannot be met, the Chairperson of the investigation committee should file, before the expiry of the deadline, a report citing progress to date and the reasons for the delay.

19.18 The investigation committee shall submit a report of its investigation, with its findings, to the Pro-Vice-Chancellor for Research, and may make recommendations for such disciplinary action as it deems appropriate.

Disciplinary action

19.19 The Pro-Vice-Chancellor for Research shall decide whether to accept or reject the committee's findings and recommendations, and shall decide what actions, if any, should be taken. The decision or recommendation of the Pro-Vice-Chancellor for Research will be conveyed to the respondent in writing. Possible sanctions include, but are not limited to:

- (a) removal from the relevant research project;
- (b) special monitoring of future work;
- (c) suspension from applying for internal or external grants in any capacity for a specified period;
- (d) a letter of reprimand;
- (e) suspension from service; and/or
- (f) termination of employment.

19.20 In cases where the Pro-Vice-Chancellor for Research recommends termination of employment, the relevant University Procedure for Staff Discipline will be followed.

19.21 In the event of an adverse judgment by the Pro-Vice-Chancellor for Research for cases not involving termination of employment, the respondent can submit an appeal in writing to the Vice-Chancellor within 15 working days.

19.22 The decision of the Vice-Chancellor will be made as soon as practicable following receipt of the appeal from the respondent. The Vice-Chancellor's decision is final and will be conveyed in writing to the respondent.

Schedules

| | |
|-------------|---|
| Schedule 1 | Definitions of types of research misconduct |
| Schedule 2 | Examples showing differences between the types of external funding |
| Schedule 3 | Arrangements for contracts |
| Schedule 4 | Overhead charges for research grants |
| Schedule 5 | Units responsible for ethics approval / advice |
| Schedule 6 | Clinical ethics guidelines |
| Schedule 7 | Guidelines for the use of experimental animals |
| Schedule 8 | Guidelines for survey and behavioral research ethics |
| Schedule 9 | Code of practice for research involving artefacts |
| Schedule 10 | Guidelines for medical research including human genetic resources related projects at the Shenzhen Research Institute |

Schedule 1
Definitions of types of research misconduct

The various kinds of research misconduct specified in Paragraph 9.3 are defined in greater detail below:

- (a) *Fabrication of research results* includes inventing data and/or results without conducting the research and reporting the data and/or results through accepted research practices. *Falsification of research results* includes the manipulation of the research process or the alteration of data to misrepresent the findings of a research project.
- (b) *Plagiarism* is passing off somebody else's work (commonly defined as their 'language, thought, ideas or expressions'), whether published or not, as one's own.
- (c) *Unacknowledged duplicate publication* (so-called 'self-plagiarism') is the reuse of significant, identical or nearly identical portions of one's own published work without proper acknowledgement or without citing the original work. It includes the practice of 'double submission', in which essentially the same piece of work is submitted and eventually published in two different languages without proper acknowledgement.
- (d) *Misleading ascription of authorship* includes (a) listing authors without their permission; (b) the attribution of work to others who did not contribute to the research; and (c) failing to give appropriate credit to work primarily produced by another person; and (d) impersonating another person to claim authorship of their work.
- (e) *Misuse of research funds/resources* includes (a) applying for funding to finance a previously-funded research project that has already been either wholly or substantially completed; (b) diverting research funds/resources to projects other than those for which they have been awarded; (c) failing to comply with conditions or restrictions attached to a research grant; and (d) failing to properly account for the usage of research funds and/or resources.
- (f) *Sabotage* includes any attempt to hamper or undermine the research activities of others in order to gain a competitive advantage.
- (g) *Non-compliance with research safety protocols* includes non-compliance (a) with the University's protocols to protect the safety of staff working with hazardous materials; and (b) with the University's general protocols to ensure that research equipment, facilities and materials are used safely.
- (h) *Non-compliance with ethical procedures* includes non-compliance with the University's ethical protocols (a) for the use of live animals in research; (b) for the use of human participants in research; and (c) for good clinical practice.
- (i) *Breach of confidentiality as described in Clause 5.8* includes, in any stages of the research, (a) failing to implement appropriate measures to ensure the privacy of the research participants and maintaining the confidentiality of research information such as health data, personal information, and proprietary data/information; (b) breaching of local and national laws and regulations, regulatory constraints, and contractual obligations in relation to confidentiality; and (c) failure to comply with relevant University guidelines and policies.
- (j) *Research related breaches of the law* include any breach of the laws of Hong Kong in the conduct of research.

Schedule 2

Examples showing differences between the types of external funding

The different types of external funding are defined in Paragraph 12. The following examples will serve to illustrate the applications of the principles.

- Education Bureau (“EDB”) funds a study of teaching in secondary schools by a University unit. PI is free to disseminate results, and the only requirement is that EDB be given a report prior to publication. The topic is one which the University unit would have worked on anyway. This will be classified as a research grant. Chairperson of Research Committee may waive overhead charges because this is a project that the unit is likely to have undertaken in any case.
- A proposal is submitted to the Hospital Authority (“HA”). The topic is decided by the PI. This will be classified as research grant. Chairperson of Research Committee may waive overhead charges because of community service.
- Correctional Services Department (“CSD”) funds a study of prisoner behaviour by a University unit. Framework and deliverables are defined by CSD. Results cannot be published without permission of CSD. This will be classified as consultancy contract, and full cost and overhead should be charged. AAPC may waive overhead because of community service.
- A private company asks for some testing of equipment. This is a contract, and full cost, overhead and charge for the use of equipment will be levied. It is unlikely that such charges will be waived.

Schedule 3
Arrangements for contracts

The arrangements for handling certain types of contracts relating to research and knowledge transfer are summarized below.

| Type | Approval Procedure | Authorized signatory | Archival responsibility | Administering responsibility |
|---|--|---|--|--|
| Employment related to contract of consultancy | AAPC, on recommendation of User Department | Assistant Secretary (Human Resources) and above | Human Resources Office | Human Resources Office in consultation with User Department and Finance Office |
| Contracts for knowledge transfer, consultancy or other services | Office of Research and Knowledge Transfer Services to advise | A designated University Officer (at present the Director of the Office of Research and Knowledge Transfer Services) | Office of Research and Knowledge Transfer Services | User Department |

Schedule 4
Overhead charges for research grants

The level of overhead charges for research grants from charitable organizations or public bodies other than RGC is determined by Research Committee. The level of overhead charges for contracts takes into account the greater complexity of contract negotiation, including legal advice. The current level fixed as at August 1999 is as follows.

| | Research grants | Contracts |
|-------------------------------------|-----------------|-----------|
| If activities take place on campus | 20% | 25% |
| If activities take place off campus | 15% | 15% |

1. *Ethics in Clinical Research*

Joint CUHK-NTEC Clinical Research Ethics Committee (CREC)

Please visit the CREC website
<http://www.crec.cuhk.edu.hk/> for details.

2. *Ethics in Animal Research*

Animal Experimentation Ethics Committee (AEEC)

Please visit the AEEC website
<http://www.aeec.cuhk.edu.hk/> for details.

3. *Ethics in Survey Research*

Survey and Behavioural Research Ethics Committee

Please visit the following website
<https://sbre.cuhk.edu.hk/sbre/CommonHome/Index> for details.

4. *Ethics in Research Involving Artefacts*

Ethics Committee for Research Involving Artefacts (ECRIA)

Please visit the following website
[<https://www.orkts.cuhk.edu.hk/en/research/research-support/research-integrity>] for details.

5. *Ethics in Medical Research at Shenzhen Research Institute*

Research Ethics Committee for Medical Research including Human Genetic Resources related projects at the Shenzhen Research Institute (SZRI-MEC)

Please visit the following website
[<https://www.orkts.cuhk.edu.hk/en/research/research-support/research-integrity>] for details.

6. *Laboratory Safety Ethics*

Please visit the University Safety Office website
<https://useo.cuhk.edu.hk/> for details.

7. *Publication Ethics*

Please visit the following website
[<https://www.orkts.cuhk.edu.hk/en/research/research-support/research-integrity>] for details.

Background

The **Joint Chinese University of Hong Kong (CUHK)-Hospital Authority New Territories East Cluster (NTEC) Clinical Research Ethics Committee (CREC)** (香港中文大學 - 新界東醫院聯網臨床研究倫理聯席委員會) serves to ensure that clinical research conducted under CUHK and the NTEC complies to the required ethical standard including the Declaration of Helsinki and whenever applicable, acts in accordance to the International Conference on Harmonization – Good Clinical Practice guidelines (ICH-GCP), the US Food and Drug Administration (US FDA), the National Medical Products Administration (NMPA), local regulations of the Hong Kong Department of Health (DOH), CUHK policies and conforms to the requirement of the Hospital Authority (HA). In particular, in accordance with the Declaration of Helsinki, it is the responsibility of clinicians who take part in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The CREC has processes in place to detect deviations and research misconduct.

Policy

1. All clinical research carried out under CUHK must be driven by an appropriate protocol.
2. All study under CUHK and/or NTEC should not be started prior to obtaining written approval from the Joint CUHK-NTEC Clinical Research Ethics Committee.
3. Local ethics approval must be obtained in addition to our CREC approval for studies initiated by CUHK staff and student that recruit subjects outside Hong Kong.
4. Clinical research project partly or wholly involves contacting subjects prospectively requires informed consent from the subjects.
5. Policy on human tissue sample
 - In general, human tissue should be removed, kept or used for research only after obtaining valid consent from participants.
 - Investigators should ensure the confidentiality of all personal and clinical information.
 - Tissue storage facilities should normally be operated on a non-profit basis
 - Consent Requirements:
 - i. If valid consent has previously been obtained and the new use clearly falls within the description of use previously authorized, it is unnecessary to obtain consent again
 - ii. If valid consent has **NOT PREVIOUSLY BEEN OBTAINED** for either storage or research use (archived clinical specimens)
 1. *where the donor is identifiable*, consent should usually be obtained from the donor OR if deceased, a close relative. However, if obtaining consent is impractical or impossible - research without consent may be possible if: a) all known details of the source and status of the tissue have been provided to the CREC; b) no reason to believe that the specimens were obtained in an unethical manner; c) no reasonable anticipation of potential harm to donors; d) there are reasons why new tissue obtained with appropriate consent would not be a reasonable alternative.
 2. *where the donor is NOT identifiable*, including de-identified (deliberately or otherwise) tissue, it may be possible to proceed with research without consent following CREC approval, provided: a) all known details of the source and status of the tissue have been provided to the Committee; b) no reason to believe that the specimens were obtained in an unethical manner; c) no reasonable anticipation of potential harm to donors; d) there are reasons why new tissue obtained with appropriate consent would not be a reasonable alternative.

Operation

The Joint CUHK-NTEC CREC meets on the first week of each month. The Chairperson, a layperson and at least five or more of the members who have reviewed the applications should be present at the meeting. The CREC should determine the outcome of its review of research project applications at meetings when this quorum is established. If a CREC member is involved in any of the application under review, the member should not review and discuss or vote / provide their opinion and / or advice on that application. The CREC Secretary should prepare minutes of each meeting. The minutes should include, but not limited, to the following:

- (a) Date and venue of the meeting
- (b) Attendance at each meeting including absentees
- (c) Confirmation of minutes of the last meeting
- (d) Applications that are reviewed and approved (with or without comments)
- (e) Applications that are reviewed with comments
- (f) Members who are abstained from reviewing and approving applications
- (g) Applications that request waiving of written informed consent
- (h) Written summary of discussion of controversial issues and the final resolution
- (i) Any other business
- (j) Date of next meeting

The following decisions should be made during the CREC review meeting after review of the study:

- Approval/favorable opinion;
- Modifications required prior to its approval/favorable opinion;
- Disapproval/negative opinion; and
- Termination/suspension of any prior approval/favorable opinion;

If approval is granted, a letter of approval should be issued to the applicant. The letter of approval should be signed by the Chairperson or CREC Secretary. The approval is normally granted for one year. No subject should be admitted to a trial before an approval is granted. Ethics approval should always be sought before any clinical research process starts. If a Principal Investigator (PI) violates the rule, a warning letter should be sent to PI and copied to the Chairperson of the CUHK department and the Chief-of-Service of the corresponding Hospital Authority department.

The CREC should keep all documents of all research proposal reviewed. Each project folder should include the following types of documents

- (a) The CREC application form
- (b) Study protocol
- (c) Investigator's Brochure including number and version (if applicable)
- (d) Investigators' Conflict of Interest Declaration Form (if applicable)
- (e) Investigators' short CV
- (f) Subject informed consent form (Chinese version is necessary and English version is optional; if reason for only English version is justified, Chinese version can be exempted)
- (g) Patient information (such as advertisement or media information) (Chinese version is necessary and English version is optional; if reason for only English version is justified, Chinese version can be exempted)
- (h) Questionnaires (Chinese version is necessary and English version is optional where applicable; if reason for only English version is justified, Chinese version can be exempted)
- (i) Supplementary Information Sheet for Phase 1 Study (required for all Phase I Studies)
- (j) Insurance Policy (if applicable)
- (k) Indemnity Agreement (if applicable)
- (l) CREC approval letter
- (m) Ethics Renewal and Research Progress Report Form
- (n) Protocol amendment application form
- (o) Serious Adverse Event (SAE) reports and correspondence
- (p) Correspondence between CREC and investigator of the project
- (q) Protocol Deviations (if applicable)

The CREC also communicates with United States Department of Health and Human Services (HHS), Office for Human Research Protection (OHRP) and submit institutional review board (IRB) registration and federal-wide assurance (FWA) compliance application to HHS.

Research Misconduct

The following is a description of the actions to be taken if research misconduct is suspected in clinical research, and to describe the procedures for identifying, documenting and reporting deviations, misconduct and serious breaches of the trial protocol and whenever applicable, the principles of GCPs, and all applicable regulatory requirements.

The PI of a study is responsible to report any deviations, research misconduct or serious breaches of the protocol to the CREC according to the CREC SOP in a timely manner.

Misconduct in research includes acts of omission as well as acts of commission. Misconduct includes fabrication, falsification, and plagiarism. It also includes a failure to follow accepted procedures or to exercise due care in carrying out responsibilities to avoid unreasonable risk or harm to participants in research, and/or a failure in the proper handling of information on individuals collected during the research.

There are a number of related issues that are closely linked to misconduct but may occur in clinical research setting that require a different but clear procedure of handling them:

Serious Breach of Contracts

Contracts between the Sponsor and the CUHK clearly define the tasks delegated, and if not properly managed by the PI and the research team may induce serious breaches of the contract or protocol with legal implication.

Deviations

On-site monitoring procedures or independent audits by either the Sponsor or internal quality control process by the PI's study team, the PI's own Department, CREC or Clinical Research Management Office may identify protocol deviations. These deviations must be reported to the CREC (within a reasonable time frame of being identified or as soon as reasonably practicable). The CREC will support prompt and appropriate action to determine whether the issue is one of poor data quality or research misconduct, whether it is a protocol deviation, and whether a serious breach of the trial protocol and/or GCP has occurred that warrants further action and onward reporting.

Poor quality

Poor quality is a persistent non-compliance with the principles of GCP. Examples of types of poor quality include:

- Missing data. Examples include persistent missing key data in the case report forms for a number of study participants.
- Inadequate source documents. Examples include persistent lack of recording of study information in the medical records, or persistent errors in documentation of informed consent.
- Protocol non-compliance. Examples include persistent failure to perform procedures specified in the protocol; persistent inclusion of study participants who fail to comply with eligibility criteria.
- GCP non-compliance. Examples include persistent late reporting of SAEs; no evidence of study team training or delegation of tasks.

Research misconduct

Research misconduct is the deliberate reporting of false or misleading data or the withholding of reportable data. For example:

- Fabrication of data (e.g. filling in the CRF with fictitious information; producing reports such as clinical assessments, laboratory analyses, X-ray images, when no tests were performed; photocopying data related to one subject to use for another; and creating fictitious subjects)
- Falsification of data (e.g. changing data in the CRF to make a patient eligible for inclusion into the study; to change or intentionally misinterpret data to provide illegitimate results)
- Omitted data (e.g. removing subjects from the study for illegitimate reasons; failing to report Adverse Events (AEs) or other clinical data)

Procedure to deal with Research Misconduct

If research misconduct is suspected, the CREC will put on table for discussion during the monthly meeting and may consider a "for-cause" audit of the study, in which the audit team would focus more on the root cause analysis of the misconduct and the suggestion for further action plan to resolve the problems. If the misconduct is confirmed by clear and unequivocal evidence, the CREC will notify the Faculty and Research Committee of CUHK and the Clinical Management Committee of the NTEC for further investigation or take action simultaneously.

Examples of serious misconducts are as follows:

- A breach of GCP or the protocol leading to the death, hospitalization or permanent disability of a trial subject
- Proof of research misconduct relating to clinical trial records or data, if the fraud is likely to have a significant impact on the integrity of trial subjects or the scientific value of the trial
- Persistent or systematic non-compliance with GCP or the protocol that has a significant impact on the integrity of trial participants or the scientific value of the trial. This might include widespread and uncontrolled

use of protocol waivers of participant eligibility criteria, or failing to stop or reduce a dose of an Investigational Medicinal Product (IMP), or persistent over-dose of an IMP

- Failure to control IMPs such that trial subjects or the public are put at significant risk, or the scientific value of the trial is compromised
- Failure to report AEs, SAEs or Suspected Unexpected Serious Adverse Reactions (SUSARs) in accordance with the protocol and/or regulatory requirements such that trial subjects or the public are put at significant risk

Possible sanction may include any of the following as the committee deemed appropriate:

- Re-analysis or exclusion of censored data (NB. no use will be made of any fraudulent data, although these will be retained in the database)
- Increase in monitoring procedures until the CREC is satisfied that the site is fully compliant
- Suspension or termination of the study or the whole Investigator site
- Determination of how to deal with patients still participating in the trial
- Re-training of the investigator and/or site staff
- A “for-cause” audit of an individual study or the whole Department, as applicable
- Dismissal or re-training of staff

**Appendix
(DH – Declaration of Helsinki)**

**WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects**

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
11. Medical research should be conducted in a manner that minimises possible harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.
26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.
28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the

group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.
30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.
31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.
32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.
36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication.

Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

Animal Experimentation Regulations at The Chinese University of Hong Kong

The Chinese University of Hong Kong (CUHK) strives to uphold the highest international standards in animal care and welfare, and thus conducts teaching and research involving live animals in accordance with Cap 340 Animals (Control of Experiments) Ordinance, The Hong Kong Code of Practice for Care and Use of Animals for Experimental Purposes, and The International Guiding Principles for Biomedical Research Involving Animals.

For these reasons:

1.1 All procedures must be appropriately designed and scientifically justified and only proceed under licence from the Department of Health, according to the Code of Practice and only following approval from the University Animal Experimentation Ethics Committee (AEEC).

Any amendments to the approved licence or procedure must be approved by the Department of Health AND the AEEC before work can continue.

1.2 When teaching and research involving animals is necessary there should be an emphasis on following the principles of the 3Rs;

- to **Replace** animals with non-animal alternatives,
- **Reduce** the number of animals used &
- **Refine** procedures so as to improve animal welfare.

Also the:

- 4thR, to **Respect** the animal's welfare during the conduct of the research is vitally important. Unnecessary pain, suffering or loss of life should be eliminated whenever possible. In the opinion of the AEEC all projects need to justify the scientific benefit versus the cost in welfare or loss of life to the animals used.

Projects not fulfilling the above principles may be rejected by the AEEC.

1.3 Humane endpoints should be applied whenever possible so as to minimise unnecessary and/or unintended pain and/or distress, and appropriate anaesthesia and/or analgesia provided when more than momentary or minimal pain is present. Any unexpected adverse events that may compromise the animals' welfare must also be reported to the AEEC.

1.4 Animals must be housed in appropriately designed areas and enclosures, and cared for by trained animal care personnel and veterinary staff. Water should be freely available at all times. Food may be withdrawn for up to 16 hours in animals smaller than 100g or up to 24 hours in larger animals, but the duration should be minimised as far as possible. Any restriction in water, or food above these values must be approved by the AEEC.

1.5 Researchers conducting microbiological, radiological or chemical treatment on animals should have the necessary safety approvals and safeguards in place to protect themselves and others.

1.6 Animals selected for research should be of appropriate species and genetic background to the type of research being conducted as well as have known nutritional, microbiological and general health status so as to ensure scientific validity and reproducibility.

1.7 So as to protect the Specified Pathogen Free (SPF) status of CUHK laboratory animals, only following approval from the Director of the Laboratory Animal Services Centre (LASEC) may any laboratory animals be permitted to be transferred within CUHK or enter CUHK.

1.8 University animal facilities may periodically be inspected with announced or unannounced visits from the Hong Kong Governments' Department of Health, as well as the University's AEEC, to ensure compliance with Cap 340 and AEEC approvals. Inspectors may ask for licence details, experimental records (e.g. Form 6) and/or details of your AEEC approvals. Licence records must be kept for the duration of validity of the licence. LASEC will also conduct Post Approval Monitoring (PAM) with regular veterinary rounds and random checking of project compliance on behalf of the AEEC,

1.9 Researchers should only undertake procedures to which they are trained and competent, and should seek assistance and/or further training if necessary. It is the responsibility of Principal Investigators to ensure that their students/staff are licensed, adequately knowledgeable and trained in the procedures they are assigned to perform, as well as informed of AEEC requirements for that project/procedure.

1.10 Failure to follow University and Government regulation, including Hong Kong Law and/or The Code of Practice, may lead to project suspension, disciplinary action and/or prosecution (See reporting guidelines for Post-Approval Monitoring of Projects involving Animal Subjects below).

Reporting guidelines for Post-Approval Monitoring of Projects Involving Animal Subjects

The Animal Experimentation Ethics Committee (AEEC) is responsible for issuing and monitoring animal experimentation approvals for all projects at CUHK that involve the use of experimental animals. The AEEC is empowered to inspect and approve all animal holding facilities and all areas where animal experimentation is conducted to ensure that they meet an appropriate standard. The AEEC can investigate any failure to comply with AEEC regulations and make recommendations to the Pro-Vice Chancellor (Research) and Research Committee for further investigation and action. Whilst the AEEC has the right to visit all CUHK animal facilities at any time, the day-to-day oversight and veterinary services of all CUHK animal facilities have been delegated to the Laboratory Animal Services Centre (LASEC) who have full authority to monitor compliance on behalf of the AEEC in all CUHK areas conducting animal experimentation.

The following details a guideline for handling different levels of non-compliance to AEEC regulations during Post-Approval Monitoring (PAM).

Category A - Minor non-compliance. (e.g. failure to complete cage cards legibly and in full, minor wounds to animals without treatment or corrective action, over stocking of cages).

A verbal reminder/advice to the user concerned will be given either in person or by telephone. Corrective action is expected within two working days. A follow-up e-mail will be issued to the user by the LASEC staff concerned, as a record.

Category B - Moderate non-compliance (e.g. failure to display a post-operative cage card and post-operative pain relief details, slight deviation from AEEC, unauthorized breeding, inappropriate housing of litters, failure to observe appropriate tumour size and/or presence of untreated ulceration, incorrect AEEC number displayed on cage card, moderate welfare concerns or on being issued more than 3 previous category A- minor non-compliance reminders).

A written notice will be issued to the Principal Investigator (PI) of the project by the Director of LASEC (or delegate). Corrective action must be taken within one working day or the Director of LASEC may suspend the project and treat the case as a category C - Serious non-compliance.

Category C - Serious non-compliance (e.g. Large deviation from the AEEC or license, serious welfare concerns, poor use of analgesia/anesthesia, failure to provide adequate food and/or water, use of unauthorized animals or animals of unknown disease status without permission, or on being issued more than 3 previous Category B - Moderate non-compliance notices).

A written warning will be issued to the PI of the project and copied to the PI's School/Department Head and AEEC Chair by the Director of LASEC. If the PI concerned is the School/Department Head, the written warning will be copied to the Faculty Dean.

The project is to be suspended immediately until a discussion is held between the PI, PI's School/Department Head, Chair of the AEEC and Director of LASEC so that corrective action and measures can be discussed and taken. If the Chair of the AEEC (or delegate), or the PI's School/Department Head are not satisfied with the outcome they may choose to report the case as a Category D- Major non-compliance.

Category D - Major non-compliance (e.g. Major deviation from the AEEC or unlicensed procedure which may cause pain or distress, animal cruelty, research misconduct, major welfare concern, use of unauthorized animals or substances which cause a disease outbreak, or on having more than 3 previous Category C – Serious non-compliance warnings).

The Director of LASEC will formally notify the AEEC Chair of the case in writing. The AEEC Chair will notify the Faculty Dean and School/Department Head of the PI concerned of the full investigation to be conducted by the AEEC. All research will be suspended until the investigation is complete and the committee's findings reported to the Pro-Vice Chancellor (Research) and Research Committee for further investigation and action.

Note 1. Deviation from the licence issued under the Animals (Control of Experiments) Ordinance (Cap 340), or contravention of the Prevention of Cruelty to Animals Ordinance (Cap 169), is also subject to prosecution under Hong Kong law.

Note 2. In the event that any animal is found to be in pain or distress, a reasonable attempt will be made to contact the user. However, at the advice of a veterinarian or the Director of LASEC, animals may be treated or humanely euthanized without prior notice on welfare grounds. It is therefore in the researcher's interest to provide a mobile number on the cage card so that advice can be sought on tissue collection or other measurements before euthanasia.

Note 3. The classification of what constitutes minor, moderate, serious and major non-compliance will adhere as closely as possible to the examples described. For cases not covered in the examples, the Director of LASEC in consultation with the LASEC veterinary team will classify the case. The AEEC may periodically expand or change classification of the severity of non-compliance.

Note 4. All rooms or areas designated for animal holding and experimentation must meet international standards and be approved by the AEEC. Schools/Departments wishing to renovate existing, or open new animal areas are advised to seek advice from the Director of LASEC and the AEEC during the design phase to ensure compliance.

Schedule 8
Guidelines for survey and behavioral research ethics

The Chinese University of Hong Kong (CUHK) strives to uphold the highest international standards in relation to survey and behavioral research, covering surveys and observations of human behavior. CUHK conducts teaching and research in accordance with the general principles set forth by the following professional bodies (in alphabetical order):

- American College of Sports Science (<http://www.acsm.org/join-acsm/membership-resources/code-of-ethics>);
- American Education Research Association (<http://www.aera.net/AboutAERA/KeyPrograms/SocialJustice/ResearchEthics/tabid/10957/Default.aspx>);
- American Planning Association / American Institute of Certified Planners (<http://www.planning.org/ethics/ethicscode.htm>);
- American Psychological Association (<http://www.apa.org/ethics/code/index.aspx>);
- American Sociological Association (<http://www.asanet.org/about/ethics.cfm>);
- American Statistical Association (<http://www.amstat.org/about/ethicalguidelines.cfm>);
- British Educational Research Association (<http://www.bera.ac.uk/>);
- Hong Kong Institute of Planners (<http://www.hkip.org.hk/En/SubContent.asp?Bid=5&Sid=12>);
- The Royal Town Planning Institute (<http://www.rtpi.org.uk/membership/professional-standards/>); and/or
- Other relevant professional bodies in the field of your study/research

as well as local legal codes, such as the Hong Kong Personal Data (Privacy) Ordinance [<http://www.pcpd.org.hk/english/ordinance/ordfull.html>].

For these reasons, all procedures related to research with human participants must be appropriately designed and scientifically justified according to these standards. All members of the university community whose research plans are within the domain of survey and behavioral research should obtain approval from the Survey and Behavioral Research Ethics Committee (SBREC) (調查及行為研究操守委員會) before they conduct their research studies.

The following general principles apply to all such research:

- 1.1 **Beneficence and nonmaleficence:** Research should be conducted to avoid any physical or psychological harm. In addition, there should be no use of power (personal, financial, social, political, organizational) to influence participants in research studies.
- 1.2 **Fidelity and responsibility:** All researchers, both quantitative and qualitative, can be trusted to maintain the confidentiality of data and to avoid exploitation during the research process. All research projects should be approved by a professional group.
- 1.3 **Integrity:** Ordinarily, no intentional misrepresentation of the facts should ever take place in the course of a research study. In the event that deception is a crucial part of the research, preparation for this deception should be made both before (by obtaining informed approval from a professional group) and after (via debriefing of participants) the study.

Justice: All are entitled to equal treatment across the research process. The boundaries of the researcher (i.e., what the researcher can and cannot provide) should be clearly specified at the outset with backup support available when necessary.

- 1.4 **Respect for individuals' rights and dignity:** Informed consent must be explained and available to all, regardless of age, education, gender, disability, or any other demographic. Insofar as it is at all possible, all participants should have their rights explained to them in language that they can understand and should independently give consent (or otherwise) before the study begins. For those deemed to be unable to give informed consent legally (e.g., children; those with certain types of disabilities), a parent/guardian is required to give formal written consent in addition.
- 1.5 **Avoidance of conflict of interest:** Research endeavors should clearly have no conflict of interest in reality, no potential for a conflict of interest, and no appearance of a conflict of interest. It is important that all disciplines take care not to compromise research endeavors by unduly influencing companies or other organizations that may have political, financial, or other types of power over the research team.

1.6 **Failure to comply with the above regulations** may lead to project suspension, disciplinary action, and/or prosecution.

A. Scope

Survey research covers surveys as well as observation of human behavior. The latter refers to first hand public/naturalistic observations on human subjects, and the observations of human subjects in experiments. Survey, defined broadly, covers the following areas:

- Questionnaire surveys, including telephone surveys (regardless of the sample size)
- Group or individual interviews
- In-depth case study of the target participant(s)
- Observation of human behavior by whatever non-clinical mean

According to the University's Policy on Research, all research proposals, contracts for consultancies and services or applications for outside practice involving surveys would need to obtain ethics approval from the SBREC of the University. It is not only an expression of the ethical concern for the rights of the participants of the research, but also in compliance with local legal codes, such as the Personal Data and Privacy Ordinance.

B. Who Should Apply For Review

All members of the university community are expected to conduct their survey research studies in a legal and ethical manner. Researchers whose research strategies and plans are within the domain of survey and behavioral research (please refer to definition in Section A above) should obtain approval from the SBREC **BEFORE** they conduct their research studies.

C. Types of Review

The SBREC conducts two types of review: an expedited review and a full review. According to the research protocol, the SBREC is ultimately responsible for determining if a research study qualifies for an expedited review (i.e. exempted from a full review) or not.

D. Use of Human Research Participants & Confidentiality of Research Data

The researcher must obtain either verbal or written consent of the data subject(s) who participate(s) in the surveys. For surveys whether they are anonymous or non-anonymous, effort must be made to protect the confidentiality of research data. Details of the requirements are provided in the Guidelines for Survey and Behavioural Research Ethics on the website of the [Office of Research and Knowledge Transfer Services \(ORKTS\)](#).

E. Test Use for Research Purposes

Both copyrighted protected tests and open access tests are generally used in research. It is a best practice for researchers to have proper arrangements prior to using these tests for research purposes.

For copyright protected tests, users should pay for their use even for research purpose and permission must be obtained from the copyright holder(s) (normally the creator(s) of the test) before using, reproducing, distributing, or displaying in public. Proper documentation on the permitted test such as the test name, edition, publication date of the original or adapted test, and permission to use should be referenced in the research. Same practices should be adopted for derivative works (i.e. a translated version of the test).

For open access tests, they may be used and generated into derivative works without permission of the test creator(s). Nevertheless, an explicit statement is advised to be included in the research regarding free usage or the conditions of usage for other researchers.

The International Test Commission, an association of national psychological associations, test commissions, publishers and other organizations, has released a statement on using tests and other assessment

instruments for research purposes. For details, please visit:
https://www.intestcom.org/files/statement_using_tests_for_research.pdf.

F. Unanticipated Issues and Non-compliance

An unanticipated issue is any unforeseen or unreasonably expected incident, experience, or outcome that is not described in the application as a risk to participants or others related to either a research intervention or interaction, or the contact of the study in general.

Non-compliance refers to any action that is conducted not in accordance with the approved study by the SBREC.

All unanticipated issues and any non-compliance must be reported to the SBREC promptly after the discovery of occurrence. The SBREC will determine if any further action is necessary.

G. Procedures for Obtaining Survey Research Ethics Approval

University staff members are responsible for seeking approval from an appropriate research ethics committee before they engage in the data collection process. If the SBREC is determined to be the appropriate channel, staff members should download the Application Form from the website of the [ORKTS](#). The Application Form, together with other relevant documents (e.g. consent form, a copy of the research questionnaire or instrument, research proposal, etc.), should be sent to the appropriate Survey and Behavioural Research Ethics Faculty Sub-committee.

With all the necessary information and documents received, the processing time of each application is approximately 6 to 8 weeks. Researchers are advised to apply well in advance of the anticipated approval obtained date.

For details, please refer to the Guidelines for Survey and Behavioural Research Ethics on the website of the [ORKTS](#).

THE CHINESE UNIVERSITY OF HONG KONG

Ethics Committee for Research Involving Artefacts

Ethical Vetting of Research Projects Involving Artefacts
Code of Practice

A. Aim

This Code of Practice¹ aims to uphold ethical standards for research on artefacts with a view to promoting responsible, respectful and sustainable study of as well as preserving against exploitation of the tangible remains of human history.

B. Definition of Artefacts

Artefacts, for the purpose of ethical vetting, are defined as ‘objects which, on religious or secular grounds, are of importance for archaeology, prehistory, history, literature, art or science’². When determining whether an object under study is an artefact, researchers can make reference to the list of cultural properties / cultural objects adopted in the Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property by the United Nations Educational, Scientific and Cultural Organisation (UNESCO), and in the Convention on Stolen or Illegally Exported Cultural Objects by the International Institute for the Unification of Private Law (UNIDROIT), excerpted at Appendix A.

C. Scope

All researchers should recognize that they are responsible for their research practice, and that they have an ethical obligation to weigh societal benefits against risks inherent in their work. Professional responsibility for good stewardship of research on behalf of others and the principle of benefit-sharing across all stakeholders are an important part of responsible research practice and research integrity.

In response to the recommendations made by Research Grants Council (RGC) and University Grants Committee (UGC) in 2019 in promoting responsible and ethical research on physical evidence of human history, the University now sets up the *Ethics Committee for Research Involving Artefacts* on approval mechanisms for research projects involving artefacts.

The role of the *Ethics Committee for Research Involving Artefacts* is to check on the researcher's adherence to best practices and due diligence on the origin of the artefact. Ascertaining authenticity of an artefact requires a wide range of expertise and some of which may fall outside the ambit of any research ethics committee.

Intangible property (such as practices, texts and concepts) is not included in the scope. Whether an object is valuable or not is irrelevant to the objective of the mechanism and the adherence to best practices in stewardship, discovery, data collection and refrainment from taking economic incentives in relation to the artefacts, as set out in this Code of Practice.

¹ It is based on the proposed Code of Practice and consultation documents prepared by the University Grants Committee in July 2020 and January 2021 respectively.

² This definition is adapted from those used by the UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property and the UNIDROIT Convention on Stolen or Illegally Exported Cultural Objects

This Code of Practice also operates in conjunction with all other relevant University policies and regulations, as well as applicable legislation and any codes of practice, terms and conditions, or guidelines issued by external funding or professional bodies.

D. Guiding Principles

The following guiding principles form the basis of this Code of Practice:

- (i) The highest possible standards should be upheld in preserving artefacts throughout the research process, including but not limited to, excavation, data collection, publication and preservation.
- (ii) Researchers should bear in mind the ethical concerns in research on artefacts, including but not limited to the dangers of looting or illicit trade in antiquities.
- (iii) Researchers should ensure all personnel working under their projects exercise due diligence when acquiring and managing artefacts, including but not limited to working with reputable sources and checking against published databases or alerts posted by UNESCO for lost or stolen items.
- (iv) Researchers should not engage in, or allow their names to be associated with, any activity that has negative impacts on artefacts and that is carried out for commercial profit derived directly from or by exploiting the artefacts³.
- (v) Researchers ought to anticipate the outcome of their research and be morally responsible for any negative impact of their work on ancient civilizations. In principle, the study of stolen artefacts is not encouraged.
- (vi) It is incumbent upon researchers to uphold ethical standards in their research on objects from non-public collections and seek guidance and approval from their respective university's research ethics committee as appropriate.

E. Identification

- (i) Researchers should determine whether their research proposals, especially for the Research Grants Council (RGC)'s funding schemes, involve the study of artefacts.
- (ii) Researchers should seek the approval of the *Ethics Committee for Research Involving Artefacts* of the University for vetting artefact-related research proposals.

F. Vetting by Ethics Committee for Research Involving Artefacts

The *Ethics Committee for Research Involving Artefacts*, when vetting the proposals, would make reference to the following criteria:

³ This is adapted from the European Association of Archaeologists' Code of Practice.

Stewardship and Discovery

- (i) Where the research involves discovering or excavating artefacts, the *Ethics Committee for Research Involving Artefacts* is satisfied that the researchers have / will endeavor to limit damage or deterioration to the artefacts being studied and minimize the environmental impact for their actions.
- (ii) The researchers have set out plans for conservation, preservation, and publication of the archaeological records to the satisfaction of the *Ethics Committee for Research Involving Artefacts*.
- (iii) In considering (i) and (ii), the *Ethics Committee for Research Involving Artefacts* would refer to the list of best practices at Appendix B⁴.

Data Collection

- (iv) Where research involves studying artefacts already excavated or processed, whether by a public or private party, the researchers have exercised due diligence in establishing that the artefacts being studied –
 - a) are in a public collection of its country of origin; or
 - b) have been in a public / private collection since before 1970; or
 - c) since 1970⁵, have not been illegally excavated, acquired, transferred and / or exported from its country of origin,to the satisfaction of the *Ethics Committee for Research Involving Artefacts*.
- (v) The due diligence in (iv) could be indicated by the actions of the researchers such as having checked information and documentation which could be reasonably obtained and consulted accessible agencies / third parties or taken other reasonable steps⁶.

Refrainment from Taking Economic Incentives

- (vi) Researchers undertake that they did not and will not personally accept gifts, emoluments, sponsorship, or funding from dealers and collectors of artefacts for the research projects⁷.

⁴ The list is excerpted from the Policy on Professional Conduct by the American Schools of Oriental Research as well as the Code of Ethics and Code of Professional Standards by the Archaeological Institute of America.

⁵ This is in line with the requirement of the Archaeological Institute of America. The benchmark of 1970 is to track back to the adoption in that year of the UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, where the international community agreed on the importance of protecting cultural properties and means of prohibiting and preventing the illicit import, export and transfer of ownership of cultural properties. The said Convention has no retrospective effect.

⁶ This method is adopted in the UNIDROIT Convention on Stolen or Illegally Exported Cultural Objects.

⁷ Similar provisions on the prohibition of taking inducements (reasonably construed as bribe) when undertaking work related to cultural objects are promulgated in the Code of Conduct by the Chartered Institute for Archaeologists of the United Kingdom.

G. Procedures for Obtaining Ethics Approval

All members of the university community (teaching and research staff, postgraduate and undergraduate students) are responsible for seeking approval from an appropriate research ethics committee before they engage in the data collection process.

The purpose of ethics review is to provide an objective assessment of how the proposed research meets the ethical standards set out in this Code of Practice. Reviewers will consider whether the appropriate balance of doing positive good and avoidance of causing harm can be achieved. In the application, researchers should provide an explanation of how this balance will be reached, demonstrate what actions will be taken to mitigate any harm, and provide justification in cases where harm cannot be avoided.

With all the necessary information and documents received, the processing time of each application is approximately 6 weeks from the time of application. Researchers are advised to apply well in advance of the anticipated approval obtained date.



香港中文大學深圳研究院

Shenzhen Research Institute

The Chinese University of Hong Kong

香港中文大學深圳研究院伦理审查申请指南（试行版）

| | |
|---------------------------------|----------------------------|
| 文件名：伦理审查申请指南 | |
| 编号：SZRI/MEC-LLSCSQZN/202204/1.0 | 版本号：1.0 |
| 起草：王慧、唐日诗 | 起草日期：2022.04 |
| 审核：医学伦理委员会 | 审核日期：2022.06.10-2022.06.20 |
| 批准：于君 | 批准/生效日期：2022.06.21 |

根据国家卫生计生委《涉及人的生物医学研究伦理审查办法》（2016年），深圳市市场监督管理局《涉及人的生物医学伦理审查规范》（2020）等法规、政策，结合香港中文大学深圳研究院（以下简称“深研院”）实际情况，为使科研项目申报、过程管理和项目验收的伦理审查申请有章可循，特制定本指南。

一、提交伦理审查的研究项目范围

凡依托深研院的涉及人的生物医学研究项目和在深研院内使用的涉及人的生物医学相关技术及活动，包括但不限于注册申报类药物/医疗器械等临床试验项目、非注册申报类科研项目以及利用人体组织或数据的研究等，均应事先申请伦理审查，经伦理委员会批准后方可进行，并接受伦理委员会的监督检查。

二、伦理审查申请的类别及要求

1. 预审申请

凡依托深研院申报的科研项目，如涉及人的生物医学研究，应在正式递交项目申报材料前至少10-20个工作日向伦理委员会提交预审申请。

2. 初始审查

“初始审查申请”是指首次向伦理委员会提交的正式审查申请（不含预审）。

符合上述范围的研究项目，应在以下时间范围内提交伦理审查申请，经批准后方可实施：

- 申报类项目：项目获批立项的 2 个月内或研究正式开始前至少 30 个工作日。
- 非申报类项目：项目合同签署前至少 30 个工作日。

3. 跟踪审查

- 修正案审查申请：研究实施过程中，经伦理委员会批准的研究材料发生变动的，项目负责人应向伦理委员会提交修正案审查申请，经伦理审查同意后，方可实施。
- 年度/定期跟踪审查申请：按照伦理审查批件/意见规定的定期跟踪审查频率，项目负责人应在截止日期前 1 个月向伦理委员会提交年度/定期跟踪审查申请。
- 严重不良事件审查申请：严重不良事件是指受试者接受某种干预后发生的导致受试者死亡、危及生命、永久或者严重的残疾或者功能丧失、需要住院治疗或者延长住院时间，以及先天性异常或者出生缺陷等不良医学事件。发生严重不良事件，应在获知后 15 日内向伦理委员会报告；临床试验发生死亡，应在获知后 7 日内向伦理委员会报告，并提交严重不良事件审查申请。
- 不依从/违背方案审查申请：研究实施过程中，出现未遵循国内相关法规开展研究，或研究违背伦理委员会批准版本方案的事件，项目负责人应在获知相关事件后及时向伦理委员会报告，并提交不依从/违背方案审查申请。
- 暂停/终止研究审查申请：研究实施过程中，项目需要暂停或终止的，项目负责人应及时向伦理委员会报告，并制定相应的受试者保护计划，向伦理委员会提交暂停/终止研究审查申请。
- 结题审查申请：项目合同结束后的 3 个月内，项目负责人应及时向伦理委员会提交结题审查申请。

4. 复审申请

上述初始审查和跟踪审查后，按伦理审查意见“作必要的修正后同意”，对方案进行修改后，应以“复审申请”的方式再次送审，经伦理委员会批准后方可实施；如果对伦理审查意见有不同的看法，可以“复审申请”的方式申诉不同意见，请伦理委员会重新考虑决定。

5. 其他情况

上述提到的伦理审查申请提交期限是常规/正常情况的时间要求，如遇项目申报期限较短等特殊情况下可酌情调整。

三、 提交伦理审查的流程

1. 送审

- 送审责任者：研究项目的送审责任者一般为本单位项目负责人/课题负责人，即伦理审查文件中的“研究者”。
- 准备送审文件：根据送审文件清单，准备送审文件；研究方案和知情同意书注明版本号和版本日期。
- 填写申请/报告的表格：根据伦理审查申请/报告的类别，填写相应的“申请”（预审申请、初始审查申请、修正案审查申请、结题申请、复审申请等），或“报告”（定期跟踪审查报告、严重不良事件报告等）。
- 提交：递交纸质档及电子档各一份整体送审材料，以及方案/知情同意书/招募材料等送至伦理委员会秘书处。

2. 接受形式审查及修改

3. 伦理委员会确定审查方式

- 预审申请一般采用简易审查的方式。
- 其他的申请类别，伦理委员会根据项目的情况选择审查方式，审查方式有会议审查、紧急会议审查、简易审查。

4. 接受会议审查的准备

- 会议时间/地点：伦理委员会秘书会邮件或电话通知。
- 准备向会议报告：项目负责人准备报告文件，并应亲自到会报告，提前 15 分钟到达会场。若因故不能到会报告，应事先向伦理委员会请假，该项目转入下次会议审查。

四、 伦理审查的时间

伦理委员会秘书或工作人员对申请材料进行形式审查的时间约3-5个工作日，申请材料通过形式审查后为正式受理的时间，再根据不同的审查方式进行伦理审查。

简易审查所需的审查时间约5-10个工作日（特殊情况除外）。

根据项目情况安排审查会议。除特殊情况外，伦理委员会受理送审文件至审查会议的最长时限一般不超过1个月（特殊情况除外），项目负责人需在会议审查前至少30个工作日向伦理委员会提交送审文件。

研究过程中出现重大或严重问题，危及受试者安全时，或发生其他需要伦理委员会召开会议进行紧急审查和决定的情况，伦理委员会将召开紧急会议进行审查。

五、 审查决定的传达

伦理委员会在做出伦理审查决定后5个工作日内，以“伦理审查意见函”、“伦理审查批件”或“伦理审查意见通知函”的书面方式传达申报前审查/审查决定，伦理证明和正式伦理批件发项目负责人。

如果审查意见为肯定性决定（同意继续研究，或不需要采取进一步的措施），并且审查类别属于严重不良事件审查，不依从/违背方案审查，暂停/终止研究审查，结题审查，以及上述审查类别审查后的复审，伦理委员会的决定可以不传达。

申请人在伦理委员会受理送审材料后2个月内没有收到伦理委员会的审查意见，视作伦理审查意见为“同意”或“不需要”采取进一步的措施。

对伦理审查决定有不同意见，可以向伦理委员会提交复审申请，与伦理委员会委员和工作人员沟通交流或申诉。

六、 免除知情同意

项目满足以下所有要求，可申请免除知情同意：

- ① 研究不大于最小风险
- ② 利用以往临床诊疗和疾病监测中获得的健康信息和/或生物标本进行的研究
- ③ 免除知情同意不会对受试者的权利产生不利影响
- ④ 不免除知情同意，研究无法实际开展
- ⑤ 不涉及后续随访或再次获取受试者信息
- ⑥ 研究项目不涉及个人隐私和商业利益的
- ⑦ 如涉及既往研究数据的二次使用，本次研究须符合原始知情同意的条件

七、 免除知情同意书签字

项目符合以下两个条件，可申请免除签署知情同意书：

- ① 研究不大于最小风险
- ② 当签署知情同意书会对受试者的隐私造成威胁，且联系受试者真实身份和研究的唯一记录是知情同意书。例如：敏感问题研究等

八、 材料要求

1. 预审申请：提交完整电子档（PDF 版）和纸质档原件资料各一份（材料清单见附录 1）。

2. 初始申请：提交完整电子档（PDF 版）和纸质档原件资料各一份（材料清单见附录 1）。若是现场会议审查，形式审查通过后，按照出席伦理委员人数准备相应份数的研究方案及知情同意书、受试者招募广告（如有）以及有关涉及患者利益的材料（如有，例如：患者治疗信息卡、受试者指南等）。
3. 再次申请：包括修正案审查、复审、严重不良事件审查、跟踪审查、结题审查等，都需提交电子档（PDF 版）及纸质档原件材料各一份。
4. 递交的文件语言须为简体中文，如有外文文件，需提供中文翻译件。
5. 电子材料提交时，所有文件打包，按照“申请人姓名-项目名称-申请类型（如：预审申请）”的格式统一命名，发送至伦理委员会电子邮箱。

九、 伦理委员会联系方式

电话： 18025382805

电子邮箱：cuhkri@cuhkri.org.cn

地址：广东省深圳市南山区粤兴二道10号407室