The Chinese University of Hong Kong

Policy on Research, Intellectual Property and Knowledge Transfer

(Formerly known as "Policy on Research, Consultancies and Intellectual Property")
(With effect from: 1 January 2015)
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PREAMBLE

1. Background

University mission

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.

Mission Statement with regard to entrepreneurship and knowledge transfer activities

1.2 As an international centre of research excellence, the University strives to nurture innovation, entrepreneurship and knowledge transfer for the advancement of humanity.

Role of research

1.3 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:

(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.

Research and knowledge transfer policy

1.4 The University has an established policy on research, intellectual property and knowledge transfer, addressing also sponsored research, conflicts of interest and commitment, knowledge transfer, professional ethics and research misconduct.

Protection of intellectual property

1.5 Much cutting-edge research conducted at the University leads to discoveries and inventions that are potentially patentable. The University needs to stake its claims and to position itself to develop these research activities to the fullest. The object is to achieve the broadest possible impact on the academic and scientific community at large, and to benefit the public locally as well as world-wide.

Greater concern for intellectual property

1.6 There has been increasing attention to intellectual property protection worldwide including Hong Kong. The University has been called upon frequently to handle matters pertaining to patents and copyrights on behalf of its teaching and research staff. Thus, these policies deal with matters of current concern.

Relationship between the University and staff in intellectual property

1.7 The relationship between the University and staff need to be better defined on matters relating to intellectual property, patents and knowledge transfer.

2. Organization and implementation of the document

Part A: Policy and principles

2.1 *Part A* of this document contains the policy and principles, and 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.

Part B: Procedures and implementation guidelines

2.2 *Part B* 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 relevant committees, viz., the Research Committee / Patent Committee / Committee on Knowledge Transfer / Committee on University Subsidiaries and Spin-off Companies, and where necessary AAPC.

Replacement of certain regulations

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.

Continuation of other regulations and contracts

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.

Exceptions

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

Distribution

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 and/or knowledge transfer activities of the University.

Acceptance of policy

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.

Intention to simplify procedure

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.

Review and feedback

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.

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. Towards these ends, the University will not normally undertake classified or proprietary research, or perform purely commercial work (see Paragraph 6).

Retention of intellectual property rights

4.2 Moreover, unless otherwise stated in this policy, the University will own all intellectual property rights arising from research, in order to ensure that the results can be exploited for the benefit of the public to the broadest extent possible.

5. Conditions for research, knowledge transfer, funding and contracts

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 academic staff member at Professor rank or Research Professor rank 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 and/or knowledge transfer award, in the form of a grant, contract, or other type of legal agreement, from an external sponsor for the support of a research and/or knowledge transfer project if the terms and conditions are consistent with the following criteria:

Scope

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

Exclusion of funding

(b) The University reserves the right to refuse acceptance of any research and/or knowledge transfer grants offered by or entering into contracts with any companies as it considers appropriate. As a rule, the University does not accept any research and/or knowledge transfer grants or contracts 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 sponsored research.

Access to technical data

(d) The Principal Investigator and other members of the research or knowledge transfer 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.

Intellectual property rights

(e) Ownership of intellectual property generated from the research shall be governed by the University's relevant policies (see Paragraphs 8 and 22).

Not for publicity

(f) The results of sponsored research or knowledge transfer 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.

Exceptions

5.3 In recognition of the possibility of special circumstances, the Research Committee or the Committee on Knowledge Transfer as appropriate is empowered to grant exceptions to the stipulations in Paragraph 5.2.

Safety

5.4 In accepting an award in support of a research or knowledge transfer 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 20).

Ethics on human and animal subjects

5.5 In any research or knowledge transfer 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 or knowledge transfer projects involving warm-blooded animals (see Paragraph 21).

6. Proprietary research or, knowledge transfer and commercial work

Limitation on

6.1 The University will undertake proprietary research or, knowledge

proprietary research or knowledge transfer activities

transfer, or purely work of service if such undertaking is consistent with the mission, policy and interest of the University.

Use of equipment, facilities or other resources

6.2 The University possesses unusual, or even unique, items of equipment, facilities or other resources. When mutually advantageous arrangements can be agreed upon, and when the work cannot be conducted as well in the sponsor's own laboratories or in a commercial laboratory in Hong Kong, such equipment, facilities or other resources may be used for tests or investigations on behalf of outside agencies, or the University may undertake to design, build, and operate special facilities on a sponsored basis. Such use of University equipment, facilities or other resources, provided that it does not pre-empt or interfere with uses for teaching or scholarly research, is consistent with the University's expressed desire to be of service to the community.

Full cost

6.3 The sponsor must be charged full cost for the work as determined by the University. The procedure for assessing full cost is described in Paragraphs 18 and 19.

Approval required

6.4 Such contract research or knowledge transfer must be centrally reviewed by the Office of Research and Knowledge Transfer Services and must receive prior approval from the supervising Pro-Vice-Chancellor for Research.

Special case of sponsored clinical trials

6.5 The sponsor of certain sponsored clinical trials may be allowed to claim ownership of intellectual property rights from the part of the clinical trial conducted by the staff member concerned at the University facilities. For such, justifications must be provided by the Principal Investigator, and the contract with the sponsor must receive the (a) endorsement by the relevant Department Chairperson, or Faculty Dean if the Department Chairperson is the Principal Investigator; (b) recommendation by the Office of Research and Knowledge Transfer Services; and (c) approval of the Pro-Vice-Chancellor for Research. Such clinical trials should be those which allow staff members of the University to participate in advanced trials involving drugs, equipment or procedures, in that clinical data are gathered from a mass subject population, and that the drug, equipment or procedure to be tested is the intellectual or proprietary property of the sponsor in the first place.

7. Outside practice

Authoritative regulations

7.1 It is recognized that members of staff may undertake outside practice related to research or knowledge transfer subject to the 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.per.cuhk.edu.hk) which may be amended from time to time.

8. Ownership of intellectual property

Definition of intellectual property (IP)

8.1 In law, intellectual property ("IP") refers to a group of proprietary rights including but not limited to patents, registered designs, copyrights, trade marks, trade names, trade secrets, knowhow, business reputation and goodwill.

Ownership of IP

8.2 Except for licence rights agreed in advance (see Paragraph 8.4), ownership requirement imposed by publisher or journal (see Paragraph 10.1) or governmental body, or allowed in sponsored clinical trials (see Paragraph 6.5), all intellectual property arising out of any work undertaken by a member of staff of the University for which such staff member has been engaged and within the scope of the duties described in the staff member's contract of employment shall reside with the University. In particular, the University will retain title and rights to all inventions and possible resulting patents arising from externally sponsored research and knowledge transfer activities (see Paragraphs 9 and 22).

Right to publish

8.3 Notwithstanding its ownership of the intellectual property, the University will not restrict the right of staff members to publish their findings; the University's rights regarding the intellectual property shall be restricted only to the financial proceeds and commercial benefits arising from the invention, patent, licensing or publication.

Licence for sponsor

8.4 The sponsor of research or knowledge transfer activities may be given a licence, with terms to be approved by the Pro-Vice-Chancellor for Research, to use or practise a knowhow or invention, whether patented or otherwise, developed or made by University employees and resulting from work supported by that sponsor at the University. The University may also negotiate to grant the sponsor the option of securing a licence with terms to be approved by the Pro-Vice-Chancellor for Research on such knowhow, inventions and resulting patents. Knowhow, inventions and resulting patents developed or made jointly by employees of the University and of the sponsor shall be jointly owned.

Copyright and royalties

8.5 Except as provided in Paragraphs 10.1 and 10.2, copyrights to, and royalties from, books, journal articles, and other copyrightable materials, produced by staff members as a part of their normal teaching and scholarly activities at the University, shall belong to the University.

Licensing of copyright

8.6 Licensing of University-owned copyrights will follow the same policies as for licensing of knowhow, inventions and patents.

Assignment by staff

8.7 All University teaching and research staff (including students employed as research assistants), postdoctoral fellows and research postgraduate students are required to sign an agreement assigning ownership of all intellectual property produced as part of University duty to the University as a condition of employment or engagement as the case may be.

9. Patent policy

Need to clarify policy

9.1 The University needs an unambiguous policy, which should offer incentives for inventors to have their innovations and discoveries patented. However, the decision on whether to apply for patent

protection must be made absolutely and solely by the University, through its Patent Committee, which will take into account various relevant circumstances and factors.

Patents assigned to the University

9.2 Subject to Paragraph 9.1 above, inventions made by employees in the course of the University's employment or with the use of University equipment, facilities or other resources may be patented in order to protect the interest of the University and the public. Such patentable properties are to be assigned to the University or the sponsor, as appropriate. The cost of acquisition of such patent properties, including legal fees, shall be borne by the University, the sponsor, or the inventor as deemed appropriate by the Patent Committee.

Use for maximum public benefit

9.3 It is the policy of the University that all knowhow, inventions and such related patentable properties be utilized for the greatest possible public benefit. If there are innovations or discoveries that result in the filing of patent applications and the acquisitions of patents, the University will seek to serve and protect the public interest by diligent efforts to transfer the technology and knowledge into public use.

Share of income for inventor(s)

9.4 In each case where royalty income is derived from the licensing of a patent, the inventor(s) will receive a percentage of the gross royalty income received by the University at a proportion allocated in accordance with the funding source stated, at the option of the inventor(s), in the University's Invention Disclosure Form and Invention Assignment as per prevailing policy of the University.

Share of income for University

9.5 (a) Unless the Department or Faculty has sustained the full costs of patent acquisition, after deduction of income for inventor(s) specified in Paragraph 9.4 and relevant expenditures from the gross royalty income:

(i) 60% of the remaining balance will be distributed to the University Central Fund; and

(ii) 40% of the remaining balance will be distributed to the Faculty concerned. The Dean will have the discretion to make appropriate distribution (from the Faculty's share) to the Department/Unit concerned.

(b) The distribution to the Faculty replaces previous arrangements on matching funding.

Staff to report innovation

9.6 All employees shall immediately report to the University any potentially patentable knowhow, innovation or discovery that arises in the course of their employment or as the result of the use of University equipment, facilities or other resources. This obligation is not intended to interfere with the prompt publication of research results. While an innovation or discovery of a patentable nature may be identified during the normal monitoring of research or knowledge transfer projects by the relevant administration offices, the burden falls primarily on the researcher(s), who is hereby reminded that "time is of the essence" in the filing of patentable inventions and research or knowledge results.

Private inventions

9.7 Inventions made by an employee outside the scope of work for which the employee has been engaged and on personal time, and without the aid of University facilities or funding, are the sole property of the inventor, and patents should be administered so as not to involve the University's name. Time spent in administering such patents should conform to the University policy on outside activities by staff members.

10. Copyrights

Copyright to printed material

10.1 Copyrights to, and royalties from, books, reference works, submissions to scholarly journals, and other copyrightable materials, with the exception of:-

(a) the ownership requirement imposed by publisher or journal for the purpose of publication of copyrightable materials; or

(b) copyrightable material the production of which has been *specifically* funded in whole or in part by the University or by a sponsor for that purpose,

shall belong to the University.

Copyright to software and A-V material

10.2 All rights to, and royalties from, computer software, including computer programmes, computer databases, associated documentation ("computer software"), and A-V material, CD, CD ROM and laser discs ("audio-visual materials"), whether copyrightable or patentable, produced by staff members in the course of the University's employment or with the use of University equipment, facilities or other resources shall belong to the University, regardless of the source of funds used to produce the computer software or educational audio-visual materials. Computer software or educational audio-visual materials produced outside the scope of employment duty and on the author(s) own time, and without the use of University equipment, facilities, other resources or funding, shall belong to the author(s) and all rights thereto may be retained or assigned by the staff.

11. Knowledge transfer of future research

Sponsorship in return for future results

11.1 The University permits staff members to seek research support from companies wishing to have the right to commercialize the possible results of their research or knowledge transfer activities. To this end, it is willing to negotiate appropriate licences to future patents in exchange for research or knowledge transfer support. In all dealings with outside companies, however, certain principles and rules apply, in order to protect the essential interests of the University, its staff and its students, and in order to have clear guidelines within which faculty members can safely operate. Where necessary, these principles and rules will be interpreted by the Patent Committee.

No substantial holdings or management control

11.2 A staff member must not have substantial holdings in or have management control of a company that supports his/her research or knowledge transfer activities, by any means other than an unrestricted grant.

Integrity of results

11.3 Neither the direction of the University's research or knowledge transfer activities nor the interpretation of research results should be altered or appear to be altered by the commercial interests of any company.

Clear delineation

11.4 Any contract granting to a company rights to license future patents arising from research or knowledge transfer activities sponsored by the company must clearly delineate the scope of that work in order to distinguish it from research or knowledge transfer activities supported by other funds, especially public funds for which the University has a special responsibility.

Acceptance of equity in company

11.5 The University may, in some circumstances, consider accepting financial interest in a company in addition to income sharing in exchange for licences to the University's intellectual properties, whether present or future. The University must then be sensitive to potential institutional conflicts of interest. It cannot, for example, permit a staff member to work on behalf of the company as part of his/her University duties.

Subcontracts and disclosure

11.6 Circumstances may arise in which an effective way to develop new technology is to award a subcontract, or to license a patent, knowhow, or copyright to a company in which either the University or a member of its staff has substantial financial interest. In such cases, care must be taken that the financial interest is fully disclosed to all parties, and that sound objective business reasons for choosing the company as subcontractor or licensee are fully documented.

Limit on commercial activities

11.7 The University may support the commercial sector, but it should not compete with it, or be a member of it. Hence, the University's laboratories should not perform commercially available tasks for the primary purpose of gaining income, nor should University equipment, facilities or other resources be used to develop and commercialize a product.

No outside control of dissemination

11.8 The University is willing to keep sponsors fully informed of the research or knowledge transfer 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.

12. Professional ethics

Quality of employees

12.1 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.

Respect right of others

12.2 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.

Recognition of contribution of others

12.3 University teachers and researchers should recognize the contributions of 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.

Principle of fairness

12.4 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.

Plagiarism

12.5 In particular, the use of the work of others (whether word-for-word or rephrased) without proper attribution of the source amounts to plagiarism and constitutes grounds for disciplinary actions.

Co-authorship

12.6 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. Teachers and research supervisors 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.

Computer ethics

12.7 The University provides computer resources for education and research and knowledge transfer 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.

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.

13. Research misconduct

General considerations

13.1 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. The policy set out in the following paragraphs aims to ensure that allegations of research misconduct are resolved both fairly and expeditiously.

Definition

13.2 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 12, and research misconduct can be broadly defined as a failure to meet these standards.

13.3 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; and

(i) research-related breaches of the law.

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

13.4 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

13.5 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.

13.6 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 Institute to properly inform their staff and students of these policies.

13.7 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.

Governing principles

13.8 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 thier 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 disciplinary action

13.9 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 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.

13.10 Cases involving research misconduct on the part of students will normally be dealt with under relevant academic honesty policies and procedures applicable to students.

13.11 If, during these procedures applicable to students in 13.10, 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.

13.12 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.

13.13 Authority on procedural matters is delegated to the Convenor or Chairman 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 Chairman to tailor the procedures to suit the particulars of the case.

13.14 The Inquiry panel and the investigation committee may receive any material and attach such weight to the material as it deems appropriate.

13.15 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.

13.16 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.

13.17 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 Chairman of the University Council for the determination of process and procedures.

13.18 Detailed procedures on preliminary inquiry, investigation, resolution, and disciplinary action are described in Paragraph 25.

14. Relationship between the University and staff — personnel policy

Patent/Copyright agreement

14.1 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 Personnel Office. Research postgraduate students receiving financial support from the University will be required to sign a similar patent/copyright release. Other postgraduate students and undergraduate students should also be requested to sign such a release if they are involved in a research project that might lead to the production of intellectual property.

Conflict of interest and commitment

14.2 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 and knowledge transfer, 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 teachers and students. On the

other hand, private sponsors of research and knowledge transfer activities may have good reasons for wanting to keep certain research or knowledge transfer results secret, at least temporarily. To cite another example, an effective means of transferring technology sometimes requires active participation by a teacher in a private enterprise, as an advisor or consultant. Faculty members deserve to be compensated for their work and ideas in this process. However, activities of this kind may pose real or apparent conflicts with the integrity and objectivity of research and knowledge transfer at the University, and with the teacher's primary professional commitment, which is to the University. To help the faculty understand their duties and responsibilities in resolving these potential conflicts, the following principles and rules have been adopted by the University.

General principles

14.3 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 and knowledge transfer 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 faculty member to protect:

(a) the integrity of all research and knowledge transfer activities done at the University;

(b) the reputation and goodwill of the University;

(c) the academic freedom and economic rights of fellow faculty, students, and postdoctoral associates; and

(d) the public interest.

Outside commitment

14.4 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 Chairman of the Research Committee and the Chairman 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

15. General considerations

Purpose

15.1 The purpose of setting down detailed guidelines is to avoid ambiguity, and to reduce many necessary steps to routine.

15.2 The Division of Research Administration 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.

15.3 The Contract team and Legal team of the Office of Research and Knowledge Transfer Services are the central contact points for all documentation, and monitoring where appropriate, related to intellectual property, knowledge and technology transfer and are guided in policy matters by the Committee on Knowledge Transfer, Patent Committee, and Committee on University Subsidiaries and Spin-off Companies.

Revisions

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

16. Types of external funding

Types

16.1 The University (and in the case of (f) 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) contracts for consultancy or other services;

(d) outside practice of individual staff members;

(e) research grants awarded to individuals; and

(f) 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

16.2 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. per.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. per.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.per.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 this document.

(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) 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

16.3 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.

Research grant

16.4 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., articles, books, conference presentations), as well as progress and final reports.

Contract

16.5 A contract for consultancy or other services is awarded to the University by a client to support work which is of specific interest to the client. It is usually initiated by the client (e.g., via a Request for Proposal), and definite deliverables may be specified. Either a single party is invited to submit a proposal, or several parties may be invited to bid. There may be penalty clauses for non-delivery or late delivery.

Outside practice

16.6 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:

(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 19).

Research grants awarded to individuals

16.7 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:

(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.

Consultancy or service by individuals

16.8 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.

Exceptions and

16.9 If research grants or contracts awarded to individuals are not

sanctions

handled according to Paragraphs 16.7 and 16.8, the member of staff must ensure that the activities are consistent with the law and with staff regulations, e.g.:

(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 16.7 and 16.8 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

16.10 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 Registrar and Secretary;

(b) the Director of Personnel; and

(c) the Chairman of the Research Committee.

17. Application and approval

Donation

17.1 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

17.2 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 20) and ethics approval (Paragraph 21);

(c) a suitable level of overhead is levied where appropriate (Paragraph 18); 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 Chairman 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

17.3 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 Paragraph 24 and *Schedule 3*.

Conditions for contracts

17.4 Approval for the University to enter into a contract for research, knowledge transfer, consultancy or the delivery of services will only be granted after the University has satisfied itself that:-

(a) the proposed activity is consonant with the general conditions for research, knowledge transfer, funding and contracts (Paragraph 5);

(b) the proposed activity has the requisite safety approval (Paragraph 20) and ethics approval (Paragraph 21) as applicable;

(c) a suitable level of overhead is charged (Paragraph 18);

(d) suitable additional charges are levied for the use of special facilities and equipment (Paragraph 19);

(e) arrangements on intellectual property rights are acceptable (the University would not claim intellectual property rights if there is full funding, including staff time, for the activities); and

(f) an acceptable arrangement has been proposed for the disbursement of any unspent balance of the contract income, and the default payments by the client (such

arrangement not being part of the contract with the client).

Not to enter contract unless authorized

17.5 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. Arrangements for contract administration are spelt out in Paragraph 24. The University will reserve its right to take necessary action against the member concerned.

Outside practice

17.6 Application for outside practice should be made to the relevant approving authorities. In cases where University facilities or equipment is used, the Personnel Office will seek advice from suitable parties and recommend a scale of charges (Paragraph 19).

18. Overhead charges

Principles

18.1 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 19).

Donation

18.2 There shall be no overhead on donations or gifts.

Research and knowledge transfer grant

18.3 In principle, there should be an overhead charge on research and knowledge transfer grants, to reflect the indirect cost of the project; the scale of overhead is given in *Schedule 4*. However, there shall be the following exceptions:

(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 Chairman of the Research Committee is authorized to approve reduction of the indirect cost, in recognition of fact that such research activities would have been undertaken in any event, and therefore any increase in the indirect cost to the University may be only marginal. However, such reduction is unlikely to be granted where the project represents a major departure from existing activities.

Contracts

18.4 The scale of overhead charges for contracts to provide research,

knowledge transfer, consultancy or other services shall be as in *Schedule 4*. Reduction in the scale of charges can only be approved by AAPC.

Outside practice

18.5 For outside practice, there will be no general overhead. However, there may be additional charges for the use of specific facilities or equipment (Paragraph 19).

19. Additional charges

Principles

19.1 Additional charges may be levied on contracts for research, knowledge transfer, consultancy and services, and 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.

Determination of charges

19.2 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 entering into the contract or for engaging in outside practice.

Separate from contract and outside practice

19.3 The approval and additional charges for the use of facilities or equipment are in principle separate from contract and/or 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 contract and/or 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.

Use of income from such charges

19.4 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.

20. Safety approval

Responsible units

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

Authorization to stop

20.2 The Chief Laboratory Safety Officer 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 Chief Laboratory Safety Officer or the Safety Officer concerned, unless the decision is overturned by the Committee on Laboratory Safety upon appeal by the investigators concerned.

Prior application

20.3 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

20.4 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

20.5 In cases where safety approval is sought, information will have to be provided to the Chief Laboratory Safety Officer, 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 Laboratory Safety.

General approval

20.6 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 Chief Laboratory Safety Officer, and shall always carry the following conditions, together with any others that may be deemed necessary:

(a) the Chief Laboratory Safety Officer 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.

21. Ethics approval

When required

21.1 Ethics approval is required in the following areas:

(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.

Prior application

21.2 All research proposals, contracts for knowledge transfer, consultancy and services or application for outside practice that involves any of the activities list in Paragraph 21.1 should either:-

(a) recommend that ethics approval is not required, or

(b) seek ethics approval.

Approval not required

21.3 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.

Approval authorities

21.4 In cases where ethics approval is sought, application should be made to the units listed in *Schedule 5*.

Ethics guidelines

21.5 The guidelines adopted by these units in considering ethics approval are given in *Schedules 6, 7 and 8*.

General approval

21.6 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 *Schedule 5*, and shall always carry the following conditions, together with any others that may be deemed necessary:-.

(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.

22. Assignment of intellectual property

Ownership

22.1 The ownership of intellectual property is governed by Paragraph 8.

New appointees

22.2 All new appointees whose employment may lead to the production of intellectual property will be required to sign an agreement to this effect as a condition of appointment.

Postgraduate students

22.3 All postgraduate students appointed to graduate assistantships or research assistantships, or receiving support in the form of postgraduate studentships are also required to sign an agreement to this effect as a condition of appointment/award.

Visitors

22.4 Visiting academic staff, visiting scholars, visiting researchers, if they receive any salary, stipend or support in cash or kind from the University, or are given the use of University equipment, facilities or other resources, may also be required to sign an agreement to this effect.

Undergraduates

22.5 Students (including both undergraduates as well as postgraduates not covered by Paragraph 22.3) who are involved in any projects that may lead to intellectual property of potential value should also

be required to sign an agreement as a condition of being permitted to take part in the project. It is the responsibility of the supervisor of the project to raise the issue, and to liaise with the relevant administration offices to ensure that the student signs such an agreement. In particular, in the event that the supervisor fails to ensure that the student(s) signs an agreement assigning the intellectual property rights to the University, and if as a result the student(s) has a claim on patent income, then such a claim will be deducted out of the share of income for the inventor(s) specified in Paragraph 9.4.

Existing staff

22.6 Staff already in employment and whose employment contract does not include an agreement specify in Paragraph 22.2 may voluntarily sign an agreement as for new staff. However, if any member of staff seeks the University's endorsement for a research proposal, requests the University to submit on his/her behalf a proposal to a funding agency, or receives a research grant or other support from the University for a project, then the member of staff will likewise be required to sign an agreement assigning to the University all intellectual property rights arising out of work done on the project in question.

Samples

22.7 A sample of the assignment is in *Schedule 9*.

23. Related entrepreneurial activities

General principles

23.1 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.

Use of a company

23.2 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.per.cuhk.edu.hk) will apply, and in brief as follows:

(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 Paragraphs 8, 9, 10, 11 and 22) 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

23.3 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.cuhk.edu.hk/kto/internal/spinoff.pdf). The Office of Research and Knowledge Transfer Services is the contact point for pursuing such possibilities.

24. Contract administration for research and knowledge transfer

Ultimate authority

24.1 The power to enter into, vary, perform and cancel contracts on behalf of the University is vested in the Council of the University (Statute 11.8(1)(f) in Schedule 2 of The Chinese University Hong Kong Ordinance, Chapter 1109 of the Laws of Hong Kong) ("Ordinance").

Delegation

24.2 Subject to the Ordinance and the Statutes contained in Schedule 2 of the Ordinance ("Statutes"), the Council may, subject to such conditions as they may impose, delegate any of their powers and duties to any Board or committees or to any officer (Section 10(3) of the Ordinance). Except for such delegation, no member of staff may make any contract or enter into any contractual commitment on behalf of the University or any of its units.

Contract made by University

24.3 Therefore, a contract made under the authority of the Council of the University, whether executed under seal (Section 17 of the Ordinance refers) or under the hand of a duly authorised agent, will be a contract made by the University. Individual units (e.g. faculties, schools, departments, institutes and centres) are not independent corporate entities and cannot enter into contracts except as a duly authorized agent acting on behalf of the University.

Duty of staff and office-bearers

24.4 Since the relationship of principal and agent may arise by express appointment or by virtue of the doctrine of estoppel, certain office-bearers may by virtue of their being placed in such positions of authority (e.g. the University Officers, Department Chairmen/Unit Heads) be assumed by third parties to represent and act for the University and in their dealing with such third parties effectively commit the University to a contract either in writing or orally. Staff and especially office-bearers are reminded that, unless duly authorized to do so, they must not act in such a manner that third parties may gain the impression that they are acting for the University. For avoidance of doubt, staff members should declare to any third party seeking their services that unless explicit authority is given through approved channels, they will not be acting as agents of the University but only in their private capacities.

Various types

24.5 Various types of contracts and/or agreements may be involved in

of contracts

relation to research, knowledge transfer and other activities, including but not restricted to the following:

(a) Contracts for appointment of research staff, to be handled by the Personnel Office.

(b) Exchange agreements, to be handled by the Office of Academic Links.

(c) Contracts for research, knowledge transfer, consultancy or related services, to be handled by the Office of Research and Knowledge Transfer Services, and described in greater detail in Paragraph 24.6.

(d) Non-disclosure agreements and other agreements for the protection of intellectual property rights, described in greater detail in Paragraph 24.7.

(e) Contracts related to sale of goods and other purchases, to be handled by the Bursar.

(f) Contracts related to buildings and works, to be handled by the Director of Campus Development.

(g) Other agreements, including but not limited to training agreements, to be handled by the University Secretary.

Procedure

24.6 The approval procedure for contracts for research, knowledge transfer, consultancy or related services shall be as follows:

(a) The staff of the Office of Research and Knowledge Transfer Services shall, with the staff inventors/investigators involved, and after negotiation with the outside party, and where necessary, also after taking legal advice and/or with the assistance of duly appointed external experts in technology transfer and licensing, prepare the draft contract.

(b) Upon authorization by the Vice-Chancellor or the Acting Vice-Chancellor or a Pro-Vice-Chancellor nominated by the Vice-Chancellor to proceed on such terms and conditions to be incorporated in the said draft contract (including the sale of products arising from research and development without a contract in writing), the Director of Office of Research and Knowledge Transfer Services with authority delegated by the Council, shall sign or otherwise deal with the said contract for (or sale of products arising from) research, knowledge transfer, consultancies, technology transfer, licensing and related matters, for and on behalf of the University.

(c) Upon the written instruction of the Vice-Chancellor or Acting Vice-Chancellor, the authority ordinarily delegated to the Director, Office of Research and Knowledge Transfer Services in Paragraph 24.6(b) above may be re-delegated to another staff member who has been nominated to exercise such authority in lieu of the Director, Office of Research and Knowledge Transfer Services.

(d) In case of contracts executed under seal, Section 17 of the University Ordinance shall continue to apply.

(e) Where appropriate, the University may require adequate insurance coverage (e.g. professional negligence indemnity) be taken out, with premium borne by the project fund, before the contract is signed.

Non-disclosure agreements

24.7 The University and its staff members are often given access to privileged documents for the purpose of reviewing and assessing research proposals, patent applications etc. For this purpose, nondisclosure agreements may be necessary, and the following arrangements are recommended:

(a) where the appointee acts purely in an individual capacity, the appointee should sign such an agreement personally; and

(b) where the information is given to the appointee in the appointee's capacity as a member of the University, such that the University is expected to have an institutional responsibility for nondisclosure, then the appointee concerned should sign together with the Director of the Office of Research and Knowledge Transfer Services.

25. Investigation into research misconduct

Introduction

25.1 The University's principles and general approach in dealing with cases of research misconduct is described in Paragraph 13. This paragraph describes the procedures to be adopted in investigations into research misconduct.

Allegations of research misconduct

25.2 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, and

(d) any suspected research-related breach of the law by a member of the University.

25.3 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.

25.4 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 25.5 to 25.10. 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 25.11 to 25.18.

Preliminary inquiry

25.5 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.

25.6 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.

25.7 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.

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

25.9 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.

25.10 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 (25.11 – 25.18). The relevant parties will be notified of

this decision.

Investigation

25.11 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.

25.12 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.

25.13 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.

25.14 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.

25.15 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 Chairman, 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.

25.16 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.

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

25.18 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

25.19 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.

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

25.21 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.

25.22 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

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Schedule 1
Definitions of types of research misconduct

The various kinds of research misconduct specified in Paragraph 13.3 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) *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

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The different types of external funding are defined in Paragraph 16. The following examples will serve to illustrate the applications of the principles.

- 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.

- 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. Chairman of Research Committee may waive overhead charges because this is a project that the unit is likely to have undertaken in any case.

- 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.

- A proposal is submitted to the Hospital Authority ("HA"). The topic is decided by the PI. This will be classified as research grant. Chairman of Research Committee may waive overhead charges because of community service.

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 (Personnel) and above	Personnel Office	Personnel Office in consultation with User Department and Bursary
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 and contracts

The level of overhead charges for research grants is determined with reference to the level of overhead or indirect charges for self-financed courses. The level of overhead charges for contracts is higher because of the greater complexity of contract negotiation, including legal advice. The current level is as follows.

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

Schedule 5
Units responsible for ethics approval

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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.med.cuhk.edu.hk/ for details.

3. Ethics in Survey Research

Survey and Behavioural Research Ethics Committee

Please visit the following website
[*http://www.cuhk.edu.hk/rao/rga/SBRE_appguide.pdf*] for details.

4. Laboratory Safety Ethics

Please visit the University Safety & Environment Office/
University Laboratory Safety Office website
http://www.cuhk.edu.hk/useo/safety/ (click Lab Safety) for details.

Schedule 6
Clinical ethics guidelines

Background

The ***Joint Chinese University of Hong Kong (CUHK)-Hospital Authority New Territories East Cluster (NTEC) 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 China Food and Drug Administration (CFDA), local regulations of the Hong Kong Department of Health (DOH), CUHK polices 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 Officer 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 Officer. 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 Chairman 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:

- 4^{th}R, 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 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 behaviour. The latter includes public/naturalistic observations, the collection of data on human subjects, and the observation of human subjects in experiments.

According to the *University's Policy on Research, Intellectual Property and Knowledge Transfer*, all research proposals, contracts for knowledge transfer, consultancy and services, or application for outside practice involving survey research would need to obtain ethics approval from the Survey and Behavioural Research Ethics Committee unless exempted.

B. Exemptions

The following categories of research are exempted from review by the Survey and Behavioural Research Ethics Committee:

1. Educational practices: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

   This exemption does not include obtaining the school records of identifiable students or interviewing instructors about them.

2. Surveys:

a. *Anonymous surveys*: In the researcher's private data as well as in any published material, responses are recorded in such a manner that the respondents cannot be identified, directly or through identifiers linked to the subjects.

b. *Non-anonymous Surveys* in which respondents cannot be identified in any published material and reasonable precaution is taken to preserve the confidentiality of the identity of individuals in the research data (e.g. subjects will be identified by a code the key to which will be kept separate from the data).

This exemption does not apply under any of the following conditions:

a. The subjects are unable to give informed consent, (e.g., minor children, mentally handicapped people).

b. Undue inducements, financial or otherwise, are provided to induce subjects to participate.

c. Deception of subjects is involved.

d. The study involves sensitive aspects of the subject's own behaviour such as illegal conduct, drug or alcohol use, and sexual conduct.

e. Disclosure of the observations on the subjects will reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

f. The study can induce undue psychological stress.

3. Public/naturalistic observations is exempt if:

a. In the researcher's private data as well as in any published material, observations are recorded in such a manner that the human subjects cannot be identified; or

b. The observations, even if disclosed outside the research, could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

4. Public officials: All research involving survey or interview procedures, or public observations is exempt when the respondents are elected or appointed public officials or candidates for public office.

5. Existing data: Research involving the collection or study of existing data, documents, records is exempt, (a) if these sources are publicly available, or (b) if the subjects cannot be identified in any published material and reasonable precaution is taken to preserve the confidentiality of the identity of individuals in the research data.

C. Informed Consent

Except in public/naturalistic observations, the researcher must obtain the informed consent of a subject to participate in research. The following guidelines should be observed in obtaining informed consent:

1. Use of verbal/written consent and information sheets

   - Voluntary informed consent, in writing, should normally be obtained from any subject who is able to give such consent.

   - Most research procedures should be explained on an information sheet written in simple language that is easily comprehensible by the potential research subject.

   - The information sheet should set out: the purpose of the investigation; the procedures; the risks (including psychological distress); the benefits to the individual or to others; a statement that the subjects are free to participate or to decline to participate, and significant factors that may be expected to influence their willingness to participate, including limitations on confidentiality.

   - For anonymous and non-anonymous surveys in which the information to be collected is not especially sensitive, a verbal response after a simple explanation may suffice.

2. Undue influence and inducement to participate

   - Subjects should be free from coercion of any kind and should not be pressured to participate in a study.

   - Inducements, such as unreasonable services or financial payments, should be avoided.

   - Reimbursement of subjects' expenses, e.g., for journeys, is not payment in the sense of reward, and can be provided.

   - All proposed payments to subjects should be submitted to the Survey and Behavioural Research Ethics Committee for examination.

3. Informed consent from others affected by the research - In situations when a third party (e.g. spouses or other health care professionals who are directly involved in the treatment and care of the potential subjects) is involved or affected by the research, consent should also be obtained from them.

4. Vulnerable subjects who need special consideration

   - Vulnerable subjects are either unable to give informed consent, or are captive subjects who are less able to protect themselves.

   - Children should not be the subjects of research that might equally well be carried out on adults. However, if their participation is indispensable, then the consent of a parent or legal guardian is always necessary. To the extent that is feasible, which will vary with age, the willing consent of the child should also be sought.

   - For research involving the mentally ill or mentally retarded, informed consent may have to come from both the subject and a legal guardian or immediate relative, and the attending physician where appropriate.

   - Some elderly or acutely ill people cannot comprehend well and in this way, resemble the case of children or the mentally handicapped people in the consideration of obtaining their informed consent to participate in research.

   - The quality of the consent of potential subjects who are in a potentially dependent relationship with the researcher (e.g., students, employees and patients) requires careful consideration, as willingness may be unduly influenced by the expectation of adventitious benefits or penalties.

5. Research involving deception of subjects

   - The use of one-way mirrors must be clearly justified.

   - In exceptional cases, the researcher may give subjects somewhat misleading information about the nature of the research. All such research must obtain approval from the Committee. The researcher must explain in detail why the research could not practicably be carried out without the deception and why the deception will not significantly affect the well-being of the subjects. Any deception must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research.

D. Guidelines on Ensuring Confidentiality of Research Data

Whatever information is obtained in research should under no circumstances be publicly disclosed in a fashion that would identify any specific person or organization (except with the subjects written consent or if subpoenaed by a court).

Except in anonymous surveys or public/naturalistic observations, the researcher should outline to prospective subjects methods to ensure confidentiality.

1. For projects in which the private information to be collected is not especially sensitive, subjects should be informed that the researcher will take precautions to preserve the confidentiality of the research data and that all reports of the research will be devoid of identifiers.

2. When dealing with more sensitive information, the researcher should specify the precautions relating to the storage, use, and disposition of the materials; for example, that data will be kept in locked files, that only the researcher will have access to them, that subjects will be identified by a code the key to which will be kept separate from the data.

3. In most cases, the researcher should give subjects full information on the proposed management, use, and disposition of photographs and audio or video recordings.

E. Information to be Submitted to the Committee

Researchers are obligated to notify the Committee of all projects involving survey research in accordance with the attached form.

Projects claiming exemption

The researcher should designate specifically which of the grounds of exemption listed above is involved. The summary of the research should be detail enough to show that the researcher is entitled to the exemption claimed.

Non-exempt projects

The researcher should submit the research proposal, together with an application for Survey and Behavioural Research Ethics approval to the Survey and Behavioural Research Ethics Committee. The application should address, where appropriate, issues of informed consent (vulnerable subjects, undue inducement to participate, or deception of subjects), precautions in guarding confidentiality of sensitive data, and risks to subjects (psychological stress, significant discomfort, or damages in the event of disclosure of research data). The risks involved should be balanced against the potential benefits of the proposed research.

Schedule 9
Assignment of IP rights

The following provisions concerning intellectual properties will be incorporated as an integral part in an employee's contract of employment:-

(a) During the period of (the staff member's) appointment, (the staff member) is required to observe at all times the University's Policy on Research, Intellectual Property and Knowledge Transfer at the Schedule attached including the procedures and implementation guidelines and any other relevant regulations in relation thereto as approved and amended by the University from time to time.

(b) In accordance with the provisions under paragraph (a) above,

(i) If at any time during (the staff member) employment under his Letter of Appointment and arising out of any work done as part of his duty, (the staff member), either by himself or jointly with any other person or persons invent, write, design, discover, make, conceive or participate in the inventions, writing, discovery, making, of any Intellectual Property[, such Intellectual Property shall be the absolute property of the University unless otherwise provided for by the University, and (the staff member) shall immediately communicate to the University full details thereof. At the request and expense of the University (the staff member) shall give and supply all such information data drawings and assistance as may be required to enable the University to exploit the aforesaid Intellectual Property to its best advantage and shall execute all documents and do all things which may be necessary or desirable for obtaining patent or other protection for the aforesaid Intellectual Property in such parts of the world as may be specified by the University and for vesting the same in the University as it may direct.

(ii) Any item of Intellectual Property shall not be subject to sub-paragraph (b)(i) above where:

(A) (the staff member) has notified the University in writing that he proposes to work on the invention, writing, discovery or making as aforesaid of such Intellectual Property, and

(B) the University, after (the staff member) has provided it with all the information it considers necessary or appropriate, has come to the conclusion that such Intellectual Property will result from permissible consulting activities without the use of University resources, facilities or any other form of University contribution and the University has notified (the staff member) of this decision in writing.

[*Intellectual Property shall mean all or any of the following:-*
i) (Trade) Mark
ii) (Trade) Name
iii) Patent and Similar Rights
iv) Know-how (Trade Secrets)
v) Copyright
vi) Registered Designs
vii) Confidential Information
viii) Goodwill