THE HONG KONG UNIVERSITY OF SCIENCE AND TECHNOLOGY

Policy on the Ethical Conduct of Research Involving Human Participants

[Approved by Research Committee of Senate on 17 April 2023]

All researchers at the Hong Kong University of Science and Technology (HKUST) must observe the highest standards of professional conduct in scholarly inquiries, as stipulated in the University's Policy on Research Conduct and Integrity. In particular, the University is committed to safeguarding the rights, welfare, and privacy of human participants in its research. We seek to uphold the highest ethical standards in accordance with international best practices as set out in the Belmont Report, Declaration of Helsinki, codes of conduct adhered to by professional bodies in researchers' respective fields[1], the Hong Kong Personal Data (Privacy) Ordinance (Cap. 486) and other applicable legislation.

1. Scope and Application

1.1 This policy establishes the framework for oversight of research that involves human participants governed by the University (hereafter "under the auspices of HKUST"). This covers all such research by faculty, staff, visiting/affiliated researchers, and students within the course of their employment and/or studies at the University, whether funded or unfunded, and regardless of whether the research is conducted on HKUST premises or using its facilities. This excludes in-class training designed to provide students an opportunity to practice methods such as interview, observation and survey techniques, as well as data analysis.

1.2 Other persons, such as those engaging in research in collaboration with HKUST or on HKUST premises, are expected to observe best practices in the ethical conduct of research.

1.3 Research involving human participants refers to investigations that involve:

(i) The collection of new data from human participants through any means, such as experiments, case studies, focus groups, interviews, surveys, questionnaires, or observation;

(ii) The use of pre-existing (i.e. secondary analysis of) personal data;[2] or

(iii) Human biological materials.

[1] Examples can be found in the Research Integrity Resources Portal.

[2] Defined in the Personal Data (Privacy) Ordinance as any data (a) relating directly or indirectly to a living individual, and (b) from which it is practicable for the identity of the individual to be directly or indirectly ascertained; and in a form which access to or processing of the data is practicable.

1.4 For research that involves artefacts, refer to the University's Code of Practice for Research Involving Artefacts.

2. Roles and Responsibilities

2.1 The University – strives to support its research community with the necessary resources and training opportunities, fostering a culture of responsible conduct of research involving human participants in accordance with principles set out in this policy.

2.2 The Human and Artefacts Research Ethics Committee (HAREC), a sub-committee of the Committee on Research Practices (CRP) – maintains ongoing oversight of all related research performed under the auspices of HKUST, including but not limited to the review of protocols, recommendations on policies and best practices, and record-keeping.

2.3 Heads of departments/divisions – should ensure their staff/students observe this policy and provide oversight of research involving human participants in their departments/divisions.

2.4 Researchers – should familiarize themselves with this policy, undertake relevant training, and comply with ethical principles and regulatory requirements in their studies.

2.5 Principal Investigators (PIs)/Research supervisors – in addition to their responsibilities as researchers, are obliged to ensure team members are trained in ethical research practices, and familiarize themselves with this policy and pertinent guidance.

3. Protocol Application and Review

3.1 All research involving human participants under the auspices of HKUST must be justified in a Human Research Ethics Protocol (HREP) application to HAREC[3] and receive approval from the committee before the study commences. Retrospective reviews will not be allowed under any circumstances.

3.2 An HREP application is usually not required for the following types of studies:

(i) Quality assurance or improvement projects exclusively for the University's internal use, such as program/course evaluations; or

(ii) Oral history studies not designed to contribute to generalizable knowledge beyond the individual being interviewed.

[3] Except those involving human genetic resources at the Shenzhen Research Institute, which should be reviewed by the Institute's Ethics Committee on Human Genetic Resources.

3.3 In principle, where collaboration with another institution is involved:

(i) When an HKUST researcher is the PI or Project Coordinator (PC), approval from HAREC is required.

(ii) When an HKUST researcher is collaborating with another Hong Kong institution as the Co-PI, Co-Investigator (Co-I) or team member, he/she should ensure that the PI has obtained ethics approval from the host institution.

(iii) When an HKUST researcher is collaborating with a non-Hong Kong institution as the Co-PI, Co-I or team member, if any part of the work by the HKUST researcher falls within the scope of this policy, they should seek HAREC approval.

Researchers should also observe specific requirements for ethical clearance from funding agencies or journals, if any.

3.4 In cases involving the use of radiation or other safety hazards, approval must also be sought from the Safety Panel.

3.5 University-sponsored research undertaken beyond HKUST premises or overseas must adhere to local practices and legislation, without compromising HKUST standards. Where applicable, ethics approval from local authorities should be obtained.

3.6 For detailed guidance, see Research Compliance Review Procedures and Research Integrity Resource Portal.

4. Post-Approval Responsibilities

4.1 PIs are obligated to ensure that study procedures are undertaken as approved in HREP(s). Any proposed changes must be brought before HAREC via an amendment application and must not be undertaken prior to approval (except in the event of remedial measures eradicating immediate risks to participants, in which case an amendment application should be filed immediately after the change is implemented).

4.2 Unanticipated issues or deviations from approved HREPs that adversely affect the rights, safety, or well-being of any participant, and/or incidences of non-compliance should be reported to HAREC without delay.

4.3 HREPs are typically approved for four years. HAREC has the discretion to approve an HREP for a shorter period if warranted by risks presented to participants. PIs will be notified ahead of their HREP(s)' expiration. Upon expiration, all related work must be ceased. Should procedures need to commence or continue beyond the expiration date,

an extension must be requested and justified for HAREC's approval at least four weeks in advance.

4.4 An HREP completion report should be filed when related procedures have concluded.

4.5 Any infringement of legal requirements and standards as set out in this policy may result in project suspension, disciplinary action, and/or criminal prosecution.

5. Ethical Principles and Practices

5.1 The following overarching principles underpin all research involving human participants at HKUST:

(i) Beneficence: Risks to participants shall be minimized and reasonable in relation to expected benefits.

(ii) Justice: Equitable recruitment and selection of participants shall be maintained. All participants shall be entitled to equal treatment throughout the research process, regardless of age, gender, education, etc.

(iii) Respect for persons: Participants shall be allowed to independently choose what shall or shall not happen to them, free from coercion or undue influence to take part.

5.2 Potential risks and burdens to participants should be evaluated and eliminated where practical. If any, the type and degree of risks, as well as remedial measures must be communicated in advance to participants. Justifications must be provided if the research design implicates adverse effects on participants' well-being.

5.3 To ensure an equitable selection of participants, researchers should consider the study's purpose, setting, and any special vulnerabilities of the subject population. Researchers are strongly recommended to attach recruitment and publicity materials to their protocol applications, especially for studies involving greater risks, vulnerable participants etc., and should provide such materials for approval if requested by HAREC.

5.4 Any potential conflict of interest must be declared and addressed, so as not to compromise the objectivity of the study or the well-being of participants. Prudence should be exercised where prospective participants have dependent or dual relationships with the researcher (e.g. students, employees, patients), to avoid undue influences from power differences or expectations of benefits/penalties.

5.5 As a general rule, voluntary informed consent must be obtained and documented.

(i) Prior to seeking prospective participants' consent, the following must be explained in a language they can comprehend, as far as practicable:
    (a) purpose, procedures, and duration of the study;
    (b) risks and benefits of the study;
    (c) compensation policy for participants;
    (d) privacy, data security, and confidentiality; and
    (e) their rights as participants, e.g. to contact the researcher or HAREC in case of concerns, to decline to take part, or withdraw from the study, at any time without adverse consequences.

    The consent process should be documented via a written informed consent form, email/online means, or an audio recording.

(ii) For vulnerable participants unable to give legal consent (e.g. children, individuals of diminished mental capacity), consent should be sought from their legally authorized representative (e.g. parent/guardian), while an assent form written in a readily understandable manner should be used for these participants.

(iii) If the use of pre-existing personal data deviates from the original purpose for which it was collected, informed consent must be sought again from participants.

(iv) Justifications must be provided to HAREC for a waiver of consent and/or documentation of consent (see Clause 5.6).

5.6 Waiver of consent may be considered in the following circumstances:

(i) The research involves the use of pre-existing personal data for the same or directly related purpose for which they were collected; or

(ii) The research will be undertaken by or subject to the approval of the government, relates to the evaluation of public service programs, and cannot be feasibly conducted without the waiver; or

(iii) If all of the following are appropriately satisfied:
    (a) Any form of recorded consent is impractical;
    (b) The waiver does not adversely affect the rights and welfare of participants;
    (c) The research involves no greater than minimal risks[4] to participants; and
    (d) Participants will be debriefed no later than immediately after their participation.

5.7 A statement informing participants of the PI (or relevant personnel) and HAREC's contact information should be available on all materials to be distributed, including recruitment materials, consent forms, information sheets, and debriefing notes.

[4] The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (U.S. Department of Health and Human Services)

5.8 Any use of deception must be justified in the HREP application for HAREC's approval. A debriefing must be provided to participants as early as practical.

5.9 Participants may be reimbursed for expenses incurred as a result of participation and/or reasonably compensated for their time, but should not be adversely induced by monetary awards. All such remuneration requires approval by HAREC[5].

5.10 Privacy of participants, confidentiality, and security of all data and recordings, regardless of anonymity, must be respected and properly preserved. Standard practices include but are not limited to the following:

(i) Participants should normally be given full information on the proposed management, use, access, and retention period of research data and records.

(ii) Public disclosure of information obtained in the study (e.g. research reports) should be devoid of personal identifiers, unless prior consent has been obtained.

(iii) Special considerations should be given to sensitive information on participants, such as using indirect identifiers and limiting access.

(iv) Research data and records should be retained for a minimum of three years after publication. Anonymization for long-term retention is encouraged.

5.11 Where appropriate, a plan for data monitoring should be in place for ensuring the safety of participants.

6. Training

Researchers are encouraged to undertake training on expected ethical standards in their work, such as the CITI Program Human Subjects Research Course, to ensure familiarity with best practice in safeguarding the rights and welfare of research participants.

7. Complaints

Expressions of concern or cases where non-compliance is suspected should be directed to HAREC, which will investigate as per the CRP's Procedures for Handling Alleged Non-Compliance and Complaints.

8. Contact

Enquiries may be directed to HAREC at harec@ust.hk.

[5] The estimated remuneration amount should be stated for HAREC's consideration. Subsequent adjustment to the proposed amount within a reasonable range does not require further approval.